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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–4633; Project Identifier MCAI–2025–01173–A; Amendment 39–23508; AD 2026–22–06]

RIN 2120–AA64

Airworthiness Directives; Diamond Aircraft Industries Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Diamond Aircraft Industries Inc. (DAI) Model DA 40, DA 40 F, and DA 40 NG airplanes. This AD was prompted by several reports of passenger door separation during flight. This AD requires revising the existing airplane flight manual (AFM) to provide the flight crew with revised operating limitations, emergency procedures, and normal operating procedures; inspecting the passenger door latching mechanism and safety hook mechanism areas and performing corrective action, as applicable; inspecting the safety hook, latching bolts, front and rear door guide blocks, canopy and passenger door warning light, carbon hinges, tension spring, retaining block, safety hook push button, latching mechanism spring, gas spring, and door frame; measuring the passenger door handle actuation force; modifying the airplane with placards; replacing the gas spring; and replacing the hook assembly, retaining block, door guide blocks, and door sealant if necessary. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 7, 2026.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 7, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–4633; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Diamond Aircraft material identified in this AD, contact DAI, 1560 Crumlin Sideroad, London, Ontario, Canada, N5V 1S2; phone: (519) 457–4041; email: *support-canada@diamondaircraft.com;* website: *diamondaircraft.com.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1100 Main, Kansas City, MO 64105. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2026–4633.

FOR FURTHER INFORMATION CONTACT: Fatin Saumik, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7300; email: *fatin.r.saumik@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all DAI Model DA 40, DA 40 F, and DA 40 NG airplanes. The NPRM was published in the **Federal Register** on May 13, 2026 (91 FR 26952). The NPRM was prompted by Transport Canada AD CF–2025–30, dated June 23, 2025 (referred to as the MCAI), issued by Transport Canada, which is the aviation authority for Canada. The MCAI states that there have been several reports of passenger door separation. DAI attributed the root cause of certain instances to the passenger door not being properly latched and subsequent attempts to latch the passenger door in flight. DAI was unable to find a definitive root cause of the remaining occurrences. Passenger door separation, if not addressed, could result in damage to the airplane structure and lead to loss of control of the airplane and injury to persons on the ground.

In the NPRM, the FAA proposed to require revising the existing AFM to provide the flight crew with revised operating limitations, emergency procedures, and normal operating procedures; inspecting the passenger door latching mechanism and safety hook mechanism areas and performing corrective action, as applicable; inspecting the safety hook, latching bolts, front and rear door guide blocks, canopy and passenger door warning light, carbon hinges, tension spring, retaining block, safety hook push button, latching mechanism spring, gas spring, and door frame; measuring the passenger door handle actuation force; modifying the airplane with placards; replacing the gas spring; and replacing the hook assembly, retaining block, door guide blocks, and door sealant if necessary. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2026–4633.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from four individual commenters. Three commenters requested that the FAA revise the applicability of the proposed AD, and one commenter requested a change concerning the service information specified in the proposed AD. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Limit Applicability

Three individual commenters requested that the FAA revise the applicability of the proposed AD to exclude newer serial-numbered airplanes. The commenters stated that the unsafe condition resulted from early generation door locking architectures and that newer airplanes are equipped with a secondary safety latch that completely eliminates the unsafe condition. The commenters stated that applying the AD to all Model DA 40, DA 40 F, and DA 40 NG airplanes would impose unnecessary maintenance requirements on airplanes already equipped with this safety mechanism.

The FAA disagrees with the request. According to DAI, there are two configurations of the door handle, an older and a newer configuration, and both configurations include a red safety hook. However, the red safety hook was not designed to hold the door closed during takeoff and, therefore, does not completely eliminate the unsafe condition. The FAA, in working with Transport Canada and DAI, has determined that the secondary safety latch does not resolve the unsafe condition and that the unsafe condition is not limited to older serial-numbered airplanes. The Model DA 40 NG is the latest model, and it has experienced several occurrences of door separation. Therefore, the FAA did not change this AD as a result of these comments.

Request To Allow Later Revisions of Service Information

An individual commenter requested that the FAA revise the proposed AD to allow the use of later revisions of the service information, rather than specifying the individual revisions of the service information for which credit would be provided. The commenter stated that allowing later revisions would permit the manufacturer to incorporate improvements into the service information without requiring owners to repeat an inspection unnecessarily.

The FAA disagrees with the request to allow credit for later revision of the service material because referring to documents that do not exist at the time the AD is published violates Office of the Federal Register (OFR) regulations regarding approval of materials ''incorporated by reference'' in rules. These OFR regulations require that either the service document be submitted for approval by the OFR as ''referenced'' material, in which case it may be simply called out in the text of an AD, or the service document contents be published as part of the actual AD language. An AD may reference only the specific service document that was submitted and approved by the OFR for ''incorporation by reference.'' In order for operators to use later revisions of the referenced document (issued after the publication of the AD), either the FAA must revise the AD to reference the specific later revisions, or operators must request the approval of their use as an alternative method of compliance (under the provisions of paragraph (l) of this AD). Therefore, the FAA did not change this AD as a result of this comment.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Diamond Aircraft Mandatory Service Bulletin MSB 40–103/MSB F4–042/MSB D4–114/MSB 40NG–084 REV. 2, dated June 5, 2025 (issued as one document), published with Diamond Aircraft Work Instruction WI–MSB 40–103/WI–MSB F4–042/WI–MSB D4–114/WI–MSB 40NG–084 REV. 2, dated June 5, 2025 (issued as one document). This material specifies procedures for inspecting the passenger door latching mechanism and safety hook mechanism areas and performing corrective action, as applicable; inspecting the safety hook, latching bolts, front and rear door guide blocks, canopy and passenger door warning light, carbon hinges, tension spring, retaining block, safety hook push button, latching mechanism spring, gas spring, and door frame; measuring the passenger door handle actuation force; modifying the airplane with placards; replacing the gas spring; and replacing the hook assembly, retaining block, door guide blocks, and door sealant if necessary for Model DA 40, DA 40 F, and DA 40 NG airplanes.

The FAA also reviewed Diamond Aircraft DA 40 AFM Doc. No. 6.01.01–E Temporary Revision TR–MAM–40–1203, Door Latching and Locking, dated December 16, 2024; Diamond Aircraft DA 40 F AFM Doc. No. 6.01.02–E Temporary Revision TR–MAM–40–1203, Door Latching and Locking, dated December 16, 2024; and Diamond Aircraft DA 40 NG AFM Doc. No. 6.01.15–E Temporary Revision TR–MAM–40–1203/a, Door Latching and Locking, dated February 18, 2025. This material specifies procedures for amending the AFM by revising the operating limitations, emergency procedures, and normal operating procedures related to door latching and locking for Model DA 40, DA 40 F, and DA 40 NG airplanes.

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

Differences Between This AD, the MCAI, and the Referenced Material

The MCAI applies to DAI Model DA 40 D airplanes, but this AD does not include this model because it does not have an FAA type certificate.

The service bulletin referred to in the MCAI specifies to contact DAI for repair instructions, but this AD requires contacting the Manager, International Validation Branch, FAA; Transport Canada; or DAI's Transport Canada Design Organization Approval (DOA) instead.

The material referenced above specifies recording any findings in the execution report and submitting the execution report to DAI, but this AD does not include that requirement.

Interim Action

The FAA considers this AD an interim action. This unsafe condition is still under investigation by the manufacturer and, depending on the results of that investigation, the FAA may consider further rulemaking action.

Costs of Compliance

The FAA estimates that this AD affects 987 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
AFM revision	1 work-hour × $85 per hour = $85	$0	$85	$83,895.
Initial inspection	3 work-hours × $85 per hour = $255	76	$331	$326,697.

ESTIMATED COSTS—Continued

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Repetitive inspections	1 work-hour × $85 per hour = $85 per inspection.	0	$85 per inspection	$83,895 per inspection.

The FAA estimates the following costs to do any replacements that would be required based on the results of the inspection. The agency has no way of determining the number of airplanes that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Gas spring replacement	2 work-hours × $85 per hour = $170	$489	$659
Hook assembly replacement	4 work-hours × $85 per hour = $340	484	824
Retaining block replacement	1 work-hour × $85 per hour = $85	166	251
Door guide block replacement	1 work-hour × $85 per hour = $85	206	291
Door sealant replacement	1 work-hour × $85 per hour = $85	15	100

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2026–22–06 Diamond Aircraft Industries Inc.: Amendment 39–23508; Docket No. FAA–2026–4633; Project Identifier MCAI–2025–01173–A.

(a) Effective Date

This airworthiness directive (AD) is effective December 7, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Diamond Aircraft Industries Inc. (DAI) Model DA 40, DA 40 F, and DA 40 NG airplanes, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 5210, Passenger/Crew Doors.

(e) Unsafe Condition

This AD was prompted by several reports of passenger door separation during flight. The FAA is issuing this AD to address this unsafe condition. The unsafe condition, if not addressed, could result in damage to the airplane structure and lead to loss of control of the airplane and injury to persons on the ground.

(f) Definition

For the purpose of this AD, the Diamond Aircraft work instruction is defined as Diamond Aircraft Work Instruction WI–MSB 40–103/WI–MSB F4–042/WI–MSB D4–114/WI–MSB 40NG–084 REV. 2, dated June 5, 2025 (issued as one document), published with Diamond Aircraft Mandatory Service Bulletin MSB 40–103/MSB F4–042/MSB D4–114/MSB 40NG–084 REV. 2, dated June 5, 2025 (issued as one document).

(g) Applicable Airplane Flight Manual (AFM) Temporary Revisions

The following presents the AFM and temporary revisions that apply to this AD and each individual model.

(1) For Model DA 40 airplanes: Diamond Aircraft DA 40 AFM Doc. No. 6.01.01–E Temporary Revision TR–MAM–40–1203, Door Latching and Locking, dated December 16, 2024.

(2) For Model DA 40 F airplanes: Diamond Aircraft DA 40 F AFM Doc. No. 6.01.02–E Temporary Revision TR–MAM–40–1203, Door Latching and Locking, dated December 16, 2024.

(3) For Model DA 40 NG airplanes: Diamond Aircraft DA 40 NG AFM Doc. No. 6.01.15–E Temporary Revision TR–MAM–40–1203/a, Door Latching and Locking, dated February 18, 2025.

(h) Compliance

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

(i) Required Actions

(1) Within 100 hours time-in-service (TIS) or 100 days, whichever occurs first after the effective date of this AD, revise the existing AFM for the airplane to include the information specified in the applicable AFM temporary revision specified in paragraphs (g)(1) through (3) of this AD.

(i) The owner/operator (pilot) holding at least a private pilot certificate may revise the existing AFM for the airplane and must enter compliance with the applicable paragraph of this AD into the airplane maintenance records in accordance with 14 CFR 43.9(a) and 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

(ii) The AFM revision required by paragraph (i)(1) of this AD may be accomplished before the initial inspection and modification required by paragraph (i)(2) or (3) of this AD for that airplane.

(2) For airplanes with less than 100 total hours TIS as of the effective date of this AD: Within 100 hours TIS or 100 days, whichever occurs first after the effective date of this AD, accomplish the initial inspection of the safety hook, latching bolts, front and rear door guide blocks and the modification of the airplane with placards in accordance with the instructions of Section III, steps 5, 20 through 23, 28, 30, 31, and 33 through 36 in the Diamond Aircraft Work Instruction specified in paragraph (f) of this AD, except accomplish the actions required by step 20(f) in accordance with paragraphs (i)(4) and (5) of this AD.

(3) For airplanes that have accumulated 100 or more total hours TIS as of the effective date of this AD: Within 100 hours TIS or 100 days, whichever occurs first after the effective date of this AD, accomplish the initial inspection of the canopy and passenger door warning light, carbon hinges, safety hook, tension spring, retaining block, safety hook push button, safety hook mechanism, latching mechanism spring, gas spring, latching bolts, front and rear door guide blocks, and door frame; measure the passenger door handle actuation force; and accomplish the modification of the airplane with placards in accordance with the instructions of Section III, steps 2 through 10, 12, 13, 15, 17, 18, 20 through 24, and 28 through 36 in the Diamond Aircraft Work Instruction specified in paragraph (f) of this AD, except accomplish the actions required by step 20(f) in accordance with paragraphs (i)(4) and (5) of this AD.

(4) If, during the inspection required by step 20(f) in the Diamond Aircraft Work Instruction specified in paragraph (f) of this AD, the force measured is less than 1.8 kg (18 N), and if the force measured during the inspection required by step 20(c) was between 2 kg (20 N) and 6 kg (60 N), perform the following:

(i) Repeat the inspection required by step 20(c) in the Diamond Aircraft Work Instruction specified in paragraph (f) of this AD every 100 hours TIS until the replacement of the gas spring required by paragraph (i)(4)(ii) of this AD is accomplished.

(ii) Within 12 months after the effective date of this AD, replace the gas spring in accordance with the Diamond Aircraft Work Instruction specified in paragraph (f) of this AD.

(5) If, during the inspection specified in step 20(f) in the Diamond Aircraft Work Instruction specified in paragraph (f) of this AD, the force measured is less than 1.8 kg (18 N), and if the force measured during the inspection required by step 20(c) was greater than 6 kg (60 N) or less than 2 kg (20 N), before further flight, replace the gas spring.

(6) If, during any inspection as required by paragraph (i)(2) or (3) of this AD, any findings, as defined in Section III, steps 5, 6, 9, 12, 20, and 23 are identified, before further flight, accomplish the applicable corrective action(s) in accordance with the instructions of Section IV, IV.1, steps 1 through 9, VI.2 [*sic*], steps 1 and 2, VI.3 [*sic*], steps 1 and 2, and VI.4 [*sic*], steps 1 through 5 in the Diamond Aircraft Work Instruction specified in paragraph (f) of this AD.

(7) Where the instructions of Section III or Section IV of the Diamond Aircraft Work Instruction specified in paragraph (f) of this AD state to contact the manufacturer ''in case of doubt'' or for approved instructions, this AD requires before further flight, using instructions approved by the Manager, International Validation Branch, FAA; Transport Canada; or DAI's Transport Canada Design Organization Approval (DOA), and within the compliance time specified therein, accomplishing those instructions. If approved by the DOA, the approval must include the DOA-authorized signature.

(j) No Reporting Requirement

Although the material referenced in paragraph (f) of this AD specifies to submit information to the manufacturer, this AD does not require that action.

(k) Credit for Previous Actions

You may take credit for the actions required by paragraph (i) of this AD if you performed those actions before the effective date of this AD using Diamond Aircraft Mandatory Service Bulletin MSB 40–103/MSB F4–042/MSB D4–114/MSB 40NG–084 REV. 1, dated May 15, 2025 (issued as one document), published with Diamond Aircraft Work Instruction WI–MSB 40–103/WI–MSB F4–042/WI–MSB D4–114/WI–MSB 40NG–084 REV. 1, dated May 15, 2025 (issued as one document); or Diamond Aircraft Mandatory Service Bulletin MSB 40–103/MSB F4–042/MSB D4–114/MSB 40NG–084 REV. 0, dated March 20, 2025 (issued as one document), published with Diamond Aircraft Work Instruction WI–MSB 40–103/WI–MSB F4–042/WI–MSB D4–114/WI–MSB 40NG–084 REV. 0, dated March 20, 2025 (issued as one document).

(l) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (m) of this AD and email to: *AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(m) Additional Information

For more information about this AD, contact Fatin Saumik, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7300; email: *fatin.r.saumik@faa.gov.*

(n) Material Incorporated by Reference

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

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

(i) Diamond Aircraft Mandatory Service Bulletin MSB 40–103/MSB F4–042/MSB D4–114/MSB 40NG–084 REV. 2, dated June 5, 2025 (issued as one document), published with Diamond Aircraft Work Instruction WI–MSB 40–103/WI–MSB F4–042/WI–MSB D4–114/WI–MSB 40NG–084 REV. 2, dated June 5, 2025 (issued as one document).

(ii) Diamond Aircraft DA 40 Airplane Flight Manual (AFM) Doc. No. 6.01.01–E Temporary Revision TR–MAM–40–1203, Door Latching and Locking, dated December 16, 2024.

(iii) Diamond Aircraft DA 40 F AFM Doc. No. 6.01.02–E Temporary Revision TR–MAM–40–1203, Door Latching and Locking, dated December 16, 2024.

(iv) Diamond Aircraft DA 40 NG AFM Doc. No. 6.01.15–E Temporary Revision TR–MAM–40–1203/a, Door Latching and Locking, dated February 18, 2025.

(3) For Diamond Aircraft material identified in this AD, contact Diamond Aircraft Industries Inc., 1560 Crumlin Sideroad, London, Ontario, Canada, N5V 1S2; phone: (519) 457–4041; email: *support-canada@diamondaircraft.com;* website: *diamondaircraft.com.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1100 Main, Kansas City, MO 64105. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on October 26, 2026.

Steven W. Thompson,

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

[FR Doc. 2026–22310 Filed 10–30–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–1322; Project Identifier AD–2025–01665–T; Amendment 39–23507; AD 2026–22–05]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain The Boeing Company Model 787–8, 787–9, and 787–10 airplanes. This AD was prompted by a report that, during production, certain sealant installations within the center wing fuel tank did not receive required visual and adhesion inspections. This AD requires a detailed inspection of certain sealant installations in the left, right, and center wing side-of-body areas, an adhesion test of the sealant, and applicable on-condition actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 7, 2026.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 7, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–1322; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2026–1322.

FOR FURTHER INFORMATION CONTACT: Tak Kobayashi, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3553; email: *takahisa.kobayashi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 787–8, 787–9, and 787–10 airplanes. The NPRM was published in the **Federal Register** on February 24, 2026 (91 FR 8791). The NPRM was prompted by a report that, during production, certain sealant installations within the center wing fuel tank did not receive required visual and adhesion inspections. In the NPRM, the FAA proposed to require a detailed inspection of certain sealant installations in the left, right, and center wing side-of-body areas, an adhesion test of the sealant, and applicable on-condition actions. The FAA is issuing this AD to address the potential for sealant defects.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from the Air Line Pilots Association, International (ALPA), United Airlines, and an individual, who supported the NPRM without change.

The FAA received additional comments from American Airlines (American), Boeing, and the Foundation for Aviation Safety. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Allow Alternative Repair Instructions

Boeing and American requested that the FAA add an exception to paragraph (h) of the proposed AD that would allow certain repairs to be accomplished using other Boeing service information. Specifically, American requested that the fuel tank repairs be accomplished using the Boeing 787 Aircraft Maintenance Manual (AMM), B787–A–28–11–00–14A–663A–A, ''Fuel Tank Structure Sealant—Standard,'' instead of using a method approved in accordance with the procedures in paragraph (i) of the proposed AD. Boeing requested that the removal and replacement of damaged sealant to restore edge seals, fillet seals, and seal caps be performed using the critical design configuration control limitations (CDCCLs) and airworthiness limitation instructions (ALIs) in the latest published Boeing 787 Special Compliance Items/Airworthiness Limitations, Document D011Z009–03–04. Boeing stated that critical features of sealant are defined in that document, and that repairs involving removal and replacement of damaged sealant, without any deviation from that document, reliably restore the airworthiness of the airplane.

The FAA agrees with Boeing's request. Sealant repairs that comply with the requirements of all applicable airworthiness limitations (AWLs) will restore the sealant installation intended by this AD and therefore should be allowed without further FAA review under the provisions of paragraph (i) of this AD. Accordingly, the FAA has revised paragraph (h)(2) of this AD to specify that, for sealant installation repairs, complying with AWL Nos. 28–AWL–83, 28–AWL–120, 28–AWL–121, 28–AWL–123, 28–AWL–124, and 28–AWL–125, as applicable, in Section D, ''Summary List of AWLs,'' of Boeing 787 Special Compliance Items/Airworthiness Limitations, D011Z009–03–04, dated August 2018, is an acceptable repair. Further, the FAA notes that operators are allowed to use the applicable AMM procedures for removal and replacement of damaged sealant, provided each repair complies with the requirements of all applicable AWL items associated with sealant installation. Therefore, the FAA has not revised this AD in response to American's comment.

Request To Clarify the Inspection Area

American requested that the FAA clarify the inspection area in Figure 1, Appendix F of Boeing Alert Requirements Bulletin B787–81205–SB570053–00 RB, Issue 001, dated November 5, 2025 (the Boeing Alert Requirements Bulletin). American stated it is unclear whether the specified adhesion test of the injection seals should be done along the yellow dashed lines or within the whole area enclosed by those lines in Figure 1. Further, American stated Figure 1 does not clearly identify the area for inspecting the interface between sealant and substrate.

The FAA notes that Figure 1 of Appendix F of the Boeing Alert Requirements Bulletin is an example of the actual inspection areas that are provided in the Accomplishment Instructions of the Boeing Alert Requirements Bulletin. For example, View J of ''Task 7 Figure 8'' shows the adhesion test area, and Step 4 of ''Task

7 Figure 8'' requires an adhesion test of injection sealant in accordance with Appendix F (as noted in footnote [5] to Table 1 of Task 7). Therefore, the adhesion test is required along the dashed lines shown in Figure 1 of Appendix F. Further, paragraph 1.C of Appendix F specifies the required sealant conditions at the transition from the substrate. When the injection sealant is tested for adhesion, the sealant transition from the substrate must be inspected in accordance with Appendix F. The FAA has not changed this AD in this regard.

Request To Clarify Status of Installation Inspections During Production

The Foundation for Aviation Safety asked if the FAA has confirmed that inspections of the installation job (*i.e.,* sealant installation within the center wing fuel tank) are now required during production.

The FAA notes the applicability of this AD is limited to certain airplanes identified in paragraph (c) of the AD due to lack of evidence substantiating that the required inspections were accomplished on those airplanes during production. The FAA has confirmed that inspections of the sealant installations within the center wing tank are being performed during production on airplanes that are outside the applicability of this AD. No change to this AD is necessary as a result of this comment.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin B787–81205–SB570053–00 RB, Issue 001, dated November 5, 2025. This material specifies procedures for a detailed inspection for any sealant defects and any surface depression defects on identified sealant installed in the left, right, and center wing side-of-body area and the area between side-of-body rib and rib 2, an adhesion test on identified sealants installed in the left, right, and center wing side-of-body area and the area between side-of-body rib and rib 2, and applicable on-condition actions. On-condition actions also include contacting Boeing for repair instructions and performing a repair.

The FAA also reviewed Section D, ''Summary List of AWLs,'' of Boeing 787 Special Compliance Items/Airworthiness Limitations, D011Z009–03–04, dated August 2018. This material specifies the AWLs (CDCCLs and ALIs) for the fuel system, including sealant installation repair.

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

Costs of Compliance

The FAA estimates that this AD affects 60 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Detailed inspection and adhesion test of sealant	34 work-hours × $85 per hour = $2,890	$0	$2,890	$173,400

The FAA has received no definitive data on which to base the cost estimates for the on-condition repairs specified in this AD.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2026–22–05 The Boeing Company: Amendment 39–23507; Docket No. FAA–2026–1322; Project Identifier AD–2025–01665–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 7, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 787–8, 787–9, and 787–10 airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin B787–81205–SB570053–00 RB, Issue 001, dated November 5, 2025.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wing.

(e) Unsafe Condition

This AD was prompted by a report that, during production, certain sealant installations within the center wing fuel tank volume did not receive required visual and adhesion inspections. The FAA is issuing this AD to address the potential for sealant defects. The unsafe condition, if not addressed, could result in development of an ignition source within the fuel tank volume and a risk of a fuel tank explosion during a lightning strike event.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin B787–81205–SB570053–00 RB, Issue 001, dated November 5, 2025, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin B787–81205–SB570053–00 RB, Issue 001, dated November 5, 2025.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin B787–81205–SB570053–00, Issue 001, dated November 5, 2025, which is referred to in Boeing Alert Requirements Bulletin B787–81205–SB570053–00 RB, Issue 001, dated November 5, 2025.

(h) Exceptions to Requirements Bulletin Specifications

(1) Where the Compliance Time column of the table in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin B787–81205–SB570053–00 RB, Issue 001, dated November 5, 2025, refers to the Issue 001 date of Requirements Bulletin B787–81205–SB570053–00 RB, this AD requires using the effective date of this AD.

(2) Where Boeing Alert Requirements Bulletin B787–81205–SB570053–00 RB, Issue 001, dated November 5, 2025, specifies contacting Boeing for repair instructions, this AD requires doing the repair using a method approved in accordance with the procedures specified in paragraph (i) of this AD. For sealant installation repairs: Complying with Airworthiness Limitations (AWLs) Nos. 28–AWL–83, 28–AWL–120, 28–AWL–121, 28–AWL–123, 28–AWL–124, and 28–AWL–125, as applicable, in Section D, ''Summary List of AWLs,'' of Boeing 787 Special Compliance Items/Airworthiness Limitations, D011Z009–03–04, dated August 2018, is an acceptable repair.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *AMOC@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, AIR–520, Continued Operational Safety Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Additional Information

(1) For more information about this AD, contact Tak Kobayashi, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3553; email: *takahisa.kobayashi@faa.gov*.

(2) Material identified in this AD that is not incorporated by reference is available at the address specified in paragraph (k)(3) of this AD.

(k) Material Incorporated by Reference

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

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

(i) Boeing Alert Requirements Bulletin B787–81205–SB570053–00 RB, Issue 001, dated November 5, 2025.

(ii) Section D, ''Summary List of AWLs,'' of Boeing 787 Special Compliance Items/Airworthiness Limitations, D011Z009–03–04, dated August 2018.

(3) For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*

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

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

Issued on October 26, 2026.

Brian Knaup,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2026–22318 Filed 10–30–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–7215; Project Identifier AD–2025–01558–T; Amendment 39–23506; AD 2026–22–04]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2023–07–09, which applied to certain The Boeing Company Model 747–400 and –8 series airplanes. AD 2023–07–09 required inspecting for wear of the transfer pump housing inlet check valves and transfer pump motor impeller inlet adapters for the horizontal stabilizer fuel tank and doing corrective actions, if necessary, and limited the installation of affected parts. This AD was prompted by the manufacturer developing further action to address the unsafe condition. This AD requires repetitive inspections for damage of the transfer pump housing inlet check valves and transfer pump motor impeller inlet adapters for the horizontal stabilizer fuel tank and applicable on-condition actions. This AD also limits the installation of affected parts under certain conditions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 7, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 7, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–7215; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The

address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2026–7215.

FOR FURTHER INFORMATION CONTACT: Samuel Dorsey, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3415; email: *samuel.j.dorsey@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2023–07–09, Amendment 39–22411 (88 FR 22895, April 14, 2023) (AD 2023–07–09). AD 2023–07–09 applied to certain Model 747–400 and –8 series airplanes. The NPRM was published in the **Federal Register** on July 9, 2026 (91 FR 42387). The NPRM was prompted by the manufacturer developing further action to address the unsafe condition. In the NPRM, the FAA proposed to require repetitive inspections for damage of the transfer pump housing inlet check valves and transfer pump motor impeller inlet adapters for the horizontal stabilizer fuel tank and applicable on-condition actions. The NPRM also proposed to limit the installation of affected parts under certain conditions. The FAA is issuing this AD to address the development of an ignition source within the horizontal stabilizer fuel tank resulting from wear to the transfer pump housing inlet check valves and transfer pump motor impeller inlet adapters of the horizontal stabilizer fuel tank. The unsafe condition, if not addressed, could, in combination with flammable fuel vapors, result in a fuel tank explosion and consequent loss of the airplane.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from Air Line Pilots Association, International (ALPA) and Boeing who supported the NPRM without change.

The FAA received an additional comment from Turkish Airlines. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Revise Applicability

Turkish Airlines requested that the FAA revise paragraph (c) of the proposed AD to be similar to the applicability of AD 2023–07–09 and to specify that airplanes equipped with an activated horizontal stabilizer fuel tank with Crane Aerospace Hydro-Aire horizontal stabilizer fuel transfer pump housings and transfer pump motor impellers are affected, instead of referencing Boeing Alert Requirements Bulletin 747–28A2373 RB, dated November 6, 2025 (Boeing Alert Requirements Bulletin 747–28A2373 RB), for identification information. Turkish Airlines stated that Boeing Alert Requirements Bulletin 747–28A2373 RB's effectivity identifies two configurations: (1) Model 747–400 and 747–8 airplanes equipped with activated horizontal stabilizer fuel tank with Crane Aerospace Hydro-Aire horizontal stabilizer fuel transfer pump housings and transfer pump motor impellers; and (2) Model 747–400 and 747–8 airplanes not equipped with an activated horizontal stabilizer fuel tank with Crane Aerospace Hydro-Aire horizontal stabilizer fuel transfer pump housings and transfer pump motor impellers. Turkish Airlines added that no action is required for airplanes in the second configuration.

The FAA disagrees. Determining whether an airplane was included in AD 2023–07–09's applicability required an examination of each airplane's configuration to determine whether the AD applied to that airplane, regardless of whether the airplane was determined to be affected by the AD's requirements. Boeing Alert Requirements Bulletin 747–28A2373 RB contains a definitive list of all airplanes that could be affected by the unsafe condition and requires an examination of their configuration. While either approach would produce an acceptable outcome, in this situation, referring to the service information to determine applicability is clearer and consistent with the principle that only airplanes to which the AD applies are subject to the requirements of this AD. No change to this AD has been made in this regard.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 747–28A2373 RB, dated November 6, 2025. This material specifies procedures for repetitive detailed inspections of the transfer pump housing inlet check valves and transfer pump motor impeller inlet adapters for any damage and applicable on-condition actions. On-condition actions include replacing the damaged transfer pump housing inlet check valve with a new or serviceable transfer pump housing inlet check valve (Option 1), or replacing the affected transfer pump housing with a transfer pump housing containing a new or serviceable transfer pump housing inlet check valve (Option 2); and replacing an affected transfer pump motor impeller with a new or serviceable transfer pump motor impeller.

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

Interim Action

The FAA considers this AD to be an interim action. The main and center wing tanks utilize the same pump design but are currently not subject to the same unsafe condition due to the shutoff logic of the pumps. However, if further analysis or reports related to the main or center tank pumps change this assessment, the FAA might consider further rulemaking for those tanks.

Costs of Compliance

The FAA estimates that this AD affects 31 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection of transfer pump housing inlet check valve (2 per airplane).	18 work-hours × $85 per hour = $1,530 per inspection cycle.	$0	$1,530 per inspection cycle	$47,430 per inspection cycle.
Inspection of transfer pump motor impeller inlet adapter (2 per airplane).	18 work-hours × $85 per hour = $1,530 per inspection cycle.	0	$1,530 per inspection cycle	$47,430 per inspection cycle.

The FAA estimates the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. The agency has no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement of transfer pump motor impeller.	2 work-hours × $85 per hour = $170	Up to $2,400	Up to $2,570.
Replacement of transfer pump housing inlet check valve (Option 1).	2 work-hours × $85 per hour = $170	$1,800	$1,970.
Replacement of transfer pump housing (Option 2).	2 work-hours × $85 per hour = $170	Up to $20,000	Up to $20,170.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2023–07–09, Amendment 39–22411 (88 FR 22895, April 14, 2023); and

■ b. Adding the following new AD:

2026–22–04 The Boeing Company: Amendment 39–23506; Docket No. FAA–2026–7215; Project Identifier AD–2025–01558–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 7, 2026.

(b) Affected ADs

This AD replaces AD 2023–07–09, Amendment 39–22411 (88 FR 22895, April 14, 2023) (AD 2023–07–09).

(c) Applicability

This AD applies to The Boeing Company Model 747–400 and –8 series airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin 747–28A2373 RB, dated November 6, 2025.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Unsafe Condition

This AD was prompted by reports of wear-through of the transfer pump motor impeller inlet adapter of the horizontal stabilizer fuel tank transfer pump caused by contact between the transfer pump housing inlet check valve and the inlet adapter. The FAA is issuing this AD to address the development of an ignition source within the horizontal stabilizer fuel tank resulting from wear to the transfer pump housing inlet check valves and transfer pump motor impeller inlet adapters of the horizontal stabilizer fuel tank. The unsafe condition, if not addressed, could, in combination with flammable fuel vapors, result in a fuel tank explosion and consequent loss of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 747–28A2373 RB, dated November 6, 2025, do all applicable

actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 747–28A2373 RB, dated November 6, 2025.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 747–28A2373, dated November 6, 2025, which is referred to in Boeing Alert Requirements Bulletin 747–28A2373 RB, dated November 6, 2025.

(h) Exceptions to Requirements Bulletin Specifications

Where the Compliance Time column of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 747–28A2373 RB, dated November 6, 2025, refers to the original issue date of Requirements Bulletin 747–28A2373 RB, this AD requires using the effective date of this AD.

(i) Parts Installation Limitation

As of the effective date of this AD, no person may install, on any airplane, a Crane Aerospace Hydro-Aire horizontal stabilizer fuel transfer pump housing, transfer pump housing inlet check valve, or transfer pump motor impeller into the horizontal stabilizer fuel tank unless the transfer pump housing inlet check valve and transfer pump motor impeller inlet adapter have been inspected as specified in paragraph (g) of this AD, as applicable, and been determined to be a serviceable part as defined in Boeing Alert Requirements Bulletin 747–28A2373 RB, dated November 6, 2025.

(j) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the airplane to a location where the actions required by this AD can be performed, provided the horizontal stabilizer fuel tank is defueled and both transfer pump circuit breakers are locked in the ''open'' position.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: *AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, AIR–520, Continued Operational Safety Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(l) Additional Information

(1) For more information about this AD, contact Samuel Dorsey, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3415; email: *samuel.j.dorsey@faa.gov.*

(2) Material identified in this AD that is not incorporated by reference is available at the address specified in paragraph (m)(3) of this AD.

(m) Material Incorporated by Reference

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

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

(i) Boeing Alert Requirements Bulletin 747–28A2373 RB, dated November 6, 2025.

(ii) [Reserved]

(3) For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*

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

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

Issued on October 26, 2026.

Brian Knaup,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2026–22317 Filed 10–30–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–11820; Project Identifier MCAI–2026–00964–E; Amendment 39–23505; AD 2026–22–03]

RIN 2120–AA64

Airworthiness Directives; BRP-Rotax GmbH & Co KG (Formerly BRP-Powertrain GMBH & CO KG and Bombardier-Rotax GmbH) Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all BRP-Rotax GmbH & Co KG (BRP-Rotax) Model 915 iSc2 C24, 915 iSc3 C24, 916 iSc2 A, 916 iSc2 C24, 916 iSc3 A, and 916 iSc3 C24 engines. This AD was prompted by a report of oil leakage from cracks in the wall of the turbocharger valve housing due to insufficient thickness. This AD requires replacement of the turbocharger valve housing and reidentification of the turbocharger. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 23, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 4, 2026.

The FAA must receive comments on this AD by December 17, 2026.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–11820; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2026–11820.

FOR FURTHER INFORMATION CONTACT: Joseph Catanzaro, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7366; email: *joseph.catanzaro@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments using a method listed under the **ADDRESSES** section. Include ''Docket No. FAA–2026–11820; Project Identifier MCAI–2026–00964–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Joseph Catanzaro, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA Emergency AD 2026–0178–E, dated September 14, 2026 (EASA Emergency AD 2026–0178–E) (also referred to as the MCAI), to correct an unsafe condition on BRP-Rotax Model 915 iSc2 A, 915 iSc3 A, 915 iSc2 C24, 915 iSc3 C24, 916 iSc2 A, 916 iSc3 A, 916 iSc3 B, 916 iSc2 C24, and 916 iSc3 C24 engines, all serial numbers. The MCAI states that an occurrence was reported where, during the final testing of a BRP-Rotax Model 916i engine on the production line, oil leakage was found in the area of the turbocharger valve housing. A manufacturer investigation revealed cracks in the wall of the valve housing due to insufficient thickness, caused by a non-conforming manufacturing process during production of the valve housing. To address this potential unsafe condition, BRP-Rotax published service material that identifies the turbochargers with the affected valve housing. This service material also contains instructions for replacement of the valve housing and for reidentification of the turbocharger. This condition, if not detected and corrected, could result in oil leakage during engine operation, smoke generation, engine compartment fire, an in-flight engine shutdown, and possible loss of control of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2026–11820.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA Emergency AD 2026–0178–E, which specifies procedures for replacement of the turbocharger valve housing and reidentification of the turbocharger. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

AD Requirements

This AD requires accomplishing the actions specified in the material already described, except as discussed under ''Differences Between this AD and the MCAI.''

Differences Between This AD and the MCAI

BRP-Rotax Model 915 iSc2 A, 915 iSc3 A, and 916 iSc3 B engines do not have an FAA type certificate, therefore this AD does not include those engines in the applicability.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some CAA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, EASA Emergency AD 2026–0178–E is incorporated by reference in this AD. This AD requires compliance with EASA Emergency AD 2026–0178–E in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA Emergency AD 2026–0178–E does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA Emergency AD 2026–0178–E. Material required by EASA Emergency AD 2026–0178–E for compliance will be available at *regulations.gov* under Docket No. FAA–2026–11820 after this AD is published.

Justification for Immediate Adoption and Determination of the Effective Date

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

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this

rule because cracks in the wall of the turbocharger valve housing could result in oil leakage during engine operation, smoke generation, engine compartment fire, an in-flight engine shutdown, and possible loss of control of the airplane. At this time, the growth rate of the cracking of the turbocharger valve housing has not been determined. For these reasons, this AD must be accomplished before further flight after the effective date of this AD. This compliance time is shorter than the time necessary for the public to comment and for publication of the final rule. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b).

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

Regulatory Flexibility Act

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

Costs of Compliance

The FAA estimates that this AD affects 51 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement of valve housing and re-identification of turbocharger.	2 work-hours × $85 per hour = $170	$150	$320	$16,320

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2026–22–03 BRP-Rotax GmbH & Co KG (formerly BRP-Powertrain GMBH & CO KG and Bombardier-Rotax GmbH): Amendment 39–23505; Docket No. FAA–2026–11820; Project Identifier MCAI–2026–00964–E.

(a) Effective Date

This airworthiness directive (AD) is effective November 4, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all BRP-Rotax GmbH & Co KG (formerly BRP–POWERTRAIN GMBH & CO KG and Bombardier-Rotax GmbH) Model 915 iSc2 C24, 915 iSc3 C24, 916 iSc2 A, 916 iSc2 C24, 916 iSc3 A, and 916 iSc3 C24 engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 8120, Exhaust Turbocharger.

(e) Unsafe Condition

This AD was prompted by a report of oil leakage from cracks in the wall of the turbocharger valve housing due to insufficient thickness. The FAA is issuing this AD to prevent cracks in the wall of the turbocharger valve housing. The unsafe condition, if not addressed, could result in oil leakage during engine operation, smoke generation, engine compartment fire, an in-flight engine shutdown, and possible loss of control of the airplane.

(f) Compliance

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

(g) Required Action

Except as specified in paragraph (h) of this AD: Perform all required actions within the compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) Emergency AD 2026–0178–E, dated September 14, 2026 (EASA Emergency AD 2026–0178–E).

(h) Exceptions to EASA Emergency AD 2026–0178–E

(1) Where EASA Emergency AD 2026–0178–E refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the ''Remarks'' section of EASA Emergency AD 2026–0178–E.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your

request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: *AMOC@faa.gov.*

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

(j) Additional Information

For more information about this AD, contact Joseph Catanzaro, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7366; email: *joseph.catanzaro@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) Emergency AD 2026–0178–E, dated September 14, 2026.

(ii) [Reserved]

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

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on October 23, 2026.

Steven W. Thompson,

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

[FR Doc. 2026–22307 Filed 10–30–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–1302]

RIN 1117–AB89

Conforming Amendment Regarding the Criminal Law Technical Amendments Act of 2002

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Criminal Law Technical Amendments Act of 2002 (''Technical Amendments Act'') became law on November 2, 2002, as part of the 21st Century Department of Justice Appropriations Authorization Act. The Technical Amendments Act amended sections 401(d), 402(c), and 403 of the Controlled Substances Act by replacing outmoded fine amounts with a reference to title 18 of the United States Code in each place that a specific fine amount had appeared. In this rulemaking, the Drug Enforcement Administration (DEA) is amending its regulations to conform them to the statutory amendments made to the Controlled Substances Act by the Technical Amendments Act.

DATES: This final rule is effective on November 2, 2026.

FOR FURTHER INFORMATION CONTACT: Heather E. Achbach, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act, as amended.[1] The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. DEA publishes the implementing regulations for these statutes in 21 CFR parts 1300 through 1399.

On November 2, 2002, the Technical Amendments Act was enacted as part of the 21st Century Department of Justice Appropriations Authorization Act.[2] The Technical Amendments Act amended sections 401(d), 402(c), and 403 of the CSA (21 U.S.C. 841(d), 842(c), and 843(d), respectively). Of particular relevance to this rulemaking, section 4002 of the Technical Amendments Act replaced the terms ''of not more than $30,000'' and ''of not more than $60,000'' with ''under title 18, United States Code'' each time the terms appeared in 21 U.S.C. 843(d). However, DEA regulations at 21 CFR 1301.17 continue to list ''a fine of not more than $30,000'' or a fine ''not exceeding $30,000'' as a possible penalty for providing false information on a registration application, intentionally misusing the affidavit procedure, and obtaining controlled substances through registration by fraudulent means.[3] In this final rule, DEA is amending its regulations to conform to the amendments made to the CSA by the Technical Amendments Act. This rule replaces those terms with ''under title 18, United States Code'' each time the terms appear in 21 CFR 1301.17.

Regulatory Analysis

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA),[4] including those requiring the publication of a prior notice of proposed rulemaking (NPRM) and the opportunity for public comment, if such actions are determined to be unnecessary, impracticable, or contrary to the public interest. DEA finds that there is good cause within the meaning of the APA to issue this amendment as a final rule without opportunity for public comment and with an immediate effective date.

This final rule amends DEA regulations only to the extent necessary to be consistent with current Federal law, as modified by the Technical Amendments Act. The Technical Amendments Act amended the penalty provisions of the CSA that DEA previously implemented in its regulations. Therefore, DEA is obligated to update those regulations. DEA is not exercising discretion with this final rule because this final rule merely amends the regulations to conform to the change to the CSA made by the Technical Amendments Act. Thus, publishing an NPRM or soliciting public comment is unnecessary.[5] In addition, because the statutory changes addressed in this rule have already been in effect since November 2, 2002, DEA finds good cause exists to make this rule effective immediately upon publication.[6]

[1] 21 U.S.C. 801–971.

[2] Public Law 107–273, 4002, 116 Stat. 1758 (2002).

[3] 21 CFR 1301.17(a), (b), and (d).

[4] 5 U.S.C. 553.

[5] *See EME Homer City Generation, L.P.* v. *E.P.A.,* 795 F.3d 118, 134 (D.C. Cir. 2015) (notice and comment are ''unnecessary'' when an agency ''lacks discretion'' in deciding how to amend its regulations).

[6] *See* 5 U.S.C. 553(b)(B) (relating to notice and comment procedures). ''[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary.'' *Gray Panthers Advocacy Comm.* v. *Sullivan,* 936 F. 2d

Continued

Therefore, DEA is issuing this amendment as a final rule, effective upon publication in the **Federal Register** (FR).

Executive Orders 12866, 13563, and 14192

DEA has determined that this rulemaking is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 (Regulatory Planning and Review). Accordingly, this final rule has not been submitted to the Office of Management and Budget (OMB) for review. This final rule was developed in accordance with Executive Order 12866 (Regulatory Planning and Review), section 1(b), Principles of Regulation; Executive Order 13563 (Improving Regulation and Regulatory Review), section 1(b), General Principles of Regulation; and Executive Order 14192 (Unleashing Prosperity Through Deregulation)

As stated above, this final rule amends DEA regulations only to the extent necessary to be consistent with current Federal law, as modified by the Technical Amendments Act. DEA has no discretion with respect to this amendment. This final rule merely codifies legal requirements that have been in effect since 2002, when the Technical Amendments Act became law. Therefore, DEA anticipates that this final rule will have no economic impact.

This final rule is not subject to Executive Order 14192 because it is not a significant regulatory action under section 3(f) of Executive Order 12866.

Executive Order 12988, (Civil Justice Reform)

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Civil Justice Reform) to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132 (Federalism)

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

Executive Order 13175, (Consultation and Coordination With Indian Tribal Governments)

This final rule does not have Tribal implications warranting the application of Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments). It does not have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, applies to rules that are subject to notice and comment under section 553(b) of the APA. As explained above, DEA determined that there is good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply to this final rule. In any event, as explained above, this rule is a conforming amendment that makes no change to the status quo.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* DEA has determined that this final rule does not include a Federal mandate that might result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted for inflation) in any one year and that it would not significantly or uniquely affect small governments. Therefore, neither a Small Government Agency plan nor any other action is required under the UMRA.

Executive Order 14267 (Reducing Anti-Competitive Regulatory Barriers)

This final rule does not reduce competition, entrepreneurship, and innovation.

Executive Order 14294 (Overcriminalization of Federal Regulations)

Executive Order 14294 specifies that all NPRMs and final rules published in the FR, the violation of which may constitute a criminal regulatory offense, must identify the authorizing statute and the mens rea requirement for each element of the offense. This final rule does not involve a criminal regulatory offense, and thus Executive Order 14294 does not apply.

Paperwork Reduction Act of 1995

This final rule does not involve a collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This final rule does not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number.

Congressional Review Act

This final rule is not a major rule as defined by subtitle E of the Congressional Review Act (CRA), 5 U.S.C. 804. This final rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects 21 CFR Part 1301

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

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

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

■ 1. The authority citation for 21 CFR Part 1301 continues to read as follows:

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

§ 1301.17 [Amended]

■ 2. Amend § 1301.17 by:

■ a. In paragraph (a), in the ''Affidavit for New Pharmacy'', removing the text ''of not more than $30,000'' and adding in its place the text ''under title 18, United States Code'';

■ b. In paragraph (b), in the ''Affidavit for Transfer of Pharmacy'', removing the text ''of not more than $30,000'' and adding in its place the text ''under title 18, United States Code''; and

■ c., In paragraph (d), removing the text ''not exceeding $30,000'' and adding in its place the text ''under title 18, United States Code''

1284, 1291 (D.C. Cir. 1991); *see also Komjathy* v. *Nat'l Transp. Safety Bd.,* 832 F.2d 1294, 1296 (D.C. Cir. 1987) (per curiam) (notice-and-comment procedures are not required when a rule ''does no more than repeat, virtually verbatim, the statutory grant of authority''). A delayed effective date is similarly unwarranted here because—by virtue of the Technical Amendments Act already being effective—''affected parties'' will not need any ''time to adjust their behavior'' to the changes in this rule. *See Riverbend Farms, Inc.* v. *Madigan,* 958 F.2d 1479, 1485 (9th Cir. 1992).

Signing Authority

This document of the Drug Enforcement Administration was signed on October 23, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2026–22285 Filed 10–30–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 251

RIN 0596–AD68

Administrative Site Leases

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Final rule.

SUMMARY: The United States Department of Agriculture (Department), Forest Service (Forest Service or Agency), this final rule will exempt administrative site leases from the regulations for special uses. The purpose of this deregulatory action is to better align Forest Service leasing activities with how leases are commonly legally defined to improve the feasibility of partnering with private developers and local municipalities for leasing and redeveloping administrative sites.

DATES: The final rule is effective December 2, 2026.

FOR FURTHER INFORMATION CONTACT: Matthew Fountain, Sales and Leasing Program Manager, 202–205–1464 or *matthew.fountain1@usda.gov.* Individuals who are deaf, hard of hearing, or have a speech disability may call 711 to reach the Telecommunications Relay Service, then provide the phone number of the person named as a point of contact for further information.

SUPPLEMENTARY INFORMATION:

Background and Need

Administrative sites are land or property controlled by the Forest Service used or acquired for administrative purposes. The 2018 Farm Bill provides that the Secretary of Agriculture may lease an administrative site that is under the Secretary's jurisdiction under Public Law 115–334 Sec. 8623. The Forest Service Facility Realignment and Enhancement Act of 2005 (FSFREA), Public Law 109–54, also provides that the Forest Service may dispose of administrative sites by sale, lease, exchange, and other methods. The Administrative Site Leasing Program, which includes leasing administrative sites under both the Farm Bill and FSFREA authorities, was initially considered a special use authorization. This prevents the Agency from issuing leases that function as they are commonly legally defined, and the terms of the existing special use framework can discourage partnerships and investment. For example, special use authorization regulatory requirements, constrain the use of the leasehold interest as collateral for loans, limits assignment and transfer of the lease, and provides for unilateral termination of the authorization by the Forest Service. These requirements limit financing options and negatively impact the marketability of leasing projects.

Exempting administrative site leasing from special use regulation requirements will remove regulatory constraints incompatible with standard real estate leasing practices and reflect the unique statutory basis and long-term real property nature of these leases. Without this regulatory change, agency partners will continue to face challenges in obtaining the financing needed to pursue affordable housing and other projects under these authorities.

This final rule is intended to provide a consistent regulatory treatment of administrative site leases under both FSFREA and the 2018 Farm Bill by removing those leases from the special-use framework. Existing special use authorizations for administrative site leasing may remain in effect under their original terms or, at the authorized officer's discretion, be replaced, upon mutual agreement with the lessee, by a lease issued under the applicable statutory authority after satisfaction of all applicable requirements.

This final rule removes administrative site leasing authorized under section 8623 of the 2018 Farm Bill and FSFREA from the scope of 36 CFR part 251, subpart B. This change is expected to increase flexibility in how leasing projects are administered by separating incompatible processes that are unnecessary, irrelevant, or do not add value, while retaining processes necessary for legal sufficiency and public accountability. Additional programmatic guidance on administrative site leases can be found in Forest Service Manual 2750.

Summary of Comments and Responses

On May 6, 2026, the Forest Service published a proposed rule in the **Federal Register** (91 FR 24494) to exempt administrative site leases from the special use requirements in 36 CFR 251 to ensure compatible business practices are possible under the Administrative Site Leasing program. The agency received 25 comments; 8 were supportive of the proposed change and 17 were not. Comments were received from local governments, housing and public finance organizations, the general public and one Tribe. Several commenters supported the rule, emphasizing the need for affordable workforce housing in high-cost communities and explaining that current special-use requirements make financing difficult or impracticable for many projects. Those who opposed the proposed change, including the Osage Nation's Historic Preservation Office, generally expressed concern that the rule could facilitate privatization or disposal of National Forest System lands. The Department does not agree that the rule has that effect. The rule does not authorize land sales, change existing land-disposal authority, or exempt administrative-site leasing projects from National Historic Preservation Act (NHPA), Archaeological Resources Protection Act (ARPA), National Environmental Policy Act (NEPA), public notice, local-government consultation, or other applicable statutory requirements.

After reviewing all comments, the Department is adopting the proposed rule without change. The Department does not believe the concerns raised by commenters warrant changes to the rule text because the rule addresses only the regulatory treatment of administrative-site leases and does not alter statutory requirements or other legal requirements independent of subpart B that apply to future administrative-site leasing decisions.

A summary of substantive comments and responses is provided below.

Comment: Some commenters, especially those in housing finance, public finance, and local governments, support the rule because it could help address the need for affordable workforce housing, especially in high-cost communities. The current special

use regulatory requirements often make financing difficult or impracticable. One commenter said their firm had reviewed multiple housing projects over five years, but lenders refused financing each time because the lease could not serve as loan collateral, the lease could not be assigned in case of default, and the Forest Service could end the lease unilaterally under the current regulatory framework.

Response: These are the type of financing and transferability concerns the Department intends to address through this de-regulatory action. The Department recognizes that the current regulatory framework limits the Forest Service's flexibility to structure administrative-site leases in a manner consistent with the underlying leasing authorities and to address community needs, including affordable housing.

Comment: Some commenters who did not support the rule, including the Osage Nation's Historic Preservation Office, expressed concern that the rule could facilitate privatization or disposal of National Forest System lands, including sales to private developers. Some of these commenters also said that allowing leased ''public'' lands and buildings to be used as collateral for loans would expose them to repossession and transfer without Federal oversight. Some commenters said that exempting administrative site leases from subpart B would enable Federal property to be conveyed to private entities, undermining public ownership protections.

Response: The rule does *not* authorize land sales or change any existing land-disposal authority. It addresses the regulatory treatment of administrative site leases by exempting them from subpart B and is intended to improve the Forest Service's ability to partner to redevelop administrative sites. Use of a leasehold interest as collateral would not convey or encumber title to the underlying National Forest System land. Any collateral, assignment, transfer, default, or lender step-in provisions would be governed by and subject to the lease terms and the applicable statutory authority, including any terms, conditions, bonding, reservations, or approvals necessary to protect the public interest and Federal ownership.

Comment: A subset of commenters objected to this rule because they believe exempting administrative site leases from the special use framework in 36 CFR part 251 would result in reduced project monitoring, environmental compliance, and public involvement. The letter from the Osage Nation also cited concerns about compliance with the NHPA, the ARPA, and the Native American Graves Protection and Repatriation Act (NAGPRA).

Response: The rule does not exempt administrative site leasing projects from NHPA, ARPA, NAGPRA or other applicable statutory requirements. Section 8623 of the 2018 Farm Bill provides that National Environmental Policy Act (NEPA) applies to leases issued under that authority and includes requirements for consultation with local government officials and public notice before an administrative site is made available for lease. Exempting administrative site leases from subpart B means that procedures and terms required solely by subpart B, including its proposal-processing and lease-administration provisions, will no longer apply to these leases. The Department has determined that those requirements need not apply categorically to administrative site leases. Administrative site leases will remain subject to the applicable statutory authority, other applicable law. As necessary, the Forest Service will provide implementing guidance for the proposal processing and other administrative procedures and will incorporate appropriate monitoring, bonding, default, resource-protection, and other requirements into the terms of individual leases.

Comment: In their letter, the Osage Nation also cited concerns specific to Tribes and the Federal government's trust responsibility to consult with Tribes. The comment stated that the proposed change would make leased administrative sites no longer subject to the Tribal consultation mandated by the NHPA or the multitude of laws that protect cultural heritage at the national level, and that a special use permit ensures Tribal consultation takes place so that lands and properties under Federal ownership that contain significant cultural resources and historical importance do not lose those protections.

Response: The Department is committed to respecting Tribal sovereignty and upholding Federal Trust responsibilities with Tribes. As stated previously, exempting administrative site leases from subpart B will not change ownership of Federal lands or facilities. It also will not change the need to ensure compliance with all applicable laws, including NHPA and NAGPRA. Where an administrative-site lease is an undertaking that affects historic properties, the Forest Service will comply with NHPA Section 106 and its implementing regulations, including applicable consultation with Tribes that attach religious and cultural significance to affected historic properties. Where NAGPRA applies to planned activities, discoveries, or excavations on Federal or Tribal lands, the applicable NAGPRA requirements will continue to apply.

Regulatory Certifications

Regulatory Planning and Review

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will determine whether a regulatory action is significant as defined by E.O. 12866 and will review significant regulatory actions. OIRA has determined that this final rule is not significant as defined by E.O. 12866. E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The Department has developed the final rule consistent with E.O. 13563.

Congressional Review Act

Pursuant to subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act) (5 U.S.C. 801 *et seq.*), OIRA has designated this final rule as not a major rule as defined by 5 U.S.C. 804(2).

National Environmental Policy Act

The final rule is purely administrative in nature, exempting administrative site leasing from 36 CFR part 251, subpart B. Departmental regulations at 7 CFR 1b.4(c)(20) exclude from documentation in an environmental assessment or environmental impact statement ''rules, regulations, or policies to establish service wide administrative procedures, program processes, or instructions.'' The Department's assessment is that this final rule falls within this category of actions and that no extraordinary circumstances exist that would require preparation of an environmental assessment or environmental impact statement.

Regulatory Flexibility Act

The Department has considered this final rule under the Regulatory Flexibility Act (5 U.S.C. 602 *et. seq.*). This final rule would not have any direct effect on small entities as defined by the Regulatory Flexibility Act. This final rule would not impose any additional recordkeeping requirements on small entities, would not affect their competitive position in relation to large entities, and would not affect their cash

flow, liquidity, or ability to remain in the market. Therefore, the Department has determined that this final rule would not have a significant economic impact on a substantial number of small entities pursuant to the Regulatory Flexibility Act.

Federalism

The Department has considered this final rule under the requirements of E.O. 13132, *Federalism.* The Department has determined that the final rule conforms to the federalism principles set out in this E.O., would not impose any compliance costs on the States; and would not have substantial direct effects 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. Therefore, the Department has concluded that this final rule would not have federalism implications.

Consultation and Coordination With Indian Tribal Governments

E.O. 13175, *Consultation and Coordination with Indian Tribal Governments,* requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. This final rule is purely administrative in nature. The Department has reviewed this final rule in accordance with the requirements of E.O. 13175 and has determined that this final rule would not have substantial direct effects on Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Therefore, consultation and coordination with Indian Tribal governments is not required for this final rule.

Family Policymaking Assessment

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277), requires Federal agencies to issue a Family Policymaking Assessment for a rule that may affect family well-being. The final rule would have no impact on the autonomy or integrity of the family as an institution. Accordingly, the Department has concluded that it is not necessary to prepare a Family Policymaking Assessment for the final rule.

Takings Implications

The Department has analyzed the final rule in accordance with the principles and criteria in E.O. 12630, *Governmental Actions and Interference with Constitutionally Protected Property Rights.* The Department has determined that the final rule would not pose the risk of a taking of private property.

Energy Effects

The Department has reviewed the final rule under E.O. 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.* The Department has determined that the final rule would not constitute a significant energy action as defined in E.O. 13211.

Civil Justice Reform

The Department has analyzed the final rule in accordance with the principles and criteria in E.O. 12988, *Civil Justice Reform.* Upon publication of the final rule, (1) all State and local laws and regulations that conflict with the final rule or that impede its full implementation would be preempted; (2) no retroactive effect would be given to this final rule; and (3) it would not require administrative proceedings before parties may file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Department has assessed the effects of the final rule on State, local, and Tribal governments and the private sector. The final rule would not compel the expenditure of $100 million or more, adjusted annually for inflation, in any one year by State, local, and Tribal governments in the aggregate or by the private sector. Therefore, a statement under section 202 of the Act is not required.

Paperwork Reduction Act

The final rule does not contain any recordkeeping or reporting requirements or other information collection requirements as defined in 5 CFR part 1320 that are not already required by law or not already approved for use. However, if implementation of this rule results in substantive or material changes to current Forest Service forms or collections previously approved under the special uses Information Collection Request (ICR), a revised ICR will be submitted to OMB for review and approval before the revised information collection is implemented.

List of Subjects in 36 CFR Part 251

Land uses.

Therefore, for the reasons set forth in the preamble, the Forest Service amends chapter II of title 36 of the Code of Federal Regulations as follows:

PART 251—LAND USES

Subpart B—Special Uses

■ 1. The authority citation for part 251, subpart B, continues to read as follows:

Authority: 16 U.S.C. 460*l*–6a, 460*l*–6d, 472, 497b, 497c, 551, 580d, 1134, 3210; 30 U.S.C. 185; 43 U.S.C. 1740, 1761–1772.

■ 2. Amend § 251.50 by revising paragraph (a) to read as follows:

§ 251.50 Scope.

(a) All uses of National Forest System lands, improvements, and resources, except those authorized by the regulations governing sharing use of roads (§ 212.9 of this chapter); grazing and livestock use (part 222 of this chapter); the sale and disposal of timber and special forest products, such as greens, mushrooms, and medicinal plants (part 223 of this chapter); minerals (part 228 of this chapter); and administrative site leases (Pub. L. 115–334, sec. 8623, and Pub. L. 109–54) are designated ''special uses.'' Before conducting a special use, individuals or entities must submit a proposal to the authorized officer and must obtain a special use authorization from the authorized officer, unless that requirement is waived by paragraphs (c) through (e)(3) of this section.

* * * * *

■ 3. Amend § 251.51 by revising the definitions of ''Lease'' and ''Special use authorization'' to read as follows:

§ 251.51 Definitions.

* * * * *

Lease—A type of special use authorization (usually granted for uses other than linear rights-of-way) that is used when substantial capital investment is required and when conveyance of a conditional and transferable interest in National Forest System lands is necessary or desirable to serve or facilitate authorized long-term uses, and that may be revocable and compensable according to its terms. This definition does not apply to administrative site leases covered under Public Law 115–334, sec. 8623, and Public Law 109–54.

* * * * *

Special use authorization—A written permit, term permit, lease, or easement

that authorizes use or occupancy of National Forest System lands and specifies the terms and conditions under which the use or occupancy may occur. This definition does not apply to administrative site leases covered under Public Law 115–334, sec. 8623, and Public Law 109–54.

* * * * *

Michael K. Boren,

Under Secretary, Natural Resources and Environment.

[FR Doc. 2026–22296 Filed 10–30–26; 8:45 am]

BILLING CODE 3411–15–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 51 and 63

[WC Docket Nos. 25–208, 25–209; FCC 26–19; FR ID 370342; FR ID 374754]

Reducing Barriers to Network Improvements and Service Changes, Accelerating Network Modernization; Correction

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction; announcement of effective date.

SUMMARY: In this document, the Wireline Competition Bureau (Bureau) withdraws all amendatory instructions inadvertently included in the notification published on October 1, 2026, announcing the effective dates of amendments to the Federal Communications Commission's network change disclosure and discontinuance rules adopted in a Report and Order (FCC 26–19) that published on April 20, 2026. In this document, the Bureau also announces the effective date for amendments published on April 20, 2026.

DATES: Amendatory instruction 7 (§ 63.62), published at 91 FR 20913, April 20, 2026, is effective on November 2, 2026, and applicable as of October 15, 2026. The corrections in this document are effective on November 2, 2026.

FOR FURTHER INFORMATION CONTACT: Michele Berlove, Assistant Division Chief, Wireline Competition Bureau, at (202) 418–0357, or by email at *Michele.Berlove@fcc.gov*. For additional information concerning the Paperwork Reduction Act information collection requirements, contact Nicole Ongele at (202) 418–2991 or *nicole.ongele@fcc.gov*.

SUPPLEMENTARY INFORMATION: On March 26, 2026, the Commission adopted a *Report and Order*, FCC 26–19, published at 91 FR 20913, April 20, 2026. In the *Report and Order*, the Commission adopted rules to reduce regulatory barriers and costs that hinder the transition from outdated legacy networks and services to next-generation, internet Protocol (IP)-based infrastructure. The Commission stated that these rule changes may contain new or modified information collection requirements and would not become effective until OMB completes its review of any information collection requirements that the Bureau determined is required under the Paperwork Reduction Act. The Commission also directed the Bureau to announce the effective date for the revisions to §§ 51.329, 51.333, 63.60, 63.62, 63.63, 63.71, and 63.602 by subsequent public notice.

On September 21, 2026, OMB approved the information collection requirements related to the discontinuance rules contained in the *Report and Order*. The OMB Control Number is 3060–0149. The Bureau publishes this document as an announcement of the effective date of § 63.62 of the service discontinuance rules adopted in the *Report and Order*. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Nicole Ongele, Federal Communications Commission, 45 L Street NE, Washington, DC 20554. Please include the OMB Control Numbers 3060–0741 and 3060–0149 in your correspondence. The Commission also will accept your comments via email at *PRA@fcc.gov*. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice).

On October 1, 2026, the Bureau published a document in the **Federal Register** (FR Doc. 2026–20192) announcing the effective dates of amendments to its network change disclosure and discontinuance rules. That document inadvertently included amendatory instructions. This document withdraws all such amendatory instructions included in the effective date notice published at 91 FR 62334, October 1, 2026.

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Bureau is notifying the public that it received final OMB approval on September 21, 2026, for the information collection requirements contained in the changes to the Commission's service discontinuance rules in 47 CFR part 63.

Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number.

The foregoing notification is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the affected respondents are as follows:

OMB Control Number: 3060–0149.

OMB Approval Date: September 21, 2026.

OMB Expiration Date: September 30, 2029.

Title: Part 63, Reducing Barriers to Network Improvements and Service Changes, Accelerating Network Modernization, WC Docket Nos. 25–208, 25–209, FCC 26–19. Form Number: N/A.

Respondents: Business or other for profit.

Number of Respondents and Responses: 78 respondents; 90 responses.

Estimated Time per Response: 6–10 hours per response.

Frequency of Response: One-time reporting requirement and third-party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in 47 U.S.C. 214 and 402 of the Communications Act of 1934, as amended.

Total Annual Burden: 648 hours.

Total Annual Cost: No Cost.

Needs and Uses: The Commission received OMB approval for revisions to an existing information collection, OMB Collection 3060–0149. Section 214 of the Communications Act of 1934, as amended, requires that a carrier must first obtain FCC authorization either to (1) construct, operate, or engage in transmission over a line of communications; or (2) discontinue, reduce or impair service over a line of communications. Part 63 of title 47 of the Code of Federal Regulations (CFR) implements section 214.

Part 63 also implements provisions of the Cable Communications Policy Act of 1984 pertaining to video which was approved under this OMB Control Number 3060–0149. In 2009, the Commission modified part 63 to extend

to providers of interconnected Voice over internet Protocol (VoIP) service the discontinuance obligations that apply to domestic non-dominant telecommunications carriers under section 214 of the Communications Act of 1934, as amended. In 2014, the Commission adopted improved administrative filing procedures for domestic transfers of control, domestic discontinuances and notices of network changes, and among other adjustments, modified part 63 to require electronic filing for applications for authorization to discontinue, reduce, or impair service under section 214(a) of the Act. In July 2016, the Commission concluded that applicants seeking to discontinue a legacy time division multiplexing (TDM)-based voice service as part of a transition to a new technology, whether internet Protocol (IP), wireless, or another type (technology transition discontinuance application) must demonstrate that an adequate replacement for the legacy service exists in order to be eligible for streamlined treatment and revised part 63 accordingly. The Commission concluded that an applicant for a technology transition discontinuance may demonstrate that a service is an adequate replacement for a legacy voice service by certifying or showing that one or more replacement service(s) offers all of the following: (i) Substantially similar levels of network infrastructure and service quality as the applicant service; (ii) compliance with existing federal and/or industry standards required to ensure that critical applications such as 911, network security, and applications for individuals with disabilities remain available; and (iii) interoperability and compatibility with an enumerated list of applications and functionalities determined to be key to consumers and competitors (the ''adequate replacement test''). In November 2017, the Commission further modified the rules applicable to section 214(a) discontinuance applications by (1) expediting applications that ''grandfather'' low speed legacy services for existing customers; (2) expediting applications to discontinue previously grandfathered legacy data services; and (3) expediting applications to discontinue legacy voice or data services below 1.544 Mbps for which the carrier has had no customers and no request for service for at least a 30-day period immediately preceding submission of the application. In June 2018, the Commission again modified the rules applicable to section 214(a) discontinuance applications. First, all carriers, whether dominant or non-dominant, that seek approval to grandfather data services below speeds of 25 Mbps download speed and 3 Mbps upload speed are subject to a uniform reduced public comment period of 10 days and an automatic grant period of 25 days. Second, all carriers, whether dominant or nondominant, seeking authorization to discontinue data services below speeds of 25 Mbps download speed and 3 Mbps upload speed that have previously been grandfathered for a period of at least 180 days are subject to a uniform reduced public comment period of 10 days and an automatic grant period of 31 days, provided they submit a statement as part of their discontinuance application that they have received Commission authority to grandfather the services at issue at least 180 days prior to the filing of the discontinuance application. The statement must reference the file number of the prior Commission authorization to grandfather the services the carrier then seeks to permanently discontinue. Third, carriers are no longer required to file an application to discontinue, reduce, or impair any service for which it has had no customers and no request for service for at least a 30-day period immediately preceding the discontinuance. Fourth, all carriers, whether dominant or nondominant, that seek approval to discontinue legacy voice service can obtain further streamlined processing with a public comment period of 15 days and an automatic grant period of 31 days, provided (1) they offer a standalone interconnected VoIP service throughout the service area, and (2) at least one alternative stand-alone, facilities-based voice service is available from an unaffiliated provider throughout the affected service area (the ''alternative options test''). Finally, all carriers, whether dominant or nondominant, that seek approval to grandfather legacy voice service are subject to a uniform reduced public comment period of 10 days and an automatic grant period of 25 days. Certain rules are now modified as described below. In March 2026, the Commission further modified the rules applicable to section 214(a) discontinuance applications by: (1) adopting one consolidated rule applicable to all technology transitions discontinuance applications, whereby an application to discontinue a currently offered retail voice service as part of a technology transition is eligible for streamlined processing if the applicant certifies that one or more of five specified categories of replacement services is available in every location throughout the affected service area; (2) granting blanket section 214(a) authority for carriers to grandfather legacy voices services, lower-speed data telecommunications services (defined as those operating at speeds below 25/3 Mbps), and interconnected Voice over internet Protocol (VoIP) service provisioned over copper wire, thus eliminating the need for carriers to file a section 214(a) application when grandfathering these services; (3) adopting requirements providing that carriers seeking authority to discontinue a service supporting interconnection trunks or the exchange of traffic must specifically identify the service to be discontinued, not just the branded name of the service being discontinued, and that they must include in such discontinuance applications a statement that at least 90 days prior to the planned discontinuance filing, the carrier provided a designated point of contact with authority to facilitate the orderly transition from legacy facilities that support 911 to the 911 Authorities, 911 service providers, and directly interconnecting local exchange service providers that support essential functions within 911 networks, including delivering 911 traffic to selective routers for transmission to public safety answering points (PSAPs) in the affected service area for coordination of the transition to ensure continued 911 connectivity, and a list of providers that received notice in the affected service area with which the carrier has coordinated and the date(s) of that coordination; (4) granting conditional forbearance relief from section 214(a) discontinuance requirements for resellers discontinuing resold services where the reseller's wholesale provider is engaging in a technology transitions discontinuance, with the condition that the discontinuing resellers provide reasonable notice to their customers; (5) applying the 31-day automatic grant period to all discontinuance applications; (6) setting forth content requirements for discontinuance applications; and (6) providing that a carrier may permanently discontinue a service after a showing that it has previously obtained emergency discontinuance authority for the service in question, that the service is one for which the requesting carrier has had no customers or reasonable requests for service during the 60-day period immediately preceding the permanent discontinuance, and that an adequate replacement service is available throughout the affected service area. The Commission also eliminated 47

CFR 63.66, 63.90, 63.100, 63.504, 63.601, and 63.602, and revised 47 CFR 63.60, 63.62, and 63.63 to account for any references or cross-references in those sections caused by the elimination of the previously enumerated rule provisions.

Corrections

PARTS 51 and 63 [CORRECTED]

■ In FR Doc. 2026–20192, published at 91 FR 62334, October 1, 2026, starting on page 62337, in the second column, for parts 51 and 63, remove the text following the signature block for Marlene Dortch (including the Words of Issuance and amendatory instructions 1 through 9).

Federal Communications Commission

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2026–22334 Filed 10–30–26; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 91, No. 210
Monday, November 2, 2026

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 40, 50, 70, and 72

[NRC–2017–0021]

RIN 3150–AJ92

Alternatives to the Use of Credit Ratings

AGENCY: Nuclear Regulatory Commission.

ACTION: Discontinuation of rulemaking activity.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is discontinuing the rulemaking activity, ''Alternatives to the Use of Credit Ratings.'' This rulemaking activity will no longer be reported in the NRC's portion of the Unified Agenda of Regulatory and Deregulatory Actions (the Unified Agenda).

DATES: Effective November 2, 2026, the rulemaking activity discussed in this document is discontinued.

ADDRESSES: Please refer to Docket ID NRC–2017–0021 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2017–0021. Address questions about NRC dockets to Helen Chang; telephone: 301–415–3228; email: *Helen.Chang@nrc.gov.*
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin ADAMS Public Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, the ADAMS accession numbers are provided in the ''Availability of Documents'' section of this document.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: David Suchy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–4130; email: *David.Suchy@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Congress passed the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the Dodd-Frank Act or the Act) to ''promote the financial stability of the United States by improving accountability and transparency in the financial system,'' (Pub. L. 111–203). In the Act, Congress found that ''ratings on structured financial products have proven to be inaccurate'' and that ''[t]his inaccuracy contributed significantly to the mismanagement of risks by financial institutions and investors, which in turn adversely impacted the health of the economy.'' In section 939A of the Act, Congress directed each Federal agency to ''review any regulation issued by such agency that requires the use of an assessment of the credit-worthiness of a security or money market instrument and any references to or requirements in such regulations regarding credit ratings.'' Section 939A of the Act further directed each such agency to ''modify any such regulations identified by the review . . . to remove any reference to or requirement of reliance on credit ratings and to substitute in such regulations such standard of credit-worthiness as each respective agency shall determine as appropriate for such regulations.'' A discussion of the NRC's decision to discontinue this rulemaking activity is provided in section II of this document.

II. Discussion

As directed by section 939A of the Dodd-Frank Act, the NRC reviewed its regulations for any references for requirements of reliance on credit ratings. In accordance with this review, the NRC issued a proposed rulemaking and associated guidance for public comment January 3, 2023 (88 FR 25). The NRC received two public comment submissions on the proposed rulemaking; the public comments were considered during the final rule revision efforts, but the NRC will not be responding due to the discontinuation of the rulemaking.

As part of the final rule revisions, the NRC reviewed Dodd-Frank Act policies and rulemakings published by other Federal agencies to examine the manner in which they implemented the removal of references to credit ratings when they are used to assess the credit-worthiness of the underlying security. In 2023, the U.S. Securities and Exchange Commission issued implementing regulations to ''remove certain existing rule exceptions that reference credit ratings for nonconvertible debt securities, nonconvertible preferred securities, and asset-backed securities and substitute in their place new exceptions that are based on alternative standards of creditworthiness,'' (88 FR 39962; June 20, 2023). The NRC staff also learned from the Office of Information and Regulatory Affairs (OIRA) that the NRC was the only non-financial regulator that submitted a rulemaking in response to section 939A of Dodd Frank for Executive Order 12866, ''Regulatory Planning and Review.'' In reviewing regulatory actions of other Federal agencies related to Dodd Frank, the NRC determined that it is in the best interest of the agency to discontinue this rulemaking as it would assess the credit-worthiness of an entity (not a security), whereas it is Federal best-practice to utilize the bottom-line credit-worthiness determination of the underlying regulation operated on a security or money market instrument.

III. Conclusion

The NRC is no longer pursuing the rulemaking for Alternatives to the Use of Credit Ratings. In the next edition of the Unified Agenda, the NRC will update the entry for this rulemaking activity and reference this document to indicate that the rulemaking activity is no longer being pursued. This rulemaking will appear in the completed actions section of that edition of the Unified Agenda but will not appear in future editions. The NRC

will inform the public of future associated rulemakings through new rulemaking entries in the Unified Agenda.

Dated: October 29, 2026.

For the Nuclear Regulatory Commission.

Jody Martin,

Secretary of the Commission.

[FR Doc. 2026–22293 Filed 10–30–26; 8:45 am]

BILLING CODE 7590–01–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201

[Docket No. 2026–4]

Exemptions To Permit Circumvention of Access Controls on Copyrighted Works; Correction

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects the preamble to a proposed rule published in the **Federal Register** on October 28, 2026, regarding Exemptions to Permit Circumvention of Access Controls on Copyrighted Works. The correction fixes a typographical error within a subsection discussing a petition to renew a current exemption.

DATES: November 2, 2026.

FOR FURTHER INFORMATION CONTACT: Rhea Efthimiadis, Assistant to the General Counsel, by email at *USCOGeneralCounsel@copyright.gov* or by telephone at (202) 707–8350.

SUPPLEMENTARY INFORMATION:

Correction

In proposed rule FR Doc. 2026–21939, beginning on page 67788 in the issue of October 28, 2026, make the following correction, in the **SUPPLEMENTARY INFORMATION** section. On page 67794 in column 1, in line 8, add the word ''not'' before the phrase ''permitted by the exemption.''

Dated: October 28, 2026.

Emily L. Chapuis,

General Counsel and Associate Register of Copyrights.

[FR Doc. 2026–22274 Filed 10–30–26; 8:45 am]

BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2026–5974; FRL–13610–01–OCSPP]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances (26–7)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for certain chemical substances that were the subject of premanufacture notices (PMNs) and are also subject to an Order issued by EPA pursuant to TSCA. Once finalized, the SNURs would require persons who intend to manufacture (defined by statute to include import) or process any of these chemical substances for an activity that is proposed as a significant new use by this rulemaking to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the conditions of that use for that chemical substance. In addition, the manufacture or processing for the significant new use may not commence until EPA has conducted a review of the required notification, made an appropriate determination regarding that notification, and taken such actions as required by that determination.

DATES: Comments must be received on or before December 2, 2026.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2026–5974, online at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, are available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information: Nicole Scharko, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1165; email address: *Scharko.Nicole@epa.gov.*

For general information on SNURs: Iliriana Mushkolaj, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–6877; email address: *Mushkolaj.Iliriana@epa.gov.*

For general information on TSCA: The TSCA Assistance Information Service Hotline, Goodwill of the Finger Lakes, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (800) 471–7127 or (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What is the Agency's authority for taking this action?

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including the factors in TSCA section 5(a)(2) (see also the discussion in Unit II.).

B. What action is the Agency taking?

EPA is proposing SNURs for the chemical substances discussed in Unit III. These SNURs, if finalized as proposed, would require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

C. Does this action apply to me?

1. General Applicability

This action applies to you if you manufacture, process, or use the chemical substances contained in this proposed rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

2. Applicability to Importers and Exporters

This action may also apply to certain entities through pre-existing import certification and export notification requirements under TSCA (*https://www.epa.gov/tsca-import-export-requirements*).

Chemical importers are subject to TSCA section 13 (15 U.S.C. 2612), the requirements in 19 CFR 12.118 through 12.127, 19 CFR 127.28, and 40 CFR 707.20. Importers of chemical substances in bulk form, as part of a mixture, or as part of an article (if required by rule) must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including regulations issued under TSCA sections 5, 6, 7 and Title IV.

Pursuant to 40 CFR 721.20, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after December 2, 2026 are subject to TSCA section 12(b) (15 U.S.C. 2611(b)) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

D. What are the incremental economic impacts of this action?

EPA has evaluated the potential costs of establishing SNUN reporting requirements for potential manufacturers (including importers) and processors of chemical substances subject to these proposed SNURs. This analysis, which is available in the docket, is briefly summarized here.

1. Estimated Costs for SNUN Submissions

If a SNUN is submitted, costs are an estimated $45,496 per SNUN submission for large business submitters and $14,976 for small business submitters. These estimates include the cost to prepare and submit the SNUN (including registration for EPA's Central Data Exchange (CDX)), and the payment of a user fee. Businesses that submit a SNUN would be subject to either a $37,000 user fee required by 40 CFR 700.45(c)(2)(ii) and (d), or, if they are a small business as defined at 13 CFR 121.201, a reduced user fee of $6,480 (40 CFR 700.45(c)(1)(ii) and (d)). The costs of submission for SNUNs will not be incurred by any company unless a company decides to pursue a significant new use as defined in these SNURs. Additionally, these estimates reflect the costs and fees as they are known at the time of this rulemaking.

2. Estimated Costs for Export Notifications

EPA has also evaluated the potential costs associated with the export notification requirements under TSCA section 12(b) and the implementing regulations at 40 CFR part 707, subpart D. For persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical, depending on the number of required notifications (*i.e.,* the number of countries to which the chemical is exported). While EPA is unable to make any estimate of the likely number of export notifications for the chemical substances covered by these SNURs, as stated in the accompanying economic analysis, the estimated cost of the export notification requirement on a per unit basis is approximately $106.

E. What should I consider as I prepare my comments for EPA?

1. Submitting CBI

Do not submit CBI to EPA through email or *https://www.regulations.gov.* If you wish to include CBI in your comment, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703.

2. Tips for Preparing Your Comments

When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Background

This unit provides general information about SNURs. For additional information about EPA's new chemical program go to *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca.*

A. Significant New Use Determination Factors

TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with the substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this Unit and discussed in Unit III.

These proposed SNURs are based on orders issued to certain companies for substances that were the subject of PMN submissions. Those orders were issued under TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). The TSCA orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs extend those protective measures to any person intending to manufacture, process, use, distribute in commerce, or dispose of the new chemical substances subject to orders and identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA orders, consistent with TSCA section 5(f)(4).

B. Rationale and Objectives of the SNURs

1. Rationale

Under TSCA section 5(a)(1)(B), no person may manufacture a new chemical substance or manufacture or process a chemical substance for a significant new use until EPA makes a determination as described in TSCA section 5(a)(3) and takes any required action. The issuance of a SNUR is not a risk determination itself, only a notification requirement for ''significant new uses,'' so that the Agency has the opportunity to review the SNUN for the significant new use and make a TSCA section 5(a)(3) risk determination.

During review of the PMNs submitted that identify chemical substances subject to these proposed SNURs, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. Based on the findings outlined in Unit III., TSCA section 5(e) Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. As a general matter, EPA believes it is necessary to follow a TSCA order with a SNUR that identifies the absence of those protective measures as significant new uses to ensure that all manufacturers and processors—not just

the party subject to a TSCA order—are held to the same standard.

2. Objectives

EPA is proposing these SNURs because the Agency has determined it is appropriate:

- To identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).
- To have an opportunity to review and evaluate data submitted in a SNUN before the submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- To be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under TSCA section 5(a)(3)(C) that the significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under TSCA section 5(a)(3)(A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.

Issuance of a proposed SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available at *https://www.epa.gov/*tsca-inventory.

C. Significant New Uses Claimed as CBI

EPA is proposing to establish certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR parts 2 and 703. Absent a final determination or other disposition of the confidentiality claim under these regulations, EPA is required to keep this information confidential. EPA promulgated a procedure at 40 CFR 721.11 to deal with the situation where a specific significant new use is CBI. Under these procedures, a manufacturer or processor may ask EPA to identify the confidential significant new use subject to the SNUR. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will identify the confidential significant new use to that person. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in 40 CFR 721.11 into a single step.

D. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to SNURs, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Pursuant to 40 CFR 721.1(c), persons subject to SNURs must comply with the same requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5), and the regulations at 40 CFR part 720. In addition, provisions relating to user fees appear at 40 CFR part 700.

Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination under TSCA section 5 before the manufacture (including import) or processing for the significant new use can commence. If EPA determines that the significant new use of the chemical substance is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

As discussed in Unit I.C.2., persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b), and persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements. See also *https://www.epa.gov/tsca-import-export-requirements.*

E. Applicability of the Proposed SNURs to Uses Occurring Before the Effective Date of the Final Rule

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review and received determinations under TSCA section 5(a)(3)(C). TSCA Orders have been issued for these chemical substances, and the PMN submitters are required by the TSCA Orders to submit a SNUN before undertaking activities that would be designated as significant new uses in these SNURs. Additionally, the identities of many of the chemical substances subject to this proposed rule have been claimed as confidential per 40 CFR 720.85, further reducing the likelihood that another party would manufacture or process the substances for an activity that would be designated as a significant new use. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses identified in Unit III. are ongoing.

When the chemical substances identified in Unit III. are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. Persons who begin manufacture or processing of the chemical substances for a significant new use identified on or after the designated cutoff date specified in Unit III.A. would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and EPA would have to take action under TSCA section 5 allowing manufacture or processing to proceed.

F. Important Information About SNUN Submissions

1. SNUN Submissions

SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E–PMN software is available electronically at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca.*

2. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require development of any particular new information (*e.g.,* generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, order, or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such information to

be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, TSCA order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. To assist with EPA's analysis of the SNUN, submitters are encouraged, but not required, to provide the potentially useful information as identified for the chemical substance in Unit III.C.

EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). For more information on alternative test methods and strategies to reduce vertebrate animal testing, *visit https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce.*

The potentially useful information described in Unit III. may not be the only means of providing information to evaluate the chemical substance associated with the significant new uses. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA sections 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information about human exposure and environmental release that may result from the significant new use of the chemical substances.

III. Chemical Substances Subject to These Proposed SNURs

A. What is the designated cutoff date for ongoing uses?

EPA designates November 2, 2026 as the cutoff date for determining whether the new use is ongoing. This designation is explained in more detail in Unit II.E.

B. What information is provided for each chemical substance?

For each chemical substance identified in Unit III.C., EPA provides the following information:

- PMN number(s) (as well as the proposed CFR citation assigned in the regulatory text section of this document).
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service Registry Number (CASRN) or Accession Number (if assigned for confidential chemical identities).
- Basis for the SNUR (*e.g.,* effective date of and basis for the corresponding TSCA Order).
- Potentially useful information.

The regulatory text section of the proposed rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated in the proposed rules, may be claimed as CBI.

These proposed SNURs include PMN substances that are subject to orders issued under TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). Those TSCA Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).

C. Which chemical substances are subject to these proposed SNURs?

The substances subject to the proposed SNURs in this document are as follows, listed by PMN number and with the proposed CFR citation:

P–20–105 (40 CFR 721.12320)

Chemical Name: 4H-Pyran-4-one, 3-[(2,5-dihydro-4-methyl-5-oxo-2-furanyl)oxy]-2-methyl-.

CASRN: 1333341–34–6.

Effective Date of TSCA Order: November 9, 2021. Modification 1: October 25, 2022.

Modification 2: May 24, 2023.

Basis for TSCA Order: The PMN states that the use will be to promote microbial activity in the soil, resulting in increased availability of nutrients in the soil, including nitrogen and phosphorus, for crops (for use on commercial farming operations). Based on submitted test data on the PMN substance, EPA has identified concerns for skin and eye irritation. Based on comparison to analogous chemical substances, EPA has also identified concerns for systemic and reproductive/developmental effects. Based on comparison to analogous vinyl esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 5 parts per billion (ppb). The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- No processing of the PMN substance other than in a facility that employs an on-site sump system used to capture fugitive dust releases and disposes the solid waste captured by this sump system by landfill;
- No processing of the PMN substance except under negative pressure when transferring the PMN substance as a solid material to minimize exposures to fugitive dust/particulates;
- No domestic manufacture of the PMN substance (*i.e.,* import only);
- No use of the PMN substance in a consumer product;
- No use of the PMN substance in non-aerial spray applications at a concentration exceeding 0.01% in formulation by weight;
- No use of the PMN substance in aerial spray applications at a concentration exceeding 0.06% in formulation by weight;
- Use of the PMN substance only to promote microbial activity in the soil, resulting in increased availability of nutrients in the soil, including nitrogen and phosphorus, for crops (for use on commercial farming operations); and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the Safety Data Sheet (SDS).

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information

may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–22–56 (40 CFR 721.12321)

Chemical Name: Tin, dioctylbis(2,4-pentanedionato-.kappa.O2,.kappa.O4).

CASRN: 54068–28–9.

Effective Date of TSCA Order: April 1, 2026.

Basis for TSCA Order: The PMN states that the use will be as a catalyst in sealants and adhesives. Based on submitted test data on the PMN substance, EPA has identified concerns for skin irritation, eye irritation, skin sensitization, systemic effects, immunotoxicity, reproductive, and developmental effects. Based on a hydrolysis product and comparison to analogous organotins, EPA has also identified concerns for acute neurotoxicity and respiratory tract irritation. Based on submitted test data on the PMN substance and comparison to analogous organotins, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 34 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Manufacture, processing, and use of the PMN substance only in a manner that does not result in inhalation exposure to the PMN substance;
- Processing for use and use of the PMN substance in a consumer product only if the concentration of the PMN substance is less than 1% by weight in the consumer product;
- No release of the PMN substance, or any waste stream containing the PMN substance, to water; and
- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of exposure monitoring may be potentially useful to characterize the human health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–23–14 (40 CFR 721.12322)

Chemical Name: 1-Naphthaleneethanol, decahydro-5,5,8a-trimethyl-2-methylene-, 1-acetate, (1R,4aR,8aR)-rel.

CASRN: 65794–67–4.

Effective Date of TSCA Order: April 27, 2026.

Basis for TSCA Order: The PMN states that the use will be as a chemical intermediate. Based on the physical/chemical properties of the PMN substance (as described in the New Chemical Program's persistent, bioaccumulative, and toxic (PBT) category at 64 FR 60194; November 1999) and in the absence of data, the PMN substance is a potential PBT chemical. EPA estimates that the PMN substance will persist in the environment for more than six months and estimates a bioaccumulation factor of greater than or equal to 5,000. Based on comparison to analogous chemical substances, EPA has identified concerns for skin sensitization, portal-of-entry effects, and systemic effects. Based on comparison to analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 0.3 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- No processing for use or use of the PMN substance in a consumer product;
- Manufacture, processing, and use of the PMN substance only in a manner that does not result in inhalation exposure to the PMN substance;
- Disposal of the PMN substance or waste streams containing the PMN substance must be by hazardous waste incineration in compliance with RCRA subtitle C and only in a manner that does not result in inhalation exposure at the incineration facility;
- No release of the PMN substance, or any waste stream containing the PMN substance, into water; and
- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of bioaccumulation, pulmonary effects, skin sensitization, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the fate, human health, and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–23–141 (40 CFR 721.12323)

Chemical Name: 2-Butenedioic acid (2Z)-, potassium salt (1:?).

CASRN: 10237–70–4.

Effective Date of TSCA Order: June 23, 2026.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a buffer solution for free chlorine determination. Based on comparison to analogous chemical substances and on information in the SDS, EPA has identified concerns for acute toxicity, skin irritation, eye irritation, respiratory tract irritation, and systemic toxicity. Based on comparison to analogous polyanionic polymers (& monomers), EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 415 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To

protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Manufacture, processing, and use of the PMN substance only in a liquid solution;
- Manufacture of the PMN substance only below the confidential annual production volume listed in the Order;
- No processing for use or use of the PMN substance in a consumer product;
- Use of the PMN substance only as a buffer solution for free chlorine determination;
- No release of the PMN substance, or any waste stream containing the PMN substance, resulting in surface water concentrations that exceed 415 ppb; and
- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation, eye irritation, acute toxicity, specific target organ toxicity, developmental toxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–24–52 (40 CFR 721.12324)

Chemical Name: Functionalized fatty acids (generic).

CASRN: Not available.

Effective Date of TSCA Order: April 22, 2026.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a chemical precursor. Based on comparison to analogous chemical substances, EPA has identified concerns for skin irritation, eye irritation, respiratory irritation, and systemic effects. Based on comparison to analogous anionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1000 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- No processing for use or use of the PMN substance in a consumer product;
- No manufacture, processing, or use of the PMN substance in a manner that generates a vapor, mist, dust, or aerosol containing the PMN substance unless in an enclosed process;
- No release of the PMN substance, or any waste stream containing the PMN substance, resulting in surface water concentrations that exceed 1000 ppb; and
- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of eye irritation, pulmonary effects, skin irritation, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–24–75 (40 CFR 721.12325)

Chemical Name: Carbamic acid, N, N′, N″-1,3,5-triazine-2,4,6-tryltris-, mixed alkyl triesters (generic).

CASRN: Not available.

Effective Date of TSCA Order: May 28, 2026.

Basis for TSCA Order: The PMN states that the use will be as a water based formaldehyde free crosslinking additive for acid resistance. Based on comparison to analogous chemical substances, EPA has identified concerns for skin sensitization, skin and eye irritation, and respiratory and systemic effects. Based on comparison to analogous substituted triazines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 68 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- Use of personal protective equipment where there is a potential for dermal exposure;
- Manufacture, processing and use of the PMN substance only in the form of a liquid solution;
- Processing and use of the PMN substance only in a liquid solution;
- No processing for use or use of the PMN substance in a consumer product;
- Use of the PMN substance only as a water based formaldehyde free crosslinking additive for acid resistance;
- Use of the PMN substance only if the concentration of the PMN substance does not exceed the confidential concentration (by weight) listed in the Order in the final coating;
- No release of the PMN substance, or any waste stream containing the PMN substance, resulting in surface water concentrations that exceed 68 ppb; and
- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of eye irritation, pulmonary effects, skin irritation, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–24–90 (40 CFR 721.12326)

Chemical Name: Glycine, N-(aminoiminomethyl)-, manuf. of, by-products from.

CASRN: 2981438–54–2.

Effective Date of TSCA Order: May 22, 2026.

Basis for TSCA Order: The PMN states that the use will be as a manure additive. Based on submitted test data on the PMN substance and comparison to analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 104 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to the environment. To protect against these risks, the Order requires:

- Use of the PMN substance only as a manure additive;
- No release of the PMN substance, or any waste stream containing the PMN substance, resulting in surface water concentrations that exceed 104 ppb. This restriction does not apply to any use stream containing the substance from any use site; and
- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of chronic aquatic toxicity testing may be potentially useful to characterize the environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–24–128 (40 CFR 721.12327)

Chemical Name: Tetramethyl disiloxanediylbis[propylcarbonyl] (generic).

CASRN: Not available.

Effective Date of TSCA Order: June 15, 2026.

Basis for TSCA Order: The PMN states that the use of the PMN substance will be as a chemical intermediate. Based on the physical/chemical properties of the PMN substance (as described in the New Chemical Program's PBT category at 64 FR 60194; November 1999) and in the absence of data, the PMN substance is a potential PBT chemical. EPA estimates that the PMN substance will persist in the environment for more than six months and estimates a bioaccumulation factor of >1000 and <5000. Based on comparison to analogous chemical substances, EPA has identified concerns for acute (oral) toxicity, corrosion to the skin, eyes, and respiratory tract, portal-of-entry (oral, inhalation) effects, skin and respiratory sensitization, and systemic effects. Based on comparison to analogous aldehydes (poly), EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- Manufacture and use of the PMN substance only as a site-limited intermediate;
- Manufacture, processing, and use of the PMN substance only using a control device serving the reactor with a 98% destruction removal efficiency.
- Disposal of the PMN substance, or waste streams containing the PMN substance, only by the confidential method listed in the Order;
- No release of the PMN substance, or any waste stream containing the PMN substance, to water; and
- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of persistence, bioaccumulation, skin irritation, skin corrosion, eye irritation, eye corrosion, pulmonary effects, skin sensitization, specific target organ toxicity, acute toxicity, and aquatic toxicity testing may be potentially useful to characterize the fate, human health, and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–24–132 (40 CFR 721.12328)

Chemical Name: Sunflower oil, oleic acid-high, maleated.

CASRN: 2205860–51–9.

Effective Date of TSCA Order: June 18, 2026.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use of the substance will be as a sizing agent. Based on submitted test data on the PMN substance, EPA has identified concerns for skin sensitization. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Processing for use and use of the PMN substance in a consumer product only if the concentration of the PMN substance does not exceed 1% by weight in the consumer product; and
- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of toxicokinetics and pulmonary effects testing may be potentially useful to characterize the human health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–24–136 (40 CFR 721.12329)

Chemical Name: Siloxanes and Silicones, di-Me, polymers with silicic acid, [(ethenyldimethylsilyl)oxyl]-terminated, reaction products with 1,1,3,3-tetramethyl-1-[1-

(trimethoxysilyl)ethyl]disiloxane and 1,1,3,3-tetramethyl-1-[2-trimethoxysilyl)ethyl]disiloxane.

CASRN: 2244924–68–1.

Effective Date of TSCA Order: June 15, 2026.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use of the substance will be as a crosslinking polymer. Based on information in the SDS, EPA has identified concerns for formaldehyde generation as a decomposition product. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

- Processing and use of the PMN substance only at temperatures below 130 °C.

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of worker exposure testing may be potentially useful to characterize the exposure effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–24–138 (40 CFR 721.12330)

Chemical Name: Phenol, dialkylalkyl [(alkyl hetero-acyl) heteropolycyclic]alkyl-(generic).

CASRN: Not available.

Effective Date of TSCA Order: May 1, 2026.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a UV-absorber. Based on the physical/chemical properties of the PMN substance (as described in the New Chemical Program's PBT category at 64 FR 60194; November 1999) and in the absence of data, the PMN substance is a potential PBT chemical. EPA estimates that the PMN substance will persist in the environment for more than six months and estimates a bioaccumulation factor of greater than or equal to 5,000. Based on comparison to analogous chemical substances, EPA has identified concerns eye irritation, skin sensitization, reproductive effects, and systemic effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 1000 where there is a potential for inhalation exposure;
- Processing of the PMN substance only with the use of a dry filter in the exhaust filtration system;
- No processing for use or use of the PMN substance in a consumer product;
- Use of the PMN substance only for the confidential use listed in the Order;
- Use of the PMN substance only if the concentration of the PMN substance does not exceed the confidential concentration listed in the Order;
- No release of the PMN substance, or any waste stream containing the PMN substance, to water; and
- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of eye irritation, skin sensitization, reproductive toxicity, specific target organ toxicity, toxicokinetics, bioaccumulation, and persistence testing may be potentially useful to characterize the human health and fate effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–24–183 (40 CFR 721.12331)

Chemical Name: 1-Butanone, 4,4,4-trifluoro-3-hydroxyl-1-(2-naphthalenyl)-3-(trifluoromethyl)-.

CASRN: 3033994–67–8.

Effective Date of TSCA Order: June 9, 2026.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a chemical intermediate. Based on comparison to analogous chemical substances, EPA has identified concerns for skin, eye, and respiratory tract corrosion and systemic, reproductive, developmental, and carcinogenicity effects. Based on comparison to analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 101 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of the PMN substance only as a chemical intermediate;
- No release of the PMN substance, or any waste stream containing the PMN substance, resulting in surface water concentrations that exceed 27 ppb; and
- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation/corrosion, eye irritation/corrosion, carcinogenicity, developmental toxicity, developmental neurotoxicity, endocrine effects, neurotoxicity, pulmonary effects, reproductive toxicity, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–24–194 (40 CFR 721.12332)

Chemical Name: Modified tall oil fatty acid polyamine condensate, hydrochlorides (generic).

CASRN: Not available.

Effective Date of TSCA Order: May 20, 2026.

Basis for TSCA Order: The PMN states that the use will be as a stabilizer in asphalt emulsions. Based on comparison to analogous chemical substances, EPA has identified concerns for acute toxicity, irritation to the skin, corrosion to the eyes and respiratory tract, skin sensitization, and systemic effects. Based on structure of the PMN substance, EPA has also identified concerns for lung effects. Based on comparison to analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Manufacture, processing, use, and disposal of the PMN substance only in a manner that does not result in inhalation exposure to the PMN substance;
- No processing for use or use of the PMN substance in a consumer product;
- No release of the PMN substance, or any waste stream containing the PMN substance, to water. This prohibition does not apply to run-off during use when that use is limited to the application of asphalt; and
- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of acute toxicity, eye irritation/corrosion, pulmonary effects, skin irritation, skin sensitization, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–25–18 (40 CFR 721.12333)

Chemical Name: Graphene platelets.

CASRN: Not available.

Effective Date of TSCA Order: May 26, 2026.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a paint coating. Based on physical/chemical properties and comparison to analogous chemical substances, EPA has identified concerns for lung effects (lung overload) and systemic effects. Due to insufficient information, EPA was unable to estimate the environmental hazard of the PMN substance. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 1000 during the confidential use listed in the Order, or an APF of 10 during all other uses, where there is a potential for inhalation exposure;
- Manufacture of the PMN substance only by import into the United States (*i.e.,* no domestic manufacture);
- Manufacture of the PMN substance only in a liquid formulation and only when the concentration of the PMN substance does not exceed the confidential percentage by weight listed in the Order;
- Processing for use and use of the PMN substance only for the confidential use listed in the Order;
- No processing for use or use of the PMN substance in a consumer product;
- Use of the PMN substance only for industrial use;
- No release of the PMN substance, or any waste stream containing the PMN substance, to water; and
- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of pulmonary effects, specific target organ toxicity, and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–25–29 (40 CFR 721.12334) and P–25–30 (40 CFR 721.12335)

Chemical Names: Graphene oxide (P–25–29 and P–25–30).

CASRNs: Not available.

Effective Date of TSCA Order: April 21, 2026.

Basis for TSCA Order: The PMNs state that the uses will be as functional additives in composites and as precursors for high-value nanomaterials. Based on comparison to analogous chemical substances, EPA has identified concerns for lung effects (lung overload). Due to insufficient information, EPA was unable to estimate the environmental hazard of the PMN substances. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Manufacture, processing, and use of the P–25–29 PMN substance only in a manner that does not result in inhalation exposure to the PMN substance;
- Use of the P–25–30 PMN substance only for the confidential use listed in the Order;
- Manufacture of the P–25–30 PMN substance only below the confidential annual production volume listed in the Order;
- Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure to the P–25–30 PMN substance;
- No release of the PMN substances, or any waste stream containing the PMN substances, to water; and
- Establishment of a hazard communication program, including human health and environmental

precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of pulmonary effects and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–25–35 (40 CFR 721.12336)

Chemical Name: Transition metal, carbomonocyclic alkyl-substituted, dialkyl (generic).

CASRN: Not available.

Effective Date of TSCA Order: May 4, 2026.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use will be as a component in polyethylene production. Based on the pyrophoric nature (violent reactivity) of the PMN substance, EPA has identified concerns for acute handling hazard and corrosion to the skin, eyes, and respiratory tract. Based on comparison to analogous chemical substances, EPA has also identified concerns for systemic effects, acute toxicity, and reproductive and developmental effects. Based on comparison to analogous chemical substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 260 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- No manufacture, processing, or use of the PMN substance in any manner that results in inhalation exposure to the PMN substance;
- No release of the PMN substance, or any waste stream containing the PMN substance, resulting in surface water concentrations that exceed 260 ppb; and
- Establishment of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of acute toxicity, skin corrosion, eye corrosion, specific target organ toxicity, reproductive toxicity, developmental toxicity, and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

P–26–29 (40 CFR 721.12337)

Chemical Name: Aromatic sulfonium tricyclo salt with dicycloalkyl carbomonocycle hetero-acid (generic).

CASRN: Not available.

Effective Date of TSCA Order: June 9, 2026.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use of the PMN substance will be as a photoacid generator. Based on the physical/chemical properties of the PMN substance (as described in the New Chemical Program's PBT category at 64 FR 60194; November 1999) and test data on structurally similar substances, the PMN substance is a potential PBT chemical. EPA estimates that the PMN substance will persist in the environment for more than six months and estimates a bioaccumulation factor of greater than or equal to 1,000. Based on comparison to analogous chemical substances, EPA identified concerns for acute toxicity, irritation to the skin and respiratory tract, eye corrosion, genetic toxicity, and neurological and systemic effects for the sulfonium cation of the PMN substance. Based on the photoreactivity of the PMN substance, EPA has also identified concerns for photosensitization. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- No manufacture of the PMN substance beyond the time limits specified in the Order without submittal to EPA of the results of certain testing described in the Testing section of the Order;
- Use of personal protective equipment where there is a potential for dermal exposure;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS;
- No processing of the PMN substance in any way that generates a vapor, dust, mist, or aerosol in a non-enclosed process;
- Use of the PMN substance only for the confidential use listed in the Order;
- No domestic manufacture of the PMN substance (*i.e.,* import only);
- Import of the PMN substance only in solution or in sealed containers weighing 5 kilograms or less; and
- No exceedance of the confidential annual importation volume listed in the Order.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information about the physical/chemical properties, fate, bioaccumulation, environmental hazard, and human health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the time limits specified in the Order without performing the required Tier I and Tier II testing outlined in the Testing section of the Order.

P–26–45 (40 CFR 721.12338)

Chemical Name: Aromatic carboxylic acid, halogenated heteromonocycle ester, polymer with haloaromatic iodonium tricyclo salt with polyhaloalkyl carbomonocycle hetero-acid, modified (generic).

CASRN: Not available.

Effective Date of TSCA Order: June 9, 2026.

Basis for TSCA Order: The PMN states that the generic (non-confidential) use of the PMN substance will be as a photoacid generator. Based on the physical/chemical properties of the PMN substance (as described in the New Chemical Program's PBT category at 64 FR 60194; November 1999) and test data on structurally similar

substances, the PMN substance is a potential PBT chemical. EPA estimates that the PMN substance will persist in the environment for more than six months and estimates a bioaccumulation factor of greater than or equal to 1,000. Based on comparison to analogous chemical substances, EPA identified concerns for acute toxicity, irritation to the skin and respiratory tract, eye corrosion, genetic toxicity, and neurological and systemic effects for the cation of the PMN substance. Based on the photoreactivity of the PMN substance, EPA has also identified concerns for photosensitization. Based on comparison to analogous chemical substances and due to limitations of the submitted test data on the PMN substance, EPA has also identified concerns for eye corrosion. Based on comparison to analogous chemical substances, EPA has also identified concerns for systemic, reproductive, and developmental effects for the anion of the PMN substance. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- No manufacture of the PMN substance beyond the time limits specified in the Order without submittal to EPA of the results of certain testing described in the Testing section of the Order;
- Use of personal protective equipment where there is a potential for dermal exposure;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS;
- No processing of the PMN substance in any way that generates a vapor, dust, mist, or aerosol in a non-enclosed process;
- Use of the PMN substance only for the confidential use listed in the Order;
- No domestic manufacture of the PMN substance (*i.e.*, import only);
- Disposal of the PMN substance only by hazardous waste incineration at a facility that is in compliance with RCRA subtitle C;
- Import of the PMN substance only in solution or in sealed containers weighing 5 kilograms or less; and
- No exceedance of the confidential annual importation volume listed in the Order.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially Useful Information: EPA has determined that certain information about the physical/chemical properties, fate, bioaccumulation, environmental hazard, and human health effects of the PMN substance may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the time limits specified in the Order without performing the required Tier I and Tier II testing outlined in the Testing section of the Order.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review

This action proposes to establish SNURs for new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866 (58 FR 51735, October 4, 1993).

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because significant new use rules for new chemicals under TSCA section 5 are exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

According to the PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to SNURs have already been approved by OMB pursuant to PRA under OMB control number 2070–0038 (EPA ICR No. 1188). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per submission. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

EPA always welcomes your feedback on the burden estimates. When submitting comments on these proposed SNURs, include comments about the accuracy of the burden estimate, and any suggested methods for improving the collection instruments or instruction or minimizing respondent burden, including through the use of automated collection techniques.

D. 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 (5 U.S.C. 601 *et seq.*). The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a ''significant new use.'' Because these uses are ''new,'' based on all information currently available to EPA, EPA has concluded that no small or large entities presently engage in such activities.

A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was 23 in FY2023, 7 in FY2024, and 10 in FY2025, and only a fraction of these submissions were from small businesses.

In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from $37,000 to $6,480. This lower fee reduces the total reporting and recordkeeping cost of submitting a SNUN to about $14,967 per SNUN submission for qualifying small firms. Therefore, the potential economic impacts of complying with these proposed SNURs are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that SNURs are not expected to have a significant economic impact on a substantial

number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars) in any one year as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by SNURs, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by these SNURs. In addition, the estimated costs of this action to the private sector do not exceed $183 million or more in any one year (the 1995 dollars are adjusted to 2023 dollars for inflation using the GDP implicit price deflator). The estimated costs for this action are discussed in Unit I.D.

F. Executive Order 13132: Federalism

This action will not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it is not expected to have a substantial direct effect on 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. Accordingly, the requirements of Executive Order 13132 do not apply to this action.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action will not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it is not expected to have substantial direct effects on Indian Tribes, significantly or uniquely affect the communities of Indian Tribal governments and does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 do not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it does not concern an environmental health or safety risk. Since this action does not concern a human health risk, EPA's 2026 Policy on Children's Health also does not apply. Although the establishment of these SNURs do not address an existing children's environmental health concern because the chemical uses involved are not ongoing uses, SNURs require that persons notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of the identified chemical substances for an activity that is designated as a significant new use by the SNUR. This notification allows EPA to assess the intended uses to identify potential risks and take appropriate actions before the activities commence.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards subject to NTTAA section 12(d) (15 U.S.C. 272 note).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: October 28, 2026.

Mary Elissa Reaves,

Director, Office of Pollution Prevention and Toxics.

For the reasons stated in the preamble, EPA proposes to amend 40 CFR chapter I as follows:

PART 721—SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. Add §§ 721.12320 through 721.12338 to subpart E to read as follows:

* * * * *

Sec.

721.12320 4H-Pyran-4-one, 3-[(2,5-dihydro-4-methyl-5-oxo-2-furanyl)oxy]-2-methyl-.
721.12321 Tin, dioctylbis(2,4-pentanedionato-.kappa.O2,.kappa.O4).
721.12322 1-Naphthaleneethanol, decahydro-5,5,8a-trimethyl-2-methylene-, 1-acetate, (1R,4aR,8aR)-rel.
721.12323 2-Butenedioic acid (2Z)-, potassium salt (1:?).
721.12324 Functionalized fatty acids (generic).
721.12325 Carbamic acid, N, N′, N″-1,3,5-triazine-2,4,6-tryltris-, mixed alkyl triesters (generic).
721.12326 Glycine, N-(aminoiminomethyl)-, manuf. of, by-products from.
721.12327 Tetramethyldisiloxanediylbis [propylcarbonyl] (generic).
721.12328 Sunflower oil, oleic acid-high, maleated.
721.12329 Siloxanes and Silicones, di-Me, polymers with silicic acid, [(ethenyldimethylsilyl)oxyl]-terminated, reaction products with 1,1,3,3-tetramethyl-1-[1-(trimethoxysilyl) ethyl]disiloxane and 1,1,3,3-tetramethyl-1-[2-trimethoxysilyl)ethyl]disiloxane.
721.12330 Phenol, dialkylalkyl[(alkyl hetero-acyl)heteropolycyclic]alkyl-(generic).
721.12331 1-Butanone, 4,4,4-trifluoro-3-hydroxyl-1-(2-naphthalenyl)-3-(trifluoromethyl)-.
721.12332 Modified tall oil fatty acid polyamine condensate, hydrochlorides (generic).
721.12333 Graphene platelets.
721.12334 Graphene oxide.
721.12335 Graphene oxide.
721.12336 Transition metal, carbomonocyclic alkyl-substituted, dialkyl (generic).
721.12337 Aromatic sulfonium tricyclo salt with dicycloalkyl carbomonocycle hetero-acid (generic).
721.12338 Aromatic carboxylic acid, halogenated heteromonocycle ester, polymer with haloaromatic iodonium tricyclo salt with polyhaloalkyl carbomonocycle hetero-acid, modified (generic).

§ 721.12320 4H-Pyran-4-one, 3-[(2,5-dihydro-4-methyl-5-oxo-2-furanyl)oxy]-2-methyl-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 4H-pyran-4-one, 3-[(2,5-dihydro-4-methyl-5-oxo-2-furanyl)oxy]-2-methyl- (PMN P–20–105; CASRN 1333341–34–6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: specific target organ toxicity, reproductive toxicity, skin irritation, and eye irritation. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (o). It is a significant new use to process the substance other than in a facility that employs an on-site sump system used to capture fugitive dust releases and disposes the solid waste captured by this sump system by landfill. It is a significant new use to process the substance except under negative pressure when transferring the substance as a solid material in order to minimize exposures to fugitive dust/particles. It is a significant new use to use the substance in non-aerial spray applications at a concentration exceeding 0.01% in formulation by weight. It is a significant new use to use the substance in aerial spray applications at a concentration exceeding 0.06% in formulation by weight. It is a significant new use to use the PMN substance other than to promote microbial activity in the soil, resulting in increases availability of nutrients in the soil, including nitrogen and phosphorus, for crops (for use on commercial farming operations).

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12321 Tin, dioctylbis(2,4-pentanedionato-.kappa.O2,.kappa.O4).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as tin, dioctylbis(2,4-pentanedionato-.kappa.O2,.kappa.O4) (PMN P–22–56; CASRN 54068–28–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured (*i.e.*, the substance has been reacted or cured to the extent that no release of the substance can be detected).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation, skin sensitization, eye irritation, reproductive toxicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance. It is a significant new use to process for use or use the substance in a consumer product unless the concentration of the substance is less than 1% by weight in the consumer product.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12322 1-Naphthaleneethanol, decahydro-5,5,8a-trimethyl-2-methylene-, 1-acetate, (1R,4aR,8aR)-rel.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1-naphthaleneethanol, decahydro-5,5,8a-trimethyl-2-methylene-, 1-acetate, (1R,4aR,8aR)-rel (PMN P–23–14; CASRN 65794–67–4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin sensitization and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance.

(iv) *Disposal.* It is a significant new use to dispose of the substance or waste streams containing the substance other than by hazardous waste incineration in compliance with Resource Conservation Recovery Act (RCRA) subtitle C and only in a manner that does not result in inhalation exposure at the incineration facility.

(v) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12323 2-Butenedioic acid (2Z)-, potassium salt (1:?).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-butenedioic acid (2Z)-, potassium salt (1:?) (PMN P–23–141; CASRN 10237–70–4) is subject to reporting under this section for the significant new uses

described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, eye irritation, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o), (t), (v)(1), (2), and (4), (w)(1), (2), and (4), and (x)(1), (2), and (4). It is a significant new use to use the substance other than as a buffer solution for free chlorine determination.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=415.

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12324 Functionalized fatty acids (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as functionalized fatty acids (PMN P–24–52) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: eye irritation, skin irritation, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the substance in any manner that generates a vapor, mist, dust, or aerosol containing the substance unless in an enclosed process.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=1000.

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12325 Carbamic acid, N, N′, N″-1,3,5-triazine-2,4,6-tryltris-, mixed alkyl triesters (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carbamic acid, N, N′, N″-1,3,5-triazine-2,4,6-tryltris-, mixed alkyl triesters (PMN P–24–75) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured (*i.e.,* the substance has been reacted or cured to the extent that no release of the substance can be detected).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation, eye irritation, specific target organ toxicity, and skin sensitization. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o), (v)(1), (2), and (4), (w)(1), (2), and (4), and (x)(1), (2), and (4). It is a significant new use to use the substance other than as a water based formaldehyde free crosslinking additive for acid resistance. It is a significant new use to use the substance unless the concentration of the substance does not exceed the confidential concentration (by weight) listed in the Order in the final coating.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=68.

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12326 Glycine, N-(aminoiminomethyl)-, manuf. of, by-products from.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as glycine, N-(aminoiminomethyl)-, manuf. of, by-products from (PMN P–24–90; CASRN 2981438–54–2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(3)(iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a manure additive.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=104. This requirement does not apply to any use stream containing the substance associated with any use of the substance from any site.

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12327 Tetramethyldisiloxanediylbis [propylcarbonyl] (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as tetramethyldisil oxanediylbis[propylcarbonyl] (PMN P–24–128) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), g(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin corrosion, serious eye damage, respiratory sensitization, skin sensitization, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(h). It is a significant new use to manufacture, process, or use the substance without using a control device serving the reactor with less than a 98% destruction removal efficiency.

(iv) *Disposal.* It is a significant new use to dispose of the substance or waste streams containing the substance other than by the confidential method listed in the Order.

(v) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12328 Sunflower oil, oleic acid-high, maleated.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as sunflower oil, oleic acid-high, maleated (PMN P–24–132; CASRN 2205860–51–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured (*i.e.*, the substance has been reacted or cured to the extent that no release of the substance can be detected).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1) and (5). For purposes of § 721.72(g)(1), this substance may cause: skin sensitization. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to process for use or use the substance in a consumer product unless the concentration of the substance does not exceed 1% by weight in the consumer product.

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12329 Siloxanes and Silicones, di-Me, polymers with silicic acid, [(ethenyldimethylsilyl)oxyl]-terminated, reaction products with 1,1,3,3-tetramethyl-1-[1-(trimethoxysilyl)ethyl]disiloxane and 1,1,3,3-tetramethyl-1-[2-trimethoxysilyl)ethyl]disiloxane.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as siloxanes and silicones, di-me, polymers with silicic acid, [(ethenyldimethylsilyl)oxyl]-terminated, reaction products with 1,1,3,3-tetramethyl-1-[1-(trimethoxysilyl)ethyl]disiloxane and 1,1,3,3-tetramethyl-1-[2-trimethoxysilyl)ethyl]disiloxane (PMN P–24–136; CASRN 2244924–68–1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured (*i.e.*, the substance has been reacted or cured to the extent that no release of the substance can be detected).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to process or use the substance other than at temperatures below 130°C.

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12330 Phenol, dialkylalkyl[(alkyl hetero-acyl)heteropolycyclic]alkyl- (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phenol, dialkylalkyl[(alkyl hetero-acyl)heteropolycyclic]alkyl- (PMN P–24–138) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured (*i.e.*, the substance has been reacted or cured to the extent that no release of the substance can be detected).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1000.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), and (g)(1) and (5). For purposes of § 721.72(g)(1), this substance may cause: eye irritation, skin sensitization, reproductive toxicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) and (o). It is a significant new use to process the substance other than with the use of a dry filter in the exhaust filtration system. It is a significant new use to use the substance above the confidential concentration listed in the Order.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12331 1-Butanone, 4,4,4-trifluoro-3-hydroxyl-1-(2-naphthalenyl)-3-(trifluoromethyl)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1-butanone, 4,4,4-trifluoro-3-hydroxyl-1-(2-naphthalenyl)-3-(trifluoromethyl)- (PMN P–24–183; CASRN 3033994–67–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin corrosion, serious eye damage, specific target organ toxicity, reproductive toxicity, and carcinogenicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=27.

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12332 Modified tall oil fatty acid polyamine condensate, hydrochlorides (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as modified tall oil fatty acid polyamine condensate, hydrochlorides (PMN P–24–194) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured (*i.e.*, the substance has been reacted or cured to the extent that no release of the substance can be detected).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, serious eye damage, skin sensitization, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance.

(iv) *Disposal.* It is a significant new use to dispose of the substance in any manner that results in inhalation exposure to the substance.

(v) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1). This requirement does not apply to run-off during use when that use is limited to the application of asphalt.

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12333 Graphene platelets.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as graphene platelets (PMN P–25–18) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured (*i.e.*, the substance has been reacted or cured to the extent that no release of the substance can be detected).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1000 during the confidential use listed in the Order and an APF of 10 during all other uses.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), (l), and (o). It is a significant new use to manufacture (import) the substance other than in a liquid formulation and only when the concentration of the substance does not exceed the confidential percentage by weight listed in the Order.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12334 Graphene oxide (P–25–29).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as graphene oxide (PMN P–25–29) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured (*i.e.*, the substance has been reacted or cured to the extent that no release of the substance can be detected).

(2) The significant new uses are:

(i) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12335 Graphene oxide (P–25–30).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as graphene oxide (PMN P–25–30) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured (*i.e.*, the substance has been reacted or cured to the extent that no release of the substance can be detected).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(4) through (6) and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) and (t).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (d), (f) through (i) and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12336 Transition metal, carbomonocyclic alkyl-substituted, dialkyl (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as transition metal, carbomonocyclic alkyl-substituted, dialkyl (PMN P–25–35) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3) and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(3)(iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin corrosion, serious eye damage, reproductive toxicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to the substance.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=260.

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12337 Aromatic sulfonium tricyclo salt with dicycloalkyl carbomonocycle hetero-acid (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as aromatic sulfonium tricyclo salt with dicycloalkyl carbomonocycle hetero-acid (PMN P–26–29; Accession No. 303936) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, serious eye damage, skin sensitization, genetic toxicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates vapor, dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.12338 Aromatic carboxylic acid, halogenated heteromonocycle ester, polymer with haloaromatic iodonium tricyclo salt with polyhaloalkyl carbomonocycle hetero-acid, modified (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as Aromatic carboxylic acid, halogenated heteromonocycle ester, polymer with haloaromatic iodonium tricyclo salt with polyhaloalkyl carbomonocycle hetero-acid, modified (PMN P–26–45) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.*, enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.*, workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity, skin irritation, serious eye damage, skin sensitization, genetic toxicity, reproductive toxicity, and specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the substance in any way that generates vapor, dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the substance longer than 9 months.

(iv) *Disposal.* It is a significant new use to dispose of the substance or waste streams containing the substance other than by hazardous waste incineration and the disposal must be at a facility that is in compliance with RCRA subtitle C.

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (j) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[FR Doc. 2026–22295 Filed 10–30–26; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[ET Docket No. 26–245; RM–11844; RM–12014; FCC 26–66; FR ID 372216]

Unleashing the Power of Unlicensed Ultra-Wideband Devices; Petition of Robert Bosch LLC for Amendment of the Part 15 Subpart F Ultra-Wideband Rules; and Petition of Alliance for Automative Innovation et al. To Amend Part 15 of the FCC's Rules To Permit the Operation of Certain Ultra-Wideband Devices

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Federal Communications Commission (Commission or FCC) proposes to update its rules for Ultra-Wideband (UWB) devices to reflect significant technological developments since the rules were first adopted in 2002. UWB technology has matured into a widely used, low-power enabler that supports applications in tracking, automation, precision location, health monitoring, athletic performance, and public safety. As capabilities of UWB have expanded, the existing rules have not kept pace with the technological change, resulting in an increasing number of waiver requests received by the Commission to authorize modern devices. The Notice of Proposed Rulemaking seeks comment on revisions intended to modernize the UWB framework, provide greater flexibility for future applications, promote continued innovation, and ensure the protection of incumbent federal and non-federal spectrum users.

DATES: Comments are due on or before December 2, 2026 and reply comments are due on or before January 4, 2027.

ADDRESSES: Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated in the **DATES** section. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). You may submit comments, identified by ET Docket No. 26–245, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *https://www.fcc.gov/ecfs.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing.
- Filings can be sent by hand or messenger delivery, by commercial courier, or by the U.S. Postal Service. All filings must be addressed to the Secretary, Federal Communications Commission.
- Hand-delivered or messenger-delivered paper filings for the Commission's Secretary are accepted between 8:00 a.m. and 4:00 p.m. by the FCC's mailing contractor at 9050 Junction Drive, Annapolis Junction, MD 20701. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.
- Commercial courier deliveries (any deliveries not by the U.S. Postal Service) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- Filings sent by U.S. Postal Service First-Class Mail, Priority Mail, and Priority Mail Express must be sent to 45 L Street NE, Washington, DC 20554.

People with Disabilities: To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530.

FOR FURTHER INFORMATION CONTACT: Syed S. Hasan of the Office of Engineering and Technology at *Syed.Hasan@fcc.gov* or (202) 418–2454.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rulemaking *(NPRM),* in ET Docket No. 26–245, FCC 26–66, adopted on September 30, 2026, and released on October 1, 2026. The full text of this document is available for public inspection during regular business hours at Commission's headquarters 45 L Street NE, Washington, DC 20554 or at the following internet address: *https://docs.fcc.gov/public/attachments/FCC-26-66A1.pdf.*

Paperwork Reduction Act Analysis. This document contains proposed information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Public and agency comments are due January 4, 2027.

Comments should address: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) way to further reduce the information collection burden on small business concerns with fewer than 25 employees. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), we seek specific comment on how we might further reduce the information collection burden for small business concerns with fewer than 25 employees.

Regulatory Flexibility Act. The Regulatory Flexibility Act of 1980, as amended (RFA), requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' Accordingly, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) concerning the potential impact of the rule and policy proposals in this document on small entities. The Commission invites the general public, particularly small businesses, to comment on the IRFA. Comments must be filed by the deadlines for comments on the Third Further Notice of Proposed Rulemaking indicated in the **DATES** section of this document and must have a separate and distinct heading designating them as responses to the IRFA.

Ex Parte Presentations. The proceeding this document initiates shall be treated as a ''permit-but-disclose''

proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.*, .doc, .xml, .ppt, searchable .pdf). Participants in the proceeding should familiarize themselves with the Commission's *ex parte* rules.

Providing Accountability Through Transparency Act. Consistent with the Providing Accountability Through Transparency Act, Public Law 1189–9, a summary of the *Notice of Proposed Rulemaking* will be available at *https://www.fcc.gov/proposed-rulemakings*.

OPEN Government Data Act. The OPEN Government Data Act requires agencies to make ''public data assets'' available under an open license and as ''open Government data assets,'' *i.e.*, in machine-readable, open format, unencumbered by use restrictions other than intellectual property rights, and based on an open standard that is maintained by a standards organization. This requirement is to be implemented ''in accordance with guidance by the Director'' of the OMB. The term ''public data asset'' means ''a data asset, or part thereof, maintained by the Federal Government that has been, or may be, released to the public, including any data asset, or part thereof, subject to disclosure under [the Freedom of Information Act (FOIA)].'' A ''data asset'' is ''a collection of data elements or data sets that may be grouped together,'' and ''data'' is ''recorded information, regardless of form or the media on which the data is recorded.''

Synopsis

I. Background

UWB is a unique and powerful technology in the arsenal of radio applications that operate on an unlicensed basis. Designed to operating at very low power, UWB uses extremely wide radio channels (typically 500 megahertz or more) that can determine both distance and direction over a short range with more precise accuracy than narrowband unlicensed technologies, such as Wi-Fi and Bluetooth.

Like all devices operating under the part 15 rules, UWB systems operate on a non-interference basis, *i.e.*, they share radio spectrum with authorized radio services, may not cause harmful interference, and must accept any interference they receive. However, UWB devices are also permitted to operate across restricted frequency bands that other unlicensed devices may not use. This is because UWB operates with a ''light touch'' on any particular frequency at any given time due to UWB's combination of low power operation across wide swaths of bandwidth; this, in turn, mitigates the risk that UWB devices can cause harmful interference to incumbent users, including those providing critical services.

Subpart F of the Commission's part 15 rules governs operation of UWB transmitters. Currently, the rules are structured to support specific categories of UWB operations—ground penetrating radars, wall imaging systems, through-wall imaging systems, surveillance systems, medical imaging systems, indoor UWB systems, and handheld UWB systems. For each of these applications, the rules specify technical requirements, including the frequency bands over which the UWB device may operate, operational constraints, and radiated emission limits that may vary by induvial device categories. In addition, each type of device is subject to additional restrictions, such as limits on the types of operation permitted and the entities that are permitted to use the device. UWB devices may not be operated on board aircraft, ships or satellites. The rules prohibit employment for the operation of toys, but do not provide any guidance on what qualifies as a toy. The Commission codified these UWB rules in a deliberate and cautious manner to ensure that the framework supported what was known at that time about UWB device characteristics, to take extremely protective steps to guard incumbent operations against harmful interference, and to limit an excessive proliferation of UWB devices that nearly a quarter century ago were considered to be new and novel.

The first UWB rules were adopted in February 2002, when the Commission permitted the marketing and operation of a range of UWB devices, including imaging systems, vehicular radars, and indoor and outdoor communication devices. Subsequent orders made further modifications to the rules but did not fundamentally alter the structure of part 15, subpart F nor abandon the cautious approach the Commission had taken when permitting the first UWB operations. Over the past two decades manufacturers have developed new and innovative applications, and the technology has likewise evolved to incorporate a wider variety of waveforms than had been accounted for when the rules were first adopted. Today's UWB devices can be designed to employ a number of different modulation types that can transmit very short, low-power pulses. Modern devices can also use chirp signals that sweep rapidly across the band. They may also employ stepped frequency or swept band techniques that move across portions of the spectrum in quick succession. As a result, the Commission has received numerous requests for waivers of the UWB rules to support these types of devices and applications, that do not conform to the rules as they exist today.

On June18, 2019, Robert Bosch LLC filed a Petition for Rulemaking requesting that the Commission modernize the UWB rules. Bosch argued that the 2002 framework had been intentionally conservative and no longer reflected how modern UWB devices were designed, measured, or used, resulting in most contemporary UWB products requiring waivers for certification. It further stated that more than a decade of operational experience, the absence of interference complaints, and advances in mitigation techniques demonstrated that the rules could be updated while maintaining protection for federal and non-federal incumbents. The Bosch Petition also pointed to more flexible international UWB regulations and urged greater harmonization to

support innovation and global manufacturing. Twenty-four parties filed comments and four parties made *ex parte* filings addressing the petition.

More recently, on December 18, 2025, the Alliance for Automotive Innovation, the Car Connectivity Consortium, the FiRa Consortium, Profibus &Profinet International/omlox, and the Ultra-Wideband Alliance (collectively, the Joint Petitioners) filed a Petition for Rulemaking seeking targeted updates to the UWB rules. The Joint Petitioners asserted that the Commission's UWB framework, largely unchanged for more than two decades, no longer reflects current UWB technologies, deployment environments, or global regulatory developments. They contended that outdated definitional, operational, and equipment-classification provisions routinely necessitated waivers for low-power UWB devices that operated similarly to existing authorized systems and posed no greater interference risk. The Commission placed the petition on Public Notice which resulted in eight parties filing comments and one party filing an *ex parte* comment.

In consideration of the evolving uses for and importance of UWB applications, recognizing the rulemaking petitions that have been filed and the large portfolio of UWB waiver petitions that the Commission have fielded to date, and considering the amount of time since the last comprehensively evaluated UWB rules, the Commission initiates the rulemaking proceeding.

II. Discussion

In this document, the Commission undertakes a comprehensive review of the UWB framework to ensure that the rules are optimized to keep pace with modern technologies, deployment environments, and advances in UWB modalities. Specifically, the Commission proposes to modify technical rules and requirements that appear to be ill-suited for the expanded scope and breadth of today's UWB devices and that warrant a fresh look considering the long span of time since their adoption. Second, the Commission proposes to create a new UWB device category to enable certification of the emerging class of location-sensing devices that have heretofore only been brought to market after completing time-consuming and increasingly repetitive rule waiver proceedings. The Commission also explores whether to establish a new class for AI-enabled UWB sensing applications. Finally, the Commission examines all existing UWB device categories to determine whether their technical, operational, eligibility, labeling, and emission related provisions remain necessary, and the Commission seeks comment on potential updates, including consolidating, simplifying, or removing redundant rules to ensure that the UWB framework remains clear, technically justified, and capable of supporting future innovation while continuing to protect incumbent services.

Modernizing Technical Rules and Requirements—UWB Transmitter Definition. The Commission's rules define a ''UWB transmitter'' as ''[a]n intentional radiator that, at any point in time, has a fractional bandwidth equal to or greater than 0.20 or has a UWB bandwidth equal to or greater than 500 MHz, regardless of the fractional bandwidth.'' In adopting the UWB rules in 2002, the Commission recognized that this definition was likely to preclude certain types of modulations, such as swept frequency (*e.g.,* Frequency Modulated Continuous Wave (FMCW)), stepped frequency, or frequency hopping systems, noting that no measurement procedure had been proposed, nor had the interference potential of such devices been analyzed.

The Commission's original ''at any point in time'' bandwidth requirement no longer accurately reflects how modern UWB systems operate. Petitioners explain that although many modern UWB devices are designed to meet the underlying bandwidth requirement, they do not satisfy it at all points in time, which results in them failing to meet the UWB transmitter definition. Moreover, devices that are purposely designed to improve the operational environment—such as a UWB device that is ''notched'' to avoid a particular frequency segment—might no longer comply with the ''at any point in time'' requirement. As a result, devices that function like UWB systems in practice but that generate individual pulses that fall outside of the defined bandwidth requirement, even momentarily, are excluded from the UWB category and must seek a waiver of the Commission's rules to operate. The Commission believes that the ''at any point in time'' requirement serves as an unnecessary impediment to developing and deploying new UWB applications. As both the Joint Petitioners and Bosch note, the Commission has granted many such waivers, consistently finding that it would not undermine the purpose of the rule because waiving the ''at any point in time'' requirement for such devices has not been shown to increase the potential for harmful interference to authorized services. The Commission specifically notes here that it has consistently found that stepped and swept frequency devices have a difficult time meeting the definition and other technical rules because the large bandwidth achieved by stepping or sweeping a narrow signal through the broader frequency range won't be instantaneously wide enough to meet the rules' specific requirements. Making this rule change will remove the requirement that has hindered the development and deployment of this technology. Therefore, the Commission tentatively concludes that it should update the UWB transmitter definition to remove the ''at any point in time'' requirement, essentially codifying the numerous granted waivers, to better accommodate popular UWB methodologies, such as frequency hopping, stepped frequency, swept frequency, and other time-varying waveforms that momentarily fall outside of the instantaneous bandwidth threshold—which is 500 MHz at all times (''at any point in time'') for UWB devices, as well as to reduce the burdens associated with the existing waiver process necessary to authorize such devices. The Commission seeks comment on its tentative conclusion. Would removing this ''at any point in time'' requirement reduce or eliminate the need for the Commission to issue waivers for devices that demonstrate UWB-like performance and have low interference potential but do not satisfy the instantaneous bandwidth threshold under the existing definition? What are the impacts on device design and the ability of devices to avoid causing harmful interference if the Commission eliminates the ''any point in time'' requirement? To ensure that the Commission has an adequate record for making decisions about the future of UWB devices, and to minimize the potential for harmful impact to incumbent licensees, the Commission requests technical analysis and coexistence studies that are in line with the Commission's goals of promoting efficient use of spectrum. In evaluating revisions to the UWB transmitter definition, the Commission emphasizes that any updated definitions or measurement procedures must include sufficient technical detail to support robust coexistence assessments with Federal systems. The Commission also expects parties to provide technical studies explicitly showing that proposed methodologies will not increase the potential for harmful interference to Federal operations, and to ensure that certification processes preserve clear visibility into waveform characteristics essential for Federal

compatibility analyses. Because modern UWB modulation techniques were not fully contemplated in 2002, the Commission wants to ensure that changes to the UWB definition or measurement framework may that alter emission characteristics are evaluated as part of this proceeding, including how such changes may correlate to instantaneous power, spectral density, temporal occupancy, aggregate emissions, and receiver susceptibility.

The Commission seeks comment on whether instantaneous bandwidths below 500MHz could result in higher instantaneous power spectral density, and if so, whether concentrating power into a narrower bandwidth could affect incumbent service protections, including for the aeronautical radionavigation service (ARNS), radionavigation satellite service/global navigation satellite service (RNSS/GNSS), mobile satellite service (MSS), radar altimeters, and weather radars. Commenters are invited to propose related measurement procedures, as well as operational or technical limits that may be necessary to ensure continued compatibility with these authorized services. The Commission also seeks comment on how this updated UWB definition aligns with ongoing work in standards bodies, such as the IEEE, and whether those efforts should inform the approach. Finally, the Commission seeks comment on whether it would need to make any additional updates to the rules for purposes of clarity and conformity.

Measurement Procedures. Section 15.31(c) requires swept frequency devices to be measured with the frequency sweep stopped at the frequencies selected for reporting. Separately, § 15.521(d) requires that when pulse gating is used, and where the transmitter is quiescent for intervals that are long compared to the nominal pulse repetition interval (*i.e.,* the break between bursts is much longer than the time it takes to send the next pulse), then measurements shall be made with the pulse train gated on (*i.e.,* ignoring the ''off'' period for measurement purposes). Together, these provisions establish how UWB transmitters must be evaluated for compliance with the Commission's radiated emission limits. Generally, devices that do not meet the radiated emission limits under the measurement procedures requirement also do not meet the UWB transmitter definition.

When the Commission adopted the UWB rules in 2002, it established technically neutral standards that allowed any modulation or technology so long as devices met the minimum bandwidth and emission limits. But it also noted that no measurement procedures existed for stepped-frequency, frequency-hopping, or swept-frequency systems and that their interference characteristics had not been evaluated using measurements taken in normal operating mode, In practical terms, these types of devices employ continuous, rapid transmission characteristics that make it technically difficult to stop the frequency sweep at a single point in time for measurement or to create a continuous pulse train without disrupting the device's normal operation. In addition, the UWB devices have very low duty cycles and quickly sweep across wide swaths of frequency bands, which mitigates any potential harmful interference to licensed receivers that are designed to detect transmissions over much longer time periods. When the rules were first adopted, the Commission noted that the test requirements of §§ 15.31(c) and 15.521(d) were optimized for pulse-based UWB signals only and different test configurations and methodologies would be necessary to measure bandwidth for other types of UWB emissions correctly. After two decades, modern UWB devices are often designed using stepped or swept frequency or frequency hopping techniques, and because of this reason the current measurement procedure for UWB rules is out of step with the changing technologies changes.

Section 15.31(c) effectively blocks certification of swept-frequency UWB devices without a waiver because the rule was written for pulse-based systems. This issue first surfaced in 2004 when the Multi-band OFDM Alliance Special Interest Group (MBOA–SIG) requested a waiver, explaining that existing procedures did not apply to multiband OFDM systems. Through testing, MBOA–SIG showed that stepped or sequenced UWB systems posed no greater interference risk than impulse-based systems. The Commission granted the waiver and later reaffirmed that measuring such devices in their normal operating mode does not increase interference potential, though the intended rule codification has never been completed.

In light of the Commission's intent since 2005 that the provisions of the MBOA–SIG waiver could be codified and the experience gained since that time, the Commission proposes to update the UWB rules to reflect the reality that modern UWB devices use a variety of waveforms that cannot easily be measured under the current procedures or where taking such measurements under those procedures would hinder the devices' utility. The record of waivers spanning different UWB applications shows that applicants have repeatedly been able to demonstrate good cause for not applying the originally adopted measurement procedures and that, in doing so, applicants have shown that their devices do not undermine the purpose of the rule, *i.e.,* to enable UWB devices to operate without causing harmful interference to authorized licensees.

The Commission proposes to update the UWB measurement procedures by making targeted changes to how they apply to UWB devices. First, the Commission proposes adding § 15.31(c) to the list of provisions in § 15.505(a) that do not apply to UWB devices. Because § 15.31(c) applies broadly to unlicensed part 15 devices, exempting UWB devices from this provision would reduce unnecessary waiver requests, improve regulatory certainty, and better align the Commission's procedures with the operation of contemporary swept-frequency UWB devices. Second, the Commission proposes modifying § 15.521(d) to specify that, if pulse gating is employed, measurements may be made in normal operating mode, thereby eliminating the need for the hop, step, or sequenced function to be stopped. This will similarly enable these frequency modulation devices to be certified without requiring a waiver. The Commission believes that these modifications would improve clarity, flexibility, and regulatory certainty for manufacturers, while maintaining appropriate protections for incumbent licensees and federal users.

The Commission seeks comment on whether exempting UWB devices from § 15.31(c) and allowing pulse-gated UWB devices to be measured in normal operating mode could negatively affect interference potential, including aggregate noise floor levels and coexistence with incumbent services. It also invites input on whether existing certification or technical standards, such as those from IEEE or other standards bodies, offer measurement methods that should inform its approach. The Commission asks whether alternative methods might better meet its objectives while protecting authorized services, and how procedures should account for modern modulation techniques outside traditional UWB frameworks. Finally, it requests technical studies demonstrating that the proposed procedures would accurately evaluate device operation and ensure protection of federal systems.

Scope of Use. Section 15.521(a) provides that ''UWB devices may not be

employed for the operation of toys.'' In addition, ''[o]peration onboard an aircraft, a ship or a satellite is prohibited.'' When adopting the prohibition on the use of UWB devices for the operation of toys in the 2002 UWB First Report and Order, the Commission explained that the prohibition was intended to ''further limit the proliferation of these products'' and was ''consistent with the desire to proceed cautiously with the introduction of UWB devices.'' The Commission acknowledged that the prohibition on the use of UWB devices for the operation of toys was precautionary in nature and stated that it may revisit the prohibition within six to twelve months, recognizing that the rule was conservative by design and based on the limited available technical data. In addition, the Commission adopted these provisions with the intention of being overly cautious while expecting that no harmful interference would occur based on the available technical analysis. As part of the rulemaking, the Commission also analyzed technical studies to consider the effect that the operation of indoor and outdoor UWB devices would have on aviation, weather and defense related systems—all resulting in the same conclusion that the UWB operations will not negatively impact those systems. Given the time that has passed since these prohibitions were adopted, the Commission believes it is appropriate to revisit utility in today's UWB communications landscape.

It is clear from the steady stream of waiver requests that the Commission receives routinely and have granted in recent years that current rules do not adequately provide an effective avenue for manufacturers to quickly develop and bring to market new and innovative UWB device types. To address the gap between what the current rules allow and permitting the UWB market to organically develop and flourish, the Commission has been operating under ''regulation by waiver.'' Operation under these waivers and their associated conditions has shown that even with widespread growth, the risk of harmful interference to authorized licensees is minimal. The Commission recognizes the benefits of expanding permissible UWB uses, but remain mindful that the current prohibitions can only be removed after understanding how device proliferation may affect the aggregate noise floor, how ubiquitous UWB-enabled devices are likely to become in the absence of existing restrictions, and how many such devices could coexist in a given environment while continuing to minimize the potential of causing harmful interference to authorized users. Accordingly, the Commission seeks comment on technical justifications that support revising § 15.521(a) to remove the prohibition on the use of UWB devices in toys, as well as whether the longstanding prohibition on UWB operations aboard aircraft, ships, or satellites remains warranted. To that end, the Commission seeks comment on whether additional technical standards need to be considered when evaluating UWB operation in aeronautical or maritime environments such as the IEC 60533, IEC 60945, RTCM 13700.0, IEC 60533 Ed.4, or others as applicable. In particular, the Commission seeks comment on how such technical standards could vary with different UWB use cases. For example, where the Commission's rules currently prohibit UWB operation on ships, could it permit UWB surveillance system use for public safety purposes? What about other types of UWB devices? Would similar reasoning be applicable for aeronautical platforms? Are there other internationally recognized maritime, aeronautical, or ITU–R standards that could inform an appropriate emissions framework for these expanded operating scenarios?

The Commission invites commenters to address whether the underlying assumptions that informed the Commission's 2002 precautionary framework remain valid considering advances in modern communication systems, such as the availability of ubiquitous high speed internet, Wi-Fi, and advanced mobile technologies like 5G, and 6G; broader adoption of technology by the public (*e.g.,* mass adoption of smart phones and smart home applications); improved coexistence techniques such as listen-before-talk, dynamic frequency selection (DFS), adaptive frequency hopping (AFH), and Automatic Frequency Coordination (AFC). The Commission notes that all these aspects of today's communication landscape were neither available nor envisioned at the time the rules were first adopted. Taking this into account, what steps can the Commission take to provide more flexibility and expansion for UWB use cases while still ensuring that they do not cause harmful interference? For example, to the extent that modern communications technologies include advanced error detection and correction algorithms, and because UWB transmissions exhibit very low duty cycle and ''bursty'' in nature, does this further dimmish the likelihood that UWB-related interference would result in the degrading, obstructing, or actual interruption of a radiocommunication service so as to rise to the level of being ''harmful''? Are there particular bands or uses—such as frequencies used for space research or radio astronomy in which there is no communications protocol for which error detection and correction algorithms can be readily employed—that warrant additional considerations and that might affect how the Commission implements any changes to its current UWB rules? If so, how can the Commission narrowly tailor any limitations on UWB use to account for such unique situations?

The Commission seeks comment on whether relaxing any or all its prohibitions of uses in § 15.521(a) would pose any meaningful risk of harmful interference. For example, would any undesired changes in aggregate noise floor levels be expected? If the noise floor level were to change, would it do so to a degree that could increase the harmful interference risk, or would it generally go unnoticed? Commenters should provide detailed technical analysis to support their positions. Similarly, how would device proliferation and operational density be expected to change? Would such changes affect the potential for harmful interference? How might geo-fencing be employed in these devices as a mitigation technique? In short, the Commission seeks to fully understand whether and how any changes it might make to the rules would affect the ability for UWB to coexist with authorized services.

As an initial matter, the Commission notes that the term ''toys'' is not defined in the rules and has become more ambiguous as the number and types of consumer-grade electronic devices have proliferated in the time since the Commission adopted the prohibition. The Commission is concerned that the lack of a clear definition may create uncertainty for manufacturers and could inadvertently discourage the development of useful UWB-enabled products. The Commission further recognizes that the original caution underlying this restriction may no longer be necessary given UWB's longstanding record of operating without causing harmful interference in other applications. The Commission seeks comment on these observations. The Commission seeks comment on whether it should remove the prohibition on toys incorporating UWB devices. The Joint Petitioners note that UWB often interacts with other wireless technologies, such as Bluetooth and Wi-

Fi that are frequently leveraged by toys and that the distinction between personal devices and toys is increasingly blurred, as devices such as tablets and phones are often used for gaming. In seeking to remove this prohibition, the Joint Petitioners do not seek any changes in the general UWB technical rules or limits that would be applicable to such devices. Were the Commission to retain a restriction on toys, are there steps it could take to limit any burdens associated with the existing prohibition? For example, should the Commission adopt a definition for ''toys''? If so, what would be critical elements for such a definition both in a qualitative and quantitative perspective? How would toys be described and what are the critical technical elements to capture, like bandwidth, duty cycle, emission limits, that are unique to toys? Noting that UWB operating specifically in toys would not alter the radiofrequency environment compared to other uses, the Commission seeks comment on whether UWB use in toys is likely to become widespread. And if so, would such use create aggregate interference concerns? Would restricting operation of UWB-equipped toys to certain channels, such as Channels 8 and 9 (the center frequency of Channels 8 and 9 is 7488 MHz and 7987.2 MHz, respectively), or otherwise limiting operation on specific frequencies be an effective means of protecting the interests of authorized spectrum users, including Federal spectrum users? Are there other use characteristics the Commission should consider? For example, is it reasonable to expect that most toys would be used indoors where building entry loss would protect many nearby licensed users? Would a use-based limitation on toys be an effective approach for providing any necessary protections?

The Commission also seeks comment on the potential for expanded UWB use on ships, including operations on inland waters, as requested by the Joint Petitioners, and whether geofencing methods, further device level controls and features, or operational restrictions could reliably ensure compliance as ships move between inland and coastal environments. Because the original UWB rules prohibited operation aboard ships and aircraft, any expansion to these platforms will be best supported by a thorough, comprehensive technical analysis. Accordingly, the Commission seeks comments on appropriate emission restrictions in the aeronautical and maritime bands to determine whether codifying expanded UWB operation in these environments is technically feasible and would adequately protect incumbent safety systems. Although the rules generally restrict UWB from operating on ships, the Commission also notes that most modern smartphones support UWB and such devices are not generally restricted from onboard use. As such UWB devices must meet the general 15.209 limits outside of the bands specified specifically for UWB use (*e.g.,* in the HF and VHF maritime bands), would any additional technical restrictions be needed to protect these bands? How would the spectral environment in such bands differ from what is already experienced today? The Commission also seeks comment whether any operational restrictions might be necessary for UWB systems to operate safely aboard vessels. For example, should the Commission restrict UWB operations to a certain distance from such a certain shipboard systems? In such cases, how could a required separation distance be enforced? Commenters advocating for relaxing or eliminating these prohibitions should provide details on what technical limits and operational controls, if any, that should be implemented for UWB devices and how such implementation can be achieved. How much detail should be in the rules and how much should be left to the standards-setting process? Commenters should provide detailed technical justifications for their positions. The Commission also seeks comment on whether the RF environment of inland waterways differs significantly from coastal or open water settings, and on whether propagation, clutter, usage density, or incumbent operations warrant distinct protections from UWB operations onboard ships. The Commission also seeks comment on whether a blanket removal of the prohibition on UWB use on ships would be appropriate.

In addition, the Commission seeks comment on whether such operational restrictions tied to specific locations should be relaxed more broadly. The Commission would expect that the density of UWB devices on cruise ships or in other non-traditional operating environments such as offshore platforms, offshore energy facilities like oil rigs, research vessels, or other maritime or near-shore structures would be much less than the general case for non-controlled environments. In such cases, are any operational restrictions necessary for certain types of UWB devices? Would the resulting RF environment present any meaningful risk of harmful interference to authorized services? And what location based controls such as geofencing, automated disablement, or environmental sensing could ensure compliance as these platforms move between inland, coastal, and open ocean environments? Commenters supporting such relaxation should identify what controls would be required, how they could be implemented at the device or system level, and which elements should be specified in the rules. The Commission also seeks comment on whether the use of specific UWB channels, such as on Channels8 and9, would lessen the potential impact on Federal systems and whether adopting such a policy would minimize or mitigate the need for continued coordination.

In addition, the Commission seeks comment on whether UWB-based autonomous drone navigation and landing systems should be permitted under the UWB rules. The Commission recognizes the emergence of commercial systems capable of high-precision, GNSS (Global Navigation Satellite System) independent positioning that support indoor and outdoor autonomous landing for multiple drones and landing stations, which even allow the use of mobile devices as UWB landing beacons, but that may not be permissible under the Commission's current rules. The Commission seeks comment on what technical and operational conditions, such as indoor-only operation, confined outdoor areas, uses only in controlled facilities like industrial and manufacturing factories, altitude limits, power restrictions, and duty cycle limits, might be necessary to protect authorized services.

The Commission also seeks comment on expanded UWB use in aircraft and satellites. In particular, the Commission seeks comment on:

- whether expanded drone-based UWB operations could alter the coexistence dynamics in shared spectrum environments;
- technical studies that model coexistence between systems and assess whether there might be any measurable effect on harmful interference risk to authorized users of the band;
- the potential use of UWB devices aboard aircraft and satellites;
- when using UWB aboard aircraft and satellites, what technical and operational safeguards such as geofencing, altitude based restrictions or other relevant restrictions would be required to prevent harmful interference to aeronautical and satellite services; and
- other technical rules that would promote compatibility for airborne use

of UWB with other authorized users, such as emission limits and UWB channel restrictions.

Commenters supporting expanded UWB use in these environments should provide detailed technical analyses, including propagation modeling, link budgets, and coexistence studies and analysis. The Commission also notes that the intent here is not to make drastic or wholesale changes to the dynamics in satellite, air and space environment via the general expansion of an unlicensed regime. Instead, the intention is to make UWB devices accessible in these environments to enable technology innovators to better serve the American public by expanding UWB capabilities to aircraft and satellites. Finally, the Commission seeks comment on whether any corresponding rule changes would be needed for other classes of UWB devices if we were to alter the use restrictions in § 15.521(a) in any of the ways discussed in this subsection.

Advance Written Coordination Requirement. Section15.525 requires UWB imaging systems to undergo written coordination by submitting notice to OET prior to operating, including providing contact information, the device FCC ID, and the intended geographic operating area for subsequent FCC–NTIA review. This process was originally established to prevent harmful interference to sensitive services such as the Global Positioning System (GPS), the personal communications service (PCS), radio astronomy, and satellite-based sensors, while still enabling the benefits of UWB imaging technologies. Over time, however, coordination has proven administratively burdensome and no longer appears to be necessary given the absence of reported harmful interference and the maturity and the predictable nature of modern UWB devices. Notably, the Commission is not aware of any instance where this written coordination information has been used to respond to an interference concern or has resulted in a follow-up investigation.

The Commission therefore proposes to eliminate the § 15.525 coordination requirement and seek comment on whether its removal would meaningfully affect interference risk, limit the ability to manage device proliferation, or otherwise reduce necessary safeguards. To the extent parties believe that there is a need to retain a coordination requirement, they should give concrete examples of when and how the current process has provided for the identification and resolution of actual UWB-based interference. If there is a reason to retain a coordination requirement, could any part of coordination process be streamlined or simplified such as by removing the requirement that the notification be sent in writing to the Commission's physical address? What are the most effective ways to ensure that the benefits of such coordination (to the extent there are any) outweigh the substantial burdens that the existing requirement creates?

Ground Penetrating Radars. Over the past two decades, the Commission has repeatedly relied on case specific waivers to authorize Ground Penetrating Radar (GPR) and related ultrawideband sensing systems that could not conform to the conservative framework adopted in the 2002 *First Report and Order* (67 FR 34852; May 16, 2002). Bosch details in its petition that virtually every significant GPR advancement has necessitated tailored relief because the rules' definitional, operational, and measurement provisions were incompatible with modern GPR designs. The Commission has consistently justified these waivers based on the longstanding absence of harmful interference, the downward-directed and ground-coupled nature of GPR emissions, and the greater public interest benefits of infrastructure monitoring, construction safety, utility detection, and transportation applications. Collectively, these waiver grants demonstrate both the need and the opportunity to update these rules so that widely used and low-risk GPR technologies no longer depend on repeated, device specific waivers for market entry. The Commission continues to see that trend as evident by more recent waiver authorizations such as Rod Radar.

The Commission observes that all of these waiver grants apply a consistent set of technical conditions tied to the same rule sections being waived namely §§ 15.503(d), 15.31(c) and 15.521(d). Across the waivers, the Commission permits stepped-frequency and other frequency-agile GPR devices to operate by waiving these provisions and requires applicants to demonstrate compliance with emissions limits while the device operates in its normal stepping mode, rather than with the sweep disabled. The Commission limits dwell time on any individual frequency band to ensure the device cannot function as a narrowband transmitter, and it requires operation only in contact with the ground, consistent with part 15 subpart F's GPR definition, to ensure downward-directed energy and reduce harmful interference potential. In addition, the Commission requires that waiver recipients must suppress emissions within restricted bands through notching or equivalent attenuation, and each device must still comply with all other technical and operational UWB GPR requirements.

The Commission seeks comment on whether:

- the rules should incorporate recurring conditions reflected across prior GPR waivers and, if so, whether there is a specific waiver (*e.g.,* Rod Radar, Proceq, or Curtiss-Wright) that should serve as the model;
- the rules should incorporate explicit technical parameters that have appeared consistently in those waivers, including reducing or limiting emissions over specific protected bands that are uniquely susceptible to harm if affected by UWB-based interference (for example, 328.6–335.4MHz and 960–1103.51MHz), defined dwell-time limits (such as the 58-microsecond maximum step duration or the 2-microsecond limit used in earlier waivers), and other provisions such as downward-directed emissions, ground-contact activation, and proximity- or motion-based interlocks;
- incorporating the recurring conditions from prior GPR waivers and tailoring them to device classes that routinely require waivers, including stepped-frequency GPR, continuous-wave GPR, vehicular or bucket-mounted systems, and infrastructure inspection radars, would reduce regulatory uncertainty, streamline equipment authorization, and ensure consistent protection for authorized services.

Commenters should identify which conditions remain necessary, which may be outdated, and how these requirements should be modernized to support current and emerging GPR technologies

New UWB Device Category. Over the past several years, the Commission has seen a sharp increase in nearly identical UWB waiver requests, particularly for outdoor keyless entry/door lock systems, vehicle and rail safety ranging systems, and other precision tracking applications, seeking relief from the requirements that UWB devices in the hand-held category must be hand held and cannot use fixed outdoor infrastructure. These waiver requests are characterized by similar technical characteristics and mitigation measures, typically generate little or no public comment, and have generated no reports of harmful interference. This consistent pattern suggests that the current rules are more restrictive than necessary and are no longer aligned with practical deployment needs. The Commission further recognizes that UWB's fine-

ranging accuracy, robust performance in multipath environments, and ability to operate across wide frequency ranges can enhance continuous spatial awareness, intent detection, multimodal sensor fusion, and autonomous navigation in emerging technologies, including AI-enabled applications.

The Commission therefore proposes to update and advance the rules by establishing a new UWB device category that reflects modern technology needs while providing a durable framework for future innovation. This category would support compact devices operating in either mobile or fixed configurations and that are capable of operating either indoors or outdoors. To protect authorized services, devices would be subject to practical physical safeguards, such as height limits, mounting restrictions, and requirements to direct emissions downward. Technical limits would further mitigate interference potential by incorporating controls, such as duty cycle limits, power spectral density constraints, antenna directivity requirements, pulse repetition frequency restrictions, or relevant combinations of these measures. To ensure efficient spectrum use, these devices would be allowed to transmit only during active, event-driven communication sessions and must remain idle otherwise, and be prohibited from forming wide-area networks. They would continue to operate at low power with duty cycles under one percent in any 24-hour period. Collectively, these safeguards would prevent continuous transmissions, minimize interference risks, reduce the need for waivers, and create a clear, technically grounded foundation for future UWB deployment.

The Commission seeks comment on these proposed technical requirements and whether and how they might alter the radiofrequency environment for users of authorized services. Because UWB is used sparingly in devices, the Commission expects these devices to have low duty cycles. Using an example of a UWB-equipped door lock that is engaged up to ten times a day, with each ranging round lasting 660 microseconds, the time the device is actively sending a signal represents an extremely small percentage of the day as a whole. For this reason, the Commission believes that a duty cycle limit at or below one percent is not only appropriate to maintain interference-free operation, but also adequately supports expected future uses cases. The Commission seeks comment on this observation and the specific duty cycle that it should adopt. In addition, the Commission seeks comment on whether the duty cycle should be measured over a period of 24 hours or over a shorter interval (*e.g.,* hourly or even on a per-minute basis). The Commission also seeks comment on appropriate emission limits. Should they match, exceed, or be more restrictive than the current UWB hand held device limits, and why? The Commission also seeks comment on what emission limits should be associated with particular frequency bands to provide maximum flexibility for UWB devices while ensuring coexistence with incumbent services.

To unlock the full breadth of benefits, UWB devices rely on specialized modulation to achieve the wide bandwidths required for UWB classification. Common UWB waveform types include: impulse-radio UWB (IR–UWB), which uses extremely short pulses for precise ranging and localization; Multi Band Orthogonal Frequency Division Multiplexing OFDM (MB–OFDM), which divides the spectrum into sub bands and employs frequency hopping for high-speed data transfer; Frequency Modulated Continuous Wave (FMCW) modulation used in radar and sensing applications; and stepped frequency waveforms that sequentially transmit discrete tones across a broad band. Each modulation requires careful management of technical parameters, such as pulse repetition frequency, dwell time, sweep rate, and pulse shaping, to ensure efficient spectrum use, minimize interference, and comply with applicable emission limits.

The Commission seeks comment on appropriate modulation-related technical requirements for this new UWB device category, including whether dwell time limits should be more restrictive, more flexible, or aligned with those adopted in prior Commission waivers. Are constraints on dwell time, number of activations per day, duration of each activation, or other operational parameters are appropriate for this new UWB device category? The Commission also invites comment on whether uniform stepping, randomized stepping, or alternative optimized sweep patterns should be permitted, so long as emissions remain compliant to the rules, and whether testing must always be performed with the stepping or sweep function active to reflect real-world behavior. The Commission also seeks comment on appropriate pulse repetition frequency (PRF) or burst timing limits, including whether constraints similar to or distinct from proposals in past filings, such as Bosch's request for PRF less than 4 MHz for a different device class, would be suitable here. The Commission seeks input on whether higher, lower, or comparable PRF limits should be adopted, and whether PRF should be tied to duty-cycle caps or minimum off-time requirements to ensure that the aggregate interference profile remains comparable to existing UWB imaging systems. The Commission also invites comment on other UWB modulation methods and parameters that may be optimal for this new device category, aiming to maximize technological benefits while maintaining strong protections for existing services.

To the extent applicable to this proposed new device class, the Commission seeks comment on the technical parameters that Bosch proposed in 2019 for a more expansive imaging system (even though the Commission is proposing a different approach by way of the new device type). Bosch's proposed device class would have bandwidths up to 2.5 GHz within the 6–9 GHz range, have mean emission limits similar to UWB, and operate with low duty cycles of typically less than 1%, with a signal transmission on time of less than 2 nanoseconds. It also proposed an antenna gain of less than 4 dBi for its system with antenna patterns restricted to a 90-degree horizontal and vertical pattern, and an antenna tilted downward from the horizon with an installation height of 2–3 meters. It claimed that this would allow motion detection to be active 24 hours per day with no appreciable interference potential and enable its system to achieve a location precision of 0.1 to 1 meter and a detection distance of 15–18 meters. The Commission seeks comment on whether some or all of these technical limits should apply to this device category, to the extent applicable, to maintain low interference potential while enabling 24-hour operation.

In addition, the Commission seeks comment on appropriate antenna pattern requirements, if any, for this new UWB device category. Historically, the previous UWB waivers have considered antenna designs that place nulls at the top and bottom of the device, concentrating emissions in the azimuthal plane to reduce radiation toward airborne and satellite receivers and to promote faster attenuation with distance. The Commission seeks comment on whether similar constraints are sufficient for indoor, outdoor, and mobile use, or whether narrower beamwidth requirements, such as 30, 60, or 90 degrees, should be adopted. Alternatively, the Commission seeks comment on whether antenna

requirements are necessary if duty cycle limits and emission limits alone are adopted that can adequately control interference. The Commission's goal is to ensure effective emission management while maximizing operational flexibility to support broader UWB deployment.

The Commission invites commenters to consider the appropriate interplay between duty cycle, power level, antenna pattern constraints, and waveform characteristics to ensure that these systems can operate flexibly while continuing to protect incumbent services. Because UWB emissions are shaped not only by average and peak power, but also by how frequently pulses are transmitted and how energy is directed spatially, would a combined framework, such as pairing low duty cycles with restrictive antenna patterns while allowing modest power increases, provide an appropriate and flexible pathway for this new category of devices? Should maximum permissible power limits vary based on antenna directivity, such as allowing slightly higher power for antennas that confine emissions to the azimuthal plane or employ narrow beamwidths (for example, ten degrees) when paired with very low duty cycles (*e.g.*, less than 1% over 24 hours)? Alternatively, would establishing uniform limits regardless of beamwidth be more appropriate? The Commission also seeks comment on whether it should specify additional waveform parameters, including limits on modulation dwell times (such as stepped-frequency continuous wave dwell times not exceeding 2 microseconds per frequency), FMCW sweep times, impulse radio pulse shaping characteristics, pulse repetition interval or other UWB signal characteristics to ensure predictable and stable rules consistent with incumbent service protection. Should such waveform requirements be paired with operational constraints that require devices to transmit only during active, event-driven communication sessions and remain idle otherwise, thereby reinforcing low average emission levels and promoting efficient spectrum use?

Are there additional operational restrictions the Commission should consider? Possible examples include installation-related limits, such as maximum mounting heights, mandatory downward tilt, or similar measures to ensure emissions remain directed toward the ground. Should the Commission adopt more permissive limits, such as allowing installations up to 20 meters, to support low altitude drone operations and other potential new UWB applications? Should device deployments that qualify under these new rules be limited to controlled environments, such as industrial or manufacturing facilities or, alternatively, be restricted to residential, non-professional use only? The Commission also asks whether it should not adopt any usage restrictions. Commenters should provide technical justification to support how any use restrictions or the absence thereof would enable coexistence and minimize the potential for harmful interference to occur. Finally, the Commission seeks comment on appropriate measurement procedures for demonstrating compliance with duty cycle, emission limits, and antenna pattern requirements, including any necessary modifications to existing part15 or part2 procedures and certification processes to capture worst-case emissions while reflecting realistic UWB device behavior.

As the Commission explores ways to modernize the rules for the next generation of technology, the Commission finds that AI is an area where updated UWB provisions may provide meaningful support. In a very short timeframe, AI has advanced through several distinct stages from generative AI, which creates text, images, code, and synthetic sensor data, to agentic AI, which can plan, reason, and take sequenced actions based on real-time environmental conditions, and is headed toward physical AI, where intelligence is embedded in robots, drones, autonomous vehicles, and other embodied systems that interact directly with the physical world. The Commission notes that the unique technical capabilities enabled by UWB such as precise ranging, spatial awareness, and reliable low-power operation position it to play a central role in supporting this transformation. In this connection, the Commission also highlights that it has been taking action to ensure that devices sold and operated in the U.S. do not pose an unacceptable risk to the national security of the United States and to the safety and security of U.S. persons. The Commission anticipates that aside from purely technical provisions, equipment will continue to be examined under this umbrella, and the Commission will take actions as appropriate to ensure that UWB systems integrated with AI technologies are aligned with the national security interest of the nation. The Commission seeks comment on these observations.

Because many contemporary AI applications do not fit existing UWB categories, the Commission seeks comment on establishing a new device class for AI-based sensing systems. Will emerging forms of AI, including agentic AI and physical AI, require distinct technical or operational considerations when paired with UWB technologies? For example, as more businesses and consumers rely on smart devices, such as those that employ robotics or other designs that can operate with a degree of autonomy, the Commission expects such devices will rely on UWB for sensing, spatial awareness, navigation, and positioning, given its ability for sub-centimeter accuracy. Are the requirements for such devices sufficiently different from other UWB devices that the Commission should create an entire category for them, and, if so, how do the requirements differ from existing UWB devices and what rules are needed? Commenters should address how such functions should be defined, and what technical requirements should be adopted or measurement procedures codified to reflect UWB AI architectures that ensure devices can operate as intended and coexist with incumbent users. How should these devices be defined? Are there specific characteristics that should be codified to differentiate these devices or form factors from other UWB devices or platforms? The Commission invites comment on appropriate technical and operational rules for AI enabled UWB systems, including whether existing power levels and emission limits are suitable for adaptive systems that have enhanced RF context awareness and onboard computing capabilities, or whether more flexible (or more restrictive) limits are warranted. The Commission also seeks comment on additional safeguards that could be implemented to minimize harmful interference, such as minimum duty cycle constraints, contention based protocols (*e.g.*, listen before talk), or other interference-avoidance mechanisms that would be appropriate for AI-enabled devices. The Commission seeks comment on whether antenna-related restrictions (*e.g.*, gain, directivity, orientation, placement) are necessary. As such devices are expected to be location-aware, could different limits be adopted for indoor versus outdoor use? Are there other categorical distinctions that could define various limits, such as industrial/manufacturing/enterprise environments versus broader use by the general public? Should there be eligibility restrictions to use certain classes of these devices, (*e.g.*, based on rule part eligibility categories or other classification schemes)? What other factors should the Commission consider

regarding potential rules for UWB intended for AI architectures?

Comprehensive Review and Modernization of the UWB Regulatory Framework. As part of this comprehensive review of the UWB framework, the Commission initiates a broad examination of whether the longstanding technical, operational, and eligibility requirements for all UWB device categories continue to be necessary. Many of these provisions were adopted more than two decades ago, reflect early-generation UWB technologies, and now form a fragmented and highly prescriptive structure that may no longer align with how modern UWB systems are designed, standardized, deployed, and used. In reassessing these rules, this proceeding presents an opportunity to modernize a framework originally crafted when UWB devices were nascent and less predictable, and to evaluate whether today's mature, well-characterized technologies warrant a more flexible, harmonized, and technologically neutral approach.

Eligibility. The Commission's rules restrict eligibility for operating UWB imaging systems. Ground penetrating radar and wall imaging systems may be operated only by entities engaged in law enforcement, firefighting, emergency rescue, scientific research, commercial mining, or construction activities, and operators must also satisfy the part90 eligibility requirements; through-wall imaging systems are further limited to law enforcement, emergency rescue, and firefighting organizations operating under state or local authority; and surveillance systems may be used only by law enforcement and fire and emergency rescue organizations, as well as certain eligible industrial entities under part 90.7 of the rules (*i.e.*, manufacturers, petroleum, and power licensees), with operators required to meet part90 licensing eligibility. Medical imaging systems are subject to an additional layer of restriction, as they may be used only at the direction of, or under the supervision of, a licensed healthcare practitioner. Collectively, these provisions demonstrate that UWB imaging devices are confined to tightly controlled professional sectors with explicitly defined eligibility requirements. The Commission adopted these operational restrictions in conjunction with the technical rules as part of its overall cautious approach to authorizing use of UWB, stating that ''[the] combination of technical standards and operational restrictions will ensure that UWB devices coexist with the authorized radio services without the risk of harmful interference while the Commission gains experience with this new technology.'' In the intervening years, increasing numbers of UWB imaging devices have been authorized for an ever-widening variety of purposes, with no record of disruption to licensed and authorized radio services. The Commission is also not aware of any situation where a UWB imaging device has caused harmful interference because it was not being used by or under the supervision of an eligible party.

Because the eligibility restrictions were adopted as part of an initial cautious approach to authorizing UWB and because the Commission intended to revisit them after UWB use had become more prevalent, the Commission now seeks comment on whether eligibility restrictions for UWB imaging systems remain relevant and necessary. Can the Commission eliminate the eligibility restrictions altogether? If so, would that unleash new consumer-grade devices, and what would be the benefits and risks associated with that development? If the Commission retains use restrictions, should it modify the list of eligible professional sectors? Could the Commission adopt a consistent eligibility framework across all imaging system categories to broaden utility? Would consolidating the multiple imaging rule parts into a unified umbrella framework provide more clarity than just adjusting eligibility criteria? The Commission encourages commenters to address technical or operational safeguards, such as coordination requirements, that would be necessary to ensure that any expanded access or streamlined framework continues to protect incumbent services. Alternatively, could there be a class of devices with different technical parameters that could be widely used by any party (*i.e.*, with no use restrictions) without increasing the potential for harmful interference? If so, what would those parameters be? The Commission also seeks comment on how existing certified devices and associated inventory should be treated upon adoption of any final rules. For example, many equipment certifications include grant notes specifying that the device, ''may not be employed for the operation of toys'' and that ''operation onboard an aircraft, a ship or a satellite is prohibited.'' To address cases where such restrictions may no longer be consistent with rules the Commission ultimately adopts and based on such devices meeting the new technical limits the Commission ends up adopting in the proceeding, should the Commission require responsible parties for equipment authorizations to request such grant notes be removed from their certifications to permit already certified equipment to operate under more flexible conditions? Are there any other data or provisions associated with equipment certifications that may need to be modified? Could the Commission adopt an administrative rule to provide such flexibility? In such a case, how could already-certified devices that meet any new rules the Commission adopts be differentiated from devices that may not comply with any new rules?

Marketing and Labeling Requirement. Section15.507 limits the marketing of certain UWB devices to parties eligible to operate them, such as law enforcement or fire and rescue organizations, and places responsibility on the ''responsible party'' (under § 2.909 of the rules) to ensure that equipment is marketed only to eligible parties. In addition to marketing restrictions, several device-specific rules impose their own labeling requirements:

- Through-wall imaging systems must display a notice restricting operation to law enforcement, emergency rescue, and firefighter personnel.
- Surveillance systems must display a notice limiting use to law enforcement, fire and rescue officials, public utilities, and certain industrial entities.
- Indoor UWB systems must display a statement restricting operation to indoor use.

These provisions impose a marketing limitation and a separate labeling restriction for UWB devices that is in addition to the eligibility requirements that govern who may use certain categories of devices. Furthermore, the multilayered marketing, labeling, and eligibility requirements are codified separately, making the UWB rule structure more complex.

The Commission seeks comment on whether the marketing restrictions in § 15.507 remain necessary given that eligibility limitations are already defined in § 15.503(l) and reiterated in the device-specific rules. The Commission further seeks comment on whether the labeling requirements in §§ 15.510(e), 15.511(f), and 15.517(f), which impose differing and unharmonized statements, continue to serve a distinct purpose. Do they impose an overly restrictive and unnecessary burden on manufacturers in light of the broader part15 and UWB framework that already govern device eligibility, usage, and marketing of UWB devices? Should these requirements be simplified, deleted, or replaced with a

single standardized labeling statement? If the Commission were to adopt a unified eligibility framework, as discussed, would that affect how the Commission should address marketing and labeling? The Commission also seeks comment on what mechanisms would best ensure continued protection of incumbent services if these requirements were streamlined or consolidated, including if the Commission were to create a new consumer-grade tier of UWB devices as discussed.

Emission Limits. Across part15, subpartF, each UWB device category is subject to its own set of frequency-dependent emission limits specified in the corresponding rule sections. In general, all UWB devices must meet the § 15.209 general radiated-emission limits at or below 960MHz, while average emissions above 960MHz are capped at levels that vary by device class and frequency band. These limits typically range from approximately −41.3dBm to −75.3dBm EIRP and are applied across bands, such as 960–1610MHz, 1610–1990MHz, 1990–3100MHz, 3100–10,600MHz, and above 10,600MHz, with more stringent protections, down to −75.3dBm or −85.3dBm EIRP, applied in the 1164–1240MHz and 1559–1610MHz frequency bands.

In addition, UWB devices are subject to more stringent OOBE requirements in the GPS bands, where emissions must be suppressed to no more than −75.3 dBm EIRP for most UWB categories and −85.3 dBm EIRP for indoor and handheld systems. Because modern UWB systems operate at extremely low power and low duty cycles, spreading energy across wide bandwidths with minimal spectral density, decades of deployments have shown that properly compliant UWB devices do not pose a harmful interference risk to GPS or other GNSS services under the existing part15 framework. As the Commission considers proposals to modify UWB rules, it highlights that it is not proposing any changes to the GPS protection regime and expects no change to the emissions radiating in those bands.

Furthermore, UWB categories are also subject to a uniform 0dBm EIRP peak-emission cap within a 50MHz bandwidth under § 15.521. As an example, handheld systems operating under § 15.519 must meet average limits ranging from −75.3dBm to −41.3dBm EIRP depending on frequency, with GNSS band limits of −85.3dBm EIRP and the same 0dBm EIRP peak requirement.

Against this backdrop, the Commission seeks comment on whether it should revisit these long-standing emission limits. Adopted more than twenty years ago, when UWB technologies were new and the interference potential less well understood, the limits were intentionally conservative and tailored to the types of UWB waveforms and device architectures represented in the record at that time. Given the Commission's decades of experience with UWB deployments, during which UWB devices have operated on a non-interference basis without reported harmful impacts, and taking into account the substantial maturation, standardization, and increased predictability of contemporary UWB devices and standards, the Commission seeks comment on whether these emission limits remain appropriate today. Specifically, would it be beneficial to revisit the radiated emission limits and consider increasing average or peak power to support expanded functionality or new use cases? The Commission also seeks comment on whether any technical, interference, or coexistence analysis would be useful to support such adjustments, and how an increase in potential power could be implemented while maintaining or improving protections for incumbent services. Finally, the Commission invites comment on whether harmonizing power limits across device classes or replacing the existing device-specific structure with a simplified unified emission limit framework would improve clarity, reduce compliance burdens, and more accurately reflect the capabilities of modern UWB systems.

Manual or Remote-Controlled Switches and the ''Ten Second'' Rule. Several categories of UWB imaging systems, including ground penetrating radars, wall-imaging systems, through-wall imaging systems, and medical imaging systems, are required to incorporate a manual or remote-controlled switch that gives the operator direct control over when transmissions occur and requires that the devices cease UWB emissions within ten seconds after the operator releases the switch. This requirement was adopted to prevent continuous or uncontrolled transmissions and to ensure that these systems operate only when intentionally activated by an authorized user.

The Commission seeks comment on eliminating, modifying, or replacing these rules. Is there any continued relevance of these transmitter control requirements in light of modern UWB device architectures, which now incorporate highly responsive digital controls, automated power management functions to conserve power, and enhanced sensing or activation mechanisms for modern devices? Is the fixed ten-second shutoff interval necessary or appropriate and, if so, should a shorter interval be considered? Or should the Commission move away from a prescribed timing requirement in favor of a more flexible, performance-based approach? More fundamentally, do contemporary UWB designs already provide sufficient safeguards to prevent unintended or continuous emissions? Would modernizing or removing manual or remote-controlled switch requirements simplify the rules and better align them with current technologies?

Removing Redundant Rules. In light of the Commission's broader initiative to eliminate obsolete rules and reduce unnecessary regulatory burdens, the Commission seeks comment on the continued relevance of these provisions in §§ 15.521 and 15.523 that appear to be less technically relevant, redundant, unnecessarily duplicative of other part15 requirements, and otherwise do not impose any distinct technical or operational obligations on UWB devices:

- Section15.521(b) (reminding manufacturers and users of the antenna provisions in §§ 15.203 and 15.204).
- Section 15.521(e) (stating that the frequency of maximum emission must fall within the UWB bandwidth, which is already inherent in the UWB definition and emission masks and codified in individual device rules).
- Section15.521(f) (reiterating that imaging systems may be used only for the functions described in § 15.503, and restating prohibitions already contained in the device-specific rules).
- Section15.521(j) (providing a reminder of cross-referenced requirements in § 15.505, including conducted-emission limits).
- Section 15.523 (stating that measurements shall be made in accordance with the procedures defined by the Commission, which should be self-evident and is clearly set forth in part 2 of the rules).

The Commission seeks comment on whether some or all of these provisions can be deleted, edited, or modernized to meet today's UWB environment without any undesired consequences for UWB device operations, authorization, or the protection of incumbent services. The Commission encourages commenters to address whether any of the identified UWB rules serve any continuing regulatory purpose or otherwise needed for preserving and highlighting the

technical requirements applicable to UWB devices. Would removing any of these provisions reduce regulatory burdens or improve the clarity and usability of the Commission's rules? Are there any UWB rules that should be consolidated into other sections? Finally, the Commission invites broad comment on all aspects of the UWB rules. For example, are there other UWB rules that the Commission have not discussed that it should modernize, modify, or eliminate, and if so, why?

Initial Regulatory Impact Analysis—Need for Regulatory Action. As discussed in this document, subpart F of the Commission's part 15 rules governs operation of UWB transmitters. Currently, the rules are structured to support specific categories of UWB operations. For each of these applications, the rules specify technical requirements including the frequency bands over which the UWB device may operate, any application-specific bandwidth limits, and radiated emission limits that vary by frequency band. Each type of device is subject to operational restrictions, such as limits on the types of operation permitted and the entities that are permitted to use the device. The UWB rules date to February 2002. Over the past 24 years, manufactures have developed new and innovative applications, and the technology has likewise evolved to incorporate a wider variety of waveforms than had been accounted for when the rules were first adopted. As a result, the Commission has received numerous requests for waivers of the UWB rules to support these types of devices and applications. The rules that the Commission proposes in this document are necessary to account for the evolving uses for and importance of UWB applications that have emerged since the last comprehensive review of the UWB rules. The Commission's proposals recognize the rulemaking petitions that have been filed and the large portfolio of UWB waiver applications that have fielded to date and aim to improve and streamline regulatory processes, increase flexibility for stakeholders, and eliminate obsolete or redundant rules.

This initial regulatory impact analysis is submitted to the Office of Information and Regulatory Affairs (OIRA) for interagency review. The analysis presents an assessment of the costs and benefits, including regulatory compliance costs, associated with the proposals in this document and is consistent with Executive Order 12866. The Commission tentatively concludes that the rules being proposed will result in significant benefits and cost savings that outweigh associated costs, if any. The Commission also tentatively concludes that the actions being proposed are deregulatory under Executive Order 14192.

Benefits and Costs. This document re-examines the Commission's rules and seeks public comment on proposals to update and enhance the rules to provide greater flexibility for UWB operations. In doing so, the Notice proposes rules changes that will have an immediate cost-cutting impact on an important category of devices, while seeking comment on additional revisions that would optimize the UWB rules to keep pace with modern technologies, deployment environments, and advances in UWB modalities. Specifically, the Commission tentatively concludes that by establishing a new UWB device category that reflects modern technology needs the Commission will be able to eliminate the need for time-consuming waivers for devices that meet the requisite technical specifications, while providing for rules that enable UWB devices to take advantage of technological innovations and still avoid harmful interference. Absent the proposed changes to the rules, assuming that the Commission would grant approximately five waivers per year on an ongoing basis, the Commission estimate that this would save approximately $44,000 per year in review costs for Commission staff and an additional approximately $27,000 per year to industry participants in time saved from putting together and filing waivers with the Commission. The Commission seeks comment on these estimates.

The Commission notes that these cost savings are likely conservatively low. For example, these cost savings do not account for contemporary AI applications that do not fit existing UWB categories and a potential corresponding increase in the number of waiver applications that the Commission is likely to see if it were to maintain the current rules. Additionally, these cost savings do not account for potential additional savings that may arise from modernizing UWB technical requirements and from the comprehensive review and modernization of the UWB regulatory framework, including anticipated savings from consolidation, simplification, or removal of redundant rules. Finally, the Commission's estimates do not account for the likely benefits to innovation that are likely to result from regulations that are more up to date and in line with the current state of UWB technology. The Commission seeks comment on the assessment and, more broadly, of benefits, costs, and cost savings that may result from the proposed rules changes. The Commission encourages commenters to submit both qualitative and quantitative assessments of the potential changes to benefits and costs.

III. Intial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Federal Communications Commission (Commission) has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the policies and rules proposed in the *Notice of Proposed Rulemaking (NPRM)* assessing the possible significant economic impact on a substantial number of small entities. The Commission requests written public comments on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments specified on the **DATES** section of the document. In addition, the *NPRM* and IRFA (or summaries thereof) will be published in the **Federal Register**.

Need for, and Objectives of, the Proposed Rules. In the *NPRM*, the Commission proposes to comprehensively modernize its Ultra-Wideband (UWB) device rules that were adopted in 2002. The existing UWB rules were intentionally restrictive and based on the technological capabilities, use cases, and measurement techniques available at that time. Over the past two decades, however, UWB technology has matured significantly and is now widely used in consumer devices, industrial automation, automotive systems, commercial, precision ranging, asset tracking, and public safety applications. UWB devices continue to operate at a very low power on a non-interference basis, and the Commission is unaware of any substantiated reports of harmful interference.

Despite this robust track record of UWB use cases, it is increasingly obvious that the existing rules are outdated and overly restrictive. This has resulted in repeated waiver requests for devices that are low risk, technologically consistent with UWB operations, and similar to equipment already on the market. The *NPRM*'s proposed rule changes are intended to update definitions, modernize measurement procedures, evaluate and potentially eliminate outdated operating restrictions, remove coordination requirements, and examine technical parameters so that our rules can better match modern UWB technologies.

The *NPRM* also proposes a new UWB device category to support emerging applications—such as locations sensing

technologies, industrial automation, mobility platforms, robotics, and AI—enabled sensing systems—that do not fit neatly within the legacy classifications. Additionally, the Commission seeks comment on whether to harmonize, consolidate, or remove prescriptive requirements across subpart F of the part 15 rules, which govern the operation of UWB transmitters. Collectively, these revisions are intended to ensure regulatory clarity, reduce unnecessary burdens, and support innovation while protecting incumbent licensees, some of which are small entities, and federal users.

Legal Basis. The proposed action is authorized pursuant to sections 4(i), 301, 302, and 303 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 201, 302a, 303, and §§ 1.407 and 1.411 of the Commission's rules.

Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A ''small business concern'' is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA. The SBA establishes small business size standards that agencies are required to use when promulgating regulations relating to small businesses; agencies may establish alternative size standards for use in such programs, but must consult and obtain approval from SBA before doing so.

Our actions, over time, may affect small entities that are not easily categorized at present. We therefore describe three broad groups of small entities that could be directly affected by our actions. In general, a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States, which translates to 34.75 million businesses. Next, ''small organizations'' are not-for-profit enterprises that are independently owned and operated and not dominant in their field. While we do not have data regarding the number of non-profits that meet that criteria, over 99 percent of nonprofits have fewer than 500 employees. Finally, ''small governmental jurisdictions'' are defined as cities, counties, towns, townships, villages, school districts, or special districts with populations of less than fifty thousand. Based on the 2022 U.S. Census of Governments data, we estimate that at least 48,724 out of 90,835 local government jurisdictions have a population of less than 50,000.

The rules proposed in the *NPRM* will apply to small entities in the industries identified in the following tables: see, Table 1. 2022 U.S. Census Bureau Dada by NAICS Code and Table 2. Telecommunications Service Provider Data, by their six-digit North American Industry Classification System (NAICS) codes and corresponding SBA size standard. Additional information regarding the number of potentially affected entities in the industries is available at Appendix B of the following internet address: *https://docs.fcc.gov/public/attachments/FCC-26-66A1.pdf*.

Description of Economic Impact and Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities. The RFA directs agencies to describe the economic impact of proposed rules on small entities, as well as projected reporting, recordkeeping and other compliance requirements, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the report or record.

The *NPRM* does not propose any new reporting or recordkeeping requirements and it is unlikely that small entities will need to hire professionals to comply with the proposed rules. Instead, the proposals are expected to reduce existing compliance burdens by eliminating the § 15.525 coordination requirement for UWB imaging devices, streamlining or removing outdated measurement procedures, reducing the need for waiver requests through the combination of rule changes and the creation of a new UWB device category, and consolidating duplicative labeling and marketing requirements. For example, establishing a new UWB device category that reflects modern technology needs will enable the Commission to eliminate the need for time-consuming waivers for devices that meet the requisite technical specifications. Assuming the Commission would grant approximately five waivers per year on an ongoing basis, we estimate a potential savings of $27,000 per year to small entities and other industry participants in time saved from putting together and filing waivers with the Commission. We seek comment from small entities on other areas in which regulatory costs and other compliance requirements can be reduced. To the extent commenters propose alternative approaches—such as modified certification tests or operational constraints—the Commission will evaluate the impact of those alternatives on small entities.

Discussion of Significant Alternatives Considered that Minimize the Significant Economic Impact on Small Entities. The RFA directs agencies to provide a description of any significant alternatives to the proposed rules that would accomplish the stated objectives of applicable statutes, and minimize any significant economic impact on small entities. The discussion is required to include alternatives such as: ''(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.''

In the *NPRM*, the Commission seeks comment on multiple approaches to minimize burdens on small entities, including whether updated definitions and measurement procedures would reduce the need for waivers and lower equipment development costs; whether eliminating certain operating restrictions—such as prohibitions on use in toys or onboard particular platforms—would remove unnecessary constraints on product design; whether consolidating or simplifying the existing prescriptive UWB device categories would provide clearer and more flexible rules for small manufacturers; whether a unified or harmonized emission framework would streamline compliance across device classes; and whether removing duplicative labeling and marketing provisions would further reduce compliance obligations.

The Commission also invites comment on alternative technical or operational frameworks that could provide equal or greater flexibility for small entities while ensuring continued protection for incumbent spectrum services. Small entities are encouraged to identify any significant alternatives—such as different technical limits, operational safeguards, or administrative processes—that would minimize economic impacts while achieving the *NPRM's* goals. The Commission's evaluation of the comments filed in this proceeding will shape the final conclusions it reaches,

the final alternatives it considers, and the actions it ultimately takes to minimize any significant economic impact that may occur on small entities resulting from the final rules.

Federal Rules that May Duplicate, overlap, or Conflict with the Proposed Rules. None.

III. Ordering Clauses

Accordingly, it is ordered, pursuant to sections 4(i), 301, 302, and 303 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 301, 302a, 303, and §§ 1.407 and 1.411 of the Commission's rules, 47 CFR 1.407, 1.411, that the *Notice of Proposed Rulemaking* is hereby adopted.

It is further ordered that the Petition for Rulemaking filed by Robert Bosch LLC and the Petition for Rulemaking filed by Alliance for Automotive Innovation, Car Connectivity Consortium, FiRa Consortium, PROFIBUS & PROFINET International/omlox, and the Ultra-Wideband Alliance are granted.

It is further ordered that, pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments on the Notice of Proposed Rulemaking on or before December 2, 2026, and replies on or before January 4, 2027. Comments and reply comments shall be filed in ET Docket No. 26–245.

List of Subjects in 47 CFR Part 15

Communications, Communications equipment, Electronic products, Telecommunications.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend part 15 of Title 47 of the Code of Federal Regulations as follows:

PART 15—RADIO FREQUENCY DEVICES

■ 1. The authority citation for Part 15 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, 304, 307, 336, 544a, and 549.

■ 2. Amend § 15.503 by revising paragraph (d) to read as follows:

§ 15.503 Definitions.

* * * * *

(d) *Ultra-wideband (UWB) transmitter.* An intentional radiator that has a fractional bandwidth equal to or greater than 0.20 or has a UWB bandwidth equal to or greater than 500 MHz, regardless of the fractional bandwidth.

* * * * *

■ 3. Amend § 15.505 by revising paragraph (a) to read as follows:

§ 15.505 Cross reference.

(a) Except where specifically stated otherwise within this subpart, the provisions of subparts A and B and of §§ 15.201 through 15.204 and 15.207 of subpart C of this part apply to unlicensed UWB intentional radiators. The provisions of §§ 15.31(c), 15.35 (c) and 15.205 do not apply to devices operated under this subpart. The provisions of Footnote US 246 to the Table of Frequency Allocations contained in § 2.106 of this chapter does not apply to devices operated under this subpart.

* * * * *

§ 15.509 [Amended]

■ 4. Amend § 15.509 by removing and reserving paragraph (b)(2).

§ 15.510 [Amended]

■ 5. Amend § 15.510 by removing and reserving paragraph (c)(2).

§ 15.511 [Amended]

■ 6. Amend § 15.511 by removing and reserving paragraph (b)(2)

■ 7. Amend § 15.513 by revising paragraph (b) to read as follows:

§ 15.513 Technical requirement for medical imaging systems.

* * * * *

(b) Operation under the provisions of this section is limited to medical imaging systems used at the direction of, or under the supervision of, a licensed health care practitioner.

* * * * *

■ 8. Amend § 15.521 by revising paragraph (a) and (d) to read as follows:

§ 15.521 Technical requirements applicable to all UWB devices.

(a) Operation onboard an aircraft, a ship not within inland waters, or a satellite is prohibited.

* * * * *

(d) Within the tables in §§ 15.509, 15.511, 15.513, 15.515, 15.517, and 15.519, the tighter emission limit applies at the band edges. Radiated emission levels at and below 960 MHz are based on measurements employing a CISPR quasi-peak detector. Radiated emission levels above 960 MHz are based on RMS average measurements over a 1 MHz or 1KHz resolution bandwidth as applicable. The RMS average measurement is based on the use of a spectrum analyzer with a resolution bandwidth of 1 MHz, an RMS detector, and a 1 millisecond or less averaging time.

* * * * *

§ 15.525 [Removed and Reserved]

■ 9. Remove and reserve § 15.525.

[FR Doc. 2026–22337 Filed 10–30–26; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 91, No. 210
Monday, November 2, 2026

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are required regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 2, 2026 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: Certified Mediation Program.

OMB Control Number: 0560–0165.

Summary of Collection: The Farm Service (FSA) is administering the (7 CFR part 785) Certified Mediation Program as mandated by Subtitle A and B of Title V of the Agricultural Credit Act of 1987 (Pub. L. 100–233), as amended, under the USDA Agricultural Mediation Program. USDA authorized FSA to administer the program. FSA makes grants to state-designated entitles that provide mediation to agricultural producers, their lenders and others that are directly affected by the action of certain USDA agencies. In mediation, a trained impartial mediator helps participants review (affected public: State, Local or Tribal Government Business-not-for-profit these respondent types includes private sectors and Public/State run institution including higher education) and discuss their conflicts, identify options to resolve disputes and agree on solutions.

Need and Use of the Information: FSA will collect information to determine whether the participants meet the eligibility requirements to be recipients of grant funds, and secondly, to determine if the grant is being administered as provided by the Agricultural Credit Act. Lack of adequate information to make these determinations could result in the improper administration and appropriation of Federal grant funds.

Description of Respondents: State, Local or Tribal Government Business-not-for-profit.

Number of Respondents: 46.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 1,334.

Rachelle Ragland-Greene,

Departmental Collection Clearance Officer.

[FR Doc. 2026–22305 Filed 10–30–26; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2026–0892]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Operations and Reporting System

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the operations and reporting system for cooperative wildlife damage management programs.

DATES: We will consider all comments that we receive on or before January 4, 2027.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2026–0892 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Please send one copy of your comment to Docket No. APHIS–2026–0892, Regulatory Analysis and Development, PPD, APHIS, 5601 Sunnyside Ave., #AP760, Beltsville, MD 20705.

Supporting documents and any comments we receive on this docket may be viewed at *www.regulations.gov* or in our reading room, which is in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the operations and reporting system for cooperative wildlife damage management programs, contact Ms. Kendra Cross, Wildlife Services, APHIS, 5601 Sunnyside Ave., 3–WS–1358 Mail Stop #AP660,

Beltsville, MD 20705; (202) 666–8250. For more information on the information collection reporting process, contact Ms. Sheniqua Harris, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2528 or email *APHIS.PRA@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Operations and Reporting System.

OMB Control Number: 0579–0335.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The Secretary of Agriculture is authorized under Section 426 of the Act of March 2, 1931, as amended (7 U.S.C. 8351–8354; 46 Stat. 1468), to conduct a program of wildlife services with respect to injurious animal species. Large populations of aggressive wildlife species, if left unmanaged, may cause tremendous amounts of damage to crops, livestock herds, and private property within the United States. Without mitigation, the damage could result in severe economic losses for agricultural businesses and private property owners. The Act authorizes the Secretary to take any action he considers necessary for the control of nuisance mammals and birds and those mammal and bird species that are reservoirs for zoonotic diseases.

The United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Wildlife Services (WS), is responsible for assisting the public with mitigating wildlife damage. WS provides advice or enters into agreements with State and local jurisdictions, Tribes, public and private agencies, organizations, institutions, and individuals to provide its services. Through its technical assistance approach, WS offers advice through telephone or onsite consultations, training sessions, demonstration projects, and other means. Mitigation activities are then performed by the requester. WS also provides a cooperative direct control approach where goods, services, and expertise are provided on a cost reimbursable basis. WS collects only information needed to determine appropriate courses of action for providing effective services. Information is used by the agency to:

- Identify cooperators appropriately;
- Identify lands on which WS personnel will work;
- Differentiate between cooperators (*i.e.,* property owners, land managers, or resource owners) who request assistance to manage damage caused by wildlife;
- Identify the land areas on which wildlife damage management activities would be conducted;
- Identify the relationship between resources or property, WS' protection of such resources or property, and the damage caused by wildlife;
- Determine the methods or damage management activities to deal with the damage;
- Establish a record that a cooperative agreement has been entered into with a cooperator;
- Document that permission has been obtained from landowners to go on the cooperator's property;
- Record wildlife damage occurrences on cooperator's property and steps to address them;
- Record occurrences which may have affected non-target species or humans during, or related to, WS project actions; and
- Determine satisfaction with service to help WS evaluate, modify, and improve its programs.

Information collection activities include work initiation documents, assistance requests, protected resource queries, project reports, order forms and sales records, equipment issuances, migratory bird damage reports, reports of injury or death to non-target animals, accident reports, pilot proficiency reviews, and invoice transmittals.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years. APHIS has renamed this information collection to Operations and Reporting System, the information collection was formerly known as National Management Information System.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.042 hours per response.

Respondents: State, local, and Tribal governments; businesses, not-for-profits, and other public sector organizations; and individuals who request services from WS or engage in wildlife damage management projects with WS.

Estimated annual number of respondents: 77,712.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 86,274.

Estimated total annual burden on respondents: 3,608 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 19th day of October 2026.

Kelly Moore,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2026–22309 Filed 10–30–26; 8:45 am]

BILLING CODE 3410–34–P

AMERICAN BATTLE MONUMENTS COMMISSION

Performance Review Board Appointments

AGENCY: American Battle Monuments Commission.

ACTION: Notice of performance review board appointments.

SUMMARY: This notice provides the names of individuals who have been appointed to serve as members of the American Battle Monuments Commission Performance Review Board. The publication of these appointments is required by section 405(a) of the Civil Service Reform Act of 1978.

DATES: These appointments are effective as of 01 October 2026.

FOR FURTHER INFORMATION CONTACT: Ryan Raymond, Chief of Human Resources and Administration, American Battle Monuments Commission, Courthouse Plaza II, Suite 500, 2300 Clarendon Boulevard, Arlington, Virginia 22201. Telephone number: (703) 584–1510.

SUPPLEMENTARY INFORMATION:

American Battle Monument Commission SES Performance Review Board—2026/2027

Dr. Erin Mahan, Chief Historian, Office of the Secretary of Defense
Eric C. Nastasi, Deputy Director, Smithsonian American Art Museum
Nealie P. Sutton, Executive Director for Management, American Battle Monuments Commission

Authority: This notice was compiled in accordance to 5 CFR 430.311(a)(4).

Signed at Arlington, VA.

Ryan L. Raymond,

Chief, Human Resources and Administration.

[FR Doc. 2026–22275 Filed 10–30–26; 8:45 am]

BILLING CODE 6120–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Virginia Advisory Committee; Cancellation of November Meeting and Revision to December Meeting Purpose and Duration

AGENCY: Commission on Civil Rights.

ACTION: Notice; cancellation of November meeting and revisions to December meeting.

SUMMARY: The Commission on Civil Rights published a notice in the **Federal Register** concerning meetings of the Virginia Advisory Committee.

The panel briefing previously noticed for Tuesday, November 10, 2026, from 10:30 a.m. (ET) to 12:30 p.m. (ET), has been cancelled.

The meeting scheduled for Tuesday, December 15, 2026, from 11:30 a.m. (ET) to 1:30 p.m. (ET) is now scheduled for approximately one hour from 11:30 a.m. (ET) to 12:30 p.m. (ET); the purpose is also revised to briefing planning. For convenience, the meeting link for the December meeting is: *https://www.zoomgov.com/webinar/register/WN_pCdY9KuQQsu3ng15k7sAyg;* Phone (Audio Only): 1–833–435–1820 USA Toll Free; Webinar ID: 165 385 914 #.

The original notice is in the **Federal Register** of Friday, October 9, 2026, in FR Doc. 2026–20702, in the third column of page 64632 and the and the first column of page 64633.

FOR FURTHER INFORMATION CONTACT: Mallory Trachtenberg, Designated Federal Officer, at (202) 809–9618 or *mtrachtenberg@usccr.gov.*

Dated: October 29, 2026.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2026–22323 Filed 10–30–26; 8:45 am]

BILLING CODE 6335–01–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; American Community Survey and Puerto Rico Community Survey

AGENCY: Census Bureau, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the revision of the American Community Survey and the Puerto Rico Community Survey, prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 4, 2027.

ADDRESSES: Interested persons are invited to submit written comments by email to *acso.pra@census.gov.* Please reference the American Community Survey and the Puerto Rico Community Survey in the subject line of your comments. You may also submit comments, identified by Docket Number USBC–2026–0760 to the Federal e-Rulemaking Portal: *https://www.regulations.gov.* Click the ''Comment'' icon, complete the required fields, and enter or attach your comments. All comments received are part of the public record. No comments will be posted to *https://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Nicole Butler, U.S. Census Bureau, American Community Survey Office, 301–763–3928, *nicole.butler@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The U.S. Census Bureau seeks a revision for the American Community Survey (ACS) and the Puerto Rico Community Survey (PRCS). The ACS program provides information every year on over 40 topics—giving communities, businesses, and governments the current information they need about our nation and its people. ACS data also help inform how trillions of dollars in federal funds are distributed each year.

The ACS content is designed to serve the data needs of federal government agencies and, in addition, provides a rich source of local area information useful to a wide variety of data users, including state and local governments, universities, and private businesses. The ACS is part of the Decennial Census Program. Historically, the decennial census sampled addresses to complete a ''long form,'' which collected detailed population and housing characteristics once a decade whereas a majority of addresses were asked to a complete a ''short form'' which collected basic demographic information. The demand for current, nationally consistent data from a wide variety of data users led federal government policymakers to consider the feasibility of collecting detailed population and housing data continuously throughout the decade. This led the Census Bureau to plan the ACS as a replacement for the ''long form.''

Since its implementation in 2005, the ACS has collected detailed social, economic, housing, and demographic data on more than 40 topics on an ongoing basis, providing more timely data than was previously possible. Every question on the ACS must meet an explicit need from one or more federal agencies. Constraining the content of the ACS was, and still is, critical because of the mandatory reporting requirement and because doing so reduces the burden on the American people. The Census Bureau periodically reviews the questions on the ACS to ensure that existing content serves the data needs of federal agencies and to evaluate new question proposals from federal agencies. The Census Bureau classifies federal agency uses of the ACS as mandatory, required, programmatic, or operational as follows:

- There is a current federal law calling for the use of decennial census

data for a particular federal program (mandatory).

- A federal law (or implementing regulation) clearly requires the use of specific data, and the decennial census was the historical or only source, or case law requirements imposed by the U.S. federal court system need the data (required).
- A federal agency indicated they use the data (or need data on a topic) but there is no explicit requirement for the use of the data, as explained for mandatory or required purposes (programmatic).
- The data are necessary to administer the survey, such as phone numbers (operational).

Only uses identified as mandatory, required, or operational result in questions on the ACS. Programmatic uses alone do not result in questions being added to the ACS.

In 2026, the Census Bureau conducted a content review of the ACS to ensure that every question on the ACS is legally justified and has a federal use. Over 60 federal agencies provided input on their use of ACS data, representing 17 independent agencies and all but three cabinet departments. The review evaluated and classified over 400 federal uses as mandatory, required, or programmatic.

As a result of this review, two ACS questions were identified as no longer having a mandatory or required federal use: Solar Panels and Veterans Period of Military Service. Therefore, the Census Bureau is proposing to remove these questions from the ACS in 2028.

The Content Review also provided the Census Bureau with an opportunity to reconsider the best methods for producing the needed data. By law (Title 13, United States Code, Section 6), the Census Bureau is directed to use existing information collected by other government agencies, to the maximum extent possible, instead of asking the public for it directly. The ACS program has prioritized using alternative data sources to meet data user needs and reduce dependence on traditional data collection methods.

Beginning in January 2024, the ACS program implemented an adaptive approach to collecting data on property lot size (acreage) using administrative property tax data purchased from a third-party vendor. Based on the quality of the property tax acreage data, business rules were developed. In this adaptive approach, the acreage question is skipped when administrative data are available for a sampled address and meet the business rules; the question is asked otherwise.

Beginning as early as 2028, the Census Bureau intends to expand the use of administrative data to reduce burden on the public. Questions on the survey that may be skipped for some respondents when administrative data are available include Agricultural Sales, Year Built, Number of Rooms, Number of Bedrooms, Units in Structure, Building Type, and Home Heating Fuel. Other questions may also be considered. After research is conducted to determine the best methods of using administrative data for the questions, results will be made public on the Census Bureau's website.

The Census Bureau invites public comments, particularly on the two ACS questions proposed for removal and the use of administrative data to replace questions asked of the public. Concurrently, federal agencies that are the principal users of data from these questions are invited to respond either directly to the Census Bureau or through this notice and provide revised or additional justification for these questions.

II. Method of Collection

The ACS is conducted throughout the United States, including in Puerto Rico, where it is called the Puerto Rico Community Survey (PRCS). The ACS samples approximately 3.54 million housing unit addresses in the United States and about 36,000 in Puerto Rico each year. A housing unit is defined as a house, an apartment, a mobile home, a group of rooms, or a single room occupied or intended for occupancy as separate living quarters. The ACS also collects detailed data from a sample of about 158,090 residents living in group quarters facilities in the United States and about 680 in Puerto Rico. Group quarters are places where people, typically unrelated to each other, live or stay in a group-living arrangement owned or managed by an entity or organization that provides housing and/or services for the residents. Group quarters include college/university student housing, residential treatment centers, skilled nursing facilities, group homes, military barracks, correctional facilities, workers' group living quarters, Job Corps centers, and emergency and transitional shelters.

Housing Units

To encourage self-response in the ACS, the Census Bureau sends up to five mailings to housing unit addresses selected for the sample. The first mailing, sent to all mailable addresses in the sample, includes an invitation to participate in the ACS online and states that a paper questionnaire will be sent in a few weeks to those unable to respond online. The second mailing is a letter that reminds respondents to complete the survey online, thanks them if they have already done so, and informs them that a paper questionnaire will be sent later if we do not receive their response. In a third mailing, the paper questionnaire is sent only to those sample addresses that have not completed the online questionnaire within two weeks of receiving the first mailing. The fourth mailing is a postcard that reminds respondents to respond and informs them that an interviewer may contact them if they do not complete the survey. A fifth mailing is sent to respondents who have not completed the survey within five weeks. This letter provides a due date and reminds the respondents to return their questionnaires. Some households are also contacted by email. If a household starts the online survey and gives an email but doesn't finish the survey, the household will receive an email reminder to complete the survey.

If the Census Bureau does not receive a response from an address in the first two months of data collection, the address is eligible to be sampled for an in-person or phone interview by a Census Bureau field representative. This nonresponse follow-up data collection operation is known as the Computer-Assisted Personal Interview (CAPI) phase. The CAPI phase of data collection lasts for one month.

At the beginning of the CAPI month, a sixth mailing is sent to all mailable addresses in the CAPI sample. This letter urges respondents to complete the survey online to avoid an in-person interview. While this phase of data collection utilizes a personal interview approach, respondents can still choose to respond online, return a paper questionnaire, or call the Telephone Questionnaire Assistance line to complete the survey over the telephone. If a household responds online, by paper questionnaire, or by phone, the address is removed from the CAPI sample workload and is no longer contacted. If they do not respond, a Census Bureau field representative attempts to contact them to obtain a response.

Group Quarters

The Census Bureau employs a separate strategy to collect data from group quarters. The Census Bureau obtains the facility information by conducting a telephone or in-person interview with a group quarter contact. During this interview, the Census Bureau obtains a roster of residents and randomly selects a subsample for

person-level interviews. The facility can also upload its facility roster to the Census Bureau online listing application. During the person-level interview phase, a field representative uses a computer-assisted personal interview automated instrument to collect detailed information for each sampled resident. The field representative may also distribute a questionnaire to residents for self-response if they are unable to complete a computer-assisted personal interview. Respondents in some group quarters may also self-respond to the survey online.

III. Data

OMB Control Number: 0607–0810.

Form Number(s): ACS–1, ACS–1(SP), ACS–1(PR), ACS–1(PR)SP, ACS–1(GQ), ACS–1(GQ)(PR), ACS Housing Unit (HU) internet electronic instrument (no form number), ACS nonresponse follow-up CAPI electronic instrument (no form number), ACS Failed Edit Follow up Computer-Assisted Telephone Interview (CATI) electronic instrument (no form number), ACS Telephone Questionnaire Assistance CATI electronic instrument (no form number). ACS Group Quarters internet listing instrument (no form number), ACS Group Quarters Facility Questionnaire CAPI GQFQ electronic instrument (no form number), ACS Group Quarters internet electronic instrument (no form number), ACS Group Quarters Resident CAPI electronic instrument (no form number). ACS Reinterview CATI/CAPI HU RI electronic instrument (no form number), ACS Reinterview CATI/CAPI GQ RI electronic instrument (no form number).

Type of Review: Regular submission, Request for a revision.

Affected Public: Individuals or households.

Estimated Number of Respondents: 3,576,000 for household respondents; 20,100 for contacts in group quarters (GQ); 158,770 people in GQ; 22,875 households for reinterview; and 1,440 GQ contacts for reinterview. The total estimated number of respondents is 3,779,185.

Estimated Time per Response: 40 minutes for the average household questionnaire; 15 minutes for a GQ facility questionnaire; 25 minutes for a GQ person questionnaire; 10 minutes for a household reinterview; 10 minutes for a GQ-level reinterview.

Estimated Total Annual Burden Hours: 2,384,000 for household respondents; 5,025 for contacts in GQ; 66,154 for GQ residents; 3,813 households for reinterview; and 240 GQ contacts for reinterview. The estimate is an annual average of 2,459,232 burden hours.

TABLE 1—ANNUAL ACS AND PRCS RESPONDENT AND BURDEN HOUR ESTIMATES

Data collection operation	Forms or instrument used in data collection	Annual estimated number of respondents	Estimated minutes per respondent by data collection activity	Annual estimated burden hours
I. ACS Household Questionnaire, Online Survey, Telephone, and Personal Visit.	ACS–1, ACS–1(SP), ACS–1PR, ACS–1PR(SP), Online Survey, Telephone, CAPI.	3,576,000	40	2,384,000
II. ACS GQ Facility Questionnaire CAPI—Telephone and Personal Visit.	CAPI GQFQ	20,100	15	5,025
III. ACS GQ CAPI Personal Interview or Telephone, Online Survey and Paper Self-response.	CAPI, ACS–1(GQ), ACS–1(GQ)(PR)	158,770	25	66,154
V. ACS Household Reinterview—CATI/CAPI	ACS HU–RI	22,875	10	3,813
V. ACS GQ-level Reinterview—CATI/CAPI	ACS GQ–RI	1,440	10	240
Total		3,779,185	N/A	2,459,232

Estimated Total Annual Cost to Public: $0. (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 U.S.C. 141, 193, 221, and 223.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee we will be able to do so.

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2026–22322 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–26–2026]

Foreign-Trade Zone (FTZ) 53; Authorization of Production Activity; Baker Hughes Oilfield Operations, LLC; (Components for Electrical Submersible Pumping Systems); Claremore, Oklahoma

On February 27, 2026, Baker Hughes Oilfield Operations, LLC submitted a

notification of proposed production activity to the FTZ Board for its facility within Subzone 53D, in Claremore, Oklahoma.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 11029, March 6, 2026). On October 28, 2026, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized on a limited basis, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14, and further subject to a two-year time period.

Dated: October 28, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–22298 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–126–2026]

Foreign-Trade Zone 72; Application for Subzone Expansion; Eli Lilly and Company; Brownsburg, Lebanon, and Whitestown, Indiana

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Indianapolis Airport Authority, grantee of FTZ 72, requesting redesignation of subzone sites for the facilities of Eli Lilly and Company located in Brownsburg, Lebanon, and Whitestown, Indiana, and currently under the alternative site framework (ASF), to a subzone under the traditional site framework (TSF). The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on October 6, 2026.

The proposed Subzone 72B expansion would consist of the following sites: *Site 5* (200 acres) 300 N 200 W, Lebanon (currently Subzone 72AB, Site 1); *Site 6* (9.42 acres) 3860 S 500 E, Suite 200, Whitestown (currently Subzone 72AB, Site 2); and, *Site 7* (18.98 acres) 10015 Archer Drive, Brownsburg (currently Subzone 72AB, Site 3). The application also requests termination of Subzone 72B, Site 3. No authorization for additional production activity has been requested at this time.

In accordance with the FTZ Board's regulations, Juanita Chen of the FTZ Staff is designated examiner to review the application and make recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is December 14, 2026. Rebuttal comments in response to material submitted during the foregoing period may be submitted through December 28, 2026.

A copy of the application will be available for public inspection in the ''Online FTZ Information System'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Juanita Chen at *juanita.chen@trade.gov.*

Dated: October 28, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–22303 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–34–2026]

Production Activity Not Authorized; Foreign-Trade Zone (FTZ) 30; Stadler US Inc.; (Passenger Rolling Stock); Salt Lake City, Utah

On March 25, 2026, Stadler US Inc. submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 30G, in Salt Lake City, Utah.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 15947, March 31, 2026). On October 28, 2026, the applicant was notified of the FTZ Board's decision that further review of the activity is warranted. The production activity described in the notification was not authorized. If the applicant wishes to seek authorization for this activity, it will need to submit an application for production authority, pursuant to section 400.23.

Dated: October 28, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–22300 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–60–2026]

Foreign-Trade Zone (FTZ) 84; Authorization of Production Activity; Tesla, Inc.; (Battery Storage Products and Components); Brookshire, Texas

On May 20, 2026, Tesla, Inc. submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 84 a.m., in Brookshire, Texas.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 34602, June 8, 2026). On October 28, 2026, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized on a limited basis, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14, and further subject to a fourteen-month time period.

Dated: October 28, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–22301 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–40–2026]

Foreign-Trade Zone (FTZ) 80; Authorization of Production Activity; StandardAero San Antonio; (Refurbished Engines); San Antonio, Texas

On March 26, 2026, StandardAero San Antonio submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 80, in San Antonio, Texas.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 20637, April 17, 2026). On October 28, 2026, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: October 29, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–22352 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–17–2026]

Foreign-Trade Zone (FTZ) 38; Authorization of Production Activity; Coroplast Tape Corporation; (Pressure Sensitive Tapes); Rock Hill, South Carolina

On February 9, 2026, Coroplast Tape Corporation submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 38W, in Rock Hill, South Carolina.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 6812, February 13, 2026). On October 28, 2026, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: October 29, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–22344 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–387–2026]

Foreign-Trade Zone 222; Approval of Subzone Status; Vulcaflex Inc.; Auburn, Alabama

On July 30, 2026, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Montgomery Area Chamber of Commerce, grantee of FTZ 222, requesting subzone status subject to the existing activation limit of FTZ 222, on behalf of Vulcaflex Inc. in Auburn, Alabama.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (91 FR 48842, August 3, 2026). 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 establish Subzone 222D was approved on October 28, 2026, subject to the FTZ Act and the Board's regulations, including section 400.13, and further subject to FTZ 222's 2,000-acre activation limit.

Dated: October 28, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–22304 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–125–2026]

Foreign-Trade Zone (FTZ) 17, Notification of Proposed Production Activity; Honeywell Aerospace US LLC; (Aircraft Components); Olathe, Kansas

Honeywell Aerospace US LLC submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Olathe, Kansas within FTZ 17. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on September 9, 2026.

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: Aircraft Identification Tag; Aircraft Knob; Inclinometer; Aircraft Switch Cap Kit; Actuator Kit; Aircraft Recording System; Programmable Industrial Control Module; Aircraft-compatible printer; Set Screw Kit; High-Stability Grounding Canted Coil Spring; Marker Beacon Receiver Installation Kit; Sensor Electronics—Signal Conditioning & Processing Module for Pressure, Temperature, and Gas Sensors; Microcontroller—Small, Single-Chip Integrated Circuit; Pin Header—male electrical connector made of one or more rows of metal pins in a plastic base; Protective Cover Top; Lamp Heatsink Assembly; Slide Hammer Assembly; Aircraft Flight Information System Display Management Unit Installation Kit; Mounting Base; Aircraft Servo Installation Kit; Aircraft Yaw Servo Installation Hardware Kit; Aircraft Avionics Mounting Bracket Kit; Single Vertical Avionics Installation Kit; Aircraft Servo Mounting Bracket Kit; Retainer Filter; Mounting Tray; Rack Mount Cooling Fan; Fan Blower; Aircraft Front Control Panel Assembly; Automatic Data Processing Printer; Circuit Card and Cable Assembly; Resolver Stator Mounting Tool; Portable Vibration Monitoring Equipment Kit in Carrying Case; Honeywell Power Supply Subassemblies—ruggedized, regulated electric power units; Universal Serial Bus Flash Drive Enable Key; Extended Handheld Download Unit; Assembly Dataload Adapter; Torquemeter Runout Calibration Device; Solder Kit; Motor Replacement Kit; Pitch Motor Assembly Kit; Wire Electrical Harness; Circuit Card Assembly; High-voltage Power Supply Circuit Board; Aircraft Power Supply and Power Conversion Module Assembly; Aircraft Power Supply Printed Circuit Board Assembly; Power Supply Bracket; Aluminum Power Supply Mounting Frame; Mechanical Housing; Lithium battery; Battery module—12-volt DC power source; Heater and Harness Assembly; Transmitter Assembly; Input/Output Processor Circuit Board; Data Transfer Unit; Communications Management Unit; Wireless Local Area Network Unit; Radio-frequency Synthesizer Circuit Card Assembly; Remote Area Microphone; Cockpit Voice Recorder Microphone Monitor Unit; Chassis Microphone Monitor; Lightweight Cockpit Voice and Flight Data Recorder; Digital Voice-Data Recorder; Solid-State Cockpit Voice Recorder; Video-Memory Module; Front-Interconnect Avionics Circuit Card; Insulated Memory Enclosure; Compact Disc Containing Diagnostic Software; Compact Flash Memory Card; Navigation Data Storage Card; Ultra-High-Frequency Radio-Frequency Identification Tag; USB Flash Drive Containing Software; Portable Navigation Data Storage Device; Crash-Survivable Memory Unit; Flat-Panel Avionics; Avionics Retrofit Kit; Touch Display Unit; Data Radio Airborne Very High Frequency Data; Communications Transceiver; Avionics electronic memory module; Signal-processing module; Electronic processing and control module; Avionics interface module; Transmitter Receiver; Aircraft avionics antenna assembly; Antenna Drive Conversion Kit; Very High Frequency Omnidirectional Range; Receiver Outline Assembly; Automatic Direction Finder Receiver; Multi-Mode Receiver Outline Assembly; Integrated

Multi-Mode Receiver; Aircraft communications avionics unit; Mode S transponder; Distance Measuring Equipment Interrogator; Aircraft Data Management Unit (DMU) Electronic Assembly; Aircraft Avionics Mounting, Connector, and Hardware Kit; High Frequency Antenna Coupler; Antenna Drive Unit: an aircraft avionics electromechanical component; Coax Termination Kit; Flight Inspection Receiver; 5 Phone Jacks is an aircraft avionics interface module; Aircraft Avionics Mounting Hardware, Equipment Housings, and Structural Components; Stainless-steel mounting plate assembly; Heatsink; Global Positioning System Navigation Systems; Weather Radar Digital Signal Processing & Processing Modules; Downconverter Modules; Power Supply Converter Modules; Gas discharge display to Light Emitting Diode; Conversion Kit; Graphics processing module; Dimming control module; Vertical Take-Off and Landing Tactical; Unmanned Aerial Vehicle specialized tooling kit; Traffic display; Stall warning computer; Mooring ring; Lamp assembly; Light Emitting Diode circuit board assembly; Electronic capacitor; Electronic Display Conversion Kit; Fixed Electrical Resistor; Bulk capacitor carrier; Traffic Alert and Collision Avoidance System; isolator modification kit; Three-position rotary switch; Control switch; Switch driver module; Dual diversity antenna radio frequency switch; control assembly; Pushbutton switch; Cable adapter; Backshell connector accessory; 15-Pin receptacle connector; Reduced height 90-degree coax adapter; Latch housing; Electrical mounting hardware, junction; enclosures, or terminal units made from molded; polymer or metal; Administrative panel assembly; Flight controller; Connector interface board; Communications Convergence Unit avionics; installation and configuration kit; Mechanical bezel assembly; Mechanical mounting tray assembly; Gas discharge display unit; Cathode ray display tube; Magnet replacement kit; Bulk Capacitor Carrier for Radar Transmitter Assembly; Selected semiconductor diode; Tested semiconductor transistor; Small-signal semiconductor transistor; Photodetector; GPS receiver; Global Navigation Satellite System; Navigation Assembly; Programmable logic device; Programmable read-only memory device; Programmable erasable read-only memory device; Automatic Direction Finder processor module; Programmed integrated circuit; Microstrip driver module; Solid State Flight Data Recorder System; Electronic memory housing assembly; Audio daughter circuit board; Interconnecting electrical cable assembly; Jumper cable assembly; Fine-pitch ribbon cable assembly; Radio-frequency interference filter circuit board; Electrical input-filtering module; Dual-channel electronic filter module; Mechanical gimbal and elevation assembly; Inertial rate-sensing device; Enhanced Ground Proximity Warning System; Aircraft radar altitude system; Aircraft Avionics Mounting and Housing Kit; Magnetic heading sensor; Long-band signal generation module; and Ground support and test kit (duty rate ranges from duty-free to 6.5%).

The proposed foreign-status materials/components include: Power Transistor; Electronic Overcurrent Trip Unit; Silicon-Controlled Rectifier; Actuator; Memory Module; Aircraft Tubing; Electrical Tape; Reflective Tape; Adhesive Disc; Electronic Tag Cover; Bumper Friction Lexan; Cap Cover; Dust Cap; Twist Lock Cable Clip; Rubber Tubing; O-Ring; Gasket Front Housing; Gasket Electromagnetic Interference Shielding; Vibration and Shock Isolation Mount; Heatsink Pad; Boot—molded rubber or elastomer cover; Blower Hose; Gold Bonding Wire; Anti Rotation Rod; Stainless Steel Safety Wire; Expendable Fastner Screw; 3-piece SEMS Screw; Corrosion-resistant, Passivated Stainless Steel Socket Head Cap Screw; Captive Socket Head Cap Screw; Clip Nut; Stainless-Steel Clinch Nut; Hex Nut; External Retaining Ring; Precision Stainless-Steel Passivated Spacer; Helical Threaded Inserts; Split Lock Washer; Joystick Spring; Stainless-Steel Light-Series Flat Washer; Stainless-Steel Formed Washers (non-spring); Rivet; Retainer Ring; Hinge Pin; Tension Spring; Curved Spring Washer; Steel Quarter Turn Panel Lock Fastener; Spring Switch; Compression Spring; Pawl Latches; Avionics Wire; Locking Nuts; Brass Nut; Copper Bonding Straps; Locking Clip; Copper/Rin-Plated, Uninsulated, Solder-Type Ring Lug; Flange; Aircraft Card Retainer—aluminum retaining device; Connector End-Plate; Engraved Identification Plate; Software Identification Plate; Steel Mechanical Spacer; Connector Plate Cover; Metal Cable Strain-Relief Clamp; Sheet Metal Dust Cover Assembly; Round Spacer; Lead Seal; Mounting Lug; Clamp; Hinge Extractor; Retainer; T-shaped control-board support; Airframe mount tray; Bracket—avionics or engine-control assembly support; Stud latch; Mounting rack/tray assembly; Side-mount roller bracket; Connector mounting bracket; Suppression filter; Mechanical retention hook; Aviation-grade connector Id label; Instruction placard; Machined hex-head bolt; Electrically powered, non-household air movement unit; Non-household fan component consisting of a motor driven impeller and supporting structural elements; Precision gram scale; Data printer assembly; Data output printer; Electronic control module; Printer and data-output system hardware; Electromechanical motor and connector assembly; Electronic programmer board; Universal Serial Bus to Ethernet adapter; Precision ball bearing; Precision bearing assembly; Radial ball bearing; Bearing (friction reducing); Geartrain bearing; Stainless Steel Ball Bearing; Ball bearing; Idler gear; Sector gear; Gear housing; Gear adjustment cam; Electric stepper motor; Brushless DC motor-driven blower; Electric motor incorporating an integral braking mechanism; Low output electric motor; Frameless resolver assembly; Brushless direct current electric motor; Electrical wiring assembly (elevation motor); Frameless brushless direct current motor assembly; Synchronous electric motor; Toroidal core power transformer; Solid state power transformer; Surface mount current sense transformer; Surface mount ethernet signal transformer; Surface-mount gate-drive transformer; Pulse signal transformer; Surface mount telecommunications isolation transformer module; Surface mount wideband radiofrequency signal transformer; Through-hole mounted signal transformer; Audio-frequency signal transformer; Toroidal-core audio-frequency signal transformer; Audio-frequency phase-inverter transformer; Miniature power transformer; Surface mount radiofrequency signal transformer; Telecommunications signal transformer; Audio-frequency interstage signal transformer; Electrical power transformer; Self-contained power conversion module; Surface mount spring type inductors; High voltage static power conversion assembly; Static power conditioning assembly; Diode bridge rectifier assembly; Discrete semiconductor rectifier; Integrated electronic module; Surface mount signal transformer; Passive fixed inductor; Passive radiofrequency ceramic inductor; Passive surface mount gate drive transformer; Passive common-mode electromagnetic interference and radio-frequency interference suppression device; Passive ferrite bead; Passive inductive choke; Passive toroidal core fixed inductor; Passive surface mount fixed inductor; Passive discrete coil; Passive fixed inductor (inductive coupling and noise filtering);

Passive fixed inductor (low value inductive filtering and current shaping); Ferrite magnetic Icore; Multi-layer ferrite chip bead; Ferrite magnetic cable core; Mechanical clamp bar; Mechanical housing assembly; Electrical transformer (push-pull circuit operation); Circuit card assembly (output module); Passive high input inductor; Circuit card assembly incorporating power conversion circuitry; Permanent magnet in disk form, axially magnetized, classified as a permanent magnet; Permanent magnet producing a static magnetic field through remanent magnetization; Primary battery (through chemical means); Rechargeable 12-volt battery module; Heater and harness assembly; Electronic data transfer unit; Data-processing input/output circuit-card assembly; Rear panel assembly; Synthesizer circuit-card assembly; Electro-acoustic microphone; Microphone assembly; Microcircuit radio frequency power amplifier; Mechanical stiffener tab; Audio-frequency servo amplifier circuit board assembly; Mechanical vibration isolator; Connector back shell; Combined audio-frequency recording apparatus; Solid-state cockpit voice recorder (SSCVR); Video memory module; Dedicated cable assembly; Rear Panel Interconnect Printed Board Assembly; Bottom cover; Mechanical gasket; Front endplate; Insulating end plug; Mechanical connector adapter; Installation disk containing prerecorded software; Flash memory card assembly; Solid-state memory assembly incorporating three-dimensional triple-level cell (3D TLC) flash technology; Secure Digital memory card; CompactFlash memory card designed for use in Personal Computer Memory Card International Association (PCMCIA)-compatible systems; Personal Computer Memory Card International Association (PCMCIA)-format flash memory card; Radio frequency identification (RFID) label; Radiofrequency identification (RFID) device incorporating an embedded RFID chip and antenna designed to store and wirelessly transmit identification data when interrogated by a compatible reader; Ultra highfrequency (UHF) radiofrequency identification (RFID) tag incorporating onboard memory with an 8 kilobyte storage capacity; Electronic module designed to provide an interface for connecting and managing removable memory cards within an electronic system; Central system management unit; Liquid crystal display module; Fully assembled radio-frequency electronic unit; Very High Frequency data radio unit; Mechanical connector bracket; Mechanical rear connector cover; Outline assembly for a very high frequency Omnidirectional Range receiver; Outline assembly for an Automatic Direction Finder receiver; Front mounting plate; Top assembly designed to serve as a structural enclosure and support component for the VOR/Marker receiver RVA–36C; Integrated navigation receiver; Outline assembly for a radar altimeter unit; Outline assembly for a Distance Measuring Equipment interrogator; Antenna connector kit; Final assembly of an antenna; Radar altimeter antenna; Mechanical pedestal; Antenna assembly; Interconnect cable assembly; Mechanical rack assembly incorporating extruded structural elements; Microwave Absorber (RF-Absorbing Material)—Antenna/Reflector Component; Mechanical rotary joint; Electronic interface module incorporating five phonestyle jack connectors; Aluminum Inner Choke; Mechanical cover plate; Front housing; Mechanical pedestal assembly; Mechanical bearing sleeving; Mechanical rotor shaft; Printed board assembly incorporating radio-frequency circuitry; Interconnect Circuit Card Assembly; Base cover; Microwave Absorber (RF-Absorbing Material)—Avionics Unit; Avionics Circuit Card Assembly (Module); Motor drive cable assembly; Radio Frequency connector; Transmitter/receiver cover; Temperature-compensated crystal oscillator with adapter assembly; Display data module; Transmitter module; Radio Frequency transceiver circuit assembly; Digital Signal Processor Analog-to-Digital module; Transmitter assembly; Rigid printed circuit board; Cover and shield assembly; Five-arrow Radio Frequency (connector bracket); Pre-amplifier cover; Power supply mounting bracket; Fan mounting bracket; Knob shaft; Chassis assembly; Axial vane fan; Power panel assembly; Front housing assembly; Rack mounting hardware; Pedestal yoke stop assembly; Protective cover; Transceiver cover; Digital printed board assembly for Transmit Data Air Transport and Regional functions; Ventilator Timer; Antenna gasket; Azimuth/elevation rotor assembly; Cradle; Chassis top plate for the Transmit Data section; Light Emitting Diode; Graphics display module with pixel matrix; Audio signal generator component producing a fixed tone; Underwater acquisition beacon; Interconnect board assembly; Navigation programmed circuit board; General-purpose printed circuit board; Adaptor plate; Housing; 3-inch display assembly; Diffuser; Traffic Collision Avoidance System chassis assembly; Radio Frequency grounding strap; Power-wiring printed circuit board; Electronic Horizontal Situation Indicator chassis assembly; Discrete through-hole capacitor; High-voltage ceramic capacitor; Tantalum capacitor; Pi-capacitor; Polymer tantalum capacitor; Hybrid tantalum capacitor; Aluminum electrolytic capacitor; Electrolytic Capacitor—Paper Dielectric, Stainless-Steel Case; Aluminum capacitor; Fixed aluminum electrolytic capacitor with radial leads; High-value aluminum electrolytic capacitor; Multilayer ceramic capacitor; Fixed surface-mount ceramic capacitor; Discrete ceramic capacitor; High-voltage ceramic capacitor; Fixed high-reliability multilayer ceramic capacitor; Ceramic chip capacitor; Fixed multilayer ceramic capacitor with C0 dielectric; Porcelain chip capacitor; Precision ceramic capacitor; Ceramic capacitor; Solid State capacitor; Mylar (polyester film) capacitor; Fixed metallized polyester film capacitor, surface-mount type; Pi filter; Polycarbonate film capacitor; Aerogel A-Series capacitor; Fixed dipped mica capacitor; Polymer aluminum capacitor with low ESR, D-case package; Discrete capacitor; Aluminum polymer surface-mount capacitor; Variable capacitor with an adjustable range of approximately 6–45 pF; Variable ceramic capacitor; Variable capacitor with zirconia dielectric; Variable capacitor with alumina dielectric; Resistor array; Fixed wirewound resistor with thermoplastic construction; Resistor network; Carbon film resistor; Fixed thick-film chip resistor; Fixed precision resistor; Surface-mount resistor network; Thick-film surface-mount resistor array; Fixed wirewound surface-mount resistor; Precision metal-film resistor; Resistor network; Radio Frequency network; Fixed Radio Frequency thin-film attenuator resistor; Sealed potentiometer; Potentiometer; Varistor; Cermet variable resistor; Carbon-film resistor; Surface-mount variable resistor; Microwave attenuator (Thermopad) with thick-film construction; Temperature-compensating microwave attenuator resistor; Thermistor; Sealed avionics-grade trimmer potentiometer; Negative Temperature Coefficient thermistor; Integrated transistor and thermistor assembly; Central Processing Unit/Power Supply printed wiring board assembly; Printed wiring board; Printed Wiring Board with Two Switches; Inline suppression printed circuit board; Printed cable assembly incorporating conductive traces on a flexible or rigid printed medium; Type-B flexible printed circuit board; Ceramic

low-impedance Electromagnetic Interference suppression device; Resistor-capacitor network; Single pole double throw slide switch; Transient voltage suppression device; Avionics-grade electrical terminal; Fast tab style ground terminal; Electrical terminal connector; Mechanical securing strap; Grooved pin; 10-amp, 125-volt surface-mount fuse; Fast-acting subminiature fuse; 5-amp miniature fuse; Avionics-grade electrical filter; Precision millimeter-wave circulator; Avionics-grade electromechanical relay; 2-pole reed relay; Dual-deck rotary switch; Avionics-grade electrical switch; Avionics-grade pushbutton switch; Key-operated rotary switch; Lamp socket assembly; Electrical plug connector; 3 mm-pitch crimp-style board-to-cable connector; 12/24-pin electrical connector; Dual-tab solder lug; Electrical termination lug; Stud ring-type terminal lug; Gray-finished avionics panel assembly; Switch-board module; Signal selector; Painted Gray Metal Panel; Controller module; Pushbutton; RF Contact Finger Strip (EMI Gasket); Rocker switch with faceplate; Front bezel; Indicator lamp; Miniature indicator lamp; Night-vision goggle compatible lamp assembly; Flash tube point-source lamp; Cathode ray tube; X-band magnetron; Silicon rectifier diode; Schottky rectifier diode; Precision signal diode; Zener diode; Radio Frequency Positive, Intrinsic, and Negative diode; General-purpose silicon switching diode; Transistor devices enclosed in molded or metal casings that contain semiconductor junctions; Analog voltage regulator microcircuit; Small-signal negative-positive-negative bipolar transistor; Radio Frequency power transistor; Transistor components of varying shapes including flat-pack or cylindrical housings; Solid-state relay; Yellow Light Emitting Diode; Green Light Emitting Diode; Light-sensitive resistor; Small-signal negative-positive-negative silicon transistor; Precision shunt voltage regulator; Bidirectional transient voltage suppressor diode; Unidirectional transient voltage suppressor diode; Surface-mount Radio Frequency transformer; Crystal oscillator; Surface-mount quartz crystal oscillator; Electrical insulation tubing; Ethernet controller integrated circuit; Field-programmable gate array integrated circuit; Synchronous dynamic random-access memory integrated circuit; Semiconductor memory integrated circuit; Interface microcircuit integrated circuit; Erasable programmable read-only memory microcircuit integrated circuit; Surface-mount integrated circuit; High-performance analog difference amplifier; Dual operational amplifier integrated circuit; Quad operational amplifier integrated circuit; Solid-state electronic integrated circuit; Surface-mount mixer integrated circuit; Resistor array integrated circuit; Microwave stripline driver module; Synchro transmitter; Solid-state flight data recorder; Memory enclosure assembly; Crash-protected memory printed board assembly; Spacer pad; White insulated copper wire; Clear-insulated electrical wire; Coaxial cable assembly; Pre-assembled cable; Dual-conductor cable; PC data loader cable; Cable tracker assembly; Bus wire; Hookup wire constructed with silver-plated copper conductors; Preamplifier cable assembly; Electrical carbon/graphite components other than electrodes or brushes, such as arc carbons, contacts, or heating resistors; Ceramic electrical insulator; Electrical Insulator; Flat, solid, thermally conductive pad; Ferrite bead; Split ferrite electromagnetic interference core; Electromagnetic and radio-frequency interference suppression device; FEP (Fluorinated Ethylene Propylene) Insulation Tubing; Insulated blocked-mount housing; Metallized electrical insulator; Thermally conductive silicone pad insulator; Ferrite bead; Ferrite shielding core; Electromagnetic interference filter using a PI-circuit configuration; Heatsink gap-filler pad; Rear mounting plate; Hex nut strap washer; Gimbal and elevation assembly; Processor circuit card assembly; Optical filters, prisms, and unmounted glass elements; Digital configuration module; DC panel meter with PC-terminal connections; Arrow indicator with flag; Handle assembly; Decal; memory board assembly; Aluminum Heatsink; Protective dust cover; Nut plate with flag; Unidirectional Transient Voltage Suppression diode with gull-wing packaging; High-temperature accelerometer; Omnidirectional Range Localizer navigation indicator; Final rate gyro support; Magnetometer circuit board assembly; Decal cutout; Thin-film temperature-sensing resistor; End cap; L-band signal generator module; Fastrak optical tracker; Fastrak kit consisting of optical tracking components; Inclinometer; Triaxial accelerometer with digital-to-analog output; Integrated Circuit Piezoelectric accelerometer and an integral mounting bracket; Enhanced Ground Proximity Warning System module; End cap with card access; Accelerometer; Panel label; Dummy weight; Frame with inserts; Data Management Unit power control module assembly; Beam-forming control module; Advanced Process Manager housing; Front panel plate assembly; Input/output module assembly equipped with wedge locks; Hardware assembly for the Enhanced Ground Proximity Warning System; Grip ring; and Samtec electrical connector (duty rate ranges from duty-free to 9.0%).

The request indicates that certain materials/components are subject to duties under section 232 of the Trade Expansion Act of 1962 (section 232) or section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 232 and 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 December 14, 2026.

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 John Frye at *John.Frye@trade.gov.*

Dated: October 28, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–22302 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–30–2026]

Production Activity Not Authorized; Foreign-Trade Zone (FTZ) 84; AuroraTe LLC; (Galvanized Steel Pipes); Houston, Texas

On March 11, 2026, AuroraTe LLC submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 84, in Houston, Texas.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 12755, March 17, 2026). On October 28, 2026, the applicant was notified of the FTZ Board's decision that further review of the activity is warranted. The production activity described in the notification was not authorized. If the applicant wishes to seek authorization for this activity, it will need to submit an application for production authority, pursuant to section 400.23.

Dated: October 28, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–22299 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Advance Notification of Sunset Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

Background

Every five years, pursuant to the Tariff Act of 1930, as amended (the Act), the U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission automatically initiate and conduct reviews to determine whether revocation of an antidumping duty or countervailing duty order or termination of an investigation suspended under section 704 or 734 of the Act would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy (as the case may be) and of material injury.

Upcoming Sunset Reviews for December 2026

Pursuant to section 751(c) of the Act, the following Sunset Reviews are scheduled for initiation in December 2026 and will appear in that month's *Notice of Initiation of Five-Year Sunset Reviews* (Sunset Review).

	Department contact
Antidumping Duty Proceedings	
No Sunset Reviews of antidumping duty proceedings are scheduled for initiation in December 2026.	
Countervailing Duty Proceedings	
No Sunset Reviews of countervailing duty proceedings are scheduled for initiation in December 2026.	

Suspended Investigations

No Sunset Reviews of suspended investigations are scheduled for initiation in December 2026.

Commerce's procedures for the conduct of Sunset Reviews are set forth in 19 CFR 351.218. The *Notice of Initiation of Five-Year* (*Sunset) Review* provides further information regarding what is required of all parties to participate in Sunset Reviews.

Pursuant to 19 CFR 351.103(c), Commerce will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service lists, it is requested that those seeking recognition as interested parties to a proceeding contact Commerce in writing within 10 days of the publication of the Notice of Initiation.

Note that if Commerce receives a Notice of Intent to Participate from a member of the domestic industry within 15 days of the date of initiation, the review will continue.

Thereafter, any interested party wishing to participate in the Sunset Review must provide substantive comments in response to the notice of initiation no later than 30 days after the date of initiation. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[1] An electronically-filed document must be received successfully in its entirety via Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS) by 5:00 p.m. Eastern Time on the day on which it is due. For further information on procedures for filing information with Commerce through ACCESS, refer to User Guide found at *https://access.trade.gov/help*.

In prior proceedings we have encouraged interested parties to provide an executive summary of their comments, including footnotes. In these sunset reviews, we request that interested parties provide, at the beginning of their comments, an executive summary for each issue raised in their comments. 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 decision memorandum that will accompany the notice to be published in the **Federal Register**. Finally, we request that interested parties include footnotes for relevant citations in the public executive summary of each issue.

Notification to Interested Parties

This notice is not required by statute but is published as a service to the international trading community.

[1] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

Dated: October 27, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–22313 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List; Note Regarding Format of Review Requests

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

SUPPLEMENTARY INFORMATION:

Background

Each year during the anniversary month of the publication of an antidumping duty (AD) or countervailing duty (CVD) order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as

amended (the Act), may request, in accordance with 19 CFR 351.213, that the U.S. Department of Commerce (Commerce) conduct an administrative review of that AD or CVD order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting date.

Commerce asks that requests for review of multiple companies include an appendix listing, in alphabetical order, the company names for which a review is requested. *See infra* for additional details regarding this request.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review (POR). We intend to release the CBP data under administrative protective order (APO) to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 35 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. Commerce invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

1. In general, Commerce finds that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating AD rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of a review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this AD proceeding (*i.e.,* investigation, administrative review, new shipper review, or changed circumstances review).

2. For any company subject to a review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection.

3. Parties are requested to: (a) identify which companies subject to review previously were collapsed; and (b) provide a citation to the proceeding in which they were collapsed.

4. Further, if companies are requested to complete a Quantity and Value Questionnaire for purposes of respondent selection, in general, each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of a proceeding where Commerce considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[1] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation, pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial Section D responses.

Opportunity to Request a Review: Not later than the last day of November 2026,[2] interested parties may request an administrative review of the following orders, findings, or suspended investigations, with anniversary dates in November for the following periods:

	Period
Antidumping Duty Proceedings	
Argentina: Oil Country Tubular Goods, A–357–824	11/1/25–10/31/26
Armenia: Aluminum Foil, A–831–804	11/1/25–10/31/26
Austria: Strontium Chromate, A–433–813	11/1/25–10/31/26
Brazil: Aluminum Foil, A–351–856	11/1/25–10/31/26
France: Strontium Chromate, A–427–830	11/1/25–10/31/26
Germany: Thermal Paper, A–428–850	11/1/25–10/31/26
India:	

[1] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[2] Or the next business day, if the deadline falls on a weekend, Federal holiday or any other day when Commerce is closed.

	Period
Paper File Folders, A–533–910	11/1/25–10/31/26
Welded Stainless Pressure Pipe, A–533–867	11/1/25–10/31/26
Indonesia:	
Certain Coated Paper Suitable For High-Quality Print Graphics Using Sheet-Fed Presses, A–560–823	11/1/25–10/31/26
Monosodium Glutamate, A–560–826	11/1/25–10/31/26
Italy: Forged Steel Fittings, A–475–839	11/1/25–10/31/26
Japan:	
Aluminum Lithographic Printing Plates, A–588–881	11/1/25–10/31/26
Thermal Paper, A–588–880	11/1/25–10/31/26
Mexico:	
Certain Freight Rail Couplers and Parts Thereof, A–201–857	11/1/25–10/31/26
Certain Circular Welded Non-Alloy Steel Pipe, A–201–805	11/1/25–10/31/26
Oil Country Tubular Goods, A–201–856	11/1/25–10/31/26
Seamless Refined Copper Pipe and Tube, A–201–838	11/1/25–10/31/26
Steel Concrete Reinforcing Bar, A–201–844	11/1/25–10/31/26
Oman: Aluminum Foil, A–523–815	11/1/25–10/31/26
Republic of Korea:	
Circular Welded Non-Alloy Steel Pipe, A–580–809	11/1/25–10/31/26
Thermal Paper, A–580–911	11/1/25–10/31/26
Republic of Türkiye: Aluminum Foil, A–489–844	11/1/25–10/31/26
Russia:	
Aluminum Foil, A–821–828	11/1/25–10/31/26
Ferrosilicon, A–821–838	11/1/25–10/31/26
Oil Country Tubular Goods, A–821–833	11/1/25–10/31/26
Sodium Nitrite, A–821–836	11/1/25–10/31/26
Socialist Republic of Vietnam: Paper File Folders, A–552–834	11/1/25–10/31/26
Spain: Thermal Paper, A–469–824	11/1/25–10/31/26
Taiwan:	
Certain Circular Welded Non-Alloy Steel Pipe, A–583–814	11/1/25–10/31/26
Certain Hot-Rolled Carbon Steel Flat Products, A–583–835	11/1/25–10/31/26
Thailand: Certain Hot-Rolled Carbon Steel Flat Products, A–549–817	11/1/25–10/31/26
The People's Republic of China:	
Aluminum Lithographic Printing Plates, A–570–156	11/1/25–10/31/26
Certain Hot-Rolled Carbon Steel Flat Products, A–570–865	11/1/25–10/31/26
Certain Coated Paper Suitable For High-Quality Print Graphic Using Sheet-Fed Presses, A–570–958	11/1/25–10/31/26
Diamond Sawblades and Parts Thereof, A–570–900	11/1/25–10/31/26
Fresh Garlic, A–570–831	11/1/25–10/31/26
Forged Steel Fittings, A–570–067	11/1/25–10/31/26
Lightweight Thermal Paper, A–570–920	11/1/25–10/31/26
Monosodium Glutamate, A–570–992	11/1/25–10/31/26
Paper Clips, A–570–826	11/1/25–10/31/26
Paper File Folders, A–570–147	11/1/25–10/31/26
Polyethylene Terephthalate (PET) Film, A–570–924	11/1/25–10/31/26
Pure Magnesium in Granular Form, A–570–864	11/1/25–10/31/26
Refined Brown Aluminum Oxide, A–570–882	11/1/25–10/31/26
Certain Cut-to-Length Carbon Steel Plate, A–570–849	11/1/25–10/31/26
Seamless Carbon and Alloy Steel Standard, Line And Pressure Pipe, A–570–956	11/1/25–10/31/26
Seamless Refined Copper Pipe and Tube, A–570–964	11/1/25–10/31/26
Sodium Gluconate, Gluconic Acid, and Derivative Products, A–570–071	11/1/25–10/31/26
Ukraine: Certain Hot-Rolled Carbon Steel Flat Products, A–823–811	11/1/25–10/31/26
United Arab Emirates: Polyethylene Terephthalate (PET) Film, A–520–803	11/1/25–10/31/26
Countervailing Duty Proceedings	
India:	
Paper File Folders, C–533–911	1/1/25–12/31/25
Welded Stainless Pressure Pipe, C–533–868	1/1/25–12/31/25
Indonesia: Certain Coated Paper Suitable For High-Quality Print Graphics Using Sheet-Fed Presses, C–560–824	1/1/25–12/31/25
Oman: Aluminum Foil, C–523–816	1/1/25–12/31/25
Republic of Korea: Oil Country Tubular Goods, C–580–913	1/1/25–12/31/25
Republic of Türkiye:	
Aluminum Foil, C–489–845	1/1/25–12/31/25
Steel Concrete Reinforcing Bar, C–489–819	1/1/25–12/31/25
Russia:	
Ferrosilicon, C–821–839	1/1/25–12/31/25
Oil Country Tubular Goods, C–821–834	1/1/25–12/31/25
The People's Republic of China:	
Aluminum Lithographic Printing Plates, C–570–157	1/1/25–12/31/25
Certain Coated Paper Suitable For High-Quality Print Graphic Using Sheet-Fed Presses, C–570–959	1/1/25–12/31/25
Chlorinated Isocyanurates, C–570–991	1/1/25–12/31/25
Forged Steel Fittings, C–570–068	1/1/25–12/31/25
Lightweight Thermal Paper, C–570–921	1/1/25–12/31/25
Seamless Carbon and Alloy Steel Standard, Line, And Pressure Pipe, C–570–957	1/1/25–12/31/25
Sodium Gluconate, Gluconic Acid, and Derivative Products, C–570–072	1/1/25–12/31/25

	Period
Suspension Agreements	
None.	

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that Commerce conduct an administrative review. For both AD and CVD reviews, the interested party must specify the individual producers or exporters covered by an AD finding or an AD or CVD order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires Commerce to review those particular producers or exporters. If the interested party intends for Commerce to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party Commerce was unable to locate in prior segments, Commerce will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for Commerce to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

Commerce is instituting a new formatting request. Specifically, Commerce asks that requests for review of multiple companies also include an appendix listing, in alphabetical order, the company names for which a review is requested. The list should be limited solely to company names and formatted as a single column, with each company name identified on a separate line, except in the case of companies that Commerce previously determined should be collapsed into a single entity or found to be cross-owned with other companies. Companies that Commerce previously determined should be collapsed or found to be cross-owned with one another should be listed together as a group, on one line—or more, as needed, for the group—with the company names within each group listed alphabetically and separated by semicolons.

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (June 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), Commerce clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to AD findings and orders.[3]

Commerce no longer considers the non-market economy (NME) entity as an exporter conditionally subject to an AD administrative review.[4] Accordingly, the NME entity will not be under review unless Commerce specifically receives a request for, or self-initiates, a review of the NME entity.[5] In administrative reviews of AD orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, Commerce will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity). Following initiation of an AD administrative review when there is no review requested of the NME entity, Commerce will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) on Enforcement and Compliance's ACCESS website at *https://access.trade.gov.*[6] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request. Interested parties should note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[7]

Commerce will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of November 2026. If Commerce does not receive, by the last day of November2026, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, Commerce will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period of the order, if such a gap period is applicable to the period of review.

[3] *See* Enforcement and Compliance's website at *https://www.trade.gov/us-antidumping-and-countervailing-duties-home-page.*

[4] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[5] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

[6] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[7] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

Establishment of and Updates to the Annual Inquiry Service List

On September 20, 2021, Commerce published the final rule titled ''*Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*'' in the **Federal Register**.[8] On September 27, 2021, Commerce also published the notice entitled ''*Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*'' in the **Federal Register**.[9] The *Final Rule* and *Procedural Guidance* provide that Commerce will maintain an annual inquiry service list for each order or suspended investigation, and any interested party submitting a scope ruling application or request for circumvention inquiry shall serve a copy of the application or request on the persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin.[10]

In accordance with the *Procedural Guidance,* for orders published in the **Federal Register** before November 4, 2021, Commerce created an annual inquiry service list segment for each order and suspended investigation. Interested parties who wished to be added to the annual inquiry service list for an order submitted an entry of appearance to the annual inquiry service list segment for the order in ACCESS and, on November 4, 2021, Commerce finalized the initial annual inquiry service lists for each order and suspended investigation. Each annual inquiry service list has been saved as a public service list in ACCESS, under each case number, and under a specific segment type called ''AISL—Annual Inquiry Service List.'' [11]

As mentioned in the *Procedural Guidance,* beginning in January 2022, Commerce will update these annual inquiry service lists on an annual basis when the *Opportunity Notice* for the anniversary month of the order or suspended investigation is published in the **Federal Register**.[12] Accordingly, Commerce will update the annual inquiry service lists for the above-listed AD and CVD proceedings. All interested parties wishing to appear on the updated annual inquiry service list must take one of the two following actions: (1) new interested parties who did not previously submit an entry of appearance must submit a new entry of appearance at this time; (2) interested parties who were included in the preceding annual inquiry service list must submit an amended entry of appearance to be included in the next year's annual inquiry service list. For these interested parties, Commerce will change the entry of appearance status from ''Active'' to ''Needs Amendment'' for the annual inquiry service lists corresponding to the above-listed proceedings. This will allow those interested parties to make any necessary amendments and resubmit their entries of appearance. If no amendments need to be made, the interested party should indicate in the area on the ACCESS form requesting an explanation for the amendment that it is resubmitting its entry of appearance for inclusion in the annual inquiry service list for the following year. As mentioned in the *Final Rule,*[13] once the petitioners and foreign governments have submitted an entry of appearance for the first time, they will automatically be added to the updated annual inquiry service list each year.

Interested parties have 30 days after the date of this notice to submit new or amended entries of appearance. Commerce will then finalize the annual inquiry service lists five business days thereafter. For ease of administration, please note that Commerce requests that law firms with more than one attorney representing interested parties in a proceeding designate a lead attorney to be included on the annual inquiry service list.

Commerce may update an annual inquiry service list at any time as needed based on interested parties' amendments to their entries of appearance to remove or otherwise modify their list of members and representatives, or to update contact information. Any changes or announcements pertaining to these procedures will be posted to the ACCESS website at *https://access.trade.gov.*

Special Instructions for Petitioners and Foreign Governments

In the *Final Rule,* Commerce stated that, ''after an initial request and placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow.'' [14] Accordingly, as stated above and pursuant to 19 CFR 351.225(n)(3), the petitioners and foreign governments will not need to resubmit their entries of appearance each year to continue to be included on the annual inquiry service list. However, the petitioners and foreign governments are responsible for making amendments to their entries of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

Notification to Interested Parties

This notice is not required by statute but is published as a service to the international trading community.

Dated: October 23, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–22345 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–867]

Large Power Transformers From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2024–2025

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that HD Hyundai Electric Co., Ltd. (Hyundai) and Iljin Electric Co., Ltd (Iljin) did not make sales of subject merchandise at less than normal value (NV) during the period of review (POR), August 1, 2024, through July 31, 2025. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable November 2, 2026.

FOR FURTHER INFORMATION CONTACT: Jinny Ahn or Harrison Tanchuck, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of

[8] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300 (September 20, 2021) (*Final Rule*).

[9] *See Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions,* 86 FR 53205 (September 27, 2021) (*Procedural Guidance*).

[10] *Id.*

[11] This segment has been combined with the ACCESS Segment Specific Information (SSI) field which will display the month in which the notice of the order or suspended investigation was published in the **Federal Register**, also known as the anniversary month. For example, for an order under case number A–000–000 that was published in the **Federal Register** in January, the relevant segment and SSI combination will appear in ACCESS as ''AISL—January Anniversary.'' Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

[12] *See Procedural Guidance,* 86 FR at 53206.

[13] *See Final Rule,* 86 FR at 52335.

[14] *Id.*

Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0339 or (202) 482–7421, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 25, 2025, based on timely requests for review, in accordance with 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the antidumping duty order on large power transformers from the Republic of Korea (Korea).[1] On January 29, 2026, Commerce selected Hyundai and Iljin as the mandatory respondents in this review.[2]

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.[3] Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.[4] On July 9, 2026, we extended the preliminary results of this review to no later than October 30, 2026.[5]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[6] A list of the topics discussed in the Preliminary Decision Memorandum is attached as an appendix 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/frnotices.*

Scope of the Order

The merchandise subject to the *Order* is large power transformers from Korea. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Constructed export prices have been calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Rate for Non-Individually Examined Companies

The Act and Commerce's regulations do not address the establishment of a rate to apply to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review.

Under section 735(c)(5)(A) of the Act, the all-others rate is normally an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any rates that are zero, *de minimis* (*i.e.,* less than 0.5 percent), or determined entirely on the basis of facts available. Where the weighted-average dumping margin for each of the individually examined companies is zero, *de minimis,* or based entirely on facts available, section 735(c)(5)(B) of the Act provides that Commerce may use ''any reasonable method to establish the estimated all-others rate for exporters and producers not individually investigated, including averaging the estimated weighted-average dumping margins determined for the exporters and producers individually investigated.'' In this review, Commerce preliminarily calculated weighted-average dumping margins of zero percent for Hyundai and Iljin. Therefore, we have preliminarily determined to continue to assign the estimated weighted-average dumping margins currently in effect to the non-selected companies subject to review. For a full discussion of the rates for non-selected companies, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

As a result of this review, we preliminarily determine the following estimated weighted-average dumping margin exists for the period August 1, 2024, through July 31, 2025:

Producer/exporter	Weighted-average dumping margin (percent)
HD Hyundai Electric Co., Ltd	0.00
Iljin Electric Co., Ltd	0.00
LS Electric Co., Ltd	4.32
Hyosung Heavy Industries Corporation	4.32

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties for these preliminary results 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).

Verification

As provided in section 782(i)(3) of the Act, Commerce intends to verify the information relied upon in making its final results.

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 review. 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.[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

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 90 FR 46173, 46176 (September 25, 2025) (*Initiation Notice*); *see also Large Power Transformers from the Republic of Korea: Antidumping Duty Order,* 77 FR 53177 (August 31, 2012) (*Order*).

[2] *See* Memorandum, ''Respondent Selection,'' dated January 29, 2026.

[3] *See* Memorandum, ''Deadlines Affected by the Shutdown of the Federal Government,'' dated November 14, 2025.

[4] *See* Memorandum, ''Tolling of all Case Deadlines,'' dated November 24, 2025.

[5] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated July 9, 2026.

[6] *See* Memorandum, ''Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review of Large Power Transformers from the Republic of Korea; 2024–2025,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[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).

in ACCESS by 5:00 p.m. Eastern Time on the established deadline.

As provided under 19 CFR 351.309(c)(2)(iii) and (d)(2)(iii), we 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. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce will inform parties of the scheduled date for the hearing.[11]

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

If any individually examined respondent's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.50 percent) in the final results of this review, Commerce intends to calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those sales. Where we do not have entered values for all U.S. sales to a particular importer, we will calculate an importer-specific, per-unit assessment rate on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales to the total quantity of those sales.[12] To determine whether an importer-specific, per-unit assessment rate is *de minimis,* in accordance with 19 CFR 351.106(c)(2), we also will calculate an importer-specific *ad valorem* ratio based on estimated entered values. If any respondent's weighted-average dumping margin is zero or *de minimis* or where an importer-specific *ad valorem* assessment rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[13]

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by each respondent for which it did not know that the merchandise was destined for the United States, we intend to instruct CBP to liquidate those entries at the all-others rate calculated in the less-than-fair-value (LTFV) investigation if there is no rate for the intermediate company(ies) involved in the transaction.[14]

For LS Electric Co., Ltd. and Hyosung Heavy Industries Corporation, the companies that were not selected for individual review, we will assign an assessment rate based on the review-specific rate, calculated as noted in the ''Rate for Non-Individually Examined Companies'' section, above. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[15]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated or reviewed companies not covered by this review, the cash deposit rate will continue to be the company-specific cash deposit rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, or the LTFV investigation, but the manufacturer is, then the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 22.00 percent, the all-others rate established in the LTFV investigation.[16] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results of review in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

[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).

[12] *See* 19 CFR 351.212(b)(1).

[13] *See* 19 CFR 351.106(c)(2); *see also Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[14] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[15] *See* section 751(a)(2)(C) of the Act.

[16] *See Order,* 77 FR 53177.

Dated: October 28, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Deadline for Submission of Updated Sales and Cost Information
IV. Scope of the *Order*
V. Rate for Non-Individually Examined Companies
VI. Discussion of the Methodology
VII. Currency Conversion
VIII. Recommendation

[FR Doc. 2026–22343 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–223]

Truck Bed Covers From the People's Republic of China: Amended Preliminary Determination of the Less-Than-Fair-Value Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is amending its preliminary affirmative determination in the less-than-fair-value (LTFV) investigation of truck bed covers from the People's Republic of China (China) to correct for significant ministerial errors. The period of investigation is July 1, 2025, through December 31, 2025.

DATES: Applicable November 2, 2026.

FOR FURTHER INFORMATION CONTACT: Christopher Maciuba or Jerry Xiao, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0413 or (202) 482- 2273, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 1, 2026, Commerce published in the **Federal Register** the *Preliminary Determination* of the less-than-fair-value investigation of truck bed covers from the People's Republic of China.[1] On October 6, 2026, a non-selected respondent who had qualified for a separate rate, Ningbo Scarman International Trading Co., Ltd (Ningbo Scarman) timely alleged that Commerce made significant ministerial errors in assigning its estimated weighted-average dumping margins.[2]

Scope of the Investigation

The products covered by this investigation are truck bed covers from China. For a complete description of the scope of this investigation, *see* the *Preliminary Determination*.[3]

Legal Framework

A ministerial error is defined as including ''errors in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication, or the like, and any other similar type of unintentional error which {Commerce} considers ministerial.''[4] A ministerial error is considered to be ''significant'' if its correction, either singly or in combination with other errors, would result in: (1) a change of at least f/ive absolute percentage points in, but not less than 25 percent of, the weighted-average dumping margin calculated in the preliminary determination; or (2) a difference between a weighted-average dumping margin of zero (or *de minimis*) and a weighted-average dumping margin of greater than *de minimis* or vice versa.[5] Pursuant to 19 CFR 351.224(e), Commerce ''will analyze any comments received and, if appropriate, correct any significant ministerial error by amending the preliminary determination.''

Analysis of Significant Ministerial Errors

In the *Preliminary Determination,* Commerce made a significant ministerial error within the meaning of section 735(e) of the Act and 19 CFR 351.224(f) and (g)(1) in incorrectly listing the producer when assigning a non-selected preliminary weighted-average dumping margin to Ningbo Scarman and its producer Ningbo Scarman Auto Parts Co., Ltd (Ningbo Auto Parts). Accordingly, pursuant to 19 CFR 351.224(e), Commerce is amending its *Preliminary Determination* to correct this error by correctly noting the producer/exporter chain as Ningbo Scarman/Ningbo Auto Parts chain, and assigning this chain the non-selected separate rate calculated in the *Preliminary Determination*.[6] For a detailed discussion of the alleged ministerial errors, as well as Commerce's analysis, *see* the Ministerial Error Memorandum.[7]

Amended Preliminary Determination

As a result of correcting this error specific to the producer/exporter combination discussed above, Commerce determines that the following estimated weighted-average dumping margin exists for the producer/exporter chain of Ningbo Scarman/Ningbo Auto Parts; no other changes have been made to any other producer/exporter combination as published in the *Preliminary Determination:*

Producer	Exporter	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Ningbo Scarman Auto Parts Co., Ltd.	Ningbo Scarman International Trading Co., Ltd. ...	49.56	49.38

Disclosure

Because no changes were made to the margin calculations from the *Preliminary Determination* as a result of this ministerial error, there are no new calculations to disclose.

Amended Cash Deposits and Suspension of Liquidation

The collection of cash deposits and suspension of liquidation will be

[1] *See Truck Bed Covers from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures,* 91 FR 62485 (October 1, 2026) (*Preliminary Determination*).

[2] *See* Ningbo Scarman's Letter, ''Ningbo Scarman's Ministerial Error Comments,'' dated October 6, 2026.

[3] *See Preliminary Determination,* 91 FR at 62498.

[4] *See* section 735(e) of the Tariff Act of 1930, as amended (the Act); *see also* 19 CFR 351.224(f).

[5] *See* 19 CFR 351.224(g).

[6] *See* Memorandum, ''Allegation of Ministerial Error in the Preliminary Determination,'' dated concurrently with this notice (Ministerial Error Memorandum).

[7] *Id.*

revised according to the rates calculated in this amended preliminary determination, in accordance with section 733(d) of the Act. Because we incorrectly identified this producer/exporter combination rate in the *Preliminary Determination,* this producer/exporter combination would have been suspended at the China-wide entity rate. Therefore, this notice corrects the Ningbo Scarman/Ningbo Auto Parts producer/exporter combination from the *Preliminary Determination,* to correct any inadvertent suspension at the incorrect cash deposit rate; the corrected producer/exporter combination identified above has a lower cash deposit rate than the China-wide entity rate that the producer and/or exporter may have been subject to since the *Preliminary Determination* published. As a result, the cash deposit instructions for this amended preliminary determination will be effective retroactively to October 1, 2026, the date of publication of the *Preliminary Determination.* We will also instruct U.S. Customs and Border Protection to issue instructions for requesting a refund of the difference between the amount of cash deposits paid as a result of the application of the *Preliminary Determination* rates applied and the amount due as a result of this amended preliminary determination.

U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, we will notify the U.S. International Trade Commission of our amended preliminary determination.

Notification to Interested Parties

This notice is issued and published in accordance with sections 735(e) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.224(e).

Dated: October 28, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–22353 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–950, A–489–858, A–520–813]

Welded Stainless Line and Pressure Pipe From India, the Republic of Türkiye, and the United Arab Emirates: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable November 2, 2026.

FOR FURTHER INFORMATION CONTACT: Catherine Bonilla at (202) 482–7955 or Luke Caruso at (202) 482–2081 (India), Charles DeFilippo at (202) 482–3797 (United Arab Emirates (UAE)), and Maria Papakostas at (202) 482–0086 (Republic of Türkiye (Türkiye)), AD/CVD Operations, Offices IV, VII, and IX, respectively, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On August 4, 2026, the U.S. Department of Commerce (Commerce) initiated less-than-fair-value (LTFV) investigations of imports of welded stainless line and pressure pipe (welded stainless pipe) from India, Türkiye, and the UAE.[1] Currently, the preliminary determinations are due no later than December 22, 2026.

Postponement of Preliminary Determinations

Section 733(b)(1)(A) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in an LTFV investigation within 140 days after the date on which Commerce initiated the investigation. However, section 733(c)(1)(A)(b)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 190 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 October 23, 2026, the petitioners[2] submitted a timely request that Commerce postpone the preliminary determinations in these LTFV investigations.[3] The petitioners stated that they request postponement ''given the size and complexity of these investigations, the number of participating respondents, and the numerous extensions of time received by respondents to submit responses to Commerce's initial questionnaire. Postponement of the preliminary determinations will allow the petitioners adequate time to analyze and comment on the respondents' questionnaire responses and develop a comprehensive record in these investigations that the petitioners can then comment on in advance of Commerce's preliminary determinations.''[4]

For the reasons stated above and because there are no compelling reasons to deny the request, Commerce, in accordance with section 733(c)(1)(A) of the Act, is postponing the deadline for the preliminary determinations by 50 days (*i.e.,* 190 days after the date on which these investigations were initiated). As a result, Commerce will issue its preliminary determinations no later than February 10, 2027. In accordance with section 735(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, unless postponed at a later date.

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: October 28, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–22308 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Welded Stainless Line and Pressure Pipe from India, the Republic of Türkiye, and the United Arab Emirates: Initiation of Less-Than-Fair-Value Investigations,* 91 FR 51462 (August 10, 2026) (*Initiation Notice*).

[2] The petitioners are Bristol Pipe and Tube Inc., Felker Brothers Corporation, and Primus Pipe and Tube Inc.

[3] *See* Petitioners' letter, ''Petitioners' Request to Postpone Preliminary Determinations,'' dated October 23, 2026.

[4] *Id.* at 2.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–863]

Corrosion-Resistant Steel Products From Mexico: Notice of Court Decision Not in Harmony With the Final Determination of Antidumping Duty Investigation; Notice of Amended Final Determination; Notice of Amended Antidumping Duty Order, in Part

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On October 19, 2026, the U.S. Court of International Trade (CIT) issued its final judgment in *Galvasid S.A. De C.V.,* v. *United States,* Slip Op. 26–128, Consol. Court no. 25–00235, sustaining the U.S. Department of Commerce's (Commerce) first remand redetermination pertaining to the less-than-fair-value (LTFV) investigation of corrosion-resistant steel products (CORE) from Mexico covering the period of investigation July 1, 2023, through June 30, 2024. Commerce is notifying the public that the CIT's final judgment is not in harmony with Commerce's final determination in that investigation, and that Commerce is amending the final determination and the resulting AD order with respect to the dumping margin assigned to Galvasid S.A. De C.V. (Galvasid) and all other producers and/or exporters.

DATES: Applicable October 29, 2026.

FOR FURTHER INFORMATION CONTACT: Katerina Katsiadas, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4929.

SUPPLEMENTARY INFORMATION:

Background

On August 29, 2025, Commerce published its *Final Determination* in the LTFV investigation of CORE from Mexico.[1] After correcting ministerial errors contained in the *Final Determination,* on December 18, 2025, Commerce published the *Amended Final Determination and Order.*[2]

Galvasid appealed Commerce's *Final Determination.* On July 24, 2026, the CIT remanded the *Final Determination,* directing Commerce to reconsider the dumping margin of Galvasid without applying facts otherwise available or an adverse inference predicated on Galvasid's failure to separately report freight or insurance revenue in the U.S. market.[3]

In its *Final Remand,* issued on September 22, 2026, Commerce reversed its finding of partial application of facts available, with an adverse inference, with respect to Galvasid's reporting of U.S. freight and insurance revenue, and revised the calculation of Galvasid's dumping margin by removing the adjustment to Galvasid's reported U.S. gross unit price, as well as the margin applied to all other companies.[4] The CIT sustained Commerce's *Final Remand*.[5]

Timken Notice

In its decision in *Timken,*[6] as clarified by *Diamond Sawblades,*[7] the U.S. Court of Appeals for the Federal Circuit held that, pursuant to section 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's October 19, 2026, judgment constitutes a final decision of the CIT that is not in harmony with Commerce's *Final Determination.* Thus, this notice is published in fulfillment of the publication requirements of *Timken.*

Amended Final Determination

Because there is now a final court judgment, Commerce is amending its *Final Determination* with respect to Galvasid and all-other producers/exporters as follows:

Exporter/producer	Weighted-average dumping margin (percent)
Galvasid S.A. De C.V	14.54
All Others	14.29

Amended Antidumping Duty Order

Pursuant to 735(c)(2) of the Act, Commerce shall ''issue an antidumping duty order under section 736'' of the Act when the final determination is affirmative. As a result of this amended final determination, Commerce is hereby amending the *Amended Final Determination and Order* to revise the weighted-average dumping margin assigned to Galvasid and all other producers and/or exporters of subject merchandise, as noted above.

Cash Deposit Requirements

Commerce will issue revised cash deposit instructions to U.S. Customs and Border Protection.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e) and 777(i)(1) of the Act.

Dated: October 28, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–22351 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Five-Year (Sunset) Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In accordance with the Tariff Act of 1930, as amended (the Act), the U.S. Department of Commerce (Commerce) is automatically initiating the five-year reviews (Sunset Reviews) of the antidumping duty (AD) and countervailing duty (CVD) orders and suspended investigations listed below. The U.S. International Trade Commission (ITC) is publishing concurrently with this notice its notice of *Institution of Five-Year Reviews* which covers the same orders and suspended investigations.

DATES: Applicable November 2, 2026.

FOR FURTHER INFORMATION CONTACT: Commerce official identified in the *Initiation of Review* section below at

[1] *See Certain Corrosion-Resistant Steel Products from Mexico: Final Affirmative Determination of Sales at Less Than Fair Value,* 90 FR 42187 (August 29, 2025) (*Final Determination*).

[2] *See Corrosion-Resistant Steel Products from Brazil and Mexico: Amended Final Antidumping Duty Determination; Corrosion-Resistant Steel Products from Australia, Brazil, Canada, Mexico, the Netherlands,* South Africa, Taiwan, the Republic of Türkiye, the United Arab Emirates, and the Socialist Republic of Vietnam: Antidumping Duty Orders, 90 FR 59494 (December 18, 2025) (*Amended Final Determination and Order*).

[3] *See Galvasid S.A. De C.V.,* v. *United States,* Consol. Court No. 25–00235 & 26–00825, Slip Op. 26–80 (CIT July 24, 2026) (*Remand Order*).

[4] *See Final Results of Redetermination Pursuant to Court Remand, Galvasid S.A. De C.V.,* v. *United States,* Slip Op. 26–80, dated September 22, 2026 (*Final Remand*), available at *https://access.trade.gov/FinalRemandRedetermination.*

[5] *See Galvasid S.A. De C.V.,* v. *United States,* Consol. Court No. 25–00235, Slip Op. 26–128 (CIT October 19, 2026).

[6] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[7] *See Diamond Sawblades Manufacturers Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond* Sawblades).

AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230. For information from the ITC, contact Mary Messer, Office of Investigations, U.S. International Trade Commission at (202) 205–3193.

SUPPLEMENTARY INFORMATION:

Background

Commerce's procedures for the conduct of Sunset Reviews are set forth in its *Procedures for Conducting Five-Year (Sunset) Reviews of Antidumping and Countervailing Duty Orders*, 63 FR 13516 (March 20, 1998) and 70 FR 62061 (October 28, 2005). Guidance on methodological or analytical issues relevant to Commerce's conduct of Sunset Reviews is set forth in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification*, 77 FR 8101 (February 14, 2012).

Initiation of Review

In accordance with section 751(c) of the Act and 19 CFR 351.218(c), we are initiating the Sunset Reviews of the following AD and CVD orders and suspended investigations:

Commerce case No.	ITC case No.	Country	Product	Commerce contact
Antidumping Duty Proceedings				
A–570–139	731–TA–1557	China	Mobile Access Equipment and Subassemblies (1st Review).	Mary Kolberg, (202) 482–1785.
A–570–001	731–TA–125	China	Potassium Permanganate (6th Review)	Thomas Martin, (202) 482–3936.
A–560–838	731–TA–1550	Indonesia	Polyester Textured Yarn (1st Review)	Emily Kutsko, (202) 482–6276.
A–557–823	731–TA–1551	Malaysia	Polyester Textured Yarn (1st Review)	Emily Kutsko, (202) 482–6276.
A–549–843	731–TA–1552	Thailand	Polyester Textured Yarn (1st Review)	Emily Kutsko, (202) 482–6276.
A–552–832	731–TA–1553	Vietnam	Polyester Textured Yarn (1st Review)	Emily Kutsko, (202) 482–6276.
Countervailing Duty Proceedings				
C–570–140	701–TA–665	China	Mobile Access Equipment and Subassemblies (1st Review).	Mary Kolberg, (202) 482–1785.

Suspended Investigations

No Sunset Reviews of suspended investigations are scheduled for initiation in November 2026.

Filing Information

All submissions in these Sunset Reviews must be filed in accordance with Commerce's regulations regarding format, translation, and service of documents. These rules, including electronic filing requirements via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), can be found at 19 CFR 351.303.

In accordance with section 782(b) of the Act, any party submitting factual information in an AD/CVD proceeding must certify to the accuracy and completeness of that information. Parties must use the certification formats provided in 19 CFR 351.303(g). Commerce intends to reject factual submissions if the submitting party does not comply with applicable revised certification requirements.

Letters of Appearance and Administrative Protective Orders

Pursuant to 19 CFR 351.103(d), Commerce will maintain and make available a public service list for these proceedings. Parties wishing to participate in any of these five-year reviews must file letters of appearance as discussed at 19 CFR 351.103(d). To facilitate the timely preparation of the public service list, it is requested that those seeking recognition as interested parties to a proceeding submit an entry of appearance within 10 days of the publication of the Notice of Initiation. Because deadlines in Sunset Reviews can be very short, we urge interested parties who want access to proprietary information under administrative protective order (APO) to file an APO application immediately following publication in the **Federal Register** of this notice of initiation. Commerce's regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[1]

Information Required From Interested Parties

Domestic interested parties, as defined in sections 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b), wishing to participate in a Sunset Review must respond not later than 15 days after the date of publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with Commerce's regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, Commerce will automatically revoke the order without further review.[2]

If we receive an order-specific notice of intent to participate from a domestic interested party, Commerce's regulations provide that *all parties* wishing to participate in a Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the **Federal Register** of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that Commerce's information requirements are distinct from the ITC 's information requirements. Consult Commerce's regulations for information regarding Commerce's conduct of Sunset Reviews. Consult Commerce's regulations at 19 CFR part 351 for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at

[1] *See Temporary Rule Modifying AD/CVD Service Requirements Due to* COVID–19, 85 FR 41363 (July 10, 2020).

[2] *See* 19 CFR 351.218(d)(1)(iii).

Commerce. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[3] An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the day on which it is due.

In prior proceedings we have encouraged interested parties to provide an executive summary of their comments, including footnotes. In these sunset reviews, we request that interested parties provide at the beginning of their comments, an executive summary for each issue raised in their comments. 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 decision memorandum that will accompany the notice to be published in the **Federal Register**. Finally, we request that interested parties include footnotes for relevant citations in the public executive summary of each issue.

Notification to Interested Parties

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218(c).

Dated: October 27, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–22312 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Initiation of Review of Management Plan for Gray's Reef National Marine Sanctuary; Request for Information

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Initiation of review of management plan; request for information.

SUMMARY: The National Oceanic and Atmospheric Administration is initiating a comprehensive review of the Gray's Reef National Marine Sanctuary management plan, to evaluate progress toward implementing the goals of the sanctuary and to revise the management plan as necessary to fulfill the purposes and policies of the National Marine Sanctuaries Act. NOAA is requesting information from individuals, companies, organizations, Tribes, and government agencies on the scope, types, and significance of issues that NOAA should address in its process to revise the management plan. In addition to receiving written comments, NOAA will hold public meetings to provide information on the management plan review process and to gather comments.

DATES: NOAA will consider all written comments in English that are received on or before 11:59 p.m. Eastern Standard Time on December 17, 2026.

NOAA will host public meetings and will accept comments at the below locations, dates, and times. Please check the website (*https://graysreef.noaa.gov/mpr*) for the most up-to-date information about public meeting locations, times, and special details.

Meeting #1: November 4, Brunswick, GA, Late Afternoon–Evening Session
Meeting #2: November 10, Okatie, SC, Late Afternoon–Evening Session
Meeting #3: November 13, Savannah, GA, Late Afternoon–Evening Session
Meeting #4: November 17, Conway, SC, Late Afternoon–Evening Session
Meeting #5: November 18, Charleston, SC, Late Afternoon–Evening Session

In addition to the five public meetings, the Sanctuary Advisory Council will discuss the management plan review at its fall meeting scheduled for Nov. 12. NOAA may record all or part of the public meetings, including the public comment portion, for administrative purposes.

ADDRESSES: Comments may be submitted by the following methods:

- *Electronic Submission: Federal eRulemaking Portal: https://www.regulations.gov/docket/NOAA-NOS-2026-2740.* To submit electronic comments via the Federal eRulemaking Portal, visit *https://www.regulations.gov* and search for Docket Number NOAA–NOS–2026–2740.
- *Mail:* Written comments may also be mailed to Gray's Reef National Marine Sanctuary (Attn: Management Plan Review), at 10 Ocean Science Circle, Savannah, GA 31411.
- *Public Meetings:* Provide comments during public meetings, as described under **DATES**. Information on how to participate in these public meetings is available at: *https://graysreef.noaa.gov/mpr/.*

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NOAA. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change, including the name of the commenter, email address, attachments, and other supporting materials will be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information such as account numbers or Social Security numbers, and do not submit comments that contain profanity, vulgarity, threats, or other inappropriate language. NOAA will accept anonymous comments through *www.regulations.gov* (enter N/A in the required fields to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Scott Kathey, Resource Protection Coordinator, 10 Ocean Science Circle, Savannah, Georgia 31411, *graysreef.mpr@noaa.gov,* or visit the sanctuary's website: *https://graysreef.noaa.gov/mpr.*

SUPPLEMENTARY INFORMATION:

I. Background

Gray's Reef National Marine Sanctuary (GRNMS) is located off the Georgia coast, about 19 miles east of Sapelo Island and 40 miles southeast of historic Savannah, Georgia. The sanctuary protects a 22-square-mile area of vibrant, live-bottom reef and surrounding sand and open ocean habitats that are representative of the marine ecosystems off much of the southeastern United States. NOAA designated the area as a national marine sanctuary in 1981 to protect its diversity of species and abundance of marine life. The sanctuary is influenced by complex ocean currents and serves as a mixing zone for temperate (colder water) and sub-tropical species. The series of rock ledges and sand expanses provide a solid base upon which temperate and tropical marine flora and fauna attach and flourish. Almost 1,000 species of invertebrates and 200 species of fish have been identified at Gray's Reef. NOAA manages GRNMS as part of the National Marine Sanctuary System, which comprises 18 national marine sanctuaries, under the National Marine Sanctuaries Act of 1972 (NMSA), 16 U.S.C. 1431 *et seq.*

The sanctuary management plan is a road map that guides sanctuary management actions and programs toward achievement of the sanctuary's goals. Subsection 304(e) of the NMSA requires NOAA to periodically review sanctuary management plans to evaluate

[3] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule*, 88 FR 67069 (September 29, 2023).

the substantive progress toward implementing the management plan and goals for the sanctuary, and to revise the management plans and regulations as necessary. This review ensures that national marine sanctuaries continue to best conserve, protect, and enhance their nationally significant resources (16 U.S.C. 1434(e)). The current GRNMS management plan was published in 2014, and is available at *https://graysreef.noaa.gov/management/plan/.* In 2019 NOAA conducted a rapid management plan review to evaluate the substantive progress made toward implementing the 2014 management plan, and determined that no urgent or immediate revisions to the management plan were needed at the time.

The comprehensive management plan review process is composed of four major stages: (1) information collection, including through this request for information; (2) preparation and release of a draft management plan, an environmental analysis document as required under the National Environmental Policy Act (NEPA), and a notice of proposed rulemaking for any proposed changes to sanctuary regulations; (3) public review and comment on the draft documents; and (4) preparation and release of a final management plan, a final environmental analysis document, and a final rule for any changes to sanctuary regulations, if applicable. NOAA will also, as applicable, address other statutory and regulatory requirements pursuant to the Endangered Species Act (ESA), Marine Mammal Protection Act (MMPA), Essential Fish Habitat (EFH) provisions of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), Coastal Zone Management Act (CZMA), National Historic Preservation Act (NHPA), and Tribal consultation responsibilities under Executive Order 13175.

II. Condition Report

To inform the management plan review, NOAA published a Condition Report for the GRNMS. The Condition Report, released in 2025, assessed the period from 2008–2022 and presents summary information describing the status and trends of sanctuary resources, covering the broad categories of human activities and pressures, water quality, habitat, living resources, and maritime heritage resources. This report also included the status and trends of ecosystem services—the ways that humans benefit from the natural and cultural resources of the sanctuary. The report is available to the public online at *https://sanctuaries.noaa.gov/science/condition/grnms/.*

III. Preliminary Goals & Strategies From GRNMS Staff Workshop

In August 2026, NOAA held a workshop to identify preliminary draft goals and strategies for effectively managing the sanctuary over the next ten years. Staff considered information from the existing 2014 GRNMS Management Plan, the 2019 rapid management plan review, the 2025 Condition Report, findings and recommendations of the Sanctuary Advisory Council, staff knowledge and expertise, and input from the public and partners since 2014.

NOAA is interested in receiving public comment on these preliminary draft goals and strategies, which will seek to further the agency's work to conserve Gray's Reef while facilitating public and private uses that are compatible with the goals and objectives of the sanctuary. NOAA is also interested in hearing any additional topics raised by the public.

GOAL 1: Improve our understanding of sanctuary resources and ecosystem services, their value to the regional and national economy, and their vulnerability to natural and human-related threats, in coordination/collaboration with partners.

- *Strategy 1.1.* Assess the state of knowledge of sanctuary resources and habitats, and direct future research and monitoring.
- *Strategy 1.2.* Enhance our understanding of sanctuary historical and cultural resources to inform management and interpretation activities.
- *Strategy 1.3.* Identify and track socioeconomic value and ecosystem service benefits provided by the sanctuary and its resources.
- *Strategy 1.4.* Facilitate scientific research and monitoring through local, regional, and national partners.

GOAL 2: Support and sustain the condition of sanctuary resources and improve and restore ecosystem structure and function when needed and where possible.

- *Strategy 2.1.* Water quality: Engage with local, regional and federal partners to monitor for emerging threats and maintain the water quality of the sanctuary.
- *Strategy 2.2.* Habitat: Work with partners to maintain healthy habitat, mitigate negative impacts, and promote recovery of degraded resources.
- *Strategy 2.3.* Living marine resources: Work with regional and federal partners to maintain the healthy condition and diversity of natural biological communities.

GOAL 3: Reduce threats to and pressures on sanctuary resources.

- *Strategy 3.1.* Identify and monitor patterns of human uses and their potential impacts.
- *Strategy 3.2.* Reduce and mitigate adverse impacts of human activities and non-native fauna to key marine species and habitats.
- *Strategy 3.3.* Facilitate and manage human use, ensuring use is compatible with sanctuary resource protection goals.

GOAL 4: Increase awareness and support for Gray's Reef National Marine Sanctuary and its resources.

- *Strategy 4.1.* Enhance public awareness through effective outreach, immersive interpretation, and quality education programs.
- *Strategy 4.2.* Maintain and enhance community-based and partner engagement to improve collaboration and coordination.
- *Strategy 4.3.* Optimize the impact of the Gray's Reef National Marine Sanctuary Ocean Discovery Center and research vessel to deliver impactful education programs and interpretation and enhance sanctuary outreach and management.

GOAL 5: Advance and support collaborative and coordinated management.

- *Strategy 5.1.* Enhance operational capabilities of the Sanctuary infrastructure (vessels, buildings, etc.) required to accomplish the mission and goals.
- *Strategy 5.2.* Maintain and enhance cooperative management with our federal, state, and local partners to advance shared resource management priorities.

GOAL 6. Improve understanding to support conservation of important natural and cultural resources across the South Atlantic Bight along the mid-Continental Shelf and beyond.

- *Strategy 6.1.* Assess the ecological connections and health in the South Atlantic Bight to inform conservation and management of Gray's Reef National Marine Sanctuary.
- *Strategy 6.2.* Expand coordination and scope of the Southeast Regional Ecosystem Assessment Initiative to include mapping and habitat characterization efforts by NOAA and other federal and state agencies.
- *Strategy 6.3.* Evaluate the need for additional protection of habitats and cultural resources in the South Atlantic Bight.

Authority: 16 U.S.C. 1431 *et seq.*

John Armor,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2026–22287 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID [0648–XG102]]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Joint Groundfish Committee and Advisory Panel to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Monday, November 16, 2026 at 9:30 a.m. EDT Webinar registration URL information: *https://nefmc-org.zoom.us/meeting/register/vbcWda0eTemIVdDgGO2YoA*.

ADDRESSES: This meeting will be held at the Hilton Garden Inn Boston Logan, 100 Boardman Street, Boston, MA 02128; Phone (617) 567–6789.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Cate O'Keefe, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Groundfish Committee and Advisory Panel will meet to discuss Framework Adjustment 74/ Specifications and Management Measures and review draft alternatives and draft impacts analysis and recommend preferred alternatives to the Committee/Council. They will also discuss Groundfish Management Transition and receive an update on planning for facilitated listening sessions. Other business will be discussed as necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Cate O'Keefe, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: October 29, 2026.

Anna Michelle Harrison,

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

[FR Doc. 2026–22327 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XG107]

Fisheries of the Caribbean; Southeast Data, Assessment, and Review; Public Meeting

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

ACTION: Notice of webinar.

SUMMARY: The Southeast Data Assessment and Review (SEDAR) 103 assessment process of Caribbean Alternate Assessment Methods will consist of a Development Workshop, a series of Assessment Webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION.**

DATE: The SEDAR 103 Assessment Application Webinar 1 will be held from 1 p.m. until 4 p.m. EDT November 20, 2026.

ADDRESSES: *SEDAR address:* 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405. *www.sedarweb.org. Meeting address:* The SEDAR 103 Assessment Application Webinar 1 will be held via webinar. The webinar is open to members of the public. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

FOR FURTHER INFORMATION CONTACT: Emily Ott, SEDAR Coordinator; (843) 302–8434. Email: *Emily.Ott@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with the NMFS and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the SEDAR process, a multi-step method for determining the status of fish stocks in the Southeast Region SEDAR is a participatory process for developing, evaluating and reviewing information used for fisheries management advice. The process may include (1) a Data stage, and (2) an Assessment stage, and (3) a Review stage. The product of the Data stage is a report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment stage is a report which compiles and evaluates recommended model configurations that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks and projects future population conditions. The product of the Review Workshop is a Review Summary documenting panel opinions regarding the strengths and weaknesses of the products reviewed. Participants for SEDAR Workshops are appointed by the Gulf, South Atlantic, and Caribbean Fishery Management Councils and NMFS Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations; International experts; and staff of Councils, Commissions, and State and Federal agencies.

The items of discussion in the Assessment Application Webinar 1 are as follows:

Decide which methods will be applied during the SEDAR 103 process. Although non-emergency issues not contained in this agenda may come before this group for discussion, those

issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency. Special Accommodations These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

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

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

Dated: October 27, 2026.

Anna Michelle Harrison,

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

[FR Doc. 2026–22246 Filed 10–30–26; 8:45 am]

BILLING CODE 3510–22–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Comment Request; NCCC Service Team Leader Application

AGENCY: Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Corporation for National and Community Service (operating as AmeriCorps) is proposing to revise an information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by January 4, 2027.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) Electronically through *www.regulations.gov* (preferred method).

(2) *By mail sent to:* AmeriCorps, Attention Sarah Reynolds, 250 E Street SW, Washington, DC 20525.

(3) By hand delivery or by courier to the AmeriCorps mailroom at the mail address given in paragraph (2) above, between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

Comments submitted in response to this notice may be made available to the public through *regulations.gov.* For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Sarah Reynolds, Systems and Operations Lead, AmeriCorps NCCC at (202) 606–6956 or by email at *sreynolds@americorps.gov.*

SUPPLEMENTARY INFORMATION:

Title of Collection: NCCC Team Leader Application.

OMB Control Number: 3045–0005.

Type of Review: Revision.

Respondents/Affected Public: Individuals and households.

Total Estimated Number of Annual Responses: 800.

Total Estimated Number of Annual Burden Hours: 1,600.

Abstract: The AmeriCorps NCCC Team Leader application, which is available electronically for all applicants, provides information AmeriCorps uses to select Team Leaders for AmeriCorps NCCC. AmeriCorps seeks to revise the information collection to add a clarifying word to question 1 and edit question 3 to refer to three consecutive months of service for Summer of Service. The current information collection expires January 31, 2027.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will be available for public inspection on *regulations.gov.*

Walter Goodson,

Director, AmeriCorps NCCC.

[FR Doc. 2026–22271 Filed 10–30–26; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Withdrawal of Notice of Intent To Prepare an Environmental Impact Statement, Port of Iberia, Louisiana

AGENCY: U.S. Army Corps of Engineers, Department of the Army, DoD.

ACTION: Notice; withdrawal.

SUMMARY: The U.S. Army Corps of Engineers (USACE) is issuing this notice to advise Federal, State, local governmental agencies, and the public and other concerned stakeholders that USACE is withdrawing the Notice of Intent (NOI) for the preparation of an Environmental Impact Statement (EIS) as part of the Port of Iberia (also referred to as 'the Port' or 'Iberia Port'), Louisiana navigation feasibility study. Since publication of the NOI, study conditions have changed; the USACE has determined that an Environmental Assessment (EA) rather than an EIS is the appropriate level of environmental documentation.

DATES: The NOI to prepare an EIS published in the **Federal Register** on October 31, 2002 (67 FR 66388), is withdrawn as of November 2, 2026.

ADDRESSES: U.S. Army Corps of Engineers, New Orleans; 7400 Leake Ave., New Orleans, Louisiana 70118.

FOR FURTHER INFORMATION CONTACT: Questions about the withdrawal of the

NOI can be directed to Elizabeth Behrens at (504) 862–2025 or by email at *Elizabeth.H.Behrens@usace.army.mil.*

SUPPLEMENTARY INFORMATION: Section 431 (Iberia Port, Louisiana) of the Water Resources Development Act (WRDA) of 2000 (Pub. L. 106–541) authorized ''a study to determine the feasibility of carrying out a project for navigation, Iberia Port, Louisiana.'' A final Feasibility Report and EIS were completed in 2006; however, a Record of Decision for the EIS was not signed. The project was subsequently authorized under Section 1001(25) of the WRDA 2007, as amended by Section 6004(a)(7) of the Water Resources Reform and Development Act of 2014.

USACE has since assessed the environmental impacts of the proposed action and determined that there would be no significant adverse impact(s) on the human and natural environment. Unavoidable impacts to wetlands will be fully mitigated; and because forecasted impacts from the proposed action can be fully mitigated, significant adverse effects are no longer a concern, an EIS is not warranted. The USACE will notify the public in advance of the availability of EA #611 and draft Finding of No Significant Impact (FONSI) through public notice. A copy of the signed FONSI will be made available for viewing and download on the project website at: *https://www.mvn.usace.army.mil/About/Projects/Port-of-Iberia/.* Any future proposed federal action(s) related to the study, or authorized project if authorized, will comply with the requirements of the NEPA of 1969, as amended (42 U.S.C. 4321 *et seq.*), the Department of War NEPA Implementing Procedures (September 3, 2026), and other related environmental review requirements.

James A. Bodron,

Programs Director, Mississippi Valley Division.

[FR Doc. 2026–22315 Filed 10–30–26; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Notice of the In-Person Meeting of the Federal Advisory Committee Known as the Western Water Cooperative Committee

AGENCY: Corps of Engineers, Department of the Army, DoD.

ACTION: Notice.

SUMMARY: The Western Water Cooperative Committee, a Federal Advisory Committee, provides a forum for discussions between the U.S. Army Corps of Engineers (''Corps'') and Western States regarding the operation of Corps projects and water rights and water laws of Western States. The Western Water Cooperative Committee will host an in-person meeting November 17 and 18, 2026, for the Committee to finalize the by-laws and discuss identified opportunities and proposed recommendations to avoid or minimize conflicts between Corps projects and state water rights and water laws. This meeting is open to the public.

DATES: The Western Water Cooperative Committee will host an in-person meeting from 8:30 a.m. MST to 5:00 p.m. MST on Tuesday, November 17, and Wednesday, November 18, 2026.

ADDRESSES: The Western Water Cooperative Committee will conduct an in-person meeting at the Homewood Suites Denver Downtown-Convention Center at 550 15th Street, Denver, Colorado. Comments or requests to speak at the meetings should be submitted in writing to the Designated Federal Officer (DFO) for the committee: Mr. Sean L. Smith, ATTN: CEEC, 441 G St. NW, Washington, DC 20314–1000; or by email at *WWCC@usace.army.mil.* Alternatively, contact the Alternate Designated Federal Officer (ADFO): Ms. Virginia K. Rynk, ATTN: CEEC, 441 G St. NW, Washington, DC 20314–1000; or by email at *WWCC@usace.army.mil.* Electronic mail is the preferred mode of submission.

FOR FURTHER INFORMATION CONTACT: The DFO for the committee: Mr. Sean L. Smith, by telephone at 202–761–0301; and by email at *WWCC@usace.army.mil;* or the ADFO, Ms. Virginia K. Rynk by telephone at 202–761–4741; and by email at *WWCC@usace.army.mil.*

SUPPLEMENTARY INFORMATION: The Committee meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Chapter 10, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: The Committee is chartered pursuant to Section 8158 of the James M. Inhofe National Defense Authorization Act (33 U.S.C. 701b–17) to ensure that the Corps flood control projects in Western States, as described in section 8158(b), are operated consistent with congressional directives by identifying opportunities to avoid or minimize conflicts between the operation of the Corps projects and water rights and water laws in such States.

Agenda: At this meeting, the agenda will include the discussion and codification of the proposed by-laws, administrative topics, and discussion of identified opportunities and proposed recommendations to avoid or minimize conflicts between Corps project and state water rights and water laws.

Availability of Materials for the Meeting: A copy of the agenda will be available on the website: *https://www.usace.army.mil/Missions/Civil-Works/Project-Planning/Legislative-Links/WRDA-2022/Western-Water-Cooperative-Committee/.* All meeting materials will be posted to the website after the meeting.

Public Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public. Any interested person may participate in the meeting, file written comments or statements with the Committee, or make verbal comments during the public meeting, at the times, and in the manner permitted by the Committee, as set forth below.

Special Accommodations: Individuals requiring any special accommodations related to the public meeting or seeking additional information about the procedures, should contact Mr. Smith, the Committee DFO, or Ms. Rynk, the ADFO, at the email addresses or telephone numbers listed in the **FOR FURTHER INFORMATION CONTACT** section, at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Written Comments or Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act, the public or interested organizations may submit written comments or statements to the Committee about its mission and/or topics to be addressed in this public meeting. Written comments or statements should be submitted to Mr. Smith, the Committee DFO, or Ms. Rynk, the Committee ADFO, via electronic mail, the preferred mode of submission, at the addresses listed in the **FOR FURTHER INFORMATION CONTACT** section in the following formats: Adobe Acrobat or Microsoft Word. The comment or statement must include the author's name, title, affiliation, address, daytime phone number, and reference to which meeting date the comment or statement is directed. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the Committee DFO or ADFO at least five (5) business days prior to the meeting so

that they may be made available to the Committee for its consideration prior to the meeting. Written comments or statements received after this date may not be provided to the Committee until its next meeting. Please note that because the committee operates under the provisions of the Federal Advisory Committee Act, as amended, all written comments will be treated as public documents and will be made available for public inspection.

Verbal Comments: Members of the public will be permitted to make verbal comments during the in-person public meeting only at the time and in the manner allowed herein. If a member of the public is interested in making a verbal comment at the in-person meeting, that individual must submit a request, with a brief statement of the subject matter to be addressed by the comment, at least five business (5) days in advance to the Committee DFO or ADFO, via electronic mail, the preferred mode of submission, at the addresses listed in the **FOR FURTHER INFORMATION CONTACT** section. The Committee DFO and ADFO will log each request to make a comment, in the order received, and determine whether the subject matter of each comment is relevant to the Committee's mission and/or the topics to be addressed in this public meeting. A 30-minute period near the end of the meeting will be available for verbal public comments. Members of the public who have requested to make a verbal comment and whose comments have been deemed relevant under the process described above, will be allotted no more than three (3) minutes during this period, and will be invited to speak in the order in which their requests were received by the DFO and ADFO.

Thomas P. Smith,

Director, Engineering and Construction Directorate, Corps of Engineers.

[FR Doc. 2026–22270 Filed 10–30–26; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Notice of Availability of the Record of Decision for the Final Supplemental Environmental Impact Statement for the Morganza to the Gulf, Louisiana, Hurricane and Storm Damage Risk Reduction Project, Terrebonne and Lafourche Parishes, Louisiana

AGENCY: U.S. Army Corps of Engineers, Department of the Army, DoD.

ACTION: Notice of availability.

SUMMARY: The U.S. Army Corps of Engineers (USACE) announces the availability of the Record of Decision (ROD) for the final Supplemental Environmental Impact Statement (SEIS) for the Morganza to the Gulf, Louisiana, Hurricane and Storm Damage Risk Reduction Project, Terrebonne and Lafourche Parishes, Louisiana. The USACE Mississippi Valley Division Commander signed the ROD on October 14, 2026.

ADDRESSES: U.S. Army Corps of Engineers, New Orleans; 7400 Leake Ave., New Orleans, Louisiana 70118.

FOR FURTHER INFORMATION CONTACT: Patrick Smith, U.S. Army Corps of Engineers, New Orleans District, at (504) 862–1583 or by email at *Patrick.W.Smith@usace.army.mil.*

SUPPLEMENTARY INFORMATION: The SEIS was prepared pursuant to the NEPA of 1969 (as amended) (42 U.S.C. 4321, *et seq.*). The NOI for the SEIS was published in the **Federal Register** on June 20, 2024, (89 FR 51875). The USACE Mississippi Valley Division Commander signed a Record of Decision outlining the conclusion of the environmental impacts analysis related to the recommended design of coastal storm risk reduction features along a portion of coastal Louisiana in Terrebonne and Lafourche Parishes. The ROD is available for viewing and download on the USACE New Orleans District study website at: *https://www.mvn.usace.army.mil/About/Projects/Morganza-to-the-Gulf/Documents/.* This Notice of Availability is published pursuant to the Department of War NEPA Implementing Procedures (September 3, 2026).

James A. Bodron,

Programs Director, Mississippi Valley Division.

[FR Doc. 2026–22314 Filed 10–30–26; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Fiscal Year 2026 Performance Review Board Membership

AGENCY: Department of the Navy (DoN), Department of Defense.

ACTION: Notice.

SUMMARY: The Department of the Navy (DON) announces the appointment of members to the DON Senior Executive Service (SES), Senior Level, and Scientific and Professional Fiscal Year 2026 Performance Review Board (PRB). The purpose of the PRB is to provide fair and impartial review of the annual SES and Senior Professional (SP) performance appraisals prepared by the SES member's or SP's first- and second-level supervisor; to make recommendations to appointing officials regarding acceptance or modification of the performance rating; and to make recommendations for performance-based bonuses and performance-based pay increases.

FOR FURTHER INFORMATION CONTACT: Kim Hanson, Director, Executive Management Program Office, Manpower and Reserve Affairs at (703) 693–8896 or *kim.t.hanson.civ@us.navy.mil.*

SUPPLEMENTARY INFORMATION: Composition of the DON PRB is provided below:

Hon. Benjamin C. Kohlmann, Ms. Jennifer LaTorre, Mr. Neil Hogg, VADM Elizabeth Okano, Ms. Lisa St. Andre, Mr. Steven Parode, Dr. Thomas Fu, Mr. Stephen Cricchi, Mr. Thomas Perotti, Ms. Karen Fenstermacher, Dr. Michael Strobl, Mr. James Lloyd, Mr. David Tremper, Mr. Todd Calhoun (Higher-Level Reviewer (HLR)), Ms. Jennifer Edgin (HLR).

(Authority: 5 U.S.C. 4314(c)(4))

Dated: October 28, 2026.

J.R. Epstein,

Lieutenant, Judge Advocate General's Corps, U.S. Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 2026–22247 Filed 10–30–26; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2026–IES–3235]

NCES Request for Information, Correction

AGENCY: National Center for Education Statistics (NCES), Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Correction notice.

SUMMARY: On October 29, 2026, the U.S. Department of Education published a notice in the **Federal Register** announcing a Request for Information (RFI) for NCES with FR DOC# 2026-22047 (91 FR 68118, pages 68118–68120). The Notice asked the public to submit comments electronically using *regulations.gov*, but the Docket No. was not properly included within the Notice. The Docket No. for this RFI is ED–2026–IES–3235.

ED is issuing this correction notice to ensure that NCES can properly receive the requested information from the field

and more effectively carry out requirements laid out in 20 U.S.C. 9543.

Ross Santy,

Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2026–22341 Filed 10–30–26; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2026–1849; FRL–13203–07–OCSPP]

Certain New Chemicals or Significant New Uses; Statements of Findings—July 2026

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Toxic Substances Control Act (TSCA) requires EPA to publish in the **Federal Register** a statement of its findings after its review of certain TSCA submissions when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to premanufacture notices (PMNs), microbial commercial activity notices (MCANs), and significant new use notices (SNUNs) submitted to EPA under TSCA. This document presents statements of findings made by EPA on such submissions during the period from July 1, 2026, to July 31, 2026.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2026–1849, is available online at *https://www.regulations.gov.* Additional information about dockets generally, along with instructions for visiting the docket in person, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information: Rebecca Edelstein, New Chemical Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–1667; email address: *edelstein.rebecca@epa.gov.*

For general information: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action provides information that is directed to the public in general.

B. What action is the Agency taking?

This document lists the statements of findings made by EPA after review of submissions under TSCA section 5(a) that certain new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment. This document presents statements of findings made by EPA during the applicable period.

C. What is the Agency's authority for taking this action?

TSCA section 5(a)(3) requires EPA to review a submission under TSCA section 5(a) and make specific findings pertaining to whether the substance may present unreasonable risk of injury to health or the environment. Among those potential findings is that the chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment per TSCA Section 5(a)(3)(C).

TSCA section 5(g) requires EPA to publish in the **Federal Register** a statement of its findings after its review of a submission under TSCA section 5(a) when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to PMNs, MCANs, and SNUNs submitted to EPA under TSCA section 5.

Anyone who plans to manufacture (which includes import) a new chemical substance for a non-exempt commercial purpose and any manufacturer or processor wishing to engage in a use of a chemical substance designated by EPA as a significant new use must submit a notice to EPA at least 90 days before commencing manufacture of the new chemical substance or before engaging in the significant new use.

The submitter of a notice to EPA for which EPA has made a finding of ''not likely to present an unreasonable risk of injury to health or the environment'' may commence manufacture of the chemical substance or manufacture or processing for the significant new use notwithstanding any remaining portion of the applicable review period.

II. Statements of Findings Under TSCA Section 5(a)(3)(C)

In this unit, EPA identifies the PMNs, MCANs and SNUNs for which EPA has made findings under TSCA section 5(a)(3)(C) that the new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment. For the findings made during this period, the following list provides the EPA case number assigned to the TSCA section 5(a) submission and the chemical identity (generic name if the specific name is claimed as confidential).

- P–26–0025, Arylpolycarboxamide, [[[(polyalkylalkyl)cycloalkyl] carbonyl] amino]- poly[(alkylalkyl)cycloalkyl]- (Generic Name).

To access EPA's decision document describing the basis of the ''not likely to present an unreasonable risk'' finding made by EPA under TSCA section 5(a)(3)(C), lookup the specific case number at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely.*

Authority: 15 U.S.C. 2601 *et seq.*

Dated: October 28, 2026.

Shari Z. Barash,

Director, New Chemicals Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2026–22291 Filed 10–30–26; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice: EIB–2026–0397]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; EIB 10–04, Notice of Claim and Proof of Loss, Working Capital Guarantee

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (Ex-Im Bank), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

DATES: Comments must be received on or before December 2, 2026 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *www.regulations.gov* (EIB 10–04) or by email to *donna.schneider@exim.gov,* or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW, Washington, DC 20038, Attn: OMB 3048–0015. The form can be reviewed at

https://img.exim.gov/s3fs-public/pub/pending/EIB%2010-04%20WCG%20Notice%20of%20Claim%20Proof%20of%20Loss_2026.pdf.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Donna Schneider <*Donna.Schneider@exim.gov.*>, 202–565–3612.

SUPPLEMENTARY INFORMATION: By neutralizing the effect of export credit support offered by foreign governments and by absorbing credit risks that the private sector will not accept, Ex-Im Bank enables U.S. exporters to compete fairly in foreign markets on the basis of price and product. Under the Working Capital Guarantee Program, Ex-Im Bank provides repayment guarantees to lenders on secured, short-term working capital loans made to qualified exporters. The guarantee may be approved for a single loan or a revolving line of credit. In the event that a borrower defaults on a transaction guaranteed by Ex-Im Bank the guaranteed lender may seek payment by the submission of a claim.

Titles and Form Number: EIB 10–04, Notice of Claim and Proof of Loss, Working Capital Guarantee.

OMB Number: 3048–0035.

Type of Review: Regular.

Need and Use: This collection of information is necessary, pursuant to 12 U.S.C. 635(a)(1), to determine if such claim complies with the terms and conditions of the relevant working capital guarantee. The Notice of Claim and Proof of Loss, Working Capital Guarantee is used to determine compliance with the terms of the guarantee and the appropriateness of paying a claim. Export-Import Bank customers are submitting this form electronically.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 10.

Estimated Time per Respondent: 6 hours.

Frequency of Response: As needed to request a working capital claim payment.

Annual Burden Hours: 60 hours.

Dated: October 29, 2026.

Andrew Smith,

Records Officer.

[FR Doc. 2026–22332 Filed 10–30–26; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0170, OMB 3060–0188; FR ID 375395]

Information Collections Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written PRA comments should be submitted on or before January 4, 2027. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

OMB Control Number: 3060–0170.

Title: Section 73.1030, Notifications Concerning Interference to Radio Astronomy, Research and Receiving Installations.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Businesses or other for-profit entities.

Number of Respondents and Responses: 57 respondents; 57 responses.

Estimated Hours per Response: 0.5 hours.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Total Annual Burden: 29 hours.

Total Annual Cost: $14,250.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 154(i) of the Communications Act of 1934, as amended.

Needs and Uses: The information collection requirements contained in 47 CFR 73.1030 state in order to minimize harmful interference at the National Radio Astronomy Observatory site located at Green, Pocahontas County, West Virginia, and at the Naval Radio Research Observatory at Sugar Grove, Pendleton County, West Virginia, a licensee proposing to operate a short-term broadcast auxiliary station pursuant to § 74.24, and any applicant for authority to construct a new broadcast station, or for authority to make changes in the frequency, power, antenna height, or antenna directivity of an existing station within the area bounded by 39°15′ N on the north, 78°30′ W on the east, 37°30′ N on the south, and 80°30′ W on the west, shall notify the Interference Office, National Radio Astronomy Observatory, P.O. Box 2, Green Bank, West Virginia 24944. Telephone: (304) 456–2011. The notification shall be in writing and set forth the particulars of the proposed station, including the geographical coordinates of the antenna, antenna height, antenna directivity if any, proposed frequency, type of emission and power. The notification shall be made prior to, or simultaneously with, the filing of the application with the Commission. After receipt of such applications, the FCC will allow a period of 20 days for comments or objections in response to the notifications indicated. If an objection to the proposed operation is received during the 20-day period from the National Radio Astronomy Observatory for itself, or on behalf of the Naval Radio Research Observatory, the FCC will consider all aspects of the problem and

take whatever action is deemed appropriate.

(2) Any applicant for a new permanent base or fixed station authorization to be located on the islands of Puerto Rico, Desecheo, Mona, Vieques, and Culebra, or for a modification of an existing authorization which would change the frequency, power, antenna height, directivity, or location of a station on these islands and would increase the likelihood of the authorized facility causing interference, shall notify the Interference Office, Arecibo Observatory, HC3 Box 53995, Arecibo, Puerto Rico 00612, in writing or electronically, of the technical parameters of the proposal. Applicants may wish to consult interference guidelines, which will be provided by Cornell University. Applicants who choose to transmit information electronically should email to: *prcz@naic.edu.*

(i) The notification to the Interference Office, Arecibo Observatory shall be made prior to, or simultaneously with, the filing of the application with the Commission. The notification shall state the geographical coordinates of the antenna (NAD–83 datum), antenna height above ground, ground elevation at the antenna, antenna directivity and gain, proposed frequency and FCC Rule Part, type of emission, and effective radiated power.

(ii) After receipt of such applications, the Commission will allow the Arecibo Observatory a period of 20 days for comments or objections in response to the notification indicated. The applicant will be required to make reasonable efforts to resolve or mitigate any potential interference problem with the Arecibo Observatory and to file either an amendment to the application or a modification application, as appropriate. The Commission shall determine whether an applicant has satisfied its responsibility to make reasonable efforts to protect the Observatory from interference.

OMB Control Number: 3060–0188.

Title: Call Sign Reservation and Authorization System, FCC Form 380.

Form Number: FCC Form 380.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, Not-for-profit institutions; and State, local, or tribal government.

Number of Respondents and Responses: 1,600 respondents; 1,600 responses.

Estimated Hours per Response: 0.166–0.25 hours.

Frequency of Response: On occasion reporting requirements.

Total Annual Burden: 333 hours.

Total Annual Cost: $162,000.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 154(i) and 303 of the Communications Act of 1934, as amended.

Needs and Uses: The information collection requirements contained in 47 CFR 73.3550 provide that all requests for new or modified call signs be made via the on-line call sign reservation and authorization. The Commission uses an on-line system, FCC Form 380, for the electronic preparation and submission of requests for the reservation and authorization of new and modified call signs. Access to the call sign reservation and authorization system is made by broadcast licensees and permittees, or by persons acting on their behalf, via the internet's World Wide Web. This on-line, electronic call sign system enables users to determine the availability and licensing status of call signs; to request an initial, or change an existing, call sign; and to determine and submit more easily the appropriate fee, if any. Because all elements necessary to make a valid call sign reservation are encompassed within the on-line system, this system prevents users from filing defective or incomplete call sign requests. The electronic system also provides greater certitude, as a selected call sign is effectively reserved as soon as the user has submitted its call sign request. This electronic call sign reservation and authorization system has significantly improved service to all radio and television broadcast station licensees and permittees.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2026–22338 Filed 10–30–26; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

[FMC–2026–0298]

Renewal of Agency Information Collection Activities: Submission for OMB Review; Comment Requested; Ocean Transportation Intermediaries; 3072–0018

AGENCY: Federal Maritime Commission.

ACTION: Notice and request for comment.

SUMMARY: The Federal Maritime Commission (Commission or FMC) is giving public notice that the agency has submitted the continuing information collection listed below in this notice to the Office of Management and Budget (OMB) for approval extension, with revision, for Collection of Information 3072–0018 (Ocean Transportation Intermediaries). The public is invited to comment on this information collection pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before December 2, 2026.

ADDRESSES: *Comments should be submitted to:* (1) the Office of Management and Budget's Office of Information and Regulatory Affairs through the portal at *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection at *Reginfo.gov* by selecting ''Currently under Review—Open for Public Comments'' or by using the search function, and (2) the Commission through the Federal eRulemaking Portal at *www.regulations.gov* (FMC–2026–0298). If your material cannot be submitted to the addresses above, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

FOR FURTHER INFORMATION CONTACT: Dr. India Wright, (202) 523–5787 *bcl@fmc.gov.*

SUPPLEMENTARY INFORMATION: The Commission invites the general public and other Federal agencies to comment on any aspect of the continuing information collection listed in this notice, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). We are particularly interested in receiving comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Comments submitted in response to this notice will be included or summarized in our request for OMB approval of the relevant information collection. All comments are part of the public record and subject to disclosure. Please do not include any confidential or inappropriate material in your comments.

Previous Request for Comments

On August 11, 2026, the Commission published a notice and request for comment in the **Federal Register** (91 FR 51707, August 11, 2026) regarding the agency's request for approval from OMB for information collections as required by the Paperwork Reduction Act of

1995. During the 60-day period, the Commission received comments from Kalé Info Solutions USA and FMC Compliance Services. Both comments support the updates to the collection, including the proposed modernization. Some recommendations (Trusted Data Exchange Through Port and Cargo Community Systems and Digital Trade Facilitation Pilot), while valuable, are currently outside the scope of 46 CFR 515 and would require expanded collection to support the recommendations adequately, increasing burden.

Information Collections Open for Comment

Title: 46 CFR 515—Licensing, Financial Responsibility Requirements and General Duties for Ocean Transportation Intermediaries and Related Forms.

OMB Control Number: 3072–0018 (Expires November 30, 2026).

Form Numbers: FMC–18, FMC–48, FMC–48A, FMC–65, FMC–67, FMC–68, FMC–69, FMC–69A.

Abstract: Sections 40101–41309 of title 46 of the United States Code, as amended, provide that no person in the United States may advertise, hold oneself out, or act as an ocean transportation intermediary (OTI) unless that person holds a license issued by the Commission. The Commission shall issue an OTI license to any person that the Commission determines to be qualified by experience and character to act as an OTI. Further, no person may act as an OTI unless that person furnishes a bond, proof of insurance, or other surety in a form and amount determined by the Commission to insure financial responsibility. The Commission has implemented the legislative requirements in regulations contained in 46 CFR part 515, including in financial responsibility Forms FMC–48, FMC–67, FMC–68, and FMC–69, Optional Rider Forms FMC–48A and FMC–69A, its related license application Form FMC–18, and the related foreign-based unlicensed non-vessel-operating common carriers (NVOCCs) registration/renewal Form FMC–65.

Type of Review: Extension with change.

Current Actions: There are no changes to the questions asked or the type of information collected. The FMC–18 will remain an electronic form. The current electronic Form FMC–18 is a legacy system that requires the use of Microsoft Internet Explorer. In 2022, Microsoft ended support for Internet Explorer and has since directed users to Microsoft Edge, which offers a built-in ''IE mode'' for legacy site compatibility but requires the end user to go through a lengthy and sometimes confusing process to enable the feature. The new FMC systems will be implemented utilizing Microsoft Entra ID (Microsoft Entra) and ServiceNow PSDS (ServiceNow). Microsoft Entra is used to securely create and manage ID logins and ServiceNow will be the platform through which the external user will submit the data collected. Both Microsoft Entra and ServiceNow will also allow the use of modern, Chromium-based browsers like Google Chrome, Microsoft Edge, Firefox, and Safari. Forms FMC–48, FMC–48A, FMC–65, FMC–69 and FMC–69A will be accessed through ServiceNow and primarily be submitted through the automated electronic system but will remain as PDF forms available on the Commission's website. Forms FMC–67 and FMC–68 will continue to be available on the Commission's website as PDF forms and continue to be accepted through email or mail. To further reduce the burden, on amendment applications for Form FMC–18, the form will auto populate with the entity information previously submitted and vetted to reduce the burden of data input and human error from the external user. This same auto populate information will be available to external users that submit Forms FMC–48, FMC–48A, FMC–69 and FMC–69A to reduce the human error commonly associated with the submission of those forms.

Total estimated burden has been amended to reflect changes in Commission estimates.

Needs and Uses: The Commission uses information obtained under part 515 and through Form FMC–18 to determine the qualifications of OTIs and their compliance with 46 U.S.C. subtitle IV and FMC regulations, and to enable the Commission to discharge its duties under 46 U.S.C. subtitle IV by ensuring that OTIs maintain acceptable evidence of financial responsibility. If the collection of information were not conducted, there would be no basis upon which the Commission could determine if applicants are qualified for licensing. The Commission would also not be able to effectively assess the compliance of foreign-based, unlicensed NVOCCs without the required registration information.

Frequency: Ad hoc basis. This information is collected when applicants apply for a license or submit a registration, complete the triennial renewal, or when existing licensees or registrants change their application forms.

Type of Respondents: The types of respondents are persons desiring to obtain or maintain a license or registration to advertise, hold themselves out as, or act as an OTI. Under 46 U.S.C. subtitle IV, OTIs may be either an ocean freight forwarder, an NVOCC, or both.

Number of Annual Respondents: The Commission estimates a potential annual respondent universe of 9,611 entities. Due to an increase in the number of OTIs, the inclusion of Form FMC–65 Change submissions and recordkeeping requirements, the Commission estimates the number of responses as 19,046. The distribution of responses is as follows: 360 New FMC–18 filings; 280 FMC–18 Amendment filings; 1,780 OTI License Renewals; 6,406 FMC–48 and FMC–69 filings; 3 FMC–48A and FMC–69A filings, 744 FMC–65 registration filings; 1,531 FMC–65 Renewal filings; 471 FMC–65 Organizational Change filings; and 9,611 recordkeeping requirements. The Commission does not anticipate receiving any filings of Forms FMC–67 or FMC–68 based on experience in recent years and so the estimate for these forms is zero. These forms are included in this renewal to remain available to respondents when applicable.

Estimated Time per Response: The time per response to complete application Form FMC–18 New filings averages two (2) hours, Form FMC–18 Amendment filings averages one (1) hour, and to complete the triennial renewal is ten (10) minutes. The time to complete a financial responsibility form (FMC–48, FMC–48A, FMC–69, or FMC–69A) is ten (10) minutes. The time to complete a financial responsibility form (FMC–67, FMC–68) averages 20 minutes. The time to complete Form FMC–65 to submit, renew or report changes to a registration as a foreign based, unlicensed NVOCC averages ten (10) minutes.

Total Annual Burden: 720 person-hours (Form FMC–18, New) + 280 person-hours (Form FMC–18, Amended/Change in Organization) + 302.63 person-hours (OTI License Renewal) + 2,113.98 person-hours (Forms FMC–48, 67, 68, 69) + 0.51 person-hours (Forms FMC–48A, 69A) + 126.48 person-hours (Form FMC–65) + 260.27 (Form FMC–65 Renewal) + 80.07 (Form FMC–65, Organizational Changes) + 2,402.75 person-hours (Recordkeeping). Total burden equals 6,286.66 person-hours.

For the Commission.

David Eng,

Secretary.

[FR Doc. 2026–22350 Filed 10–30–26; 8:45 am]

BILLING CODE 6730–02–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, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than December 2, 2026.

A. Federal Reserve Bank of Minneapolis Mark Nagle, Assistant Vice President; 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291. Comments can also be sent electronically to *MA@mpls.frb.org:*

1. *C3 Holdings, Inc., Random Lake, Wisconsin;* to become a bank holding company by acquiring Northern Financial Corporation, and thereby indirectly acquiring Independence State Bank, both of Independence, Wisconsin.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–22333 Filed 10–30–26; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–26–0179]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Focus on Advancing Support and Transition with the Fragile X Online Registry with Accessible Database (FAST FORWARD)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on April 28, 2026, to obtain comments from the public and affected agencies. CDC received two related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Focus on Advancing Support and Transition with the Fragile X Online Registry with Accessible Database (FAST FORWARD)—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Fragile X Syndrome (FXS) is a genetic disorder caused by changes in a gene called fragile X messenger ribonucleoprotein 1 (FMR1). FMR1 usually makes a protein called Fragile X Messenger Ribonucleoprotein (FMRP) that is needed for brain development. People with FXS make little or no FMRP. FXS is the most prevalent known cause of inherited intellectual disability and the most common monogenic cause of autism. Physical features of FXS include a narrow face with prominent jaw and forehead and large ears. Medical features can include dental crowning, otitis media, sinus infections, sleep disorder, and strabismus; developmental features can include intellectual disability, motor delays, poor eye contact, repetitive behaviors, seizure disorder, speech-language disorder, and symptoms of attention deficit hyperactivity disorder. FXS is typically diagnosed in early childhood when physical, medical, and developmental features are more recognized. It is estimated that one in 7,000 males and one in 11,000 females have FXS.

The proposed data collection builds on and improves upon four previous CDC-funded data collection efforts focused on FXS. The first project (CDC–RFA–DD–07–003; 2008–2011) piloted an infrastructure to conduct data collection on people with FXS across multiple sites. The second project (CDC–RFA–DD–11–007; 2011–2015) developed and piloted the infrastructure for a registry and for longitudinal data collection. The third project (CDC–RFA–DD–15–003; 2015–2020) established the Fragile X Online Registry With Accessible Research Database (FORWARD), and the fourth project (CDC–RFA–DD–21–002; 2021–2026), which extended FORWARD to include Multiple Assessments for Research Characterization (FORWARD–MARCH) built on the foundation of the first two projects and continued data collection to conduct analyses to better characterize the natural history of FXS and meaningful outcome measures to improve the lives of people with FXS.

Congressional Language accompanying the 2026 Consolidated Appropriations Act funding for CDC's FXS activities encourages CDC to support additional strategies to promote earlier identification of children with FXS, to ensure populations with FXS conditions are being properly diagnosed and are made aware of available medical services, and support people with FXS and associated conditions and disorders across the lifespan.

This information collection request (ICR), consistent with Congressional intent, is developed to employ clinic-based enrollment of eligible participants aged 40 years old or younger with full mutation of FXS that attend clinics affiliated with the three U.S. sites funded for this project. Each participating clinic will recruit a minimum of 200 eligible persons with FXS for a total of 600 across all three sites. Information will be collected on diagnosis, co-occurring conditions and behaviors, communication, adaptive abilities, healthcare utilization and service needs, education, transition planning and experience, activities and social participation, future planning, caregiver supports, demographics, participant strengths, and other topics consistent with the goals of the project. Data will be collected through online caregiver surveys.

CDC requests OMB approval for an estimated 200 annual burden hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Parents/Caregivers	Survey	200	1	1

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2026–22329 Filed 10–30–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–27–1291]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Generic Information Collection Request for Cognitive Testing and Pilot Testing for the National Center for Chronic Disease Prevention and Health Promotion'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a Proposed Data Collection Submitted for Public Comment and Recommendations notice on March 9, 2026, to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Generic Information Collection Request for Cognitive Testing and Pilot Testing for the National Center for Chronic Disease Prevention and Health Promotion (OMB Control No. 0920–1291, Exp. 5/31/2026)—Reinstatement—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) established a Generic Clearance to support information collection for cognitive testing and pilot testing activities.

Information collections that support the Behavioral Risk Factor Surveillance System (BRFSS) and other NCCDPHP programs are expected to be the major focus of activity under this Generic Clearance. Additional information collections may also be considered for submission through this Generic Clearance if they are relevant to BRFSS and NCCDPHP programs or collaborations.

Cognitive testing and pilot testing are methodological procedures conducted to prepare for a large scale or key information collection. Cognitive and pilot testing activities are designed to improve information quality and the efficiency of information collection by addressing issues such as the use of new or existing survey questions, question formatting, survey protocols, data collection software systems and other related processes.

Cognitive testing is a technique used to clarify the meaning of survey questions and/or the response options for questions. Cognitive testing contributes to the understanding of the validity and reliability of questions used for a variety of public health purposes. Cognitive testing is conducted early in the process of considering questions for use in a survey or other information collection activity. This type of testing is usually conducted in a controlled setting, such as an office. Respondents participate in a discussion or interview with a trained interviewer and may respond individually or as members of focus groups.

Questions may undergo cognitive testing because they have not been used in previous surveys; for example, questions related to the emergence of a new public health concern (such as e-cigarettes). In addition, testing may be conducted on previously used questions to assess their use in a different information collection mode; for example, testing might be conducted to convert questions developed for a paper survey to an interview format or an electronic survey format; or testing might be conducted to identify issues specific to a subpopulation or language translation. Respondents are asked to review questions and/or surveys to discuss their impressions of the items under consideration, the questions, the response set, individual words within the question, or the focus of the questionnaire itself. Incentives may be offered to respondents who participate in the in-person phase of cognitive testing since these activities involve additional burden and inconvenience.

Pilot testing is used to determine whether methods or modes of data collection (such as phone or mail surveys, in-person interviews or online data collection) are appropriate and efficient ways of collecting data. Pilot testing may include testing of changes in sampling or contacting potential respondents.

The majority of participants in cognitive and pilot testing activities are expected to be adults >18 years of age. Information may be collected during the recruitment process to assist in the selection of respondents. Respondents may be recruited to take part in testing through online or newspaper advertisements. If the participants are not recruited to be present at a physical location, they may be called and recruited by telephone.

Cognitive and pilot testing are efficient means of identifying problems with questions and procedures prior to implementation of data collection. Thus, they are cost effective approaches to providing evidence on survey questionnaire performance. A consequence of cognitive and pilot testing is to maintain high levels of participation in the information collection process itself.

Initial response and burden estimates are based on anticipated information collection needs for the Generic Information Collection Request for Cognitive Testing and Pilot Testing for the National Center for Chronic Disease Prevention and Health Promotion, with an additional allocation for a variety of NCCDPHP programs and collaborators. Each information collection activity conducted through this Generic Clearance will be submitted to OMB for approval in a project-specific information collection request package that describes its purpose and methods.

Participation in cognitive and pilot testing is voluntary, but respondents will be encouraged to participate by explanations of the need for their input in the introduction of each survey. CDC requests OMB approval for an estimated 11,450 annual burden hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General U.S. Population or Selected Sub-population.	Screening for cognitive testing	2,500	1	15/60
	Screening for pilot testing	2,400	1	15/60
	Cognitive testing in person	1,500	1	60/60
	Cognitive testing by phone	1,500	1	45/60
	Cognitive testing by ABS/mail/web	600	1	60/60
	Pilot testing in person	1,000	1	30/60
	Pilot testing by phone	3,000	1	30/60
	Pilot testing by ABS/mail/web	10,000	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2026–22330 Filed 10–30–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10599]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is requesting that an information collection request revision for the *Review Choice Demonstration or Home Health Services* (CMS–10599/0938–1311) processed under the emergency clearance process associated with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA). Public harm is reasonably likely to occur if normal, non-emergency clearance procedures are followed. The approval of this data collection process is essential to ensure that the Review Choice Demonstration (RCD) for Home Health (HH) Services is expanded to California within the specified timeframe. A delay in the expansion means an extended time the public will be harmed through the continuation of significant fraud found in the traditional Medicare home health benefit in California through the waste of taxpayer money, a loss of funds from the Medicare Trust Funds that could have been used for truly needed care, paying for care that is never delivered, and beneficiaries potentially receiving non-medically necessary care.

Under the PRA, federal agencies are required to publish notice in the **Federal Register** concerning each proposed ICR. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this ICR including the necessity and utility of the proposed ICR for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by November 16, 2026.

ADDRESSES: When commenting, please reference the document identifier (CMS–10599) or OMB control number (0938–1311). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–10599/OMB Control Number 0938–1311, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following ICR. More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public: submit reports, keep records, or provide information to a third party. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Pre-Claim Review Demonstration For Home Health Services; *Use:* Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1(a)(1)(J)) authorizes the Secretary to ''develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act).'' Pursuant to this authority, the CMS seeks to develop and implement a Medicare demonstration project, which CMS believes will help assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring among Home Health Agencies (HHA) providing services to Medicare beneficiaries.

This revised demonstration helps assist in developing improved procedures for the identification, investigation, and prosecution of potential Medicare fraud. The demonstration helps make sure that payments for home health services are appropriate through either pre-claim or post payment review, thereby working towards the prevention and identification of potential fraud, waste, and abuse; the protection of Medicare Trust Funds from improper payments; and the reduction of Medicare appeals. CMS has implemented the demonstration in Illinois, Ohio, North Carolina, Florida, and Texas with the option to expand to other states in the Palmetto/JM jurisdiction. Under this demonstration, CMS offers choices for providers to demonstrate their compliance with CMS' home health policies. Providers in the demonstration states may participate in either 100 percent pre-claim review or 100 percent post payment review. These providers will continue to be subject to a review method until the HHA reaches the target affirmation or claim approval rate. Once an HHA reaches the target pre-claim review affirmation or post-payment review claim approval rate, it may choose to be relieved from claim reviews, except for a spot check of their claims to ensure continued compliance. Providers who do not wish to participate in either 100 percent pre-claim or post payment reviews have the option to furnish home health services and submit the associated claim for payment without undergoing such reviews; however, they will receive a 25 percent payment reduction on all claims submitted for home health services and may be eligible for review by the Recovery Audit Contractors.

The information required under this collection is required by Medicare contractors to determine proper payment or if there is a suspicion of fraud. Under the pre-claim review option, the HHA sends the pre-claim review request along with all required documentation to the Medicare contractor for review prior to submitting the final claim for payment. If a claim is submitted without a pre-claim review

decision on one file, the Medicare contractor will request the information from the HHA to determine if payment is appropriate. For the post payment review option, the Medicare contractor will also request the information from the HHA provider who submitted the claim for payment from the Medicare program to determine if payment was appropriate. *Form Number:* CMS–10599 (OMB control number: 0938–1311); *Frequency:* Frequently, until the HHA reaches the target affirmation or claim approval threshold and then occasionally; *Affected Public:* Private Sector (Business or other for-profits and Not-for-profits); *Number of Respondents:* 4,700; *Number of Responses:* 3,173,016; *Total Annual Hours:* 1,600,608. (For questions regarding this collection contact Jennifer McMullen (410) 786–7635.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–22297 Filed 10–30–26; 8:45 am]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–437]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 4, 2027.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier: __/OMB Control Number: __, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Inpatient Psychiatric Unit Criteria Work Sheet; *Use:* We request a reinstatement with change of the OMB approval for the CMS form approved under OMB Control number 0938–0358. We have made non-substantive formatting changes to section 1 of the CMS–437 form including providing separate data field for the name, street address, city, state and zip code for the Inpatient Psychiatric Unit (IPU). We also added new data fields for the CCN number and telephone number for the IPU. In section 2 we have updated the text of several CFR code sections for accuracy.

Medicare has several types of schedules with which payments are made to inpatient hospitals. Acute care hospitals are paid by Medicare using the Inpatient Prospective Payment System (IPPS). Hospital outpatient services are paid by Medicare using the Medicare Hospital Outpatient Prospective Payment System (HOPPS). Inpatient Psychiatric Facilities (IPFs) and Inpatient Psychiatric Units (IPUs) are paid by Medicare using the Inpatient Psychiatric Facility Prospective Payment System (IPU PPS).

For IPFs and IPUs to be paid by Medicare under the higher paying Inpatient Psychiatric Facility Prospective Payment System (IPF PPU), they must prove that they meet the requirements to be exempt from receiving payment from Medicare under the lower paying hospital IPPS. The CMS–437 form is used by IPUs to attest that they meet the necessary requirements that make them exempt from receiving Medicare payments under the lower hospital rate provided by the IPPS and instead are eligible to receive a higher payment rate under the IPU PPS.

New IPUs must submit an initial CMS–437 to CMS when they apply for participation in the Medicare program to request new IPPS excluded status. Thereafter, the existing IPUs are required to submit completed CMS–437 forms annually to maintain their IPPS exclusion status, as required by 42 CFR 412.25. The IPUs submit their completed CMS–437 form to the CMS Locations (formerly named CMS Regional Offices) via the applicable SAs.

Prior to November 2007, SA surveyors conducted onsite IPPS exclusion surveys to verify that the IPPS exclusion criteria were met by the facility. The SA surveyor completed the CMS–437 form prior to placing an IPU into IPPS excluded status. However, on November 5, 2007, CMS suspended the requirement for onsite IPPS exclusion surveys and instead began allowing IPUs to self-attest to meeting the IPPS exclusion criteria by completing and submitting the CMS–437 form. (See: Survey & Certification Memo 08–03, dated 11/05/2007). As a result, instead of having the SAs perform IPPS exclusion surveys, the IPUs are now required to complete the CMS–437 form annually as a self-attestation indicating they continue to meet the IPPS exclusion criteria. *Form Number:* CMS–437 (OMB control number: 0938–0358); *Frequency:* Annually; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 1,534; *Total Annual Responses:* 1,534; *Total Annual Hours:* 1,551. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

William N. Parham III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–22326 Filed 10–30–26; 8:45 am]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0517]

Proposed Information Collection Activity; Federal Fiscal Year (FFY) 2027 Child Care and Development Fund (CCDF) Quality Progress Report

AGENCY: Office of Child Care, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year reinstatement with changes to information collection: Child Care and Development Fund (CCDF) Quality Progress Report (QPR)—(Office of Management and Budget #0970–0517, expiration December 31, 2024).

DATES: Comments due January 4, 2027.

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The CCDF QPR annually collects information from states and territories to describe investments to improve the quality of care available for children from birth to age 13. This report is one of the primary oversight mechanisms for an estimated $4.2 billion in CCDF funding invested in overall quality improvement activities and $605 million in CCDF funding in fiscal year 2023 dedicated to improving the supply and quality of care for infants and toddlers. The report meets the requirements in the Child Care and Development Block Grant (CCDBG) Act of 2014 for Lead Agencies to submit an annual report that describes how quality funds were expended, including the activities carried out and the measures used to evaluate progress in improving the quality of child care programs and services.

Outcomes from the information collected will primarily be used to support program administration and oversight and inform technical assistance and support for states and territories.

The new form reduces duplication and the overall volume of information requested from states compared to prior years, and asks clearer, more specific questions with examples to better capture quantitative outcomes, while continuing to collect information that is required by law.

Respondents: State and Territory CCDF Lead Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
FFY 2027 CCDF Quality Progress Report	56	3	9.5	1,596	532
Estimated Total Annual Burden Hours					532

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 9858e(d).

Samantha L. Illangasekare,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–22279 Filed 10–30–26; 8:45 am]

BILLING CODE 4184–87–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/.*

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 Advisory Child Health and Human Development Council.

Date: June 7–8, 2027.

Open: June 07, 2027, 9:00 a.m. to 2:00 p.m.

Agenda: NICHD Director's Report; NIH Strategic Plan for Disability Health Research; Voice of the trainee; Presentation; Concept Clearance; Council Statement of Understanding.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 31 Center Drive Bethesda, MD 20892.

Meeting Format: In Person.

Closed: June 08, 2027, 2:00 p.m. to 5:00 p.m.

Agenda: Review of Applications, Closing remarks; Adjournment.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 31 Center Drive, Bethesda, MD 20892.

Meeting Format: In Person.

Contact Person: Joseph Gindhart, Ph.D., Deputy Director, Division of Extramural Activities, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2322, Bethesda, MD 20817, 301–435–6975, *joe.gindhart@nih.gov.*

Registration is not required to attend the open portion of this meeting.

Any interested person may file written comments with the committee by forwarding the 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.

In the interest of security, NIH has procedures at *https://security.nih.gov/visitors/Pages/visitor-campus-access.aspx* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility 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.

Information is also available on the Institute's/Center's home page: *https://www.nichd.nih.gov/about/advisory/council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: October 28, 2026.

Margaret N. Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–22319 Filed 10–30–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Catheter-Based Intramyocardial Ablation for Treating Ventricular Arrhythmia in a Human

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to AntaraCore, Systems, Inc., located in Dover, Delaware, to practice the inventions embodied in the patent applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development December 2, 2026 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michael Shmilovich, Esq., MS, CLP, Acting Director, phone number 301–435–5019 or *shmilovm@nih.gov.*

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective license to AntaraCore Systems, Inc.:

NIH Ref. No.	Patent No. or Application No.	Filing date	Title
E–017–2024–0–US–01	66/555,802	2/20/2024	Systems and Methods for Intramyocardial Ablation (VINTAGE).
E–017–2024–1–US–01	63/716,145	11/4/2024	Systems and Methods for an Ablation Catheter for Intramyocardial Ablation.
E–017–2024–2–US–01	63/716,158	11/4/2024	Systems and Methods for a Myocardial Accessor Catheter for Intramyocardial Ablation.
E–017–2024–1–PC–01	PCT/US2025/053823	11/3/2025	SYSTEMS and Methods for an Ablation Catheter for Intramyocardial Ablation.
E–017–2024–2–PC–01	PCT/US2025/053825	11/3/2025	SYSTEMS and Methods for a Myocardial Accessor Catheter for Intramyocardial Ablation.
E–017–2024–3–PC–01	PCT/US2025/016665	2/20/2025	Systems and Methods for Intramyocardial Ablation (Vintage).
E–017–2024–3–US–01	19/616,776	8/19/2026	Systems and Methods Intromyocardial Ablation (Vintage).
E–017–2024–3–EP–01	25711938.8	8/6/2026	Systems and Methods for Intromyocardial Ablation.
E–061–2022–0–PC–01	PCT/US2023/021238	5/5/2023	Systems and Method for Synchronous Circumferential Intramyocardial Resynchronization and Pacing.
E–061–2022–0–US–02	18/863,596	11/6/2024	Systems and Method for Synchronous Circumferential Intramyocardial Resynchronization and Pacing.
E–061–2022–0–IL–01	316835	11/5/2024	Systems and Method for Synchronous Circumferential Intramyocardial Resynchronization and Pacing.
E–061–2022–0–EP–01	23729551.4	11/3/2024	Systems and Method for Synchronous Circumferential Intramyocardial Resynchronization and Pacing.

The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective exclusive patent license territory may be worldwide and in a field of use limited to catheter-based intramyocardial ablation, for treating ventricular arrhythmia in a human.

This patent license covers two patent estates as shown above, namely the invention described in the E–017–2024 estate, and the invention described in the E–061–2022 estate. ''Intramural substrates'' are the crux of the clinical challenge addressed by the subject patent estates and the proposed field of use. Specifically, these intramural substrates are the electrically conducting and hard-to-reach arrhythmogenic tissue located within the depth of the myocardial wall—the mid-myocardium—rather than on the endocardial (inner) or epicardial (outer) surfaces. The inventions being exclusively licensed herein provide a catheter-based system and method to access these intramyocardium tissues, and a synchronous circumferential intramyocardial resynchronization and pacing (SCIRP) system intended to improve cardiac resynchronization therapy. Both of these inventions together provide a new and improved device, system and method to enable electrophysiologists to access and treat arrhythmogenic intramural substrates located within the ventricular myocardial wall, which currently is not systematized.

The invention described in E–017–2024, for which we have 3 provisional applications, 3 PCT applications, a pending U.S. national stage application and a pending European national stage application, covers a catheter-based system and method for performing ablation directly within the intramyocardium and particularly targeting ventricular tachycardia that is otherwise difficult to reach using existing ablation devices and methods. The system, referred to as VINTAGE (Ventricular Intramyocardial Navigation for Tachycardia Ablation Guided by Electrograms), principally uses a small flexible ablation microcatheter that tracks coaxially over a steerable, electrically insulated guidewire. Proximal to the catheter tip are mapping electrodes and a conductive ablation electrodes with perforations that can elute irrigants directly into the surrounding myocardial tissue. The physician navigates to the desired deep target using fluoroscopy, ultrasound, electroanatomic mapping and/or electrogram-based depth navigation (EDEN); once the ablation electrode reaches the target, irrigant is delivered through its openings and radiofrequency energy applied while irrigation continues, producing a controlled lesion in the abnormal tissue responsible for the arrhythmia. The irrigant may be an electrolyte acting to alter the electrical and/or physicochemical characteristics of the target myocardial substrate (such as increasing ionic conductivity), act as a thermo-conductive ''virtual ablation electrode'', or may alternatively be a caustic agent intended to effect adjunctive chemoablation.

The invention described in E–061–2022, for which we have a PCT application, a pending U.S. national stage application, a pending Isreali national stage application and a pending European application, covers a synchronous circumferential intramyocardial resynchronization and pacing (SCIRP) system intended to improve cardiac resynchronization therapy by placing a flexible, multi-electrode pacing lead inside the ventricular myocardium rather than on an endocardial or epicardial surface. The lead contains multiple small ring electrodes and is implanted along a curved trajectory that can extend at least 180 degrees—and potentially substantially around the circumference—of the left ventricle, including through the interventricular septum near the His bundle or left bundle branch. Of particular import is the ability to introduce these electrodes into the ventricular intramural spaces through a navigated guidewire introduced through the myocardium using electrograms or pace mapping, and leaving the electrode-bearing lead embedded in the heart muscle. A multichannel pulse generator then energizes selected myocardium implanted electrodes in unipolar or bipolar configurations directly stimulate ventricular muscle and, where appropriately positioned, the native His/LBB conduction system. In essence, instead of trying to resynchronize the ventricle from a few conventional surface pacing sites, the invention creates an intramyocardial array of pacing sites distributed around the ventricle, intended to re homogenize synchronization.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within thirty (30) days from the date of this published notice, the NHLBI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act,* 5 U.S.C. 552.

Dated: October 28, 2026.

Michael Shmilovich,

Acting Director, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development, National Institutes of Health.

[FR Doc. 2026–22339 Filed 10–30–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) provides notice of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

FOR FURTHER INFORMATION CONTACT: Anastasia Flanagan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–2600 (voice); *Anastasia.Flanagan@samhsa.hhs.gov* (email).

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) publishes a notice listing all HHS-certified laboratories and Instrumented Initial Testing Facilities (IITFs) in the **Federal Register** monthly, in accordance with Section 9.19 of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and Section 9.17 of the Mandatory Guidelines using Oral Fluid. If any laboratory or IITF certification is

suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at *https://www.samhsa.gov/workplace/drug-testing-resources/certified-lab-list.*

The Mandatory Guidelines using Urine were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); January 23, 2017 (82 FR 7920); and on October 12, 2023 (88 FR 70768).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020, and subsequently revised in the **Federal Register** on October 12, 2023 (88 FR 70814).

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for Federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using Urine and/or Oral Fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards.

HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid effective October 10, 2023 (88 FR 70814), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens:

At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

HHS-Certified Instrumented Initial Testing Facilities Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine effective February 1, 2024 (88 FR 70768), the following HHS-certified IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190, (Formerly: Gamma-Dynacare Medical Laboratories), *Note: DOT does not allow IITFs to test DOT-regulated specimens.*

HHS-Certified Laboratories Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine effective February 1, 2024 (88 FR 70768), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

Desert Tox, LLC, 5425 E Bell Rd, Suite 125, Scottsdale, AZ, 85254, 602–457–5411/623–748–5045

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

Dynacare, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630, (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

Laboratory Corporation of America Holdings, 7207 N Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

MedTox Laboratories, Inc., 402 W County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088, Testing for Veterans Affairs (VA) Employees Only

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only

Carlos Castillo,

Public Health Analyst, OAS.

[FR Doc. 2026–22321 Filed 10–30–26; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0120]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Application for Free Training for Civics and Citizenship Teachers of Adults; Civics and Citizenship Toolkit

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting 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. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until December 2, 2026.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2011–0001. All submissions received must include the OMB Control Number 1615–0120 in the body of the letter, the agency name and Docket ID USCIS–2011–0001.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on January 7, 2026, at 91 FR 514, allowing for a 60-day public comment period. USCIS did receive comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2011–0001 in the search box. Comments must be submitted in English, or an English translation must be provided. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Free Training for Civics and Citizenship of Adults; Civics and Citizenship Toolkit.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* G–1190, G–1515; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. This information is necessary to register for civics and citizenship of adults training and to obtain a civics and citizenship toolkit.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection Form G–1190 is 2,500 and the estimated hour burden per response is 0.083 hours. The estimated total number of respondents for the information collection Form G–1515 is 1,200 and the estimated hour burden per response is responses is 0.166 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 407 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $0. The registration occurs electronically which eliminates any cost for postage, and no other costs are incurred by the respondent.

Dated: October 29, 2026

John R. Pfirrmann-Powell,

Acting Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2026–22320 Filed 10–30–26; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[4820000549]

Exxon Valdez Oil Spill Public Advisory Committee; Call for Nominations

AGENCY: Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: The Department of the Interior is soliciting nominations for the *Exxon Valdez* Oil Spill Public Advisory Committee (Committee). This Committee advises the *Exxon Valdez* Oil Spill Trustee Council (Trustee Council) on decisions related to the planning, evaluation, allocation of funds, and conduct of injury assessment and restoration activities related to the T/V *Exxon Valdez* oil spill of March 1989.

DATES: All nominations must be received by February 1, 2027.

ADDRESSES: Send nomination packages via email to Shiway Wang, Executive Director, *Exxon Valdez* Oil Spill Trustee Council, at *shiway.wang@alaska.gov.* Also please copy Joy Maglaqui, Executive Assistant, on any email correspondence at *joy.maglaqui@alaska.gov.*

FOR FURTHER INFORMATION CONTACT: Lisa Fox, Department of the Interior, Office of Environmental Policy and Compliance, telephone number: (907) 227–3783; email: *lisa_fox@ios.doi.gov.* Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services.

Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Committee was created pursuant to Paragraph V.A.4 of the Memorandum of Agreement and Consent Decree entered into by the United States of America and the State of Alaska on August 27, 1991, and approved by the United States District Court for the District of Alaska in settlement of *United States of America* v. *State of Alaska,* Civil Action No. A91–081 CV. The Committee advises the Trustee Council on matters relating to decisions on injury assessment, restoration activities, or other use of natural resource damage recoveries obtained by the government. The Trustee Council consists of representatives of the U.S. Department of the Interior, U.S. Department of Agriculture, National Oceanic and Atmospheric Administration, Alaska Department of Fish and Game, Alaska Department of Environmental Conservation, and Alaska Department of Law.

The Committee consists of 10 members to reflect balanced representation from each of the following principal interests: aquaculture/mariculture, commercial fishing, commercial tourism, conservation/environmental, native landownership, recreation, subsistence use, science/technology, sport hunting/fishing, and public-at-large.

We are soliciting nominations for five positions that represent science and technology, native landownership, subsistence use, recreation, and public-at-large interests. The Committee members will be selected and appointed by the Secretary of the Interior to serve a four-year term.

Nomination Process: Nominations for membership may be submitted by any source. Nominations should include a résumé providing an adequate description of the nominee's qualifications, including information that would enable the Department of the Interior to evaluate the nominee's ability to meet Committee membership requirements and to contact a potential member.

Authority: 5 U.S.C. Ch. 10.

Lisa Fox,

Regional Environmental Officer, Office of Environmental Policy and Compliance.

[FR Doc. 2026–22290 Filed 10–30–26; 8:45 am]

BILLING CODE 4334–21–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–CONC–43450: PPWOBSADC0, PPMVSCS1Y.Y00000]

Notice of Intent To Extend and Continue Concession Contracts and Award a Temporary Concession Contract

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service (NPS) announces its intent to extend, continue, and award concession contracts in accordance with 36 CFR part 51. To avoid interruptions in visitor services while new long-term contracts are developed and awarded, the NPS intends to extend certain existing contracts, continue others, and issue one temporary contract to maintain essential services until a new competitive contract becomes effective. These administrative actions ensure that visitor services remain uninterrupted across the affected park units.

DATES: The National Park Service intends that the concession contract extensions, continuations, and temporary concession contract will be effective on the dates shown in the tables below, as applicable.

FOR FURTHER INFORMATION CONTACT: Kurt Rausch, Program Chief, Commercial Services Program, National Park Service, 1849 C Street NW, Mail Stop 2410, Washington, DC 20240; Telephone: 202–513–7156.

SUPPLEMENTARY INFORMATION: Under 36 CFR 51.23 the NPS proposes to extend each contract listed in Table 1 until the date shown in the ''Extension Expiration Date'' column or until the effective date of a new contract, whichever comes first. The NPS has determined that the proposed extensions are necessary to avoid an interruption of visitor services and has taken all reasonable and appropriate steps to consider alternatives to avoid such an interruption. The extension of the existing contracts does not confer or affect any rights with respect to the award of new contracts.

The concession contracts listed in Table 2 below have been extended for the maximum time allowable under 36 CFR 51.23. Under the provisions of the existing contracts and pending the issuance of prospectuses and the completion of the public solicitation process to award new concession contracts, the NPS intends to continue the existing contracts until the date shown in the ''Continuation Expiration Date'' column or until the effective date of a new contract, whichever comes first. The continuation of the existing contracts does not confer or affect any rights with respect to the award of new concession contracts.

The NPS proposes awarding a temporary concession contract, in accordance with 36 CFR 51.24(a), to provide the visitor services currently provided under the contract listed in Table 3 below. The temporary contract will have a term not to exceed one year and will be awarded to a qualified person. The National Park Service anticipates that the temporary contract will be effective on the date shown in the ''Effective Date'' column. This notice is not a request for proposals.

The publication of this notice reflects the intent of the National Park Service but does not bind the National Park Service to extend, continue, or award any of the contracts listed below.

TABLE 1—CONCESSION CONTRACTS EXTENDED UNTIL THE EXPIRATION DATE SHOWN OR UNTIL THE EFFECTIVE DATE OF A NEW CONTRACT, WHICHEVER COMES FIRST

Park unit	CONCID	Concessioner	Extension effective date	Extension expiration date
Bighorn Canyon NRA	BICA007–17	Crow Tribe of Indians	1/1/2027	12/31/2027
Blue Ridge Parkway	BLRI003–15	Parkway Inn, Inc	3/1/2027	2/28/2029
Bryce Canyon NP	BRCA002–17	Bryce-Zion Trail Rides Inc	1/1/2027	12/31/2027
Canyonlands NP	CANY022–16	Moab Scenic Adventures, LLC	1/1/2027	12/31/2027
Canyonlands NP	CANY024–16	Myke Hughes, Inc	1/1/2027	12/31/2027
Canyonlands NP	CANY025–16	NAVTEC Expeditions, Inc	1/1/2027	12/31/2027
Curecanti NRA	CURE001–16	Elk Creek Marina, LLC	1/1/2027	12/31/2027
Everglades NP	EVER102–17	Gator Park, Inc	9/1/2027	8/31/2029
Everglades NP	EVER103–17	Everglades Safari, Inc	9/1/2027	8/31/2029

TABLE 1—CONCESSION CONTRACTS EXTENDED UNTIL THE EXPIRATION DATE SHOWN OR UNTIL THE EFFECTIVE DATE OF A NEW CONTRACT, WHICHEVER COMES FIRST—Continued

Park unit	CONCID	Concessioner	Extension effective date	Extension expiration date
Glacier Bay NP&P	GLBA001–15	Aramark Sports and Entertainment Services, LLC.	10/1/2027	9/30/2028
Great Basin NP	GRBA001–17	Donald Landon Crouch	3/1/2027	2/29/2028
Great Smoky Mountains NP	GRSM001–15	Tsiyahi, LLC	1/1/2027	12/31/2027
Great Smoky Mountains NP	GRSM004–16	National and State Park Concessions Riding Stables, Inc.	1/1/2027	12/31/2027
Great Smoky Mountains NP	GRSM007–17	Loftis Family Enterprises Incorporated	1/1/2027	12/31/2027
Gulf Islands NS	GUIS001–15	Pan Isle, Inc	1/1/2027	12/31/2027
Haleakalā NP	HALE002–18	Valley Isle Excursions, Inc	1/1/2028	12/31/2028
Haleakalā NP	HALE003–18	Skyline Eco-Adventures, LLC	1/1/2028	12/31/2028
Haleakalā NP	HALE004–18	Polynesian Adventure Tours, LLC	1/1/2028	12/31/2028
Katmai NP&P	KATM001–16	Katmailand, Inc	1/1/2027	12/31/2028
Lake Clark NP&P	LACL901–17	Arno Krumm	1/1/2027	12/31/2027
Lake Clark NP&P	LACL902–17	Timothy Winslow	1/1/2027	12/31/2027
Lake Clark NP&P	LACL903–17	Timothy Winslow	1/1/2027	12/31/2027
Lake Mead NRA	LAKE004–13	ARAMARK Sports and Entertainment Services, LLC.	12/6/2026	12/5/2027
Mesa Verde NP	MEVE001–15	Aramark Sports and Entertainment Services, LLC.	1/1/2027	12/31/2028
Olympic NP	OLYM008–16	Olympic Peninsula Hospitality, LLC	1/1/2028	12/31/2029
Sequoia & Kings Canyon NPs	SEKI004–16	DNC Parks & Resorts at Sequoia, Inc	11/1/2028	10/31/2029
Sequoia & Kings Canyon NPs	SEKI006–13	DNC Parks & Resorts at Kings Canyon, Inc.	11/1/2028	10/31/2029
White Sands NP	WHSA001–15	White Sands Trading, LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL102–16	Adventures Outfitting, LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL103–16	Triangle X Ranch	1/1/2027	12/31/2027
Yellowstone NP	YELL105–16	Absaroka Beartooth Outfitters, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL106–16	Wildland Llamas, LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL107–16	Boulder Basin Outfitters, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL108–16	Sunrise Pack Station, L.L.C	1/1/2027	12/31/2027
Yellowstone NP	YELL110–16	Mountain Sky Guest Ranch, LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL115–16	Yellowstone Horse and Mule LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL117–16	Black Mountain Outfitters, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL118–16	Yellowstone Mountain Guides, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL120–16	Slough Creek Outfitters, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL121–16	Kenneth Sinay Company	1/1/2027	12/31/2027
Yellowstone NP	YELL122–16	Ronald D Good	1/1/2027	12/31/2027
Yellowstone NP	YELL123–16	Duenas Ranch and Outfit, LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL124–16	Jake's Horses, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL125–16	Cache Creek Outfitters, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL126–16	Sunrise Pack Station, L.L.C	1/1/2027	12/31/2027
Yellowstone NP	YELL127–16	Thomas M. Heintz	1/1/2027	12/31/2027
Yellowstone NP	YELL130–16	Skyline Guest Ranch and Guide Service, Inc.	1/1/2027	12/31/2027
Yellowstone NP	YELL131–16	Hell's A' Roarin' Outfitters, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL132–16	Nine Quarter Circle Ranch, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL137–16	R. K. Miller's Wilderness Pack Trips Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL138–16	AC Enterprises, LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL140–16	Black Otter, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL141–16	Yellowstone Mountain Guides, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL146–16	Yellowstone Mountain Guides, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL147–16	Yellowstone Mountain Guides, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL148–16	Dry Ridge Outfitters, LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL156–16	Heart 6 Ranch LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL157–16	Horsetrack Outfitters LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL158–16	Wilderness Trails, Inc	1/1/2027	12/31/2027
Yellowstone NP	YELL159–16	Hidden Creek Outfitters, LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL162–16	Rand Creek Outfitters, LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL164–16	TNT Ranch, LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL165–16	The Lone Mountain Ranch Incorporated	1/1/2027	12/31/2027
Yellowstone NP	YELL166–16	E.R. Ranch Corporation	1/1/2027	12/31/2027
Yellowstone NP	YELL168–16	The Wildland Trekking Company, LLC	1/1/2027	12/31/2027
Yellowstone NP	YELL170–16	Rockin' HK Outfitters Inc	1/1/2027	12/31/2027
Zion NP	ZION001–15	Bryce-Zion Trail Rides Inc	1/1/2027	12/31/2027

TABLE 2—CONCESSION CONTRACTS CONTINUED UNTIL THE EXPIRATION DATE SHOWN OR UNTIL THE EFFECTIVE DATE OF A NEW CONTRACT, WHICHEVER COMES FIRST

Park unit	CONCID	Concessioner	Continuation effective date	Continuation expiration date
Glen Canyon NRA	GLCA002–88	Aramark Sports and Entertainment Services, LLC.	1/1/2027	12/31/2027
Glen Canyon NRA	GLCA003–69	Aramark Sports and Entertainment Services, LLC.	1/1/2027	12/31/2027
Lake Mead NRA	LAKE002–82	LMNRA Guest Services, LLC	1/1/2027	12/31/2027
Lake Mead NRA	LAKE005–97	LMNRA Guest Services, LLC	1/1/2027	12/31/2027
Lake Mead NRA	LAKE006–74	Las Vegas Boat Harbor, Inc	1/1/2027	12/31/2027
Lake Mead NRA	LAKE009–88	LMNRA Guest Services, LLC	1/1/2027	12/31/2027
National Mall and Memorial Parks	NACC003–86	Guest Services, Inc	1/1/2027	12/31/2027

TABLE 3—TEMPORARY CONCESSION CONTRACT

Park unit	CONCID	Services	Effective date
Everglades NP	EVER004	Interpretive Tram Tours, Bicycle Rentals, Retail, Bicycle/ Hiker Pickup.	1/1/2027

Nicole Woody,

Acting Associate Director, Business Services.

[FR Doc. 2026–22325 Filed 10–30–26; 8:45 am]

BILLING CODE 4312–53–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–811 and 731–TA–1813 (Preliminary)]

Shopping Carts and Parts Thereof From China; Institution of Antidumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–811 and 731–TA–1813 (Preliminary) pursuant to the Tariff Act of 1930 to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of shopping carts and parts thereof from China, provided for in subheading 8716.80.50 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of China. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by December 14, 2026. The Commission's views must be transmitted to Commerce within five business days thereafter, or by December 21, 2026.

DATES: October 28, 2026.

FOR FURTHER INFORMATION CONTACT: Kristina Lara ((202) 205–3386), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to petitions filed on October 28, 2026, by Precision Wire Products, Inc., Commerce, California and Wanzl North America, Denver, North Carolina.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Office of Investigations will hold a staff conference in connection with the preliminary phase of these investigations beginning at 9:30 a.m. on

November 18, 2026. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before noon on November 16, 2026. Please provide an email address for each conference participant in the email. Information on conference procedures, format, and participation, including guidance for requests to appear as a witness via videoconference, will be available on the Commission's Public Calendar (Calendar (USITC) | United States International Trade Commission). A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

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.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before 5:15 p.m. on November 23, 2026, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than 4:00 p.m. on November 17, 2026. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations 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 these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: October 28, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22281 Filed 10–30–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–660–661 and 731–TA–1543–1545 (Review)]

Utility Scale Wind Towers From India, Malaysia, and Spain; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the countervailing duty orders on utility scale wind towers from India and Malaysia and the antidumping duty orders on utility scale wind towers from India, Malaysia, and Spain would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: October 5, 2026.

FOR FURTHER INFORMATION CONTACT: Laurel Schwartz—(202) 205–2398), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION:

Background.—On October 5, 2026, the Commission determined that the domestic interested party group response to its notice of institution (91 FR 40578, July 2, 2026) of the subject five-year reviews was adequate and that the domestic interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.[1] Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Act (19 U.S.C. 1675(c)(3)).[2]

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report.—A staff report containing information concerning the subject matter of the reviews has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for these reviews on January 7, 2027. A public version will be issued thereafter, pursuant to § 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in § 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,[3] and any party other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before January 14, 2027 and may not contain

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

[2] Commissioner Samuel T. Negatu did not participate.

[3] The Commission has found the response submitted on behalf of the Wind Tower Trade Coalition and Ventower Industries LLC to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by January 14, 2027. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures*, available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*, elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.62 of the Commission's rules.

By order of the Commission.
Issued: October 28, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22311 Filed 10–30–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1550–1553 (Review)]

Polyester Textured Yarn From Indonesia, Malaysia, Thailand, and Vietnam; Institution of Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to the Tariff Act of 1930, as amended, to determine whether revocation of the antidumping duty orders on polyester textured yarn from Indonesia, Malaysia, Thailand, and Vietnam would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted November 2, 2026. To be assured of consideration, the deadline for responses is December 2, 2026. Comments on the adequacy of responses may be filed with the Commission by January 12, 2027.

FOR FURTHER INFORMATION CONTACT: Judson Monson (202–205–3314), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On December 14, 2021, the Department of Commerce (''Commerce'') issued antidumping duty orders on imports of polyester textured yarn from Indonesia, Malaysia, Thailand, and Vietnam (86 FR 71031). The Commission is conducting reviews pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR part 201, subparts A and B, and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct full or expedited reviews. The Commission's determinations in any expedited reviews will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to these reviews:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by Commerce.

(2) The *Subject Countries* in these reviews are Indonesia, Malaysia, Thailand, and Vietnam.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determinations, the Commission defined a single *Domestic Like Product* as polyester textured yarn, that is coextensive with the scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determinations, the Commission defined the *Domestic Industry* as all producers of polyester textured yarn.

(5) The *Order Date* is the date that the antidumping duty orders under review became effective. In these reviews, the *Order Date* is December 14, 2021.

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has

advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post-employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to § 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is on or before 5:15 p.m. on December 2, 2026. Pursuant to § 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is on or before 5:15 p.m. on January 12, 2027. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings. Also, in accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

No response to this request for information is required if a currently valid Office of Management and Budget (''OMB'') number is not displayed; the OMB number is 3117 0016/USITC No. 26–5–710, expiration date July 31, 2029. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to § 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to § 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determinations in the reviews.

Information To Be Provided in Response to This Notice of Institution: If you are a domestic producer, union/worker group, or trade/business association; import/export *Subject Merchandise* from more than one *Subject Country;* or produce *Subject Merchandise* in more than one *Subject Country,* you may file a single response. If you do so, please ensure that your response to each question includes the information requested for each pertinent *Subject Country.* As used below, the term ''firm'' includes any related firms.

Those responding to this notice of institution are encouraged, but not required, to visit the USITC's website at *https://usitc.gov/reports/response_noi_worksheet,* where one can download and complete the ''NOI worksheet'' Excel form for the subject proceeding, to be included as attachment/exhibit 1 of your overall response.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how, including whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise,* a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty orders on the *Domestic Industry* in

general and/or your firm/entity specifically. In your response, please discuss the various factors specified in § 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in § 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in each *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries since the *Order Date.*

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2025, except as noted (report quantity data in pounds and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2025 (report quantity data in pounds and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms, which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. commercial shipments of *Subject Merchandise* imported from each *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from each *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2025 (report quantity data in pounds and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms, which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in each *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in each *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in each *Subject Country* since the *Order Date,* and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in each *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

By order of the Commission.

Issued: October 27, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22349 Filed 10–30–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 701–TA–665 and 731–TA–1557 (Review)]

Certain Mobile Access Equipment (MAE) and Subassemblies Thereof From China; Institution of Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to the Tariff Act of 1930, as amended, to determine whether revocation of the antidumping and countervailing duty orders on certain mobile access equipment (''MAE'') and subassemblies thereof from China would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted November 2, 2026. To be assured of consideration, the deadline for responses is December 2, 2026. Comments on the adequacy of responses may be filed with the Commission by January 12, 2027.

FOR FURTHER INFORMATION CONTACT: Richard Whiting (202–205–2039), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On December 10, 2021, the Department of Commerce (''Commerce'') issued a countervailing duty order on imports of MAE and subassemblies from China (86 FR 70439). Additionally, on April 14, 2022, Commerce issued an antidumping duty order on imports of MAE and subassemblies from China (87 FR 22190). The Commission is conducting reviews pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR part 201, subparts A and B, and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct full or expedited reviews. The Commission's determinations in any expedited reviews will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to these reviews:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by Commerce.

(2) The *Subject Country* in these reviews is China.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determinations, the Commission defined a single *Domestic Like Product* as finished MAE and MAE subassemblies coextensive with the scope of the investigation.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determinations, the Commission defined the *Domestic Industry* as all producers of finished MAE and subassemblies and firms that conducted activities involved in the assembly of MAE subassemblies into finished MAE.

(5) The *Order Dates* are the dates that the orders under review became effective. In the review concerning the countervailing duty order on imports of MAE from China, the *Order Date* is December 10, 2021. In the review concerning the antidumping duty order on imports of MAE from China, the *Order Date* is April 14, 2022.

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post-employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person

submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to § 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is on or before 5:15 p.m. on December 2, 2026. Pursuant to § 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is on or before 5:15 p.m. on January 12, 2027. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings. Also, in accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

No response to this request for information is required if a currently valid Office of Management and Budget (''OMB'') number is not displayed; the OMB number is 3117 0016/USITC No. 26–5–709, expiration date July 31, 2029. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to § 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to § 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determinations in these reviews.

Information To Be Provided in Response to This Notice of Institution: As used below, the term ''firm'' includes any related firms.

Those responding to this notice of institution are encouraged, but not required, to visit the USITC's website at *https://usitc.gov/reports/response_noi_worksheet,* where one can download and complete the ''NOI worksheet'' Excel form for the subject proceeding, to be included as attachment/exhibit 1 of your overall response.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how, including whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise,* a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping and countervailing duty orders on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in § 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in § 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries since the *Order Dates.*

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2025, except as noted (report quantity data in short tons and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2025 (report quantity data in short tons and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping and/or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2025 (report quantity data in short tons and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping and/or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* since the *Order Dates*, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

By order of the Commission.

Issued: October 27, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22348 Filed 10–30–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–649 and 731–TA–1523 (Review)]

Twist Ties From China; Scheduling of Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of full reviews pursuant to the Tariff Act of 1930 to determine whether revocation of the countervailing and antidumping duty orders on twist ties from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. The Commission has determined to exercise its authority to extend the review period by up to 90 days.

DATES: October 28, 2026.

FOR FURTHER INFORMATION CONTACT: Peter Stebbins (202–205–2039), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On June 5, 2026, the Commission determined that responses to its notice of institution of the subject five-year reviews were such that full reviews should proceed (91 FR 37423, June 23, 2026); accordingly, full reviews

are being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's website.

Participation in these reviews and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in these reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of these reviews need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to these reviews.

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

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.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these reviews available to authorized applicants under the APO issued in the review, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the review. A party granted access to BPI following publication of the Commission's notice of institution of these reviews need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in these reviews will be placed in the nonpublic record on February 16, 2027, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.—The Commission will hold an in-person hearing in connection with these reviews beginning at 9:30 a.m. on March 9, 2027. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before 5:15 p.m. on March 3, 2027. Any requests to appear as a witness via videoconference must be included with your request to appear. Requests to appear via videoconference must include a statement explaining why the witness cannot appear in person; the Chairman, or other person designated to conduct the review, may in their discretion for good cause shown, grant such a request. Requests to appear as remote witness due to illness or a positive COVID–19 test result may be submitted by 3 p.m. the business day prior to the hearing. Further information about participation in the hearing will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.*

A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference, if deemed necessary, to be held at 9:30 a.m. on March 4, 2027. Parties shall file and serve written testimony and presentation slides in connection with their presentation at the hearing by no later than noon on March 8, 2027. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony in camera no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to these reviews may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is 5:15 p.m. on March 1, 2027. Parties shall also file written testimony in connection with their presentation at the hearing, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is 5:15 p.m. on March 22, 2027. In addition, any person who has not entered an appearance as a party to these reviews may submit a written statement of information pertinent to the subject of these reviews on or before 5:15 p.m. on March 22, 2027. On April 16, 2027, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before 5:15 p.m. on April 20, 2027, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to these reviews must be served on all other parties to these reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

The Commission has determined that these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend these reviews period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: October 28, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22282 Filed 10–30–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1454]

Certain Wi-Fi Routers, Wi-Fi Devices, Mesh Wi-Fi Network Devices and Components Thereof; Notice of a Commission Determination To Review-in-Part a Final Initial Determination Finding a Violation; Extension of the Target Date for Completion of the Investigation; Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined to review-in-part a final initial determination (''FID'') of the presiding administrative law judge (''ALJ''). The Commission requests briefing from the parties on certain issues under review, as set forth in this notice. The Commission also requests written submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below. The Commission has also determined to extend the target date for completion of the investigation to January 14, 2027.

FOR FURTHER INFORMATION CONTACT: Jonathan D. Link, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3103. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 23, 2025, based on a complaint filed on behalf of Estelgia, LLC (''Estelgia'') of Dover, Delaware. 90 FR 26608–09 (June 23, 2025). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain Wi-Fi routers, Wi-Fi devices, mesh Wi-Fi network devices and components thereof by reason of the infringement of certain claims of U.S. Patent Nos. 7,936,714 (''the '714 patent''); 11,246,016 (''the '016 patent''); 10,735,973 (''the '973 patent''); 10,531,518 (''the '518 patent''); 9,775,164 (''the '164 patent''); and 9,277,591 (''the '591 patent''). The complaint, as supplemented, further alleges that an industry in the United States exists as required by the applicable Federal Statute. The Commission's notice of investigation names seven (7) respondents: Linksys Holdings, Inc. and Linksys USA, Inc. (collectively, ''Linksys Respondents'') of Irvine, CA; ASUStek Computer Inc. of Taipei City, Taiwan and ASUS Computer International of Fremont, CA (collectively ''ASUS''); D-Link Corporation of Taipei, Taiwan and D-Link Systems, Inc. of Irvine, CA (collectively, ''D-Link Respondents''); and Plume Design Inc. (''Plume'') of Palo Alto, CA. *Id.* at 26609. The Office of Unfair Import Investigations (''OUII'') is also named as a party in this investigation.

On December 19, 2025, the Commission terminated the Linksys Respondents from the investigation based on a settlement agreement. *See* Order No. 12 (Nov. 25, 2025), *unreviewed by* Comm'n Notice (Dec. 19, 2025).

On January 29, 2026, the Commission terminated claim 14 of the '714 patent; claims 1–5, 7–17, and 20 the '016 patent; claims 2, 3, 5–7, 10, and 13 of the '973 patent; claims 12 and 13 of the '518 patent; claims 2, 4, 5, 7, 9, 11, 13–15, 17–21, 23, 25, 27, 28, and 30–33 of the '164 patent; and claims 1, 2, 5, 9, 10, 12, and 14–20 of the '591 patent from the investigation based on the withdrawal of allegations by Estelgia. *See* Order No. 17 (Jan. 6, 2026), *unreviewed by* Comm'n Notice (Jan. 29, 2026).

On March 17, 2026, the Commission terminated the '016, the '518, the '164, and the '591 patents from the investigation based on the withdrawal of allegations by Estelgia. *See* Order No. 20 (Feb. 19, 2026), *unreviewed by* Comm'n Notice (Mar. 17, 2026).

On April 27, 2026, the Commission terminated the D-Link Respondents from the investigation based on a consent order. *See* Order No. 30 (Mar. 26, 2026), *unreviewed by* Comm'n Notice (Apr. 27, 2026).

On August 6, 2026, the ALJ issued the FID finding a violation of section 337 by respondents ASUS and Plume (collectively ''Respondents''). On August 18, 2026, Respondents and OUII each filed a petition for review of the FID, while Estelgia filed a contingent petition for review. On August 26, 2026, Estelgia and Respondents each filed responses. On September 2, 2026, OUII filed its response.

Having reviewed the record of the investigation, including the FID and the parties' submissions to the ALJ and to the Commission, the Commission has determined to review-in-part the FID. Specifically, the Commission has determined to review the FID's findings on (1) the construction of the preamble of claim 13 of the '714 patent and related subsidiary findings, including infringement by ASUS and Plume and the technical prong of the domestic industry requirement; (2) indirect infringement by ASUS of claim 13 of the '714 patent; (3) infringement by ASUS and Plume and the technical prong of the domestic industry requirement for the claim elements ''prioritizing the one or more channels . . . based on the measured channel condition'' and ''assigning . . . at least one channel having a lower priority to a second UE having a lower priority for communication'' in the asserted claim of the '973 patent; (4) written description and obviousness of the '973 patent; and (5) the economic prong of the domestic industry requirement.

The Commission has determined not to review, and thus adopts, the FID's findings regarding invalidity for the '714 patent. With respect to the FID's finding that Sorrells-836 in view of Sorrells-296 does not render claim 13 of the '714 patent obvious, the Commission has further determined that Respondents did not present in their post-hearing briefs the additional arguments in Respondents' petition for review regarding a motivation to use MMDS and IEEE 802.11, and therefore Respondents have waived these arguments. The Commission has determined not to review the remainder of the FID's findings.

The Commission has also determined to extend the target date for completion of the investigation to January 14, 2027.

Finally, the Commission requests a response to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

(1) For the '973 patent, whether the ''based on'' language in claim elements 1[d] and 8[f] has a different meaning than the ''based, at least in part, on''

language in claim elements 1[b], 1[e], 1[f], 8[d], 8[g], and 8[h].

(2) For the '973 patent, explain whether the FID's finding regarding written description that ''both parties' experts acknowledge that 'when you're prioritizing a band, and you're selecting a band, you're selecting a channel in a band. You don't transmit or communicate on a band. You communicate on channels in bands' '' (FID at 137) can be reconciled with its obviousness finding that ''Novak's network may comprise 'multiple bands,' including 'the interleaved communication channels of the TV bands'—but it does not disclose prioritization of the channels, as opposed to the bands'' (FID at 167)

(3) Explain whether Estelgia submitted into evidence any foreign plant and equipment and/or labor or capital investments, including contract manufacturing, relating to manufacturing of the DI products and whether Estelgia provided any DI economic prong analysis that considers such foreign investments.

(4) Please discuss the following statutory terms and the evidence of record pertaining to these terms:

a. whether the statutory language of section 337(a)(3)(A) ''plant and equipment,'' in view of the legislative history and judicial precedents, defines the physical ''plant and equipment'' to be limited to land, buildings, machinery, apparatus, and fixtures employed in the physical production or industrial activity in the United States concerning articles protected by the asserted patents;

b. whether the statutory language of section 337(a)(3)(B) ''employment of labor,'' in view of the legislative history and judicial precedents is confined to the employment of a subset of workers who are wage earners engaged in physical production or industrial activity in the United States with respect to articles protected by the asserted patents;

c. whether the statutory language of section 337(a)(3)(B) ''employment of . . . capital,'' in view of the legislative history and judicial precedents, is confined to the employment of capital goods and capital expenditures not otherwise accounted for by categories of capital assets and expenditures other than those recited in subsections 337(a)(3)(A) or (C); and

d. whether the evidence of investments and employment in the categories so defined indicates that they are ''significant'' as required in subsections 337(a)(3)(A) and (B).

The parties are invited to brief only the discrete issues requested above. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia,* (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and a cease and desist order would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation are requested to file written submissions on the questions identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

In its initial submission, Complainant is also requested to identify the remedy sought and Complainant is requested to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. All initial written submissions, from the parties and/or third parties/interested government agencies, and proposed remedial orders from the parties must be filed no later than close of business on November 12, 2026. All reply submissions must be filed no later than the close of business on November 19, 2026. Opening submissions from the parties are limited to 30 pages. Reply submissions from the parties are limited to 15 pages. All submissions from third parties and/or interested government agencies are limited to 10 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above pursuant to 19 CFR 210.4(f). Submissions should refer to the investigation number (Inv. No. 337–TA–1454) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable

Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on October 28, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 28, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22280 Filed 10–30–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–125 (Sixth Review)]

Potassium Permanganate From China; Institution of a Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to the Tariff Act of 1930, as amended, to determine whether revocation of the antidumping duty order on potassium permanganate from China would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted November 2, 2026. To be assured of consideration, the deadline for responses is December 2, 2026. Comments on the adequacy of responses may be filed with the Commission by January 12, 2027.

FOR FURTHER INFORMATION CONTACT: David McDonald (202–205–3378), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION:

Background.—On January 31, 1984, the Department of Commerce (''Commerce'') issued an antidumping duty order on imports of potassium permanganate from China (49 FR 3897). Following first five-year reviews by Commerce and the Commission, effective November 24, 1999, Commerce issued a continuation of the antidumping duty order on imports of potassium permanganate from China following Commerce's and the Commission's first five-year reviews, effective November 24, 1999 (64 FR 66166), second five-year reviews, effective June 21, 2005 (70 FR 35630), third five-year reviews, effective October 25, 2010 (75 FR 65448), fourth five-year reviews, effective March 18, 2016 (81 FR 14835), and fifth five-year reviews, effective December 9, 2021 (86 FR 70113). The Commission is now conducting a sixth review pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR part 201, subparts A and B, and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct a full or expedited review. The Commission's determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by Commerce.

(2) The *Subject Country* in this review is China.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determinations, its full first five-year review determinations, and its expedited second, third, and fourth five-year review determinations, and full fifth five-year review determination, the Commission defined a single *Domestic Like Product* as potassium permanganate, coextensive with Commerce's scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determinations, its full first five-year review determinations, and its expedited second, third, and fourth five-year review determinations, full fifth five-year review determination, the Commission defined the *Domestic Industry* as all domestic producers of potassium permanganate.

(5) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission

five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post-employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to § 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is 5:15 p.m. on December 2, 2026. Pursuant to § 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is 5:15 p.m. on January 12, 2027. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings. Also, in accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

No response to this request for information is required if a currently valid Office of Management and Budget (''OMB'') number is not displayed; the OMB number is 3117 0016/USITC No. 26–5–708, expiration date July 31, 2029. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to § 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to § 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determination in the review.

Information To Be Provided in Response to This Notice of Institution:—As used below, the term ''firm'' includes any related firms.

Those responding to this notice of institution are encouraged, but not required, to visit the USITC's website at *https://usitc.gov/reports/response_noi_worksheet,* where one can download and complete the ''NOI worksheet'' Excel form for the subject proceeding, to be included as attachment/exhibit 1 of your overall response.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how, including whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandi*se, a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty order on the *Domestic Industry* in general and/or your firm/entity

specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in § 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2020.

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2025, except as noted (report quantity data in pounds and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2025 (report quantity data in pounds and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2025 (report quantity data in pounds and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* after 2020, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

By order of the Commission.

Issued: October 27, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22347 Filed 10–30–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–657 and 731–TA–1537 (Review)]

Chassis and Subassemblies From China; Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the countervailing and antidumping duty orders on chassis and subassemblies from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[2]

Background

The Commission instituted these reviews on April 1, 2026 (91 FR 16223) and determined on July 6, 2026, that it would conduct expedited reviews (91 FR 62745, October 2, 2026).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on October 29, 2026. The views of the Commission are contained in USITC Publication 5806 (October 2026), entitled *Chassis and Subassemblies from China: Investigation Nos. 701–TA–657 and 731–TA–1537 (Review).*

By order of the Commission.

Issued: October 29, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22342 Filed 10–30–26; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Commissioner Samuel T. Negatu not participating.

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1511]

Certain Dynamic Random Access Memory (DRAM) Devices, Products Containing the Same and Components Thereof (II); Notice of a Commission Determination Not To Review an Initial Determination Granting a Joint Motion To Terminate the Investigation as to All Respondents and To Limit Service of the Settlement Agreement; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined not to review an initial determination (''ID'') (Order No. 7) of the presiding administrative law judge (''ALJ'') granting a joint motion to terminate the above-captioned investigation as to all respondents based on a settlement agreement. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Michelle Klancnik, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2593. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission Instituted this investigation on July 20, 2026, based on a complaint filed by Netlist, Inc. of Irvine, California. 91 FR 45286–87 (July 20, 2026). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain dynamic random access memory (DRAM) devices, products containing the same, and components thereof by reason of infringement of claims 1–8, 10, 11, 14–17, 19, and 20 of U.S. Patent No. 12,646,537 and claims 1–7 and 18–20 of U.S. Patent No. 12,650,937. *Id.* at 45286. The Commission's notice of investigation named the following respondents: Samsung Electronics Co., Ltd. of Gyeonggi-do, Korea; Samsung Electronics America, Inc. and Samsung Semiconductor, Inc. of Plano, Texas; Google LLC of Mountain View, California; Super Micro Computer, Inc. of San Jose, California; NVIDIA Corp. of Santa Clara, California; and Broadcom Inc. of Palo Alto, California. *Id.* at 45287. The complaint further alleged that a domestic industry exists or is in the process of being established. *Id.* at 45286. The Office of Unfair Import Investigations is also a party to the investigation. *Id.* at 45287.

On August 18, 2026, Complainant Netlist, Inc. (''Netlist'') and Respondents Samsung Electronics Co., Ltd., Samsung Electronics America, Inc., and Samsung Semiconductor, Inc. (together ''Samsung''), (collectively, the ''Moving Parties''), moved to terminate the investigation as to all respondents based on a settlement agreement. The Moving Parties additionally moved to limit service of the confidential version of their settlement agreement.

On September 28, 2026, the ALJ issued the subject ID (Order No. 7) granting the motion to terminate the investigation as to all respondents. The ID found that the motion complies with the requirements of Commission Rule 210.21(b)(1) (19 CFR 210.21(b)(1)). ID at 2. The ID also found that the proposed settlement does not adversely affect the public interest in accordance with Commission Rule 210.50(b)(2) (19 CFR 210.50(b)(2)). ID at 3. The ID also granted the Moving Parties' request to limit service of the agreement. ID at 4. No petitions for review of the subject ID were filed.

The Commission has determined not to review the subject ID. The investigation is terminated in its entirety.

The Commission vote for this determination took place on October 28, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 28, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22283 Filed 10–30–26; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 1793]

Bulk Manufacturer of Controlled Substances Application: AJNA Biosciences

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: AJNA Biosciences 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 January 4, 2027. Such persons may also file a written request for a hearing on the application on or before January 4, 2027.

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 September 30, 2026, AJNA Biosciences, 8022 Southpark Circle, Suite 500, Littleton, Colorado 80120–5659, 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 and initiate a new Food and Drug Administration (FDA) regulated drug program cultivating whole plant marihuana (7350, 7360 and 7370) to support internal research, clinical trials, and analytical purposes as well as to distribute for sale to its customers. No other activities for these drug codes are authorized for this registration.

Justin Wood,

Deputy Assistant Administrator.

[FR Doc. 2026–22289 Filed 10–30–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1792]

Importer of Controlled Substances Application: Globyz Pharma LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Globyz 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 December 2, 2026. Such persons may also file a written request for a hearing on the application on or before December 2, 2026.

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 September 29, 2026, Globyz Pharma LLC., 6 Horne Drive, Folcroft, Pennsylvania 19032–1806, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Fentanyl	9801	II

The company plans to import the listed controlled substance in dosage form for use in analytical testing and 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.

Justin Wood,

Deputy Assistant Administrator.

[FR Doc. 2026–22288 Filed 10–30–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Bureau of Prisons

Annual Determination of Average Cost of Incarceration Fee (COIF)

AGENCY: Bureau of Prisons, Justice.

ACTION: Notice.

SUMMARY: This Notice publishes the Fiscal Year (FY) 2025 Cost of Incarceration Fee (COIF) for Federal inmates.

DATES: This determination is effective as of November 2, 2026.

ADDRESSES: Office of General Counsel, Federal Bureau of Prisons, 320 First Street NW, Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Whittington C. Wiman, Assistant General Counsel/Rules Administrator, Federal Bureau of Prisons, at the address above or at (202) 353–4885.

SUPPLEMENTARY INFORMATION: Pursuant to 28 CFR 0.96c and 28 CFR 505.2, this Notice publishes the FY 2025 COIF for Federal inmates. Title 28 of the Code of

Federal Regulations, part 505, allows for assessment of a fee to cover the average cost of incarceration for Federal inmates. We calculate the COIF by dividing the number representing the Bureau of Prisons (Bureau) facilities' monetary obligation (excluding activation costs) by the number of inmate-days incurred for the fiscal year, and then by multiplying the quotient by the number of days in the fiscal year.

Based on FY 2025 data, the average annual COIF for a Federal inmate housed in a Bureau or non-Bureau facility in FY 2025 was $47,564 ($130.31 per day). The average annual COIF for a Federal inmate housed in a Residential Reentry Center for FY 2025 was $43,499 ($119.18 per day).

Sean D. Francisco,

Acting Assistant Director/General Counsel, Federal Bureau of Prisons.

[FR Doc. 2026–22340 Filed 10–30–26; 8:45 am]

BILLING CODE 4410–05–P

LEGAL SERVICES CORPORATION

Notice of Intent To Award—Grant Awards for the Delivery of Civil Legal Services to Eligible Low-Income Clients Beginning January 1, 2027

AGENCY: Legal Services Corporation.

ACTION: Announcement of the Legal Services Corporation's intent to make 2027 Basic Field Grant Awards.

SUMMARY: The Legal Services Corporation (LSC) hereby announces its intention to award grants to provide effective and efficient delivery of high-quality civil legal services to eligible low-income clients, starting January 1, 2027.

DATES: All comments and recommendations must be received on or before the close of business on December 2, 2026.

ADDRESSES: Basic Field Grant Awards, Legal Services Corporation; 1825 I St. NW, Suite 800; Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Christine Williams, Program Manager for Basic Field Competition, Office of Program Performance, at (202) 295–1602 or *williamsc@lsc.gov.*

SUPPLEMENTARY INFORMATION: Under LSC's Notice of Funding Availability, 91 FR 11578, Mar. 10, 2026, and LSC's grant application process beginning on April 13, 2026, LSC intends to award funds to organizations that provide civil legal services in the indicated service areas. Applicants for each service area are listed below. The grant award amounts below are estimates based on the 2026 grant awards to each service area. The funding estimates may change based on the final 2027 appropriation. In addition, Agricultural Worker service area population estimates are subject to change based on U.S. Department of Labor review and comments LSC receives during the 30-day comment period.

LSC will post all updates and changes to this notice at *https://www.lsc.gov/grants/basic-field-grant/basic-field-awards.* Interested parties are asked to visit *https://www.lsc.gov/grants/basic-field-grant* regularly for updates on the LSC grants process.

Name of applicant organization	State	Service area	Estimated annualized 2027 funding
Alaska Legal Services Corporation	AK	AK–1	$1,120,120
Alaska Legal Services Corporation	AK	NAK–1	784,099
Legal Services Alabama, Inc	AL	AL–4	8,415,245
Legal Aid of Arkansas, Inc	AR	AR–8	4,896,378
American Samoa Legal Aid	AS	AS–1	301,968
DNA-Peoples Legal Services, Inc	AZ	AZ–2	587,928
Community Legal Services, Inc	AZ	AZ–3	6,450,553
Southern Arizona Legal Aid, Inc	AZ	AZ–5	2,817,450
Community Legal Services, Inc	AZ	MAZ	469,074
DNA-Peoples Legal Services, Inc	AZ	NAZ–5	3,783,315
Southern Arizona Legal Aid, Inc	AZ	NAZ–6	924,155
California Indian Legal Services, Inc	CA	CA–1	23,555
Inland Counties Legal Services, Inc	CA	CA–12	5,858,146
Legal Aid Society of San Diego, Inc	CA	CA–14	3,328,538
Community Legal Aid SoCal	CA	CA–19	4,305,253
Greater Bakersfield Legal Assistance, Inc	CA	CA–2	1,631,496
Central California Legal Services	CA	CA–26	3,619,291
Legal Services of Northern California, Inc	CA	CA–27	4,826,749
Bay Area Legal Aid	CA	CA–28	5,844,723
Legal Aid Foundation of Los Angeles	CA	CA–29	6,872,778
Neighborhood Legal Services of Los Angeles County	CA	CA–30	5,386,528
California Rural Legal Assistance, Inc	CA	CA–31	6,234,396
California Rural Legal Assistance, Inc	CA	MCA	4,396,090
California Indian Legal Services, Inc	CA	NCA–1	1,280,923
Colorado Legal Services	CO	CO–6	5,809,144
Colorado Legal Services	CO	MCO	308,952
Colorado Legal Services	CO	NCO–1	139,238
Statewide Legal Services of Connecticut, Inc	CT	CT–1	4,051,199
Statewide Legal Services of Connecticut, Inc	CT	NCT–1	22,699
Neighborhood Legal Services Program of the District of Columbia	DC	DC–1	1,038,527
Legal Services Corporation of Delaware, Inc	DE	DE–1	1,176,631
Maryland Legal Aid	DE	MDE	32,438
Legal Services of North Florida, Inc	FL	FL–13	2,141,806
Three Rivers Legal Services, Inc	FL	FL–14	3,253,102
Community Legal Services of Mid-Florida, Inc	FL	FL–15	6,633,562
Bay Area Legal Services, Inc	FL	FL–16	5,077,450
Florida Rural Legal Services, Inc	FL	FL–17	5,639,858
Coast to Coast Legal Aid of South Florida, Inc	FL	FL–18	3,208,847
Legal Services of Greater Miami, Inc	FL	FL–5	4,169,001
Florida Rural Legal Services, Inc	FL	MFL	1,002,714

Name of applicant organization	State	Service area	Estimated annualized 2027 funding
Atlanta Legal Aid Society, Inc	GA	GA–1	4,984,340
Georgia Legal Services Program	GA	GA–2	10,994,273
Georgia Legal Services Program	GA	MGA	685,661
Legal Aid Society of Hawaii	HI	HI–1	1,891,734
Legal Aid Society of Hawaii	HI	NHI–1	332,115
Iowa Legal Aid	IA	IA–3	3,706,864
Iowa Legal Aid	IA	MIA	298,371
Idaho Legal Aid Services, Inc	ID	ID–1	1,780,293
Idaho Legal Aid Services, Inc	ID	MID	427,846
Idaho Legal Aid Services, Inc	ID	NID–1	94,194
Land of Lincoln Legal Aid, Inc	IL	IL–3	3,390,282
Legal Aid Chicago	IL	IL–6	7,451,133
Prairie State Legal Services, Inc	IL	IL–7	5,148,221
Legal Aid Chicago	IL	MIL	277,850
Indiana Legal Services, Inc	IN	IN–5	9,170,110
Indiana Legal Services, Inc	IN	MIN	196,819
Kansas Legal Services, Inc	KS	KS–1	3,645,166
Legal Aid of the Bluegrass	KY	KY–10	1,961,413
Legal Aid Society	KY	KY–2	2,083,531
Appalachian Research and Defense Fund of Kentucky	KY	KY–5	2,194,777
Kentucky Legal Aid	KY	KY–9	1,674,293
Southeast Louisiana Legal Services Corporation	LA	LA–13	4,657,493
Acadiana Legal Service Corporation	LA	LA–15	4,591,003
Community Legal Aid, Inc	MA	MA–10	2,402,825
Volunteer Lawyers Project of the Boston Bar Association	MA	MA–11	2,864,345
South Coastal Counties Legal Services	MA	MA–12	1,519,162
Northeast Legal Aid, Inc	MA	MA–4	1,187,563
Maryland Legal Aid	MD	MD–1	6,401,133
Maryland Legal Aid	MD	MMD	146,367
Pine Tree Legal Assistance, Inc	ME	ME–1	1,494,597
Pine Tree Legal Assistance, Inc	ME	MMX–1	378,874
Pine Tree Legal Assistance, Inc	ME	NME–1	93,449
Michigan Advocacy Program	MI	MI–12	2,351,748
Lakeshore Legal Aid	MI	MI–13	5,974,974
Legal Services of Eastern Michigan	MI	MI–14	2,183,610
Legal Aid of Western Michigan	MI	MI–15	2,775,030
Legal Services of Northern Michigan, Inc	MI	MI–9	1,153,129
Michigan Advocacy Program	MI	MMI	691,143
Michigan Indian Legal Services, Inc	MI	NMI–1	238,669
Southern Minnesota Regional Legal Services, Inc	MN	MMN	531,073
Justice North	MN	MN–1	567,406
Justice North	MN	MN–4	510,089
Southern Minnesota Regional Legal Services, Inc	MN	MN–5	2,066,887
Central Minnesota Legal Services, Inc	MN	MN–6	2,261,266
Anishinabe Legal Services, Inc	MN	NMN–1	346,486
Legal Aid of Western Missouri	MO	MMO	205,137
Legal Aid of Western Missouri	MO	MO–3	2,626,090
Legal Services of Eastern Missouri, Inc	MO	MO–4	2,609,190
Mid-Missouri Legal Services Corporation	MO	MO–5	624,820
Legal Services of Southern Missouri	MO	MO–7	2,147,760
Micronesian Legal Services Corporation	MP	MP–2	2,138,201
Mississippi Center for Legal Services	MS	MS–10	3,301,581
North Mississippi Rural Legal Services, Inc	MS	MS–9	2,178,248
Mississippi Center for Legal Services	MS	NMS–1	120,519
Montana Legal Services Association	MT	MMT	173,035
Montana Legal Services Association	MT	MT–1	1,307,211
Montana Legal Services Association	MT	NMT–1	230,855
Legal Aid of North Carolina, Inc	NC	MNC	787,867
Legal Aid of North Carolina, Inc	NC	NC–5	14,599,031
Legal Aid of North Carolina, Inc	NC	NNC–1	316,423
Southern Minnesota Regional Legal Services, Inc	ND	MND	139,063
Legal Services of North Dakota	ND	ND–3	702,980
Legal Services of North Dakota	ND	NND–3	390,550
Legal Aid of Nebraska	NE	MNE	238,047
Legal Aid of Nebraska	NE	NE–4	2,066,396
Legal Aid of Nebraska	NE	NNE–1	47,925
603 Legal Aid	NH	NH–1	1,081,288
South Jersey Legal Services, Inc	NJ	MNJ	173,582
Legal Services of Northwest Jersey, Inc	NJ	NJ–15	729,296
Central Jersey Legal Services, Inc	NJ	NJ–17	1,797,742
Northeast New Jersey Legal Services Corporation	NJ	NJ–18	2,706,644
South Jersey Legal Services, Inc	NJ	NJ–20	3,379,789
Essex-Newark Legal Services Project, Inc	NJ	NJ–8	1,325,331

Name of applicant organization	State	Service area	Estimated annualized 2027 funding
New Mexico Legal Aid	NM	MNM	207,294
DNA-Peoples Legal Services, Inc	NM	NM–1	273,581
New Mexico Legal Aid	NM	NM–5	3,723,296
DNA-Peoples Legal Services, Inc	NM	NNM–2	32,940
New Mexico Legal Aid	NM	NNM–4	673,656
Nevada Legal Services, Inc	NV	NNV–1	192,792
Nevada Legal Services, Inc	NV	NV–1	4,304,922
Legal Aid Society of Mid-New York, Inc	NY	MNY	376,477
Legal Services of the Hudson Valley	NY	NY–20	2,886,598
Legal Aid Society of Northeastern New York, Inc	NY	NY–21	2,138,252
Legal Aid Society of Mid-New York, Inc	NY	NY–22	2,396,712
Legal Assistance of Western New York, Inc	NY	NY–23	2,483,560
Neighborhood Legal Services, Inc	NY	NY–24	1,954,418
Legal Services of Long Island	NY	NY–7	1,979,932
Legal Services NYC	NY	NY–9	16,607,512
Legal Aid of Western Ohio, Inc	OH	MOH	241,864
Legal Aid Society of Greater Cincinnati	OH	OH–18	2,278,133
Community Legal Aid Services, Inc	OH	OH–20	2,830,615
The Legal Aid Society of Cleveland	OH	OH–21	3,056,871
Legal Aid of Western Ohio, Inc	OH	OH–23	4,000,522
Legal Aid of Southeast and Central Ohio	OH	OH–24	5,015,580
Legal Aid Services of Oklahoma, Inc	OK	MOK	332,354
Oklahoma Indian Legal Services, Inc	OK	NOK–1	1,187,120
Legal Aid Services of Oklahoma, Inc	OK	OK–3	6,808,419
Legal Aid Services of Oregon	OR	MOR	620,052
Legal Aid Services of Oregon	OR	NOR–1	267,643
Legal Aid Services of Oregon	OR	OR–6	5,156,392
Philadelphia Legal Assistance Center	PA	MPA	467,507
Philadelphia Legal Assistance Center	PA	PA–1	3,396,636
Legal Aid of Southeastern Pennsylvania	PA	PA–23	2,162,801
North Penn Legal Services, Inc	PA	PA–24	2,975,578
MidPenn Legal Services, Inc	PA	PA–25	3,621,363
Northwestern Legal Services	PA	PA–26	877,333
Summit Legal Aid	PA	PA–27	1,569,649
Neighborhood Legal Services Association	PA	PA–8	2,045,447
Puerto Rico Legal Services, Inc	PR	MPR	69,822
Puerto Rico Legal Services, Inc	PR	PR–1	13,982,613
Community Law Office, Inc	PR	PR–2	288,809
Rhode Island Legal Services, Inc	RI	RI–1	1,296,101
South Carolina Legal Services, Inc	SC	MSC	307,460
South Carolina Legal Services, Inc	SC	SC–8	7,980,688
Dakota Plains Legal Services, Inc	SD	NSD–1	1,353,726
East River Legal Services	SD	SD–2	639,002
Dakota Plains Legal Services, Inc	SD	SD–4	554,786
Legal Aid Society of Middle Tennessee and the Cumberlands	TN	TN–10	4,314,247
West Tennessee Legal Services, Inc	TN	TN–4	2,030,093
West Tennessee Legal Services, Inc	TN	TN–7	1,038,308
Legal Aid of East Tennessee	TN	TN–9	3,520,362
Texas RioGrande Legal Aid, Inc	TX	MSX–2	3,268,464
Texas RioGrande Legal Aid, Inc	TX	NTX–1	45,377
Lone Star Legal Aid	TX	TX–13	17,395,449
Legal Aid of NorthWest Texas	TX	TX–14	12,698,489
Texas RioGrande Legal Aid, Inc	TX	TX–15	15,321,030
Utah Legal Services, Inc	UT	MUT	122,438
Utah Legal Services, Inc	UT	NUT–1	119,278
Utah Legal Services, Inc	UT	UT–1	3,347,112
Central Virginia Legal Aid Society, Inc	VA	MVA	351,779
Southwest Virginia Legal Aid Society, Inc	VA	VA–15	1,109,067
Legal Aid Society of Eastern Virginia	VA	VA–16	2,082,710
Virginia Legal Aid Society, Inc	VA	VA–17	1,188,628
Central Virginia Legal Aid Society, Inc	VA	VA–18	1,719,931
Blue Ridge Legal Services, Inc	VA	VA–19	1,241,247
Legal Services of Northern Virginia, Inc	VA	VA–20	2,163,866
Legal Services of the Virgin Islands, Inc	VI	VI–1	220,523
Legal Services Vermont	VT	VT–1	623,978
Northwest Justice Project	WA	MWA	1,151,972
Northwest Justice Project	WA	NWA–1	413,014
Northwest Justice Project	WA	WA–1	7,907,345
Legal Action of Wisconsin, Inc	WI	MWI	534,324
Legal Action of Wisconsin, Inc	WI	NWI–1	224,902
Legal Action of Wisconsin, Inc	WI	WI–2	1,314,967
Legal Action of Wisconsin, Inc	WI	WI–5	5,185,315
Legal Aid of West Virginia, Inc	WV	WV–5	3,258,925

Name of applicant organization	State	Service area	Estimated annualized 2027 funding
Legal Aid of Wyoming, Inc	WY	NWY–1	250,539
Legal Aid of Wyoming, Inc	WY	WY–4	733,366

These grants will be awarded under the authority conferred on LSC by section 1006(a)(1) of the Legal Services Corporation Act, 42 U.S.C. 2996e(a)(l). Grant awards are made to ensure civil legal services are provided in every service area, although no listed organization is guaranteed a grant award. Grants will become effective, and grant funds will be distributed, on or about January 4, 2027.

LSC issues this notice pursuant to 42 U.S.C. 2996f(f). Comments and recommendations concerning potential grantees are invited and should be delivered to LSC within 30 days from the date of publication of this notice.

Authority: (42 U.S.C. 2996f(f).)

Dated: October 28, 2026.

Stefanie Davis,

Deputy General Counsel and Ethics Officer, Legal Services Corporation.

[FR Doc. 2026–22284 Filed 10–30–26; 8:45 am]

BILLING CODE 7050–01–P

OFFICE OF MANAGEMENT AND BUDGET

Request for Information; Reopening of Comment Period

AGENCY: Office of Management and Budget.

ACTION: Request for information; reopening of response period.

SUMMARY: The Office of Management and Budget (OMB) published in the **Federal Register** a request for information (RFI) regarding new and unused (idle) domestic, U.S.-based, and near shore production capabilities for Finished Dose Forms, Active Pharmaceutical Ingredients, and Key Starting Materials associated with the Administration for Strategic Preparedness and Response (ASPR) 86 List of essential medicines. The RFI provided for a 30-day response period which closed on October 26, 2026. OMB has determined that reopening the comment period until November 27, 2026, is appropriate. This action will allow interested parties additional time to prepare information and responses.

DATES: The response period for the notice published on September 25, 2026 (91 FR 60983), regarding the RFI on Domestic and Near Shore Manufacturing of Essential Medicines on the ASPR 86 List, is reopened. Responses must be received on or before November 27, 2026.

ADDRESSES: Responses must be submitted electronically through *regulations.gov.* Mailed paper submissions will not be accepted, and electronic submissions received after the deadline may not be considered.

Instructions: Federal eRulemaking Portal: Go to *www.regulations.gov* search ''Domestic and Near Shore Manufacturing of Essential Medicines RFI'' to submit your comments electronically. 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*). Should you choose to include proprietary information or confidential business information in your submission, please ensure you use appropriate markings and handling instructions to alert OMB as to the nature of information being submitted and maintain proper handling. Your response will be shared with other Federal agencies and entities.

Privacy Act Statement: OMB is issuing this request for information (RFI) pursuant to its authorities under 31 U.S.C. 501 *et seq.* Comments and commenter information are maintained under the OMB Public Input System of Records, OMB/INPUT/01. The system of records notice accessible at 88 FR 20913 (*https://www.federalregister.gov/documents/2023/04/07/2023-07452/privacy-act-of-1974-system-of-records*) includes a list of routine uses associated with the collection of this information.

Disclaimer: Participation in this RFI is strictly voluntary. OMB will use your feedback to inform sound decision-making on topics related to this RFI regarding potential government-wide actions to revitalize the domestic manufacturing base, create new opportunities for U.S. firms and workers, and position U.S. businesses to compete and lead globally in strategic industries. This announcement should not be construed as a commitment of any kind by the U.S. Government. The U.S. Government is in no way liable to pay for or reimburse any companies or entities that respond to this announcement. Nothing in this announcement constitutes an obligation on the part of the U.S. Government. A response to this RFI will not be viewed as a binding commitment to develop or pursue the project or ideas discussed.

FOR FURTHER INFORMATION CONTACT: Please direct questions regarding this Notice to Robert Orr, Deputy to the Associate Director of Economic Policy, Office of Management and Budget, tel: 202–395–1390, or email the Made in America Office at *MadeInAmerica@omb.eop.gov* with ''Domestic and Near Shore Manufacturing of Essential Medicines on the ASPR 86 List'' in the subject line.

SUPPLEMENTARY INFORMATION: On September 25, 2026, OMB published in the **Federal Register** an RFI soliciting responses on new and unused (idle) domestic, U.S.-based, and near shore production capabilities for Finished Dose Forms, Active Pharmaceutical Ingredients, and Key Starting Materials associated with the ASPR 86 List of essential medicines. The RFI stated that the response period would close on October 26, 2026. OMB has received requests to reopen the response period. Reopening the response period will allow interested parties additional time to prepare information and comments. Therefore, OMB is reopening the response period for the RFI until November 27, 2026.

Michael Stumo,

Director, Made in America Office.

[FR Doc. 2026–22328 Filed 10–30–26; 8:45 am]

BILLING CODE 3110–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–26–0529; NARA–2027–007]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on *regulations.gov* for records

schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: We must receive responses on the schedules listed in this notice by December 17, 2026.

ADDRESSES: To view a records schedule in this notice, or submit a comment on one, use the following address: *https://www.regulations.gov/docket/NARA-26-0529/document.*

This is a direct link to the schedules posted in the docket for this notice on *regulations.gov*. You may submit comments by the following method:

• *Federal eRulemaking Portal: https://www.regulations.gov*. On the website, enter either of the numbers cited at the top of this notice into the search field. This will bring you to the docket for this notice, in which we have posted the records schedules open for comment. Each schedule has a 'comment' button so you can comment on that specific schedule. For more information on *regulations.gov* and on submitting comments, see their FAQs at *https://www.regulations.gov/faq.*

If you are unable to comment via *regulations.gov,* you may email us at *request.schedule@nara.gov* for instructions on submitting your comment. You must cite the control number of the schedule you wish to comment on. You can find the control number for each schedule in parentheses at the end of each schedule's entry in the list at the end of this notice.

FOR FURTHER INFORMATION CONTACT: Richard Green, Records Management Operations, by email at *richard.green@nara.gov* or at 301–395–7825. For information about records schedules, contact Records Management Operations by email at *request.schedule@nara.gov* or by phone at 301–395–7825.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule.

We have uploaded the records schedules and accompanying appraisal memoranda to the *regulations.gov* docket for this notice as ''other'' documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the *regulations.gov* portal, you may contact *request.schedule@nara.gov* for instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we may or may not make changes to the proposed records schedule. The schedule is then sent for final approval by the Archivist of the United States. After the schedule is approved, we will post on *regulations.gov* a ''Consolidated Reply'' summarizing the comments, responding to them, and noting any changes we made to the proposed schedule. You may elect at *regulations.gov* to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. If you have a question, you can submit it as a comment, and can also submit any concerns or comments you would have to a possible response to the question. We will address these items in consolidated replies along with any other comments submitted on that schedule.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at *https://www.archives.gov/records-mgmt/rcs,* after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of State, Permanent Missions to the United Nations Officers Entitled to Diplomatic Privileges and Immunities List (DAA–0084–2026–0001).
2. Department of the Treasury, Benefits Administration and Disbursement Oversight Records (DAA–0056–2026–0001).
3. Bureau of Engraving and Printing, NICE System Audio Recordings (DAA–0318–2026–0001).
4. Central Intelligence Agency, Civil Liberties Complaint Records (DAA–0263–2026–0003).
5. Denali Commission, OIG, General Counsel, Planning, and Project Database (DAA–0591–2025–0001).
6. National Security Agency Central Security Service, Updates to National Security Agency Records Disposition Schedule (DAA–0457–2024–0004).
7. Veterans Health Administration, Patient Advocacy (DAA–0015–2025–0014).
8. Veterans Health Administration, Sterile Processing Services (DAA–0015–2026–0049).

Laura Besong,

Chief Records Officer for the U.S. Government.

[FR Doc. 2026–22257 Filed 10–30–26; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Notice of Proposed Information Collection Requests: Native American Library Services Basic Grants Notice of Funding Opportunity

AGENCY: Institute of Museum and Library Services, National Foundation on the Arts and the Humanities.

ACTION: Notice, request for comments on this collection of information.

SUMMARY: The Institute of Museum and Library Services (IMLS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The purpose of this notice is to communicate the agency's intent to request renewal of the clearance for IMLS's Native American Library Services Basic Grants (NAB), a discretionary grant program designed to assist Native American tribes in improving library services for their communities. A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this Notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before January 02, 2027.

ADDRESSES: Send comments to Sandra Narva, Lead Senior Grants Management Specialist, Office of General Counsel, ATTN: Grants Management, Institute of Museum and Library Services, 200 Constitution Ave NW, Suite N–3629, Washington, DC 20210. Ms. Narva can be reached by telephone, 202–653–4634, or by email at *snarva@imls.gov.* Office hours are from 8:30 a.m. to 5 p.m., E.T., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lisa Solomson, Deputy Director, Office of Library Services, Institute of Museum and Library Services, 200 Constitution Ave NW, Suite N–3629, Washington, DC 20210. Ms. Solomson can be reached by telephone, 202–653–4617, or by email at *lsolomson@imls.gov.* Office hours are from 8:30 a.m. to 5 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: IMLS is particularly interested in public comments that help the agency to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques, or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

I. Background

IMLS is the primary source of Federal support for the Nation's libraries and museums. The agency advances, supports, and empowers America's museums, libraries, and related organizations through grant making, research, and policy development. For more information about IMLS, visit *www.imls.gov.*

II. Current Actions

This action will renew the NAB Notice of Funding Opportunities clearance, which expires February 28, 2027, for an additional three years.

The NAB program assists eligible Native Communities in establishing, sustaining, and improving library services and operations with their communities. As information needs change, Tribal libraries must be able to serve as knowledge and resource centers to benefit their users and the wellness of their communities. The NAB program supports Native Communities across the country to address their individual information needs and priorities.

The two goals for this program are (1) to improve library and archival services for accessing, learning, and preserving information with the community, and (2) to improve library and archival services for accessing, learning, and preserving information with the community.

Agency: Institute of Museum and Library Services.

Title: Native American Library Services Basic Grants Notice of Funding Opportunity.

OMB Control Number: 3137–0093.

Agency Number: 3137.

Respondents/Affected Public: Federally Recognized Indian Tribes.

Estimated Number of Annual Respondents: 170.

Frequency of Response: Once per request.

Estimated Average Hours per Response: 10.

Estimated Total Average of Burden Hours: 1,700.

Total Annual Cost Burden: $49,776.

Total Annual Federal Costs: $19,324.

Public Comments Invited: Comments submitted in response to this notice will be summarized and/or included in the request for OMB's clearance of this information collection. This collection is authorized by 20 U.S.C. 9161, ''Services for Native Americans.''

Dated: October 29, 2026.

Suzanne Mbollo,

Grants Management Specialist, Institute of Museum and Library Services.

[FR Doc. 2026–22324 Filed 10–30–26; 8:45 am]

BILLING CODE 7036–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2026–0001]

Sunshine Act Meetings

TIME AND DATE: Week of October 26, 2026.

PLACE: Via Teleconference.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Week of October 26, 2026

Friday, October 30, 2026

1:45 p.m. Affirmation Session (Public Meeting) (Tentative); Final Rule [W1–8]—Streamlining Contested Adjudications in Licensing Proceedings (RIN 3150–AL58) (Tentative); (Contact: Wesley Held: 301–287–3591)

Additional Information: By a vote of 5–0 on October 27, 2026, the Commission determined pursuant to 5 U.S.C. 552b(e)(1) and 10 CFR 9.107 this item be affirmed with less than one week notice to the public. This item will be affirmed in the meeting being held on October 30, 2026. The public is invited to attend the Commission's meeting live; via teleconference. Details for joining the teleconference in listen only mode can be found at *https://www.nrc.gov/pmns/mtg.*

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: https://www.nrc.gov/public-involve/public-meetings/schedule.html.

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please contact the Reasonable Accommodations Resource by email at *Reasonable_Accommodations.Resource@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Betty.Thweatt@nrc.gov* or *Samantha.Miklaszewski@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: October 29, 2026.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2026–22294 Filed 10–29–26; 11:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 11006380; NRC–2019–0213]

Perma-Fix Northwest Richland, Inc.; Export License Renewal Application

AGENCY: Nuclear Regulatory Commission.

ACTION: Opportunity to provide comments, request a hearing, and petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering approval of an export application, received on August 21, 2026, from Perma-Fix Northwest Richland, Inc. (Perma-Fix). In the application, Perma-Fix seeks to amend and renew existing license, XW027/02, authorizing the export of radioactive waste to Germany. The NRC is providing notice of the opportunity to comment, request a hearing, and petition for leave to intervene on Perma-Fix's application. This action will renew the existing export license for an additional 5 years to expire on September 1, 2031, and amend the existing export license to decrease the total volume of waste from 800,000 kilograms (kg) to 200,000 kg, decrease the maximum activity of all shipments from 8.5 Terabecquerels (TBq) to 2.4 TBq, and add two radionuclides to the license.

DATES: Submit comments by December 2, 2026. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date. A request for a hearing or petition for leave to intervene must be filed by December 2, 2026.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0213. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301–415–1003; email: *Bridget.Curran@nrc.gov.* For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Hearing.Docket@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. eastern time (ET) Federal workdays; telephone: 301–415–1677.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Shannon Doane, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7000; email: *Shannon.Doane@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0213 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0213.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin ADAMS Public Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. ET, Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2019–0213 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information

before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

Perma-Fix was issued export license XW027/02 on May 2, 2023. Export license XW027/02 authorized the export of up to 800,000 kg of radioactive waste containing byproduct material in the form of residual ash, residual metal and/or non-combustible material to Germany and it expired on September 1, 2026 (ADAMS Accession No. ML23124A053). Perma-Fix submitted license application XW027/03 on August 21, 2026, requesting to renew and amend the export license authorizing the export of radioactive waste from Perma-Fix facilities in the State of Washington to Germany (ADAMS Accession No. ML26252A211).

III. Opportunity To Comment

The NRC is providing notice of the receipt of the application; providing the opportunity to submit written comments concerning the application. Within 30 days from the date of publication of this notice, persons may submit written comments concerning the actions in this notice, as provided in section 110.81 of title 10 of the *Code of Federal Regulations* (10 CFR) ''Written comments.'' The NRC will consider and may, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted as described in the ''Addresses'' section of this notice.

IV. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 30 days after the date of publication of this notice any person may file a request for a hearing or petition for leave to intervene with respect to the actions in this notice. A hearing request or petition for leave to intervene must include the information specified in 10 CFR 110.82(b). Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner in accordance with 10 CFR 110.89(a), either by delivery, by mail, or filed with the NRC electronically in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). Detailed guidance on electronic submissions may be found in the ''Guidance for Electronic Submissions to the NRC'' (ADAMS Accession No. ML13031A056) and on the NRC's public website (*https://www.nrc.gov/site-help/e-submittals.html*).

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *Hearing.Docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

The information concerning this application for an export license follows.

NRC EXPORT LICENSE APPLICATION

Application Information	
Name of Applicant	Perma-Fix Northwest Richland, Inc.
Date of Application	August 21, 2026.
Date Received	August 21, 2026.
Application No	XW027/03.
Docket No	11006380.
ADAMS Accession No	ML26252A211.
Description of Material	
Material Type	Mixed waste contaminated with byproduct materials.
Total Quantity	200,000 kilograms.
End Use	Disposal in Germany.
Country of Destination	Germany.

Authority: 42 U.S.C. 2011 *et seq.*

Dated: October 27, 2026.

For the Nuclear Regulatory Commission.

Victor Hall,

Director, Office of International Programs.

[FR Doc. 2026–22286 Filed 10–30–26; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106761; File No. SR–NASDAQ–2026–089]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Revise Nasdaq's Interpretive Material, IM–8310–3

October 28, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 15, 2026, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[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 IM–8310–3 to provide for the public release of disciplinary complaints and disciplinary decisions (as defined in the proposed rule) on its website *Nasdaq.com*. The proposed rule change also would eliminate the $10,000 monetary threshold below which the Exchange currently does not release information or publish the disciplinary decision. Additionally, the proposed rule change would provide for the public release of eligibility decisions (as specified in the proposed rule) involving members or associated persons previously subject to statutory disqualification.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on November 14, 2026.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings,* and at the principal office of the Exchange.

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

Nasdaq IM–8310–3 (Release of Disciplinary Complaints, Decisions and Other Information) governs the release of disciplinary complaints, decisions, and other information by Nasdaq. In general, this proposed rule change seeks to promote broader accessibility of Nasdaq disciplinary complaints and disciplinary decisions (as defined in the rule). In particular, the proposed rule would provide for the public release of Nasdaq disciplinary complaints and temporary cease and desist notices. In addition, the proposed rule would conform IM–8310–3 to Nasdaq's existing practice of releasing specified categories of disciplinary decisions on its website. The proposed rule also would expand the release of disciplinary decisions by publishing temporary cease and desist decisions and orders and by eliminating the $10,000 threshold below which the Exchange currently does not release information or publish the disciplinary decision.

Under this proposed rule change, Nasdaq would publish copies of disciplinary complaints and disciplinary decisions instead of summaries of (*i.e.,* ''information about'') such documents. By publishing copies of disciplinary complaints and disciplinary decisions on Nasdaq's website, the proposed rule would make it unnecessary to publish summaries of such documents instead of, or in addition to, such documents. In addition, the proposed rule change would conform IM–8310–3 to Nasdaq's existing practice of releasing eligible disciplinary decisions on its website.

The proposed rule also would define the terms ''disciplinary complaint'' and ''disciplinary decision,'' which current IM–8310–3 does not define. The Exchange believes that defining these terms would provide current and prospective members and associated persons with more clarity about the items that Nasdaq would publish under IM–8310–3.

The Exchange also proposes to provide for the public release of eligibility decisions (as specified in the proposed rule) involving members or associated persons previously subject to statutory disqualification. The Exchange believes that the public release of eligibility decisions involving members or associated persons previously subject to statutory disqualification will promote transparency by providing current and prospective members and associated persons with greater insight into the Exchange's decision-making process in resolving admissions applications by members and persons previously subject to statutory disqualification.

The proposed rule change is modeled after, and substantially similar to, the rules of several other Self-Regulatory Organizations (''SROs''), including Financial Industry Regulatory Authority (''FINRA'') Rule 8313 and New York Stock Exchange LLC (''NYSE'') Rule 8313. In particular, the rules of FINRA and NYSE provide for the public release of disciplinary complaints and disciplinary decisions, including disciplinary decisions that impose a monetary fine less than $10,000. Making disciplinary complaints and disciplinary decisions available to the public also would follow the practice of the Commission.

Background on Current IM–8310–3

If a party requests a copy of an identified disciplinary complaint or disciplinary decision issued by Nasdaq or any committee thereof, current IM–8310–3(a) requires Nasdaq to provide the requesting party with a copy of the requested document. Current IM–8310–3(a) does not provide for the release by Nasdaq of a copy of a disciplinary complaint issued by FINRA's Department of Enforcement on behalf of Nasdaq.

Current IM–8310–3(a)(1)–(4) detail the statement that accompanies the release of a disciplinary complaint, disciplinary decision, or information with respect to such a document. The accompanying statement varies depending, for example, on the type of document to be released or described (*i.e.,* disciplinary complaint vs. disciplinary decision), the finality of a disciplinary decision, and whether the Commission has stayed the effectiveness of sanctions imposed by Nasdaq.

Current IM–8310–3(b) and (c) provide that Nasdaq shall release ''information'' with respect to certain disciplinary complaints initiated by FINRA's Department of Enforcement on behalf of Nasdaq and with respect to certain disciplinary decisions of Nasdaq. Specifically, current IM–8310–3(b) provides that Nasdaq Regulation shall release to the public information with respect to any disciplinary complaint initiated by the FINRA Department of Enforcement acting on behalf of Nasdaq pursuant to the Nasdaq-FINRA Regulatory Services Agreement (''RSA'') that contains an allegation of a violation of a designated rule.[3] Nasdaq Regulation Department also may release information about any disciplinary complaint, or group of disciplinary complaints, that involve a significant policy or enforcement determination where Nasdaq's Chief Regulatory Officer deems the release of information to be in the public interest.

Current IM–8310–3(c)(1) provides that Nasdaq Regulation shall release to the public information regarding any disciplinary decision that: imposes a suspension, cancellation, or expulsion of a member; imposes a suspension or revocation of the registration of a person associated with a member; imposes a suspension or bar of a member or person associated with a member from

[3] Under current IM–8310–3(b), a designated rule means a ''designated statute, rule or regulation of the Commission or Nasdaq, as determined by the Chief Regulatory Officer of Nasdaq.''

association with all members; imposes monetary sanctions of $10,000 or more upon a member or a person associated with a member; or contains an allegation of a violation of a designated rule as defined in current IM–8310–3(b). Current IM–8310–3(c)(1) also provides that Nasdaq Regulation shall release to the public information with respect to any temporary cease and desist order issued pursuant to the Rule 9800 Series. Nasdaq currently releases copies of the aforementioned categories of disciplinary decisions (principally, Letters of Acceptance, Waiver, and Consent) on its website *Nasdaq.com*.[4]

In addition, current IM–8310–3(c)(1) provides that Nasdaq Regulation may release to the public information with respect to: any disciplinary decision (or group of decisions) that involve a significant policy or enforcement determination where Nasdaq's Chief Regulatory Officer deems the release to be in the public interest; any decision issued pursuant to the Rule 9550 Series imposing a suspension or cancellation of the member or a suspension or bar of the association of a person with a member, unless Nasdaq Regulation determines otherwise; and any disciplinary or other decision issued pursuant to the Rule 9000 Series (not specifically enumerated in current IM–8310–3(c)(1)) regardless of the sanction imposed, so long as the names of the parties and other identifying information is redacted.

Current IM–8310–3(c)(1)(A) and (B) establish the standards for public release of information in an appeal or review of a disciplinary decision where the underlying decision qualified for release but the appellate decision does not, or where the sanction imposed on some but not all of the respondents in a multi-respondent disciplinary matter qualifies for release. If the information about an underlying decision was released in unredacted form because the underlying decision met current IM–8310–3(c)(1)'s release criteria, current IM–8310–3(c)(1)(A) also requires the release in unredacted form of information about the appellate decision. In an appeal or review of a multi-respondent matter where information about the underlying disciplinary decision against a particular respondent qualified for release and was released in unredacted form, current IM–8310–3(c)(1)(B) requires the release of information in unredacted form with respect to that particular respondent's appeal or review. Nasdaq may release information to the public in redacted form about a respondent who does not meet the release criteria in current IM–8310–3(c)(1).

If a member or associated person appeals to the Commission from a Nasdaq decision imposing an expulsion, revocation, suspension, bar on associating with all members, or a monetary sanction of $10,000 or more, current IM–8310–3(g) provides that Nasdaq shall notify the membership and press as soon as possible after receiving the appeal. The notice must state whether the effectiveness of the Nasdaq Board's decision has been stayed pending the outcome of Commission proceedings. In the event of an appeal to the courts from a Commission decision that resolves a Nasdaq decision imposing an expulsion, revocation, suspension, bar on associating with all members, or a monetary sanction of $10,000 or more, current IM–8310–3(h) provides that Nasdaq shall notify the membership as soon as possible after receiving a formal notice of appeal. The notice must state whether the order of the Commission was stayed.

Proposed Rule Change

i. Definitions

Modeled after FINRA and NYSE Rules 8313, proposed IM–8310–3(a)(1) and (2) respectively define the terms ''disciplinary complaint'' and ''disciplinary decision,'' which current IM–8310–3 does not define. Under proposed IM–8310–3(a)(1), a ''disciplinary complaint'' means any complaint issued pursuant to the Rule 9200 Series or any notice issued pursuant to Rules 9400 or 9810.[5] The proposed inclusion of notice issued pursuant to Rule 9400 would result in the publication of notices seeking expedited suspension proceedings against a member alleged to have violated Nasdaq General 9, Section 53 (Disruptive Quoting and Trading Activity Prohibited). The proposed inclusion of notice issued pursuant to Rule 9810 would result in the publication of temporary cease and desist notices issued by Nasdaq Regulation or FINRA's Department of Enforcement. Current IM–8310–3 does not expressly provide for the publication of, or provision of information about, notice issued pursuant to Rules 9400 or 9810.[6]

Proposed IM–8310–3(a)(2) defines ''disciplinary decision'' to mean:

> any decision issued pursuant to the Rule 9000 Series, including decisions issued by a Hearing Officer, Hearing Panel, Extended Hearing Panel, Nasdaq Review Council, the Nasdaq Board, or any committee or subcommittee thereof; orders accepting offers of settlement; Letters of Acceptance, Waiver and Consent; suspension orders pursuant to Rule 9400; and temporary cease and desist decisions and orders pursuant to the Rule 9800 Series; provided, however, such term does not include decisions issued pursuant to the Rule 9550 Series, or decisions, notifications, or notices issued pursuant to the Rule 9520 Series, which are addressed by paragraphs (b)(2) and (b)(3) of this Rule. Minor rule violation plan letters issued pursuant to Rule 9216 are not subject to this Rule.

The proposed definition of ''disciplinary decision'' specifies which items would be subject to publication as ''disciplinary decisions'' pursuant to proposed IM–8310–3(b). The proposed definition excludes decisions issued pursuant to the Rule 9550 Series and decisions, notifications, or notices issued pursuant to the Rule 9520 Series, which items are addressed by proposed paragraphs IM–8310–3(b)(2) and (b)(3) (discussed below). The proposed definition also excludes minor rule violation plan (''MRVP'') letters from IM–8310–3, maintaining Nasdaq's current practice of not publishing, or releasing information about, such letters.[7] The proposed definition of ''disciplinary decision'' also does not cover exemptive-relief decisions issued under the Rule 9600 Series because Rule 9620 already governs the release of exemptive-relief decisions.

Proposed IM–8310–3(a)(3) would specify the terms that carry the same meanings as defined in existing Rule 9120, such as ''Department of Enforcement,'' ''Hearing Panel,'' ''Nasdaq Regulation Department,'' and ''Nasdaq Review Council.''

ii. General Standards

Proposed IM–8310–3(b)(1)(i) provides that Nasdaq Regulation would release to

[4] *See https://www.nasdaq.com/market-regulation/americas/disciplinary.*

[5] Defining ''disciplinary complaint'' to include notices issued pursuant to Rules 9400 or 9810 differs from the definitions of FINRA (which covers only FINRA disciplinary complaints issued pursuant to FINRA's Rule 9200 Series) and NYSE (which does not cover temporary cease and desist notices issued pursuant to NYSE's analogous Rule 9810). *See* FINRA and NYSE Rules 8313(e)(1).

[6] Although current IM–8310–3 does not expressly provide for the publication of, or provision of information about, notice issued pursuant to Rules 9400 or 9810, current IM–8310–3(b) provides that Nasdaq Regulation may release information with respect to a disciplinary complaint initiated by FINRA's Department of Enforcement involving a significant policy or enforcement determination where the release of information is deemed by Nasdaq's Chief Regulatory Officer to be in the public interest.

[7] MRVP letters do not qualify for release under current IM–8310–3 because, pursuant to Rule 9216(b) and IM–9216, they involve a fine not to exceed $2,500 and/or a censure.

the public a copy of any disciplinary complaint issued by Nasdaq Regulation or FINRA's Department of Enforcement acting on behalf of Nasdaq.[8] The proposed release of disciplinary complaints would follow the practices of FINRA and NYSE, which release disciplinary complaints to the public under their respective Rules 8313(a). As noted above, Nasdaq proposes to release to the public a copy of the disciplinary complaint itself, mooting the need to release a summary of (that is, ''information about'') such document.

While current Nasdaq IM–8310–3(a) requires releasing a copy of an identified disciplinary complaint issued by ''Nasdaq or any committee thereof,'' the proposed IM–8310–3(b)(1)(i) would reflect that FINRA's Department of Enforcement also may issue a disciplinary complaint on Nasdaq's behalf. The proposed rule also would specify the department within Nasdaq (namely, Nasdaq Regulation Department) that issues Nasdaq's disciplinary complaints. In addition to posting eligible disciplinary complaints and disciplinary decisions on Nasdaq's website (as specified in proposed IM–8310–3(c)(4), discussed in greater detail below), Nasdaq would continue to provide a requesting party with a copy of an identified disciplinary complaint or disciplinary decision of the Exchange, as provided in current IM–8310–3(a).[9]

Under proposed IM–8310–3(b)(1)(ii), Nasdaq Regulation also would release to the public a copy of any disciplinary decision of the Exchange. Under proposed IM–8310–3(a)(2), disciplinary decisions of the Exchange would include those issued under the Rule 9000 Series by adjudicators within FINRA's Office of Hearing Officers acting pursuant to a Nasdaq-FINRA RSA. Expanding the availability of Nasdaq disciplinary decisions, this proposal would provide for the release to the public of all disciplinary decisions imposing a monetary penalty (eliminating the current $10,000 threshold below which the Exchange does not currently release or provide information about such decisions) as well as the release of temporary cease and desist decisions and orders.[10] As noted above, Nasdaq Regulation's public release of disciplinary decisions would moot the need to release a summary of (*i.e.,* ''information about'') disciplinary decisions instead of, or in addition to, releasing such documents.

Proposed IM–8310–3(b)(2) provides that Nasdaq shall release to the public a copy of any statutory disqualification decision, notification, or notice issued by the Exchange or FINRA's Department of Member Regulation pursuant to the Rule 9520 Series that will be filed with the Commission. Current IM–8310–3 does not expressly provide for the publication of, or release of information about, decisions, notifications, or notices issued pursuant to the Rule 9520 Series. As noted above, Nasdaq Regulation's public release of a statutory disqualification decision, notification, or notice that will be filed with the Commission would moot the need to also release a summary of (*i.e.,* ''information about'') such document.[11]

Proposed IM–8310–3(b)(3) provides that Nasdaq shall release to the public information with respect to any suspension, cancellation, expulsion, limitation, prohibition, or bar imposed pursuant to the Rule 9550 Series that constitutes final Exchange action. This proposed provision replaces the discretionary release of information (''may release'' under current IM–8310–3(c)(1)) with mandatory publication (''shall release'' under proposed IM–8310–3(b)(3)), subject to Nasdaq Regulation's discretion not to publish such information in appropriate limited circumstances (detailed in Section 3(a)(iv) of this proposal). Proposed IM–8310–3(b)(3) also newly provides for the publication of information about a ''limitation'' or ''prohibition'' on a member's or associated person's access to services pursuant to the Rule 9550 Series or about the summary suspension or expulsion of a member organization or the summary revocation of the registration of a covered person for a failure to pay fines, other monetary sanctions, or costs pursuant to Rule 8320. By publishing information about a ''limitation'' or ''prohibition'' imposed under the Rule 9550 Series that constitutes final Exchange action, proposed IM–8310–3(b)(3) would govern comprehensively the publication of information about any sanction or preventative measure that may be imposed under the Rule 9550 Series.[12]

Finally, proposed IM–8310–3(b)(4) newly provides that Nasdaq may release to the public a copy of any other disciplinary decision not governed by subsection IM–8310–3(b)(1) or (2) that is appealable to the Commission under Section 19(d). Proposed IM–8310–3(b)(4) aligns with NYSE Rule 8313(a)(4), except that proposed IM–8310–3(b)(4) does not mention exemptive-relief decisions because existing Nasdaq Rule 9620 already governs the release of exemptive-relief decisions, as noted above.[13] In addition, proposed IM–8310–3(b)(4) does not provide for publication of information about a disciplinary decision published under proposed IM–8310–3(b)(4) because Nasdaq believes that publishing the disciplinary decision itself moots the need to also release a summary of the disciplinary decision.

Given that proposed IM–8310–3(b)(1)(i) and (ii) broadly provide for the public release of the Exchange's disciplinary complaints and disciplinary decisions (as discussed in greater detail above), proposed IM–8310–3 omits current IM–8310–3(b)(1)'s and (c)(1)'s respective provisions permitting the release of information about a disciplinary complaint or disciplinary decision where Nasdaq's Chief Regulatory Officer deems the information release to be in the public interest and where the disciplinary complaint or disciplinary decision involves a significant policy or enforcement determination. As

[8] In February 2025, the Commission approved a proposal that enables Nasdaq Regulation to litigate contested disciplinary proceedings arising out of Nasdaq-led investigations and enforcement activities. *See* SEC Release No. 34–102385 (Feb. 10, 2025), 90 FR 9647 (Feb. 14, 2025) (approving SR–NASDAQ–2024–083). Previously, FINRA's Department of Regulation acting under an RSA or a third-party law firm or other SRO would handle all disciplinary litigation on Nasdaq's behalf.

[9] Reflecting that a Nasdaq-FINRA RSA permits FINRA's Department of Enforcement to issue a disciplinary complaint on behalf of Nasdaq and permits FINRA's Office of Hearing Officers to issue a disciplinary decision on behalf of Nasdaq, proposed IM–8310–3(b)(1) uses the term ''of the Exchange'' rather than ''issued by Nasdaq or any committee thereof'' (the term in current IM–8310–3(a)) in describing the disciplinary complaints and disciplinary decisions that Nasdaq would provide upon request. In addition, Nasdaq also would provide upon request disciplinary complaints and disciplinary decisions it issues.

[10] Although FINRA's and NYSE's respective definitions of ''disciplinary decision'' omit temporary cease-and-desist decisions and orders, both SROs publicly release such orders under their respective Rules 8313(a)(2).

[11] Like proposed IM–8310–3(b)(2), FINRA's and NYSE's respective Rules 8313(a)(2) require releasing to the public a copy of a statutory disqualification decision, notification, or noticed issued by those respective SROs. However, unlike proposed IM–8310–3(b)(2), FINRA's and NYSE's respective Rules 8313(a)(2) also permit releasing ''information about'' such a document. As discussed throughout this proposal, Nasdaq believes that the release of a statutory disqualification decision, for example, would moot the need to also release a summary of the decision.

[12] NYSE and FINRA Rules 8313(a)(3) do not expressly mention the publication of a copy of, or information about, a ''limitation'' or ''prohibition'' pursuant to their respective Rule 9550 Series.

[13] FINRA Rule 8313(a)(5) is broader in several respects than the NYSE Rule 8313(a)(4) upon which Nasdaq bases its proposed IM–8310–3(b)(4). FINRA Rule 8313(a)(5) also covers ''any decision or notice issued pursuant to [FINRA] Rule 6490,'' which relates to trading in non-exchange listed OTC securities, or FINRA's ''Rule 9700 Series,'' which relates to grievances in automated quotation, execution, or communication systems owned or operated by FINRA or FINRA Regulation.

discussed throughout this proposal, Nasdaq believes that releasing a copy of a disciplinary complaint or disciplinary decision makes it unnecessary to also release a summary of such document. In providing generally for the publication of the Exchange's disciplinary complaints and disciplinary decisions (as discussed in greater detail above) and omitting a provision that permits informational releases if the Exchange's Chief Regulatory Officer deems the informational release to be in the public interest, proposed IM–8310–3 aligns with NYSE Rule 8313 (which similarly does not provide for an informational release where a NYSE officer deems such a release to be in the public interest).[14]

iii. Release Specifications

Proposed IM–8310–3(c)(1) and (2) are substantially similar to current IM–8310–3(a)(1)–(3), which they replace and supersede. Proposed IM–8310–3(c)(1) provides that copies of any disciplinary complaint released to the public pursuant to proposed IM–8310–3(b) shall indicate that a disciplinary complaint represents the initiation of a formal proceeding by the Exchange in which findings as to the allegations in the complaint have not been made and does not represent a decision as to any of the allegations contained in the complaint.[15] [16] Proposed IM–8310–3(c)(2) provides that copies of, and information with respect to, any disciplinary decision or other decision, order, notification, or notice released to the public pursuant to proposed IM–8310–3(b) prior to the expiration of the time period provided for an appeal or call for review as permitted under Exchange rules or the Exchange Act, or while such an appeal or call for review is pending, shall indicate as appropriate that the findings and sanctions imposed therein are subject to review and modification by the Exchange or the Commission.

Proposed IM–8310–3(c)(3) is substantially similar to current IM–8310–3(k), which it replaces and supersedes. As a result of proposed IM–8310–3(c)(3), releases of information would identify the Nasdaq or Commission rule violated and the conduct constituting the violation. Under the proposed subparagraph (c)(3), the requirement that a ''release'' describe the rule violated and the conduct constituting the violation would apply only to ''releases of information.'' Nasdaq disciplinary complaints and disciplinary decisions necessarily identify the rules violated and the conduct constituting the violation, making it unnecessary for IM–8310–3(c)(3) to also cover Nasdaq disciplinary complaints and disciplinary decisions. For example, under Rule 9212, a disciplinary complaint must ''specify in reasonable detail the conduct alleged to constitute the violative activity and the rule, regulation, or statutory provision the Respondent is alleged to be violating or to have violated.'' Under Rule 9216, which governs letters of Acceptance, Waiver, and Consent (''AWCs''), an AWC must describe the ''act or practice engaged in or omitted, the rule, regulation, or statutory provision violated, and the sanction or sanctions to be imposed.''

Proposed IM–8310–3(c)(4) specifies that Nasdaq would release disciplinary complaints, disciplinary decisions, information, notices, or any other items required to be released to the public pursuant to the Rule by posting such items on the Exchange's website. By posting such items to the Exchange's publicly accessible website, Nasdaq Regulation would satisfy the requirement to release to the public the documents and information specified in proposed IM–8310–3.

iv. Discretion To Redact Certain Information or Waive Publication

Proposed IM–8310–3(d)(1) provides that, notwithstanding proposed IM–8310–3(b) and (c)(4), the Exchange may, in its discretion and on a case-by-case basis, redact information that contains confidential customer information, including customer identities, or information that raises significant identity theft, personal safety, privacy, or other concerns that are not outweighed by investor protection concerns. While the Exchange anticipates that most redactions would protect the privacy of third parties, the more general term ''other concerns'' is intended to preserve the Exchange's flexibility to redact information outside the specified privacy- and safety-related categories but that the Exchange nevertheless determines warrants redaction after weighing investor protection concerns.[17] Current IM–8310–3 does not specifically provide for the redaction of information raising significant identity theft, personal safety, privacy, or other concerns after weighing such concerns against investor protection concerns.

Proposed IM–8310–3(d)(2) provides that, notwithstanding proposed IM–8310–3(b) and (c)(4), the Exchange may determine, in its discretion, to waive the requirement to release a copy of, or information with respect to, any disciplinary complaint, disciplinary decision or other decision, order, notification, or notice under those extraordinary circumstances where the release of such information would violate fundamental notions of fairness or work an injustice. This proposed subparagraph, which replaces and supersedes current IM–8310–3(c)(1), does not change the standard for waiving the public-release requirement, *i.e.,* it employs the same standard of ''fundamental notions of fairness or work an injustice'' as current IM–8310–3(c)(1). Given that proposed IM–8310–3(b) would provide newly for the release of disciplinary complaints, proposed IM–8310–3(d)(2)'s ''fundamental notions of fairness or work an injustice'' standard would apply newly to disciplinary complaints (not just disciplinary decisions, as does current IM–8310–3(c)(1)).

v. Other Items

Proposed IM–8310–3(e), titled ''Notice of Appeals to the Commission of Exchange Decisions,'' would replace and supersede current IM–8310–3(g). This proposed subparagraph provides that the Exchange shall provide notice to the public when a disciplinary decision of the Exchange is appealed to the Commission, and the notice shall state whether the effectiveness of the decision has been stayed pending the outcome of proceedings before the Commission. Proposed IM–8310–3(e) would expand the categories of appeals for which the Exchange would provide public notice of the appeal to include the appeal of all disciplinary decisions (as defined in proposed IM–8310–

[14] Unlike NYSE Rule 8313 and proposed IM–8310–3, FINRA Rule 8313(a)(6) provides that FINRA may release specified documents or information where such release is deemed by FINRA's Chief Executive Officer (''CEO''), or such other senior officer as FINRA's CEO may designate, to be in the public interest, in such format as he or she finds appropriate.

[15] The language in proposed IM–8310–3(c)(1) accompanying the release of a disciplinary complaint makes clear that the complaint contains only the Exchange's allegations. As a result, proposed IM–8310–3(c)(1) does not contain current IM–8310–3(a)(1)'s requirement that a public release also contain an accompanying statement that, ''[b]ecause this complaint is unadjudicated, you may wish to contact the respondent before drawing any conclusions regarding the allegations in the complaint.'' FINRA's and NYSE's respective Rules 8313 similarly do not require that such language accompany the release of a disciplinary complaint.

[16] As noted throughout this proposal, the Exchange believes that the requirement to make public a copy of a disciplinary complaint makes it unnecessary to also release information about (*i.e.,* a summary of) the complaint in addition to, or in lieu of, publishing the disciplinary complaint.

[17] FINRA's and NYSE's respective Rules 8313(c)(1) governing redaction contain no general ''other concerns'' language permitting redaction after weighing investor protection concerns.

3(a)(2), discussed above). In contrast, current IM–8310–3(g) more narrowly requires Nasdaq to notify its membership and the press of appeals to the Commission from Nasdaq disciplinary decisions only if the sanction is at least $10,000 or involves an expulsion, revocation, or suspension of a member or a bar on an associated person's associating with all members. While current IM–8310–3(g) requires Nasdaq to provide notice to the ''membership and to the press,'' proposed IM–8310–3(e) would require Nasdaq to provide notice to the public more broadly. As discussed above, Nasdaq would provide notice under proposed IM–8310–3(c)(4) by posting such notices on the Exchange's publicly accessible website.

Proposed IM–8310–3(f), titled ''Notice of Appeal to the Courts of Commission Decisions,'' would replace and supersede current IM–8310–3(h). This proposed subparagraph provides that the Exchange shall provide notice to the public if a decision by the Commission in a case previously appealed to it from a disciplinary decision of the Exchange is appealed to the courts, and the notice shall state whether the order of the Commission has been stayed. Proposed IM–8310–3(f) also would expand the categories of appeals for which the Exchange would provide notice of the appeal. While current IM–8310–3(h) requires providing notice of an appeal to the courts from a Commission decision involving Nasdaq's imposition of monetary sanctions of at least $10,000 or an expulsion, revocation, suspension, or bar of a member or associated person, proposed IM–8310–3(f) provides that Nasdaq would provide notice of appeal to the courts from any disciplinary decision of the Exchange (as defined in proposed IM–8310–3(a)(2)), even if the monetary sanction is less than $10,000. While current IM–8310–3(h) requires providing notice to the ''membership,'' proposed IM–8310–3(f) would require Nasdaq to provide notice to the public more broadly. As discussed above, Nasdaq would provide notice under proposed IM–8310–3(c)(4) by posting such notices on the Exchange's publicly accessible website.

Current IM–8310–3(e) would be renumbered to proposed IM–8310–3(h). Additionally, the proposed subparagraph (h) would reflect that FINRA's Office of Disciplinary Affairs may accept an AWC under Rule 9216 or an offer of settlement under Rule 9270 that imposes an expulsion or bar and that, consistent with proposed subparagraph IM–8310–3(b)(1), Nasdaq Regulation would release the disciplinary decision imposing the expulsion or bar. Nasdaq Regulation's authority to release the disciplinary decision imposing an expulsion or bar immediately upon approval would remain unchanged.

Current IM–8310–3(i), which would be renumbered to proposed IM–8310–3(j), would clarify that Nasdaq will provide public notice of specified Commission orders only in cases previously appealed to the Commission from a decision of Nasdaq. Consistent with the elimination of the $10,000 threshold for publishing disciplinary decisions, Nasdaq also would notify the public as soon as possible after receiving a Commission order imposing any monetary sanction in a case that originates from a Nasdaq disciplinary decision. As discussed above, Nasdaq would provide notice under proposed IM–8310–3(c)(4) by posting such notices on the Exchange's publicly accessible website.

The text of current IM–8310–3(d), (f), and (j) would remain unchanged but would be renumbered as follows: current subsection IM–8310–3(d) would become subsection IM–8310–3(g); current subsection IM–8310–3(f) would become subsection IM–8310–3(i); and current subsection IM–8310–3(j) would become subsection IM–8310–3(k).

The text and numbering of current IM–8310–3(l) would remain unchanged.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[18] in general, and furthers the objectives of Section 6(b)(5) of the Act,[19] 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. By providing for the publication of Nasdaq disciplinary complaints and expanding the category of disciplinary decisions published on Nasdaq's website, the proposed rule makes disciplinary complaints and disciplinary decisions more readily accessible to member firms, associated persons, the securities industry, and the public at large. In doing so, Nasdaq's proposed rule promotes just and equitable principles of trade and protects investors and the public interest.

Specifically, the Exchange believes that greater access to Nasdaq disciplinary decisions will provide valuable guidance and information to member organizations, associated persons, investors, and the securities industry generally. The publication of disciplinary decisions can deter and prevent misconduct by firms and improve overall business standards in the securities industry, as well as allowing prospective firm customers to consider firms' and representatives' disciplinary histories when deciding whether to conduct business with them. In addition, the publication of disciplinary decisions allows member organizations to use that information in educating their compliance staffs and informing their compliance procedures that involve similar business lines, products, or industry practices. Eliminating the $10,000 monetary threshold below which the Exchange does not currently release disciplinary decisions also would align the Exchange's publication rule with those of FINRA and NYSE.

The Exchange believes that the public release of Nasdaq disciplinary complaints (including temporary cease and desist notices) on Nasdaq's website will allow member firms to more quickly identify conduct that Nasdaq Regulation views as violating applicable Nasdaq or Commission rules and, if necessary, to curtail sooner similar conduct in which the member firms may be engaged. The Exchange also believes that prospective customers of a member firm would benefit from the opportunity to review a disciplinary complaint, accompanied by an appropriate statement noting that the complaint's factual allegations remain unadjudicated, as the prospective customers consider whether to conduct business with the member firm. Publishing the disciplinary complaint or the disciplinary decision itself often will provide member firms and the public with more detail about the violative conduct (or allegedly violative conduct in the case of a disciplinary complaint) than would a summary of the document.

In addition, the Exchange believes that defining the terms ''disciplinary complaint'' and ''disciplinary decision'' will provide member firms and associated persons with greater clarity about which discipline-related items the Exchange would publish, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system and, in general, protecting investors and the public interest. Similarly, the Exchange believes that the incorporation in proposed IM–8310–3(a)(3) of specified definitions from Rule 9120 would promote consistency and clarity by making clear that Rule 9120's

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(5).

definitions apply to such defined terms when used in proposed IM–8310–3.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change involves the administration of the Exchange's disciplinary procedures and raises no competitive concerns. Rather than addressing competitive issues, the proposed rule change would make Nasdaq disciplinary complaints and disciplinary decisions more readily available to member firms, associated persons, investors, and the public at large.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [20] and subparagraph (f)(6) of Rule 19b–4 thereunder.[21]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

[20] 15 U.S.C. 78s(b)(3)(A)(iii).

[21] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

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–NASDAQ–2026–089 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–NASDAQ–2026–089. 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 filing 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–NASDAQ–2026–089 and should be submitted on or before November 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22266 Filed 10–30–26; 8:45 am]

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[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106751; File No. SR–NSCC–2026–011]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Concerning the Automated Customer Account Transfer Service Account Transfer Process for Insurance and Retirement Products

October 28, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 16, 2026, National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. NSCC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(4) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change amends the NSCC Rules & Procedures (''NSCC Rules'') concerning the Automated Customer Account Transfer Service (''ACATS'') account transfer process for insurance and retirement products.[5]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4).

[5] Capitalized terms not defined herein shall have the meaning assigned to such terms in the NSCC Rules, *available at dtcc.com/legal/rules-and-procedures.*

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to amend the NSCC Rules to discontinue certain ACATS functionality for transmitting information necessary to re-register insurance products (*e.g.,* annuities) through NSCC's Insurance & Retirement Solutions (''I&RS'') service and transfer responsibility for insurance product registration and confirmation to NSCC's I&RS services system.

The proposed rule change is discussed in detail below.

Background

ACATS Overview

ACATS is a non-guaranteed service provided by NSCC that enables Members to effect transfers of customer accounts among themselves. ACATS complements Financial Industry Regulatory Authority (''FINRA'') Rule 11870 regarding customer account transfers, which requires FINRA members to use automated clearing agency customer account transfer services and to effect customer account transfers within specified time frames.[6] ACATS automates and standardizes procedures for the transfer of assets in a customer account, allowing Members to efficiently and automatically enter, review, and generate instructions to settle customer account transfers. The timing and procedures with respect to ACATS customer account transfers are intended to be consistent with the timing and processes set forth in FINRA Rule 11870.

ACATS provides functionality for account transfers that include I&RS Products such as annuities (referred to as the ''ACATS/Insurance Processing Service'' or ''ACATS/IPS'').[7] ACATS/IPS automates the changes in distributors of record for an annuity when clients transfer their accounts from one brokerage firm to another. ACATS/IPS enables distributors to include annuity assets, along with other securities, when transferring accounts and gives them automated, timely access to important information about their customers' portfolios. The service also facilitates representative of record and broker-identification number changes within a contract.

ACATS is primarily described in NSCC Rule 50 and Procedure XVIII of the NSCC Rules.[8] Pursuant to NSCC Rule 50, an NSCC Member to whom a customer's account will be transferred (the ''Receiving Member'') initiates the transfer by submitting a transfer initiation request to NSCC, which contains the customer detail information that the NSCC Member who currently has the account (the ''Delivering Member'') requires to transfer the account.[9] The Delivering Member must either reject the customer account transfer request or submit detailed customer account asset data to NSCC.[10] NSCC then provides a report detailing the customer account asset data to the Receiving Member,[11] who has one business day after receipt of the report to review the account and: (i) accept all assets; (ii) reject one or more assets, to the extent such a rejection is permitted by the Receiving Member's Designated Examining Authority (*i.e.,* FINRA), and allow the transfer of the remaining assets; (iii) request the Delivering Member to make adjustments to the customer account asset list; or (iv) reject the account, to extent such a rejection is permitted by NSCC or FINRA.[12] Once a customer account has been accepted by the Receiving Member, ACATS facilitates the settlements associated with the account transfer at the appropriate asset settling location (*e.g.,* through NSCC's Continuous Net Settlement system (''CNS'') for CNS-eligible securities, DTC for securities otherwise eligible for DTC settlement services, Fund/SERV for eligible mutual fund products, or I&RS for annuities).

Currently, Members utilize ACATS to both identify insurance products (primarily annuities) to be included in an account transfer and to manage the registration changes for those assets with broker-dealers and insurance carriers. Pursuant to Section 8 of NSCC Rule 50, if I&RS Eligible Products (or ''I&RS Products'') are to be transferred the Receiving Member shall, within one (1) Business Day after receipt from NSCC of the report detailing the I&RS Products data or simultaneous with the submission of an acceleration instruction, submit to NSCC detailed transfer instructions, which are processed through I&RS in accordance with Section 6 of NSCC Rule 57.[13] Each day NSCC also produces a report to the Receiving and Delivering Member, indicating the I&RS Eligible Products transfers which have been confirmed or rejected by the Insurance Carrier/Retirement Services Member in accordance with Section 6 of NSCC Rule 57, or which have been deleted.[14] NSCC is proposing changes to Section 8 of NSCC Rule 50 in connection with the proposed enhancements discussed herein.

Proposed Changes

NSCC proposes to modify the NSCC Rules to enhance the account transfer process for I&RS Products. As discussed above, ACATS is currently responsible for both identifying insurance products to be included in an account transfer and managing registration changes with broker-dealers and insurance carriers. NSCC proposes to enhance this process by transferring responsibility for insurance product re-registration and confirmation to NSCC's I&RS services system. ACATS would continue to allow firms to initiate and submit insurance assets for transfers but would pass those assets on to the I&RS system to complete the transfer process. The proposed change would streamline and simplify operational processes for Members by aligning the ACATS process for account transfers to the standard operational process used for insurance product re-registrations in the I&RS service.

Under the proposal, Members would continue to use ACATS to initiate a transfer, Delivering Members would continue to use ACATS to add insurance assets to a transfer, and ACATS would validate that the CUSIP and Receiving Member are ACATS/IPS eligible. However, the remaining processing of the re-registration and transfer of such assets would be completed through NSCC's I&RS service. Under the proposed enhancements, Receiving Members would receive a notification from I&RS that a broker-dealer of record change is required in connection with an account transfer, the Receiving Member would

[6] *See* FINRA Rule 11870, *available at www.finra.org/rules-guidance/rulebooks/finra-rules/11870.* NSCC also permits Qualified Securities Depositories (*i.e.,* The Depository Trust Company (''DTC'')) to utilize ACATS on behalf of their participants (*e.g.,* DTC member banks) on a voluntary basis. *See* Section 1 of NSCC Rule 50, *supra* note 5.

[7] *See www.dtcclearning.com/products-and-services/insurance-retirement-services/acats-ips.html.*

[8] *See* NSCC Rule 50 (Automated Customer Account Transfer Service) and Procedure XVIII (ACATS Settlement Accounting Operation) of the NSCC Rules, *supra* note 5.

[9] *See* Sections 2 and 3 of NSCC Rule 50, *supra* note 5.

[10] *See* Section 5 of NSCC Rule 50, *supra* note 5.

[11] *See* Section 7 of NSCC Rule 50, *supra* note 5.

[12] *See* Section 8 of NSCC Rule 50, *supra* note 5. Pursuant to FINRA Rule 11870(d)(8), a Receiving Member may reject a transfer of account assets in whole if the account is not in compliance with the Receiving Member's credit policies or minimum asset requirements. *See supra* note 7.

[13] *See* Section 8 of NSCC Rule 50 and Section 6 of NSCC Rule 57 (Insurance and Retirement Solutions), *supra* note 5.

[14] *See* Section 8 of NSCC Rule 50, *supra* note 5.

send the broker-dealer of record change directly to the I&RS system, I&RS would send data to Insurance Carrier and the Carrier would confirm back to I&RS, and I&RS would send a confirmation to the Receiving Member.

In connection with the proposed enhancements, NSCC would decommission a number of ACATS instructions, files and records, which would no longer be needed when these processes move to the I&RS system. This includes, for example, the decommissioning of (i) the Insurance Registration (IR) Record, which facilitates the re-registration of annuity assets; (ii) the insurance statistics file to confirm accepted and rejected transactions by the insurance carrier; and (iii) Receiver and Deliver (R&D) Insurance Instructions for IR records that were either rejected by the insurance carrier or not completed within twenty business days. Eligible assets would continue to be assigned to the I&RS services system when both the CUSIP and receiving broker qualify for I&RS processing.

In connection with the proposed changes, NSCC would remove references to I&RS Products and certain associated instructions and reports concerning I&RS Product transfers from Section 8 of NSCC Rule 50. Specifically, NSCC would modify Section 8 of NSCC Rule 50 to remove references to I&RS Products as products for which a Receiving Member must provide detailed transfer instructions through ACATS. Under the proposed enhancements, these instructions would be processed through the I&RS service and would no longer be processed through the ACATS system. NSCC would also modify Section 8 of Rule 50 to delete rule text describing the daily issuance of reports by NSCC to the Receiving and Delivering Member indicating the I&RS Eligible Products transfers which have been confirmed or rejected by the Insurance Carrier/Retirement Services Member in accordance with Section 6 of NSCC Rule 57, or which have been deleted. These reports would no longer be applicable under the enhanced I&RS Product transfer process.

NSCC notes that the ACATS/IPS service has seen only modest adoption and usage since its introduction in 2005. Fewer than ten Members currently use the ACATS/IPS service to process transfers of insurance products (particularly annuities) through the I&RS services system. These Members are also current users of the I&RS service. As NSCC continues to modernize its systems, NSCC believes that there is a substantial opportunity to improve and refine existing ACATS processes and potentially expand the volume of I&RS Products transferred via the ACATS platform. As noted above, the proposed change would streamline and simplify operational processes for Members by aligning the ACATS process for account transfers to the standard operational process used for annuity re-registrations in the I&RS service. This in turn may reduce the burden of maintaining separate processes for ACATS and non-ACATS re-registrations and encourage further use of the ACATS platform for account transfers. NSCC has performed outreach to Members currently using the ACATS/IPS service to inform them of the changes and assist in their transition to the new process for transferring I&RS Products.[15]

Implementation Timeframe

NSCC would implement the proposed rule change on November 20, 2026.

2. Statutory Basis

NSCC believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. Section 17A(b)(3)(F) of the Act[16] requires that the rules of a clearing agency be designed to, among other things, promote the prompt and accurate clearance and settlement of securities transactions. NSCC believes the proposed rule change is consistent with the requirements of Section 17A(b)(3)(F) of the Act for the reasons stated below.

As described above, NSCC is working with the industry to enhance the account transfer process for I&RS Products by transferring responsibility for insurance product registration and confirmation from ACATS to NSCC's I&RS services system. Members would continue to have the ability to initiate account transfers for I&RS Products within ACATS, but ACATS would then pass those assets on to the I&RS system to complete the transfer process. The proposed change would streamline and simplify the operational processes for Members by aligning the ACATS process for account transfers to the standard operational process used for insurance product re-registrations in the I&RS service. This in turn may reduce the burden of maintaining separate processes for ACATS and non-ACATS re-registration and encourage further use of the ACATS platform for account transfers. As a result, NSCC believes the proposed rule change would promote the prompt and accurate settlement of account transfers involving insurance products, consistent with the requirements of Section 17A(b)(3)(F) of the Act.[17]

(B) Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Act[18] requires that the rules of the clearing agency do not impose any burden on competition not necessary or appropriate in furtherance of the Act. The proposed rule change is designed to streamline and simplify operational processes for Members by aligning the ACATS process for account transfers to the standard operational process used for insurance product re-registrations in the I&RS service. While the proposed rule change would decommission certain ACATS functionality used by Members to transfer I&RS Products, those Members would continue to have the ability to initiate account transfers for accounts containing I&RS Products within ACATS and to complete the processing of such transfers using NSCC's I&RS service. This simplified process may in turn reduce the burden of maintaining separate processes for ACATS and non-ACATS re-registrations and encourage further use of the ACATS platform for account transfers. NSCC therefore believes the proposed rule change would not impose any burden on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

NSCC has not received or solicited any written comments relating to this proposal. If any written comments are received, they will be publicly filed as an Exhibit 2 to this filing, as required by Form 19b–4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b–4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

[15] NSCC has issued Important Notices to Members that contain additional details regarding the proposed enhancements *available at https://files.dtcc.com/download/assets/a9761-26/a01d4ba4957911f189704ec37e043074* and *https://files.dtcc.com/download/assets/a9767/a00c1d7a957911f1ad9bc258faf12821.*

[16] 15 U.S.C. 78q–1(b)(3)(F).

[17] *Id.*

[18] 15 U.S.C. 78q–1(b)(3)(I).

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at www.sec.gov/rules-regulations/how-submit-comment.* General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at *tradingandmarkets@sec.gov* or 202–551–5777.

NSCC reserves the right not to respond to any comments received.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [19] and paragraph (f) of Rule 19b–4 thereunder.[20] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–NSCC–2026–011 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to file number SR–NSCC–2026–011. 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 filing will be available for inspection and copying at the principal office of NSCC and on DTCC's website (*https://dtcc.com/legal/sec-rule-filings.aspx*). 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–NSCC–2026–011 and should be submitted on or before November 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22259 Filed 10–30–26; 8:45 am]

BILLING CODE 8011–01–P

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106756; File No. SR–NYSENAT–2026–28]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Bylaws of the Exchange

October 28, 2026.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on October 22, 2026, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the bylaws of the Exchange to (a) remove the requirement that the fair representation director be an ETP Holder or Person Associated with an ETP Holder; (b) make a conforming change to the title; and (c) update a cross reference. The proposed rule change is available on the Exchange's website at *www.nyse.com* and at the principal office of the Exchange.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Eighth Amended and Restated By-laws of the Exchange (the ''Bylaws'') to (a) remove the requirement that the fair representation director be an ETP Holder or Person Associated with an ETP Holder; [4] (b) make a conforming change to the title; and (c) update a cross reference.

Nominating Committee

The Exchange proposes to remove the requirement, in the first sentence of Article III, Section 3.4(b) (Nomination and Election), that the Nominating Committee [5] publish the names of ETP Holders or Persons Associated with an ETP Holder as its nominee for Non-Affiliated Director.[6] Rather, it would be able to name the individual of its choice as its nominee.

Currently, the Nominating Committee is limited to someone who is currently an ETP Holder or Person Associated with an ETP Holder. For example, the Nominating Committee cannot name someone who was until recently, but is not at present, a Person Associated with an ETP Holder. The proposed change would give the Nominating Committee more options: they still could name an ETP Holder or Person Associated with an ETP Holder Participant but could name another individual as well.

The Exchange proposes to amend the first sentence of Article III, Section

[4] ''ETP Holder'' and ''Person Associated with an ETP Holder'' are defined in Bylaws Article I, Section 1.1 (Definitions).

[5] The Nominating Committee is appointed by the Board and is composed of Non-Affiliated Directors and/or ETP Holder Representatives. *See* Bylaws Article V, Section 5.7 (Nominating Committee).

[6] ''Non-Affiliated Director'' is defined in Bylaws Article III, Section 3.2(a) (General Composition) as an ''individual[ ] nominated by the ETP Holders of the Exchange''.

3.4(b) so that the Nominating Committee may name individuals of its choice as nominees. More specifically, the Exchange proposes to make the following change (proposed addition underlined, proposed deletion in brackets):

The Nominating Committee shall publish the name(s) of one or more [ETP Holders or Persons Associated with an ETP Holder (in any combination)]*individuals* as its nominee(s) for Non-Affiliated Directors of the Board of Directors of the Exchange.

The proposed change would be consistent with the New York Stock Exchange LLC and NYSE American LLC, affiliates of the Exchange, which have no equivalent requirement.[7] The Exchange notes that the proposed change also would be consistent with the governing documents of other self-regulatory organizations, such as the Nasdaq Stock Market LLC[8] and CBOE BYX Exchange, Inc.[9]

Title

The Exchange proposes to make a non-substantive technical and conforming change to the title of the Bylaws, to replace ''Eighth'' with ''Ninth.''

Cross Reference

The Exchange proposes to make a non-substantive corrective change to a cross-reference in Article V, Section 5.7, from a reference to Section 3.5 (Chairman) to a reference to Section 3.4. Section 3.5, which the section currently refers to, does not address the Nominating Committee ''approving and submitting names of candidates for election to the position of Non-Affiliated Director'' unlike Section 3.4, which does.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act,[10] in general, and furthers the objectives of Section 6(b)(1)[11] in particular, in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange. The Exchange believes that the proposed rule change is consistent with Section 6(b)(3) of the Exchange Act,[12] in that it would ensure a fair representation of its members in the selection of its directors and administration of its affairs. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(5) of the Exchange Act,[13] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the change would enable it to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and would ensure a fair representation of its members in the selection of its directors and administration of its affairs because it would allow the Nominating Committee to name the individuals of its choice as its nominees, and not be limited to individuals that are currently ETP Holders or Persons Associated with an ETP Holder. The proposed changes would allow the Exchange to ensure that it remains in compliance with the Exchange Act.[14]

The Exchange believes that for the same reason the rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest, as it would remove the limitation, and therefore give the Nominating Committee more options.

The proposed change to Section 3.4(b) would make the Bylaws consistent with the New York Stock Exchange LLC and NYSE American LLC, affiliates of the Exchange, which have no equivalent requirement.[15]

The proposed change to the title and cross-reference in Section 5.7 (''Non-Substantive Changes'') are non-substantive changes that do not impact the governance or ownership of the Exchange. The Exchange believes that the proposed Non-Substantive Changes would enable the Exchange to continue to be so organized as to have the capacity to carry out the purposes of the Exchange Act and comply and enforce compliance with the provisions of the Exchange Act by its members and persons associated with its members, because making the Non-Substantive Changes would contribute to the orderly operation of the Exchange by adding clarity and transparency to the Bylaws, ensuring that market participants can more easily navigate, understand and comply with the governing documents of the Exchange. For the same reason, the Exchange believes that the proposed Non-Substantive Changes would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest. The proposed rule changes would reduce potential investor or market participant confusion.

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 Exchange Act. The proposed rule change is not intended to address competitive issues but rather is concerned solely with ensuring that the Nominating Committee has more options in naming its nominees and making Non-Substantive changes to the Bylaws.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[16] and Rule 19b–4(f)(6) thereunder.[17] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which

[7] *See id.,* Article II, Section 2.03, and Thirteenth Amended and Restated Operating Agreement of NYSE American LLC, Article II, Section 2.03. *See also* Securities Exchange Act Release No. 87914 (January 8, 2020), 85 FR 2191 (January 14, 2020) (SR–NYSE–2019–62) (Order Approving Proposed Rule Change To Amend Article II, Section 2.03 of the Twelfth Amended and Restated Operating Agreement of the Exchange To Remove the Independence Requirement for the Director Elected by Exchange Membership Organizations).

[8] *See* Bylaws of the Nasdaq Stock Market LLC, Article I (noting that a ''Member Representative Director may, but is not required to be, an officer, director, employee, or agent of a Nasdaq Member'').

[9] See Ninth Amended and Restated Bylaws of CBOE BYX Exchange, Inc., Article III, Sections 3.1 and 3.2.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(1).

[12] 15 U.S.C. 78f(b)(3).

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78f(b)(3).

[15] *See* note 7, *supra.*

[16] 15 U.S.C. 78s(b)(3)(A)(iii).

[17] 17 CFR 240.19b–4(f)(6).

it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[18]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[19] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSENAT–2026–28 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSENAT–2026–28. 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 filing 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–NYSENAT–2026–28 and should be submitted on or before November 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22263 Filed 10–30–26; 8:45 am]

BILLING CODE 8011–01–P

[18] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[19] 15 U.S.C. 78s(b)(2)(B).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106750; File No. SR–NYSEARCA–2026–105]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 3.2(b)(3)(C)(ii)

October 28, 2026.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on October 15, 2026, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 3.2(b)(3)(C)(ii) so that the nominating committee may name any individuals as its nominees for the board of directors of the Exchange. The proposed rule change is available on the Exchange's website at *www.nyse.com* and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 3.2(b)(3)(C)(ii) (Exchange Committees) so that the nominating committee may name any individuals as its nominees for the board of directors (''Board'') of the Exchange.

Currently, the first sentence of Rule 3.2(b)(3)(C)(ii) provides that the Nominating Committee[4] shall ''publish the name of one (1) or more OTP Holders or Associated Persons of an OTP Firm or ETP Holder or Associated Persons of an ETP Holder as its nominee(s)''[5] for non-affiliated directors of the Board of the Excahange.

This limits the Nominating Committee in naming the individuals of its choice: it can only name someone who is *currently* an OTP Holder or Associated Person of an OTP Firm or ETP Holder or Associated Person of an ETP Holder. For example, if someone was until recently, but is not at present, an Associated Person of an OTP Firm or Associated Person of an ETP Holder, the Nominating Committee cannot name them as a candidate.

The Exchange proposes to amend the first sentence of Rule 3.2(b)(3)(C)(ii) so that the Nominating Committee may name individuals of its choice as nominees. More specifically, the Exchange proposes to make the following change (proposed deletion bracketed, proposed addition underlined):

The Nominating Committee shall publish the name of one (1) or more [OTP Holders or Associated Persons of an OTP Firm or ETP Holder or Associated Persons of an ETP Holder] *individuals* as its nominee(s) for Non-Affiliated Directors of the Board of Directors of the NYSE Arca, Inc.

The proposed change would be consistent with the New York Stock

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Nominating Committee is appointed by the Board of the Exchange and has six members, consisting of three OTP Holders or Associated Persons of an OTP Firm and three ETP Holders or Associated Persons of an ETP Holder. *See* Rule 3.2(b)(3)(A) and (B). *See also* Rule 1.1 (Definitions).

[5] Rule 3.2(b)(3)(C)(ii).

Exchange LLC and NYSE American LLC, affiliates of the Exchange, which have no equivalent requirement.[6] The Exchange notes that the proposed changes also would be consistent with the governing documents of other self-regulatory organizations, such as the Nasdaq Stock Market LLC[7] and CBOE BYX Exchange, Inc.[8]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act,[9] in general, and furthers the objectives of Section 6(b)(1)[10] in particular, in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange. The Exchange believes that the proposed rule change is consistent with Section 6(b)(3) of the Exchange Act,[11] in that it would ensure a fair representation of its members in the selection of its directors and administration of its affairs. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(5) of the Exchange Act,[12] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the change would enable it to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and would ensure a fair representation of its members in the selection of its directors and administration of its affairs because it would allow the Nominating Committee to name the individuals of its choice as its nominees, and not be limited to individuals that are currently OTP Holders or Associated Persons of an OTP Firm or ETP Holder or Associated Persons of an ETP Holder. The proposed changes would allow the Exchange to ensure that it remains in compliance with the cited Exchange Act requirement.[13]

The Exchange believes that for the same reason the rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest, as it would remove the limitation, and therefore give the Nominating Committee more options.

The Exchange believes these changes are non-controversial and raise no novel regulatory, governance, or competitive issues. The proposed rule change would be consistent with the New York Stock Exchange LLC and NYSE American LLC, affiliates of the Exchange, neither of which require their nominating committees to limit their nominees.[14] The proposed change is intended solely to harmonize the Exchange's rules with an existing governance framework that has already been established and subject to regulatory review.

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 Exchange Act. The proposed rule change is not intended to address competitive issues but rather is concerned solely with ensuring that the Nominating Committee has more options in naming its nominees.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[15] and Rule 19b–4(f)(6) thereunder.[16] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[17]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[18] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–NYSEARCA–2026–105 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

[6] *See* Fourteenth Amended and Restated Operating Agreement of the New York Stock Exchange LLC, Article II, Section 2.03 and Thirteenth Amended and Restated Operating Agreement of NYSE American LLC, Article II, Section 2.03. *See also* Securities Exchange Act Release No. 87914 (January 8, 2020), 85 FR 2191 (January 14, 2020) (SR–NYSE–2019–62) (Order Approving Proposed Rule Change To Amend Article II, Section 2.03 of the Twelfth Amended and Restated Operating Agreement of the Exchange To Remove the Independence Requirement for the Director Elected by Exchange Membership Organizations).

[7] *See* Bylaws of the Nasdaq Stock Market LLC, Article I (noting that a ''Member Representative Director may, but is not required to be, an officer, director, employee, or agent of a Nasdaq Member'').

[8] See Ninth Amended and Restated Bylaws of CBOE BYX Exchange, Inc., Article III, Sections 3.1 and 3.2.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(1).

[11] 15 U.S.C. 78f(b)(3).

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78f(b)(3).

[14] *See* note 6, *supra.*

[15] 15 U.S.C. 78s(b)(3)(A)(iii).

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 15 U.S.C. 78s(b)(2)(B).

Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2026–105. 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 filing 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–NYSEARCA–2026–105 and should be submitted on or before November 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22258 Filed 10–30–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106752; File No. SR–NYSETEX–2026–38]

Self-Regulatory Organizations; NYSE Texas, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Bylaws of the Exchange

October 28, 2026.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on October 15, 2026, the NYSE Texas, Inc. (''NYSE Texas'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the title, Article II, Sections 1, 2 and 3, Article IV, Section 7, and Article IX, Section 1, of the bylaws of the Exchange to (a) replace the term ''Permit Holders'' with ''Participants,'' (b) clarify the definition of ''Participant,'' (c) remove the requirement that the fair representation director be a Participant, and (d) make a conforming change. The proposed rule change is available on the Exchange's website at *www.nyse.com* and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the title, Article II, Sections 1 (Powers), 2 (General Composition and Term of Office) and 3 (Nomination and Election), Article IV, Section 7 (Nominating Committee), and Article IX, Section 1 (Management of the Corporation), of the bylaws of the Exchange to (a) replace the term ''Permit Holders'' with ''Participants,'' (b) clarify the definition of ''Participant,'' (c) remove the requirement that the fair representation director be a Participant, and (d) make a conforming change.

Replacing Permit Holders With Participants

The Exchange Act requires that every exchange have rules that ''assure a fair representation of its members in the selection of its directors and administration of its affairs''.[4] In compliance with this requirement, the Exchange's bylaws set forth the process by which its fair representation directors, the ''Non-Affiliated Directors,'' are chosen.

Currently, the bylaws provide that Permit Holders nominate the Non-Affiliated Directors, may submit a different candidate, vote on contested nominations for Non-Affiliated Directors, and serve on the Nominating Committee.[5] ''Permit Holders'' are defined as ''trading permit holders who are permitted to trade on the [Exchange]'s facilities for the trading of equities that are securities as covered by the Exchange Act.''[6]

The Exchange recently made a filing to add a new membership category known as ''Limited Underwriting Members.'' Limited Underwriting Members are a type of non-trading Exchange membership solely for the limited purpose of acting as a principal underwriter of an underwritten public offering.[7] As such, they do not have trading permits, and so are not Permit Holders, but are members under the Exchange Act.[8]

Accordingly, to ensure that all ''members'' (as defined in the Exchange Act) have ''fair representation . . . in the selection of its directors and administration of its affairs''[9] the Exchange proposes to amend Article II, Sections 1, 2 and 3, and Article IV, Section 7 of the bylaws of the Exchange in order to replace references to ''Permit Holders'' with ''Participants.''

The proposed changes would make the bylaws consistent with the New York Stock Exchange LLC, an affiliate of the Exchange, which does not require a member be a permit holder in order to participate in the selection of fair representation directors.[10]

Definition of Participant

Currently, ''Participant'' is defined twice: in Article II, Section 1 as an ''individual, corporation, partnership or

[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78f(b)(3).

[5] The Nominating Committee is appointed by the board of directors. *See* Bylaws of NYSE Texas, Inc., Article IV, Section 2 (Appointment; Vacancies; and Removal). Currently Permit Holder representatives and Non-Affiliated Directors may serve on the Nominating Committee. *See* Bylaws of NYSE Texas, Inc., Article IV, Section 7 (Nominating Committee).

[6] Bylaws of NYSE Texas, Inc., Article II, Section 2.

[7] *See* Securities Exchange Act Release No. 104899 (February 26, 2026), 91 FR 10425 (March 9, 2026) (SR–NYSETex–2026–06) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Establishing Limited Underwriting Members).

[8] *See id.* at note 10. The filing stated that ''Limited Underwriting Members would be 'members' of a national securities exchange under the [Exchange] Act based on their agreement to be regulated by the Exchange in connection with underwriting activity.''

[9] 15 U.S.C. 78f(b)(3).

[10] *See* Fourteenth Amended and Restated Operating Agreement of the New York Stock Exchange, Article II, Section 2.03(a)(iv) and (v).

other entity that holds a permit issued by the [Exchange] to trade securities on the market operated by the [Exchange]''; and in Article IX, Section 1, as a ''member[ ], as that term is defined in Section 3 of the Exchange Act''.

The Exchange believes that these definitions are consistent, but for the avoidance of doubt and in case they become inconsistent, it proposes to replace the first definition with the second (and remove the definition from Article IX, Section 1). At the same time, it proposes to remove the reference to Section 3 of the Exchange Act and simply provide that ''Participant'' means ''any member as defined in the Exchange Act.''

Nominating Committee

The Exchange proposes to remove the requirement, in the first sentence of Article II, Section 3(b), that the Nominating Committee publish the name of a Participant as its nominee for Non-Affiliated Director. Rather, it would be able to name the individual of its choice as its nominee.

Currently, the Nominating Committee is limited to someone who is currently a Participant. For example, the Nominating Committee cannot name someone who was until recently, but is not at present, a Participant. The proposed change would give the Nominating Committee more options: they still could name a Participant but could name another person as well.

The proposed change would be consistent with the New York Stock Exchange LLC and NYSE American LLC, affiliates of the Exchange, which have no equivalent requirement.[11] The Exchange notes that the proposed change also would be consistent with the governing documents of other self-regulatory organizations, such as the Nasdaq Stock Market LLC[12] and CBOE BYX Exchange, Inc.[13]

Non-Substantive Change

The Exchange proposes to make a non-substantive technical and conforming change to the title, to add ''First Amended and Restated'' to it.

Proposed Changes

The Exchange proposes to make the following changes (proposed additions italicized, proposed deletions in brackets):

• Article II, Section 1 would be amended to read as follows:

The business and affairs of the Corporation shall be managed by its Board of Directors. The Board of Directors, acting in accordance with the terms of these bylaws and the rules of the Corporation (''rules''), shall be vested with all powers necessary for the governing of the Corporation as an ''exchange'' within the meaning of the Securities Exchange Act of 1934, as amended (the ''Exchange Act''), the regulation of the business conduct of any *member as defined in the Exchange Act*[individual, corporation, partnership or other entity that holds a permit issued by the Corporation to trade securities on the market operated by the Corporation] (each, a ''Participant''), and the promotion of the welfare, objects and purposes of the Corporation.

• Article II, Section 2(a) would be amended to read as follows:

Subject to Section 2(b), the Board shall consist of a number of directors (''Directors'') as determined from time to time by the stockholders; provided that (1) at least fifty percent (50%) of the directors will be persons from the public and will not be, or be affiliated with, a broker-dealer in securities or employed by, or involved in any material business relationship with, the Corporation or its affiliates (''Public Directors''); and (2) at least twenty percent (20%) of the directors shall consist of individuals nominated by the [trading permit holders who are permitted to trade on the Corporation's facilities for the trading of equities that are securities as covered by the Exchange Act (collectively, such individuals ''Permit Holders'')]*Participants* (such directors, ''Non-Affiliated Directors''). For purposes of calculation of the minimum number of Non-Affiliated Directors, if 20 percent of the Directors is not a whole number, such number of Directors to be nominated and selected by the [Permit Holders]*Participants* will be rounded up to the next whole number. The term of office of a director shall not be affected by any decrease in the authorized number of directors.

• Article II, Section 3(b) and (c) would be amended to read as follows:

(b) The Nominating Committee shall publish the name(s) of one or more [Participants]*individuals* as its nominee(s) for Non-Affiliated Directors of the Board of Directors of the Corporation. A director shall qualify as a Public Director or Non-Affiliated Director only so long as such director meets the requirements for that position. The Nominating Committee shall name sufficient nominees so that at least twenty percent (20%) of the Directors consist of Non-Affiliated Directors. The names of the nominees shall be published on a date in each year (the ''Announcement Date'') sufficient to accommodate the process described in this Section 3(b). After the name of proposed nominee(s) is published, [Permit Holders]*Participants* in good standing may submit a petition to the Corporation in writing to nominate additional eligible candidate(s) to fill Non-Affiliated Director position(s) during the next term. If a written petition of at least 10 percent of [Permit Holders]*Participants* in good standing is submitted to the Nominating Committee within two weeks after the Announcement Date, such person(s) shall also be nominated by the Nominating Committee; provided, however, that no [Permit Holders]*Participants,* either alone or together with other [Permit Holders]*Participants* that are deemed its affiliates, may account for more than 50% of the signatories to the petition endorsing a particular petition nominee for the Non-Affiliated Director position(s) on the Board of Directors of the Corporation. Each petition for a petition candidate must include a completed questionnaire used to gather information concerning director candidates (the Corporation shall provide the form of questionnaire upon the request of any [Permit Holder]*Participant*). Notwithstanding anything to the contrary, the Nominating Committee shall determine whether any petition candidate is eligible to serve on the Board of Directors (including whether such person is free of any statutory disqualification (as defined in section 3(a)(39) of the Exchange Act)), and such determination shall be final and conclusive.

(c) In the event that the number of nominees exceeds the number of available seats, the Nominating Committee shall submit the contested nomination to the [Permit Holders]*Participants* for selection. [Permit Holders]*Participants* shall be afforded a confidential voting procedure and shall be given no less than 20 calendar days to submit their votes. Each [Permit Holder]*Participant* in good standing may select one nominee for the

[11] *See id.,* Article II, Section 2.03, and Thirteenth Amended and Restated Operating Agreement of NYSE American LLC, Article II, Section 2.03. *See also* Securities Exchange Act Release No. 87914 (January 8, 2020), 85 FR 2191 (January 14, 2020) (SR–NYSE–2019–62) (Order Approving Proposed Rule Change To Amend Article II, Section 2.03 of the Twelfth Amended and Restated Operating Agreement of the Exchange To Remove the Independence Requirement for the Director Elected by Exchange Membership Organizations).

[12] *See* Bylaws of the Nasdaq Stock Market LLC, Article I (noting that a ''Member Representative Director may, but is not required to be, an officer, director, employee, or agent of a Nasdaq Member'').

[13] See Ninth Amended and Restated Bylaws of CBOE BYX Exchange, Inc., Article III, Sections 3.1 and 3.2.

contested seat on the Board of Directors; provided, however that no [Permit Holder]*Participant,* either alone or together with other [Permit Holders]*Participants* who are deemed its affiliates, may account for more than 20% of the votes cast for a particular nominee for the Non-Affiliated Director position(s) on the Board of Directors of the Corporation. With respect to the contested position, the nominee for the Board of Directors receiving the most votes of [Permit Holders]*Participants* shall be submitted by the Nominating Committee to the Board of Directors of the Corporation. Similarly, the Nominating Committee shall submit uncontested nominees to the Board of Directors. Tie votes shall be decided by the Board of Directors at its first meeting following the election.

• Article IV, Section 7 would be amended to read as follows:

The Nominating Committee shall consist solely of Non-Affiliated Directors, as defined above, and/or [Permit Holder]*Participant* representatives, and shall be responsible for approving and submitting names of candidates for election to the position of Non-Affiliated Director pursuant to, and in accordance with, Article II, Section 3. ''[Permit Holder]*Participant* representative'' shall mean an officer, director, employee or agent of a [Permit Holder]*Participant.*

• Article IX, Section 1 would be amended to read as follows:

In connection with managing the business and affairs of the Corporation, the Board of Directors shall consider applicable requirements for registration as a national securities exchange under Section 6(b) of the Exchange Act, including, without limitation, the requirements that (a) the rules of the Corporation shall be designed to protect investors and the public interest and (b) the Corporation shall be so organized and have the capacity to carry out the purposes of the Exchange Act and to enforce compliance by its [members, as that term is defined in Section 3 of the Exchange Act (such statutory members being referred to in the Corporation's bylaws and rules as '']Participants[''])] and persons associated with Participants, with the provisions of the Exchange Act, the rules and regulations under the Act and the rules of the Corporation.

The title would be amended by adding ''First Amended and Restated'' to it.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act,[14] in general, and furthers the objectives of Section 6(b)(1) [15] in particular, in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange. The Exchange believes that the proposed rule change is consistent with Section 6(b)(3) of the Exchange Act,[16] in that it would ensure a fair representation of its members in the selection of its directors and administration of its affairs. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(5) of the Exchange Act,[17] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The proposed rule changes replacing ''Permit Holders'' with ''Participants,'' conforming the definition of ''Participants,'' and removing limitations on who can be named by the Nominating Committee (collectively, the ''Proposed Changes'') would enable the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and ensure a fair representation of its members in the selection of its directors and administration of its affairs because they would ensure that all members are equal in selecting its Non-Affiliated Directors, whether or not they have a trading permit. The Proposed Changes would allow the Nominating Committee to name the individuals of its choice as its nominees and not be limited to individuals that are currently Participants.

The Proposed Changes would allow the Exchange to ensure that all ''members'' (as defined in the Exchange Act) have ''fair representation . . . in the selection of its directors and administration of its affairs'' [18] by including member organizations that do not have trading permits. The Proposed Changes would allow the Exchange to ensure that it remains in compliance with the cited Exchange Act requirement and make the bylaws consistent with the rules of the Exchange.

The Proposed Changes would make the bylaws consistent with the New York Stock Exchange LLC, an affiliate of the Exchange, as it does not require a member be a permit holder in order to participate in the selection of fair representation directors [19] and neither the New York Stock Exchange LLC nor NYSE American LLC require their nominating committees to limit their nominees.[20]

The proposed rule change to the title and moving up the definition of ''Participants'' (the ''Non-Substantive Changes'') are non-substantive changes that do not impact the governance or ownership of the Exchange. The Exchange believes that the proposed Non-Substantive Changes would enable the Exchange to continue to be so organized as to have the capacity to carry out the purposes of the Exchange Act and comply and enforce compliance with the provisions of the Exchange Act by its members and persons associated with its members, because making the Non-Substantive Changes would contribute to the orderly operation of the Exchange by adding clarity and transparency to its rules.

Further, the Exchange believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest. The Proposed Changes would make the bylaws consistent with the rules of the Exchange and therefore would ensure that market participants can more easily navigate, understand and comply with the governing documents of the Exchange. he proposed Non-Substantive Changes would ensure that market participants can more easily navigate, understand and comply with the governing documents of the Exchange. The proposed rule changes would therefore reduce potential investor or market participant confusion.

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 Exchange Act. The proposed rule change is not

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(1).

[16] 15 U.S.C. 78f(b)(3).

[17] 15 U.S.C. 78f(b)(5).

[18] 15 U.S.C. 78f(b)(3).

[19] *See* note 10, *supra.*

[20] *See* note 11, *supra.*

intended to address competitive issues but rather is concerned solely with making the bylaws consistent with the rules of the Exchange and making non-substantive changes to the bylaws.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [21] and Rule 19b–4(f)(6) thereunder.[22] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[23]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [24] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSETEX–2026–38 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSETEX–2026–38. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing 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–NYSETEX–2026–38 and should be submitted on or before November 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Sherry R. Haywood,

Assistant Secretary.

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[21] 15 U.S.C. 78s(b)(3)(A)(iii).

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[24] 15 U.S.C. 78s(b)(2)(B).

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106762; File No. SR–SAPPHIRE–2026–36]

Self-Regulatory Organizations; MIAX Sapphire, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Fees and Rebates for Professional Customer Orders for QCC and cQCC Transactions and Establish a Tiered Fee Structure for Away Market Maker Facilitation of Customer QFOs or cQFOs

October 28, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 15, 2026, MIAX Sapphire, LLC (''MIAX Sapphire'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Sapphire Options Exchange Fee Schedule (''Fee Schedule'') to: (1) reduce the initiating and contra-side fees applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book and Trading Floor; (2) reduce the rebates applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book and Trading Floor; and (3) establish a tiered fee structure applicable to Trading Floor transactions where a Member firm directs a paired order to the Trading Floor, the agency side of the paired order is a customer of the Member firm, and the contra-side origin of the paired order is an Away Market Maker of the same Member firm, depending on certain monthly breakup percentages and minimum sizes (all terms described below).

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-sapphire/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to: (1) reduce the initiating and contra-side fees applicable to Professional Customer [3] orders for QCC [4] and cQCC [5] transactions on the Exchange's Electronic Book [6] and Trading Floor; [7] (2) reduce the rebates applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book and Trading Floor; and (3) establish a tiered fee structure applicable to Trading Floor transactions where a Member [8] firm directs a paired QFO [9] or cQFO [10] to the Trading Floor, the agency side of the paired order is a customer of the Member firm, and the contra-side origin of the paired order is an Away Market Maker [11] of the Member firm, depending on certain monthly breakup percentages and minimum sizes.

The Exchange initially filed this proposal on July 31, 2026.[12] On August 17, 2026, the Exchange withdrew SR–SAPPHIRE–2026–31 and refiled this proposed rule change.[13] On October 15, 2026, the Exchange withdrew SR–SAPPHIRE–2026–34 and refiled this proposed rule change.

Proposal To Reduce Initiating and Contra-Side Fees for Professional Customer Orders for QCC and cQCC Transactions

First, the Exchange proposes to amend Sections 1)a)ii)–iii) and 1)c)ii)–iii) of the Fee Schedule to reduce the initiating and contra-side fees applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book and Trading Floor. Currently, the Exchange assesses Professional Customers the same initiating and contra-side fee of $0.12 per contract side for QCC and cQCC transactions that occur either on the Exchange's Electronic Book or on the Trading Floor. The Exchange now proposes to reduce this fee such that the Exchange will assess Professional Customers the same initiating and contra-side fee of $0.00 per contract side for QCC and cQCC transactions that occur either on the Exchange's Electronic Book or on the Trading Floor. The purpose of these changes is for business and competitive reasons. The proposed changes will also align the Exchange's fee for such transactions with the similar fee structures in place at other exchanges for both electronic and trading floor QCC (and/or cQCC) transactions for professional customer orders.[14]

Proposal To Reduce Rebates Applicable to Professional Customer Orders for QCC and cQCC Transactions

Next, the Exchange proposes to amend Sections 1)a)ii)–iii) of the Fee Schedule to reduce the rebates applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book. Currently, for EEMs [15] entering Professional Customer orders for both QCC and cQCC electronic transactions, the Exchange provides EEMs the following rebates: ($0.07) per contract when the contra-side is a Priority Customer; [16] ($0.17) per contract when the contra-side is a Professional Customer; and ($0.25) per contract when the contra-side is all other market participants (*i.e.,* MIAX Sapphire Market Maker,[17] Away Market Maker, Non-Member Broker-Dealer, and Firm). The Exchange now proposes to reduce these rebates. In particular, the Exchange proposes that for EEMs entering Professional Customer orders for both QCC and cQCC electronic transactions, the Exchange will provide EEMs the following rebates: ($0.00) per contract when the contra-side is a Priority Customer; ($0.00) per contract when the contra-side is a Professional Customer; and ($0.17) per contract when the contra-side is all other market participants (*i.e.,* MIAX Sapphire Market Maker, Away Market Maker, Non-Member Broker-Dealer, and Firm).

Next, the Exchange proposes to amend Sections 1)c)ii)–iii) of the Fee Schedule to reduce the rebates applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Trading Floor. Currently, for Floor Brokers [18] entering

[3] ''Professional Customer'' for the purposes of the Fee Schedule shall mean a Public Customer that is not a Priority Customer. *See* the Definitions section of the Fee Schedule. ''Public Customer'' means a person that is not a broker or dealer in securities. *Id.*

[4] A QCC transaction is comprised of an 'initiating order' to buy (sell) at least 1,000 contracts that is identified as being part of a qualified contingent trade, coupled with a contra-side order to sell (buy) an equal number of contracts. *See* Fee Schedule, Sections 1)a)ii) and 1)c)ii).

[5] A cQCC transaction is comprised of an 'initiating complex order' to buy (sell) where each component is at least 1,000 contracts that is identified as being part of a qualified contingent trade, coupled with a contra-side complex order or orders to sell (buy) an equal number of contracts. The stock handling fee for the stock leg of cQCC transactions is described in Section 1)a)v) of the Fee Schedule for electronic transactions. The stock handling fee for the stock leg of cQCC transactions is described in Section 1)c)vi) of the Fee Schedule for Trading Floor transactions. *See* Fee Schedule, Sections 1)a)iii) and 1)c)iii).

[6] ''Electronic Book'' means the Exchange's Simple Order Book and Strategy Book. *See* the Definitions section of the Fee Schedule and Exchange Rule 100. The ''Simple Order Book'' is the Exchange's regular electronic book of orders and quotes. *See* Exchange Rule 100. The ''Strategy Book'' is the Exchange's electronic book of complex orders. *Id.*

[7] ''Trading Floor'' or ''Floor'' means the physical trading floor of the Exchange located in Miami, Florida. The Trading Floor shall consist of one ''Crowd Area'' or ''Pit'' where Floor Participants will be located and option contracts will be traded. The Crowd Area or Pit shall be marked with specific visible boundaries on the Trading Floor, as determined by the Exchange. A Floor Broker must represent all orders in an ''open outcry'' fashion in the Crowd Area. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[8] *See* Exchange Rule 100.

[9] ''Qualified Floor Order'' or ''QFO'' is a two-sided order with an initiating side and a contra-side. QFOs may also be complex orders as defined in Rule 518(a) (''cQFO'') with no more than the applicable number of legs as determined by the Exchange and communicated to Participants via Regulatory Circular. *See* the Definitions section of the Fee Schedule and Exchange Rule 2040.

[10] ''Complex Qualified Floor Order'' or ''cQFO'' has the meaning ascribed to such term in the Exchange Rules. *See* the Definitions section of the Fee Schedule and Exchange Rule 2040.

[11] ''Away Market Maker'' for the purposes of the Fee Schedule shall mean a non MIAX Sapphire Market Maker. *See* the Definitions section of the Fee Schedule.

[12] *See* Securities Exchange Act Release No. 106093 (August 12, 2026), 91 FR 53311 (August 17, 2026) (SR–SAPPHIRE–2026–31).

[13] *See* Securities Exchange Act Release No. 106232 (August 28, 2026), 91 FR 56518 (September 2, 2026) (SR–SAPPHIRE–2026–34).

[14] *See, e.g.,* BOX Exchange LLC (''BOX'') Fee Schedule, Section IV.D. (assessing professional customers $0.00 per contract for both the agency side and contra-side of QCC transactions); Nasdaq PHLX LLC (''PHLX''), Options 7: Pricing Schedule, Section 4, QCC Transaction Fee (providing that customers and professionals are not assessed a QCC transaction fee and that the QCC transactions fees apply to both electronic and floor QCC orders).

[15] ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is a Member representing as agent Public Customer Orders or Non-Customer Orders on the Exchange and those non-Market Maker Members conducting proprietary trading. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[16] ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial accounts(s). The number of orders shall be counted in accordance with Interpretation and Policy .01 of Exchange Rule 100. *See* Exchange Rule 100, including Interpretation and Policy .01, and the Definitions section of the Fee Schedule.

[17] ''Market Maker'' means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of Exchange Rules. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[18] ''Floor Broker'' means an individual who is registered with the Exchange for the purpose, while

Continued

Professional Customer orders for both QCC and cQCC transactions on the Trading Floor, the Exchange provides Floor Brokers the following rebates: ($0.07) per contract when the contra-side is a Priority Customer or where the Firm met the Firm Fee Cap; [19] ($0.17) per contract when the contra-side is a Professional Customer; and ($0.25) per contract when the contra-side is all other market participants (*i.e.,* Floor Market Maker, Away Market Maker, Broker-Dealer, and Firm), except for Firm origin orders where that Firm met the Firm Fee Cap. The Exchange now proposes to reduce these rebates. In particular, the Exchange proposes that for Floor Brokers entering Professional Customer orders for both QCC and cQCC transactions on the Trading Floor, the Exchange will provide Floor Brokers the following rebates: ($0.00) per contract when the contra-side is a Priority Customer or where the Firm met the Firm Fee Cap; ($0.00) per contract when the contra-side is a Professional Customer; and ($0.17) per contract when the contra-side is all other market participants (*i.e.,* Floor Market Maker, Away Market Maker, Broker-Dealer, and Firm), except for Firm origin orders where that Firm met the Firm Fee Cap.

The purpose of these changes is for business and competitive reasons. The Exchange believes that even with the proposal to remove the rebate payable to an EEM (or Floor Broker) entering a Professional Customer order as part of a QCC or cQCC transaction (electronic or on the Trading Floor) where the contra-side is a Priority Customer or Professional Customer, the Exchange's QCC and cQCC rebates remain competitive with those of other exchanges for Professional Customer orders.[20] The Exchange believes these changes will also align the Exchange's QCC and cQCC rebates with those of other exchanges for Professional Customer orders where the contra-side is a Priority Customer or Professional Customer.[21]

Proposal To Establish a Tiered Fee Structure for Away Market Makers Facilitation of Customer QFOs or cQFOs on the Trading Floor

Next, the Exchange proposes to amend Section 1)c)i) of the Fee Schedule to establish a tiered fee structure applicable to Trading Floor transactions where a Member firm directs a paired QFO or cQFO to the Trading Floor, the agency side of the paired order is a customer of the Member firm, and the contra-side origin of the paired order is an Away Market Maker of the Member firm, depending on certain monthly breakup percentages and minimum sizes.

For background, the Exchange assesses fees and applies rebates to both executed sides of the paired QFO or cQFO on the Trading Floor. cQFO fees and rebates are per executed side per leg. Floor Broker rebates are only payable on the Floor Brokers' billable sides. The rebates do not apply to Priority Customer, Professional Customer, Firm/Broker-Dealer Facilitating a Priority Customer or Professional Customer, competing Floor Broker orders, Floor Market Maker (sides) executions, and Firm (sides) executions where the Firm Fee Cap threshold has been met for the relevant Clearing Corporation [22] account in the relevant month. Fees for Floor Market Maker volume executed via a Floor Broker are assessed to the Floor Market Maker. Fees and rebates for Floor Broker volume, other than the executing Floor Broker's own orders, entered on behalf of a competing Floor Broker, are assessed to the competing Floor Broker.

Currently, the Exchange assesses a $0.25 per contract fee for QFO and cQFO transactions in SPY/QQQ/IWM, Penny classes (excluding SPY/QQQ/IWM), and non-Penny classes, for Away Market Maker, Firm, and Broker-Dealer origins. The Exchange does not assess a fee (or provide a rebate) for QFO and cQFO transactions in SPY/QQQ/IWM, Penny classes (excluding SPY/QQQ/IWM), and non-Penny classes, for Firm and Broker-Dealer origins that are facilitating a Priority Customer or Professional Customer order.

The Exchange now proposes to establish a new row in the table in Section 1)c)i) of the Fee Schedule that will apply to transactions for Away Market Maker facilitation of customer orders for the same Member firm. The Exchange proposes to specify in third explanatory paragraph below the table of fees in Section 1)c)i) of the Fee Schedule that the rates for Away Market Maker Facilitation will apply to any Trading Floor transaction where a Member firm directs a paired order to the Trading Floor, where the agency order is a customer of the Member firm, and where the contra-side of the transaction is the Away Market Maker of the Member firm. Further, the Away Market Maker firm must notify the Exchange for participation in the Away Market Maker Facilitation program.

The Exchange proposes to establish a new table at the end of the explanatory text in Section 1)c)i) of the Fee Schedule, which will be titled ''Away Market Maker Facilitation Breakup Table'' (referred to herein as the ''Breakup Table''). The Breakup Table [23] will provide the proposed tiered reduced fees (instead of the $0.25 per contract fee that would otherwise apply to an Away Market Maker Floor transaction) for transactions where a Member firm directs a paired QFO or cQFO to the Trading Floor, the agency order is a customer of the Member firm, and the contra-side of the transaction is the Away Market Maker of the Member firm, depending on the following breakup percentages: 0 to 5% breakup will be assessed a per contract fee of $0.10; greater than 5% to 15% breakup will be assessed a per contract fee of $0.09; greater than 15% to 25% breakup will be assessed a per contract fee of $0.08; greater than 25% to 35% breakup will be assessed a per contract fee of $0.07; greater than 35% to 40% breakup will be assessed a per contract fee of

on the Trading Floor, of accepting and handling options orders. A Floor Broker must be registered as a Floor Participant prior to registering as a Floor Broker. A Floor Broker may take into his own account, and subsequently liquidate, any position that results from an error made while attempting to execute, as Floor Broker, an order. *See* the Definitions section of the Fee Schedule and Exchange Rule 2015. ''Floor Participant'' means Floor Brokers as defined in Rule 2015 and Floor Market Makers as defined in Rule 2105(b). *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[19] *See* Fee Schedule Section 1)c)vii) for a description of the Firm Fee Cap.

[20] *See, e.g.,* NYSE American LLC (''NYSE American'') Options Fee Schedule, Section I.F. (providing no fee or rebate for customer and professional customer orders where the contra-side is a customer or professional customer in a QCC transaction and providing a rebate of ($0.12) per contract where a floor broker executes a customer or professional customer order where the contra-side is a market maker, firm or broker dealer in a QCC transaction); NYSE Arca Inc. (''NYSE Arca'') Options Fees and Charges, page 7 (providing no fee or rebate for QCC transactions involving all customers and providing a rebate of ($0.16) per contract when a customer order trades against a non-customer).

[21] *Id.*

[22] The term ''Clearing Corporation'' means The Options Clearing Corporation. *See* Exchange Rule 100.

[23] A breakup of a QFO or cQFO generally refers to the scenario where a paired order is interacted with by a Floor Market Maker. Similarly, using the Away Market Maker facilitation as example, a breakup of a QFO or cQFO refers to the scenario where a paired customer order is facilitated for execution on the Trading Floor with the Away Market Maker being the contra-side of the transaction and having the order interacted with by a Floor Market Maker. For purposes of determining the breakup percentage for the Away Market Maker facilitation, the Exchange proposes to aggregate each month all QFOs with at least 1,000 initiating sides per order, and all cQFOs where the smallest leg is at least 1,000 contracts per order. The Exchange proposes to exclude from the breakup percentage calculation non-eligible QFOs with less than 1,000 initiating sides per order and non-eligible cQFOs where the smallest leg is less than 1,000 contracts per order.

$0.06; and greater than 40% breakup will be assessed a per contract fee of $0.05.

The Exchange also proposes to add the new note ''*'' to the Breakup Table and the corresponding note below table, which will provide as follows:

* These rates only apply to QFO or cQFO orders that are not part of a QCC, cQCC or Strategy transaction. For QFO volume to count towards the calculation to qualify for these rates, the Away Market Maker must facilitate at least 1,000 initiating sides per order. For cQFO volume to count towards the calculation to qualify for these rates, the smallest leg must be at least 1,000 initiating sides per order. The order breakup percentage is calculated on a monthly basis.

The Exchange also proposes to amend the second sentence in the first paragraph of explanatory text below the tables in Section 1)c)i) of the Fee Schedule to specify that Floor Brokers will not be entitled to receive rebates from Away Market Maker Facilitation transactions.

This reduced fee structure is similar in concept to another program offered by the Exchange, where the Exchange assesses a lower fee for a Firm or Broker-Dealer that facilitates a Priority Customer or Professional Customer QFO or cQFO (in that case, $0.00 per contract), and subsequently does not provide a rebate to the executing Floor Broker.[24] In that scenario, similar to the proposed Away Market Maker facilitation, a Firm or Broker-Dealer directs a paired order to the Trading Floor, where the agency side is an order for a Priority Customer or Professional Customer of that Firm or Broker-Dealer and the contra-side of the transaction involves the Firm or Broker-Dealer.[25]

The purpose of these changes is for business and competitive reasons. The proposed Breakup Table provides the lower tiered fees that the Away Market Maker may be assessed instead of the fee that would otherwise apply to such Floor transactions, *i.e.,* $0.25 per contract. The Exchange believes that the proposed changes may encourage Members to aggregate liquidity to send paired customer orders to the Trading Floor where the contra-side of the paired order is an affiliate Away Market Maker of the Member and the QFO or cQFO, as applicable, has met the proposed minimum size requirements (*i.e.,* for QFOs, at least 1,000 initiating sides per order and for cQFOs, the smallest leg is at least 1,000 initiating sides per order). The Exchange believes that this may, in turn, increase open outcry participation due to larger size QFOs and cQFOs being brought to the Trading Floor via the Away Market Maker facilitation size requirements, which may promote increased executions on the Trading Floor to the benefit of all Floor Participants that can interact with the larger sized orders.

Market participants sending paired orders with agency and contra-sides to an exchange via an auction/solicitation mechanism or to a broker to execute on a physical trading floor is not a new or novel concept. Further, the paired order may typically originate from affiliates of the same member firm. Additionally, the concept of the paired order (or orders) being broken up by different market participants and causing the fees assessed (or rebates provided) for the agency and contra-sides to change is not new or novel. The Exchange believes its proposal is within the bounds of these concepts—for an Away Market Maker Facilitation to apply such that the Away Market Maker receives reduced contra-side fees, the Member firm must direct a paired order to the Trading Floor, the agency side of the paired order must be a customer of the Member firm (*i.e.,* affiliated), and the contra-side of the transaction must be an Away Market Maker of the same Member firm. So long as those parameters are met and the minimum size requirements are achieved, the fees assessed to the Away Market Maker's contra-side orders will be reduced according to the monthly breakup percentages in the proposed Breakup Table.

In keeping with the above concepts, the Exchange's proposal contemplates a Member submitting a paired order to the Exchange's Trading Floor with agency and contra-sides, where the agency side of the paired order is a customer of the Member firm, and the contra-side origin of the paired order is an Away Market Maker of the Member firm (*i.e.,* affiliated to the customer side of the order). The Exchange believes the auction mechanisms (PRIME [26] and cPRIME [27]) in place at the Exchange's affiliate, MIAX,[28] likewise provide for a member firm to submit a paired order to MIAX, where the agency side and contra-side of the transaction are affiliates of the EEM [29] submitting the order into the auction. The Exchange's proposal then provides for the possibility of reduced contra-side fees based on a breakup percentage of the paired orders that meet the requirements for an Away Market Maker facilitation. MIAX's PRIME and cPRIME auctions provide the possibility for EEMs' paired orders to receive altered fees assessed (or rebates provided) to such orders and provide the opportunity for a member to earn higher agency rebates and/or breakup rebates instead of the rates that would otherwise apply for non-paired orders. In the same nature for the Trading Floor, the Exchange believes that the Away Market Maker sending a paired and facilitated order to be able to earn discounted fees based on an order (or orders) being broken up are not conceptually different.

The Exchange also believes that the Breakup Table is similar in concept to a table that is currently in place at MIAX, related to agency credits provided to Priority Customer orders entered into MIAX's cPRIME auction. The Exchange notes that there are differences between the proposed Breakup Table and the auction mechanisms discussed above for PRIME and cPRIME on MIAX. Whereas the proposed Breakup Table provides the opportunity for Away Market Makers to earn discounted fees for facilitating customer orders on the MIAX Sapphire Trading Floor based on the monthly percentage breakup of the order that meets the minimum size requirements, MIAX provides its members the opportunity to receive increasing tiered agency credits for cPRIME Agency Orders for Priority Customers dependent upon the breakup percentage of the order, with certain exceptions.[30] Another difference is that the Exchange's proposal contemplates calculating the breakup percentage on a monthly basis for all qualifying orders, PRIME and cPRIME calculate the reduced agency fees or increased breakup credits on an order-by-order basis for orders qualifying for PRIME and cPRIME.

The concept of the proposed Breakup Table to show the applicable fees based on an order (or orders) being broken up is also for clarity purposes. Fees based on order breakup percentage in a table format is similar in concept to ones used by MIAX for PRIME and cPRIME auctions where, in those instances, the agency rebates are dependent on the order breakup, and also similar to the automated improvement mechanism

[24] *See* Fee Schedule, Section 1)c)i).

[25] *See id.* (providing, additionally, that for the Broker-Dealer facilitation, the Broker-Dealer and the Priority Customer or Professional Customer both clear through the same clearing firm and the Broker-Dealer clears in the customer range).

[26] *See, generally,* MIAX Rule 515A.

[27] *See, generally,* MIAX Rule 515A, and Interpretation and Policy .12 for a description of the cPRIME auction process.

[28] ''MIAX'' means Miami International Securities Exchange, LLC. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[29] *See* MIAX Rule 100.

[30] *See* MIAX Fee Schedule, Section 1)a)iii), cPRIME Agency Order Break-up Table.

(''AIM'')[31] offered by Cboe EDGX Exchange, Inc. (''EDGX''), where the fees are dependent on the order interaction rate.[32]

In addition, the Exchange offers a similar fee program for Firms and Broker-Dealers that facilitate certain customer orders. In particular, the Exchange offers Firms and Broker-Dealers the opportunity to not be assessed a fee when a Firm or Broker-Dealer facilitates a Priority Customer or Professional Customer QFO or cQFO on the Trading Floor.[33]

The proposed changes are immediately effective.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[34] in general, and furthers the objectives of Section 6(b)(5) of the Act,[35] in particular, in that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposal is consistent with Section 6(b)(4) of the Act[36] because it represents an equitable allocation of reasonable dues, fees and other charges among its Members or issuers using its facilities.

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.''[37]

There are currently 18 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based and singly-listed options, no single exchange had more than approximately 11–12% of the multiply-listed equity options market share for the month of July 2026.[38] Therefore, no exchange possesses significant pricing power. More specifically, the Exchange had a market share of approximately 3.79% of executed volume of multiply-listed equity options for the month of July 2026.[39]

Proposal To Reduce Initiating and Contra-Side Fees for Professional Customer Orders for QCC and cQCC Transactions

The Exchange believes its proposal to reduce the initiating and contra-side fees applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book and Trading Floor is reasonable, equitable and not unfairly discriminatory because it may further incentivize Professional Customer orders to be submitted as QCC and cQCC transactions. The Exchange believes that this may, in turn, encourage Members to submit more Professional Customer orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads. The Exchange believes the proposed changes are equitable and not unfairly discriminatory because the reduced fees will apply equally to all market participants who provide Professional Customer orders as part of QCC and cQCC transactions either electronically or via the Exchange's Trading Floor. The Exchange also believes the proposed changes are reasonable because the changes will align the Exchange's fee for such transactions with the similar fee structures in place at other exchanges for both electronic and trading floor QCC (and/or cQCC) transactions for professional customer orders.[40]

Proposal To Reduce Rebates Applicable to Professional Customer Orders for QCC and cQCC Transactions

The Exchange believes its proposal to reduce the rebates applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book and Trading Floor is reasonable, equitable and not unfairly discriminatory because the changes are for business and competitive reasons. The Exchange believes that even with the proposal to remove the rebate payable to an EEM (or Floor Broker) entering a Professional Customer order as part of a QCC or cQCC transaction (electronic or on the Trading Floor) where the contra-side is a Priority Customer or Professional Customer, the Exchange's QCC and cQCC rebates remain competitive with those of other exchanges.[41] The Exchange believes these changes are reasonable because they will align the Exchange's QCC and cQCC rebates with those of other exchanges for Professional Customer orders where the contra-side is a Priority Customer or Professional Customer.

Proposal To Establish a Tiered Fee Structure for Trading Floor Transactions for Away Market Makers Facilitation of Customer Orders

The Exchange believes its proposal to establish a tiered fee structure where a Member firm directs a paired QFO or cQFO to the Trading Floor, the agency order is a customer of the Member firm, and the contra-side of the transaction is the Away Market Maker of the Member firm, depending on certain breakup percentages and minimum sizes is reasonable, equitable and not unfairly discriminatory because these changes are for business and competitive reasons. The Exchange believes that the proposed changes may encourage Members to submit more customer orders to the Trading Floor where the contra-side is the Away Market Maker of the Member firm in order to be assessed the lower tiered fees than would otherwise apply to such transactions. The Exchange believes that this may, in turn, increase open outcry participation, which may promote increased executions on the Trading Floor to the benefit of all Floor Participants.

The Exchange believes the proposal to establish a tiered fee structure where a Member firm directs a paired QFO or cQFO to the Trading Floor, the agency side of the order is a customer of the Member firm, and the contra-side of the transaction is the Away Market Maker of the Member firm, depending on certain breakup percentages and minimum sizes is equitably allocated and not unfairly discriminatory. The proposed reduced contra-side fees are not automatically applied to all Away Market Maker transactions on the Trading Floor. In order to achieve the reduced contra-side fees, the Member submitting an order for an Away Market Maker Facilitation must satisfy several criteria. First, the Member must submit a paired QFO or cQFO for execution on the Trading Floor. The agency side of the paired order must be a customer of the Member and the contra-side of the transaction must be an Away Market Maker affiliated with that same Member firm. The final criteria are the size requirements—an Away Market Maker must facilitate at least 1,000 initiating sides per order for QFO volume or have the smallest leg of the order be at least 1,000 initiating sides per cQFO volume

[31] *See* EDGX Rule 21.19.

[32] *See, generally*, EDGX Options Fee Schedule, AIM and SAM Pricing sections.

[33] *See* Fee Schedule, Section (1)(c)9i).

[34] 15 U.S.C. 78f(b).

[35] 15 U.S.C. 78f(b)(5).

[36] 15 U.S.C. 78f(b)(4).

[37] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[38] *See* the ''Market Share'' section of the Exchange's website, *available at https://www.miaxglobal.com/* (last visited August 12, 2026).

[39] *See id*.

[40] *See supra* note 14.

[41] *See supra* note 20.

to count towards the monthly breakup percentage for reduced contra-side fees.

The Exchange believes this proposal is not unfairly discriminatory because it may incentivize QFO and cQFO volume. As discussed above, Members must submit orders with minimum size requirements (*i.e.,* for QFOs, at least 1,000 initiating sides per order and for cQFOs, the smallest leg is at least 1,000 initiating sides per order), among other requirements, in order to have those orders counted towards the monthly breakup percentage and corresponding reduced contra-side fees. The Exchange believes that the set minimum size requirement contemplates Members submitting larger sized paired orders which may, in turn, increase open outcry participation to interact with that order flow. A higher rate of interactions should promote increased executions on the Trading Floor to the benefit of all Floor Participants by providing more trading opportunities and tighter spreads. To the extent QFO and cQFO volume increases by the proposal, market participants may increasingly compete for the opportunity to trade on the Trading Floor by responding to such larger sized orders. Accordingly, the Exchange believes it is equitable and not unfairly discriminatory to offer Away Market Makers the reduced contra-side fees contained in the proposed Breakup Table.

The concept of charging different fees based on origin for paired orders, like in auctions or facilitations as on the Trading Floor, is not new or novel. In particular, the contra fees assessed by EDGX to members who submit paired orders into the EDGX AIM (and SAM [42]) mechanisms vary based on the contra origin.[43] Further, EDGX members submitting paired orders in the EDGX AIM mechanism can receive better economics for the trade based on order interaction percentages, just like the Exchange proposes for Away Market Maker facilitations where orders are broken up based on a monthly percentage.

The Exchange believes this proposal is equitably allocated and not unfairly discriminatory because it is open to all Members that submit paired QFOs or cQFOs where the contra-side is an Away Market Maker of that Member firm, so long as the minimum size threshold is met. The Exchange believes the proposal to offer tiered reduced fees applicable to qualifying Away Market Maker transactions is equitable and not unfairly discriminatory because all Away Market Makers are eligible for the reduced fees each month so long as they facilitate qualifying customer QFO or cQFO volume to the Floor and take the contra-side of the transaction.

The Exchange believes this proposed change is reasonable because it is based on similar concepts regarding paired orders being facilitated or submitted for execution that are already in place at the Exchange, its affiliate MIAX, as well as other equity options exchanges. The Exchange's proposal contemplates a Member submitting a paired order to the Exchange's Trading Floor with agency and contra-sides, where the agency side of the paired order is a customer of the Member firm, and the contra-side origin of the paired order is an Away Market Maker of the Member firm (*i.e.,* affiliated to the customer side of the order). The Exchange believes the auction mechanisms (PRIME and cPRIME) in place at the Exchange's affiliate, MIAX, likewise provide for a member firm to submit a paired order to MIAX, where the agency side and contra-side of the transaction are affiliates of the EEM submitting the order into the auction. The Exchange's proposal then provides for the possibility of reduced contra-side fees based on a breakup percentage of the paired orders that meet the requirements for an Away Market Maker facilitation. MIAX's PRIME and cPRIME auctions provide the possibility for EEMs' paired orders to receive altered fees assessed (or rebates provided) to such orders and provide the opportunity for a member to earn higher agency rebates and/or breakup rebates instead of the rates that would otherwise apply for non-paired orders. In the same nature for the Trading Floor, the Exchange believes that the Away Market Maker sending a paired and facilitated order to be able to earn discounted fees based on an order (or orders) being broken up are not conceptually different.

In addition, the Exchange believes that the proposal, which applies only to Away Market Makers facilitating eligible customer trades of certain sizes executed on the Trading Floor, is not unfairly discriminatory to other market participants because its purpose is to attract large order flow to the Trading Floor, where such orders can be better handled in comparison with electronic orders that are not negotiable. To the extent that this purpose is achieved, all of the Exchange's Floor Participants should benefit from the improved market liquidity, particularly as the Trading Floor continues to ramp up operations since its launch in September 2025.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule changes will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Inter-Market Competition

The proposed changes do not impose an undue burden on inter-market competition. The Exchange believes the proposed changes to reduce the fees and rebates applicable to initiating and contra-side Professional Customer orders entered as part of a QCC or cQCC transaction do not impose any burden on inter-market competition because other exchanges have similar fee structures for similar transactions.[44] The Exchange believes the proposed changes to establish a tiered fee structure where a Member firm directs a paired QFO or cQFO to the Trading Floor, the agency order is a customer of the Member firm, and the contra-side of the transaction is the Away Market Maker of the Member firm, depending on certain breakup percentages and minimum sizes does not impose any burden on inter-market competition because other exchanges that offer trading floors can offer similar incentives to their market participants.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

The Exchange believes that the proposed changes reflect this competitive environment because the changes modify the Exchange's fees and rebates in a manner designed to continue to incent participants to direct trading interest to the Exchange (both electronically and on the Trading Floor), to provide liquidity and to attract additional order flow. To the extent that Away Market Makers are encouraged to facilitate more Priority Customer and Professional Customer QFOs and

[42] *See* EDGX Rule 21.21.

[43] *See* EDGX Options Fee Schedule, AIM and SAM Pricing section (assessing contra fees ranging from free to $0.18 per contract based on origin).

[44] *See supra* notes 14 and 20.

cQFOs, all Exchange market participants stand to benefit from the improved market quality and increased opportunities for price improvement. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

Intra-Market Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional QCC and cQCC liquidity from Professional Customers (both electronically and on the Trading Floor), thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed changes further the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders.

The proposed change to establish a tiered fee structure where a Member firm directs a paired QFO or cQFO to the Trading Floor, the agency order is a customer of the Member firm, and the contra-side of the transaction is the Away Market Maker of the Member firm, depending on certain breakup percentages and minimum sizes is designed to attract additional customer order flow to the Trading Floor. Greater liquidity benefits all market participants on the Exchange and increased order flow would increase opportunities for execution of other trading interest.

The Exchange believes the proposal to offer tiered reduced fees applicable to qualifying Away Market Maker transactions does not impose any burden on intra-market competition because all Away Market Makers are eligible for the reduced fees each month so long as they facilitate qualifying customer QFO or cQFO volume to the Floor and take the contra-side of the transaction.

The Exchange believes this proposed change does not place any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act because it is based on similar concepts regarding paired orders being facilitated or submitted for execution that are already in place at the Exchange, its affiliate MIAX, as well as other equity options exchanges. The Exchange's proposal contemplates a Member submitting a paired order to the Exchange's Trading Floor with agency and contra-sides, where the agency side of the paired order is a customer of the Member firm, and the contra-side origin of the paired order is an Away Market Maker of the Member firm (*i.e.,* affiliated to the customer side of the order). The Exchange believes the auction mechanisms (PRIME and cPRIME) in place at the Exchange's affiliate, MIAX, likewise provide for a member firm to submit a paired order to MIAX, where the agency side and contra-side of the transaction are affiliates of the EEM submitting the order into the auction. The Exchange's proposal then provides for the possibility of reduced contra-side fees based on a breakup percentage of the paired orders that meet the requirements for an Away Market Maker facilitation. MIAX's PRIME and cPRIME auctions provide the possibility for EEMs' paired orders to receive altered fees assessed (or rebates provided) to such orders and provide the opportunity for a member to earn higher agency rebates and/or breakup rebates instead of the rates that would otherwise apply for non-paired orders. In the same nature for the Trading Floor, the Exchange believes that the Away Market Maker sending a paired and facilitated order to be able to earn discounted fees based on an order (or orders) being broken up are not conceptually different. In addition, the Exchange believes that the proposal, which applies only to Away Market Makers facilitating customer trades of certain sizes executed on the Trading Floor, may enhance competition by attracting large order flow to the Trading Floor, where such orders can be better handled in comparison with electronic orders that are not negotiable. To the extent that this purpose is achieved, all of the Exchange's Floor Participants should benefit from the improved market liquidity, particularly as the Trading Floor continues to ramp up operations since its launch in September 2025.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[45] and Rule 19b–4(f)(2)[46] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–SAPPHIRE–2026–36 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–SAPPHIRE–2026–36. 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 filing 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–SAPPHIRE–2026–36 and should be submitted on or before November 23, 2026.

[45] 15 U.S.C. 78s(b)(3)(A)(ii).

[46] 17 CFR 240.19b–4(f)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[47]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22267 Filed 10–30–26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106763; File No. SR–LTSE–2026–26]

Self-Regulatory Organizations: Long-Term Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 11.280 Concerning the Resumption of Trading Following a Level 3 Market-Wide Circuit Breaker Halt

October 28, 2026.

Pursuant to the provisions of Section 19(b)(1) under the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 23, 2026, Long-Term Stock Exchange, Inc. (''LTSE'' or the ''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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend Rule 11.280 (''Market-Wide Circuit Breakers'') concerning the resumption of trading following a Level 3 market-wide circuit breaker halt in connection with the industry's expansion of trading hours to 23 hours per day, 5 days per week.

The text of the proposed rule change is available at the Exchange's website at *https://longtermstockexchange.com/* and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement on 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 self-regulatory organization 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 Rule 11.280 (''Market-Wide Circuit Breakers'') concerning the resumption of trading following a Level 3 market-wide circuit breaker (''MWCB'') halt (''Level 3 Market Decline'') in connection with the industry's expansion of trading hours to 23 hours per day, 5 days per week (''23/5 Trading''). Some exchanges are planning to offer overnight trading,[3] and as a result, the uniform Level 3 Market Decline rules of each exchange are being modified, as explained further below.[4]

Background

The MWCB mechanism under Rule 11.280 provides an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when U.S. securities markets experience extreme broad-based declines. All U.S. equity exchanges and FINRA (collectively, the self-regulatory organizations or ''SROs'') adopted uniform rules relating to the MWCB mechanism in 2012, which are designed to slow the effects of extreme price movement through coordinated trading halts across U.S. securities markets when severe price declines reach levels that may exhaust market liquidity.[5] Such market-wide circuit breakers provide for trading halts in all U.S. cash equity and equities options markets during a severe market decline as measured by a single-day decline in the S&P 500 Index during regular trading hours.

Pursuant to Rule 11.280, a market-wide trading halt will be triggered if the S&P 500 Index declines in price by specified percentages from the prior day's closing price of that index. Currently, the triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 halt after 9:30 a.m. ET and before 3:25 p.m. ET would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. ET would not halt market-wide trading. If a Level 3 Market Decline occurs at any time during the trading day, trading in all stocks will halt on the Exchange for the remainder of the trading day, and will resume the following trading day at 4:00 a.m. ET.

Proposal

The Exchange now proposes to amend Rule 11.280 to reflect extended trading hours under 23/5 Trading. On December 6, 2026, several exchanges intend to offer new overnight trading sessions that would be available from 9:00 p.m. ET to 4:00 a.m. ET, increasing their hours of operation.

As discussed, consistent with the uniform rules in place across all SROs, current Rule 11.280(b)(2) provides that if a Level 3 Market Decline occurs at any time during the trading day, the Exchange shall halt trading in all stocks on the Exchange for the remainder of the trading day. Currently, that means that the earliest that any exchange would re-open trading after a Level 3 Market Decline is 4:00 a.m. ET the following day, since no SROs are open for trading before 4:00 a.m. ET.

Unless amended, when 23/5 Trading is launched, the current rule's reference to halting ''for the remainder of the trading day'' [6] would require SROs participating in 23/5 Trading to reopen trading at an earlier time, *i.e.,* 9:00 p.m. ET on the same calendar day, when those SROs' systems would generally become available for overnight trading. The Exchange does not believe that this is an expected or desired result and is therefore amending this rule in coordination with the other SROs such that trading on any SRO will not resume until 4:00 a.m. ET or later on the following trading day, consistent with current market practice. This proposed rule change is therefore not intended to make any substantive changes to the MWCB mechanism. Rather, the proposed rule change would preserve the current resumption time following a Level 3 Market Decline.

To effect this change, the Exchange proposes to delete the language in Rule 11.280(b)(2) that provides that trading in

[47] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See, e.g.,* Securities Exchange Act Release No. 105532 (May 21, 2026), 91 FR 31509 (May 27, 2026) (SRNYSEARCA–2026–53) (''NYSE Arca 23/5 Trading Notice'').

[4] The Exchange does not intend to implement 23/5 Trading at this time.

[5] *See* Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–BATS2011–038; SR–BYX–2011–025; SR–BX–2011–068; SR–CBOE–2011–087; SR–C2–2011–024; SR–CHX–2011–30; SR–EDGA–2011–31; SR–EDGX–2011–30; SR–FINRA–2011–054; SR–ISE–2011–61; SR–NASDAQ2011–131; SR–NSX–2011–11; SR–NYSE–2011–48; SR–NYSEAmex–2011–73; SR–NYSEArca–2011–68; SRPhlx–2011–129) (''MWCB Approval Order'').

[6] *See* Rule 11.280(b)(2).

all stocks will halt on the Exchange ''for the remainder of the trading day'' if a Level 3 Market Decline occurs at any time during the trading day, and replace it with new language that explicitly provides that trading in all stocks would halt on the Exchange until 4:00 a.m. ET or later on the following trading day.

Implementation

The Exchange plans to implement the proposed rule change on December 6, 2026, the date on which several exchanges intend to offer new overnight trading sessions that would be available from 9:00 p.m. ET to 4:00 a.m. ET.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The MWCB mechanism described in Rule 11.280 is an important, automatic mechanism that is invoked to promote stability and investor confidence during periods of significant stress when U.S. securities markets experience extreme broad-based declines. The proposed rule change, when applied uniformly by all SROs, would ensure that the current 4:00 a.m. ET resumption time following a Level 3 halt continues to apply under 23/5 Trading, notwithstanding current rule text implying that the resumption time would coincide with the start of overnight trading on SROs operating an overnight session.

Rather than leave the rule in place as is, which would result in an earlier resumption time than originally contemplated when the rule was adopted, the Exchange, the other U.S. equity exchanges, and FINRA met alongside industry representatives to determine the appropriate resumption time. Following those discussions, the collective decision was made to retain the 4:00 a.m. ET resumption time, notwithstanding the fact that an earlier resumption time would be possible with the introduction of 23/5 Trading. The proposed rule change codifies this decision into the Exchange's rules. The Exchange understands that the other SROs will also be filing similar proposed rule changes. As a result, the market as a whole, including on- and off-exchange, will continue to be subject to harmonized rules for the resumption of trading following a Level 3 Market Decline.

While the SROs had previously decided to tie the resumption time following a Level 3 halt to the earliest SRO opening time, the upcoming transition to 23/5 Trading raises various concerns that warrant a change from the current approach.

First, the Exchange notes that the MWCB mechanism was designed to provide a cooling-off period where market participants would be provided with additional time to evaluate the market events that led to the decline before determining how to position their trading activity for the next day. With the introduction of 23/5 Trading and the start of overnight trading on some SROs at 9:00 p.m. ET, however, this cooling-off period could be materially shortened, reducing one of the key benefits that the MWCB mechanism was designed to provide in the first place. Rather than shorten the cooling-off period and risk this benefit, the Exchange believes the market would be better served by a change to the length of the associated trading halt that mirrors current market practice. Under the proposed rule, as is the case today, after a Level 3 halt, all SROs would re-open trading at 4:00 a.m. ET or later, and no SRO would offer an overnight trading session starting on the day of a Level 3 halt.

Second, overnight trading may be subject to different liquidity and participation considerations than the current pre-market sessions that start at or after 4:00 a.m. ET. Notably, while retail investors have expressed interest in overnight trading, the Exchange expects that institutional investors will take more time to transition to a round-the-clock model. However, such institutional participation may be of heightened importance following a Level 3 halt, as these investors are likely to have views on the underlying market events that led to the Level 3 Market Decline in the first place. The Exchange is concerned that opening during hours that such participants do not normally trade may impact the quality of price discovery at a time of significant market volatility. Waiting until 4:00 a.m. ET to resume trading would facilitate broader participation and therefore price discovery.

Finally, the Exchange notes that the Commission recently approved an amendment to the Plan to Address Extraordinary Market Volatility (''LULD Plan'') that would establish new price protections from 9:00 p.m. ET to 4:00 a.m. ET.[9] While these price bands would help to assure a fair and orderly market during normal market conditions, it is possible that they would instead prevent normal price discovery following a Level 3 Market Decline. Rather than allowing trading to resume with such price bands in effect, which would represent a change from the current trading reopening following a Level 3 Market Decline, the Exchange believes that requiring SROs to wait until 4:00 a.m. ET or later to resume trading would ensure that price discovery can occur unimpeded during pre-market trading, as it does today, which may further inform prices going into the opening auction and regular market hours trading following a Level 3 halt.

Given the factors discussed above, the Exchange believes that trading in all securities on the Exchange should not resume before 4:00 a.m. ET on the trading day after a Level 3 halt. This decision, which the Exchange understands will also be reflected in the rules of the other SROs, would promote a fair and orderly market at a time of significant market volatility, and thereby protect investors and the public interest. In addition, while the actual Level 3 resumption time would not be changing in practice—as proposed, the current resumption time and future resumption time would both be 4:00 a.m. ET at the earliest—the Exchange believes that it is appropriate to amend its rules to ensure that its rules reflect the upcoming changes due to 23/5 Trading. Without this change, market participants may mistakenly believe that the Exchange intends for trading to re-open on overnight trading exchanges at 9:00 p.m. ET following a Level 3 halt. The proposed rule change would therefore facilitate operational transparency while providing for a fair and orderly market.

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 because the proposal would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across U.S.

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(5).

[9] *See* Securities Exchange Act Release No. 106042 (August 5, 2026), 91 FR 51515 (August 10, 2026) (Order Granting Approval of the Twenty-Seventh Amendment to the National Market System Plan to Address Extraordinary Market Volatility to Establish Temporary Price Band Protections in Overnight Trading).

securities markets. Further, the Exchange understands that the other SROs intend to file proposed rule changes to ensure a consistent resumption time at 4:00 a.m. or later ET across markets. Thus, the proposed rule change will help to ensure consistency across

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(iii) [10] of the Act and Rule 19b–4(f)(6) [11] thereunder in that it effects a change that: (i) does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) of the Act [12] to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–LTSE–2026–26 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–LTSE–2026–26. 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 filing 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–LTSE–2026–26 and should be submitted on or before November 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22268 Filed 10–30–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0745]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 18a–5

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 18a–5, under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 18a–5 enumerates the recordkeeping and reporting requirements for security-based swap dealers (''SBSDs'') and major security-based swap participants (''MSBSPs''). More specifically, Rule 18a–5 establishes recordkeeping requirements applicable to stand-alone SBSDs, stand-alone MSBSPs, bank SBSDs, and bank MSBSPs. Rule 18a–5 was modeled on Rule 17a–3 under the Exchange Act, which applies to broker-dealers, but Rule 18a–5 does not include a parallel requirement for every requirement in Rule 17a–3 because some of the requirements in Rule 17a–3 relate to activities that are not expected or permitted of SBSDs and MSBSPs. The collections of information under Rule 18a–5 include the following types of records that are required to be created: trade blotters, general ledger, ledgers for customers and non-customer accounts, stock record, memoranda of brokerage orders, memoranda of proprietary orders, confirmations, accountholder information, options positions, trial balances and computation of net capital, associated person's employment application, account equity and margin calculations under Rule 18a–3, possession or control requirements for security-based swap customers, customer reserve requirements for security-based swap customers, unverified transactions, political contributions, and compliance with business conduct requirements. The purpose of requiring stand-alone SBSDs, stand-alone MSBSPs, bank SBSDs, and bank MSBSPs to create the records specified in Rule 18a–5 is to enhance regulators' ability to protect investors. These records and the information contained therein are used by examiners and other representatives of the Commission to determine whether stand-alone SBSDs, stand-alone MSBSPs, bank SBSDs, and bank MSBSPs are in compliance with the Commission's anti-fraud and anti-manipulation rules, financial responsibility program, and other laws, rules, and regulations.

Not all types of records enumerated in Rule 18a–5 are required to be made by each of the entities to which Rule 18a–5 applies. For example, Rule 18a–5 requires thirteen types of records to be made and kept current by stand-alone

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file a proposed rule change under that subsection at least five business days prior to the date of filing, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 15 U.S.C. 78s(b)(2)(B).

[13] 17 CFR 200.30–3(a)(12).

SBSDs and stand-alone MSBSPs.[1] Rule 18a–5 also requires three types of records to be made and kept current by stand-alone SBSDs.[2] Rule 18a–5 requires 10 types of records to be made and kept current by bank SBSDs and bank MSBSPs, all of which are limited to the firm's business as an SBSD or MSBSP.[3] Further, Rule 18a–5 includes paragraphs (b)(9), (b)(10), and (b)(12) which requires bank SBSDs to make and keep current various records for security-based swaps.[4]

As of September 24, 2026, there are 15 stand-alone SBSDs, zero stand-alone MSBSPs, 29 bank SBSDs, and zero bank MSBSPs registered with the Commission. The Commission estimates that each recordkeeping provision of Rule 18a–5 imposes on each firm that is subject to the provision an initial burden and an ongoing annual burden. The total initial industry hour burden attributable to Rule 18a–5 is estimated to be 12,340 hours in the first year and the total industry ongoing hour burden attributable to Rule 18a–5 is estimated to be 15,425 hours per year (including the first year). Over a three-year period, the total estimated industry burden is estimated to be 58,615 hours, or about 19,538 hours per year when annualized. These burdens are recordkeeping burdens.

In addition, the Commission estimates that Rule 18a–5 causes a stand-alone SBSD or stand-alone MSBSP to incur an initial dollar cost of approximately $1,000 to purchase recordkeeping system software and an ongoing dollar cost of $4,650 per year to provide adequate physical space and computer hardware and software for storage. As of September 24, 2026, there are 15 respondents (15 stand-alone SBSDs and zero stand-alone MSBSPs), resulting in an estimated industry-wide initial burden of $15,000 and an industry-wide ongoing burden of $69,750 per year. Over a three-year period, the total estimated industry burden would be $224,250, or about $74,750 per year when annualized.

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.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC's estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to *PaperworkReductionAct@sec.gov* by January 4, 2027.

Dated: October 29, 2026.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22346 Filed 10–30–26; 8:45 am]

BILLING CODE 8011–01–P

[1] *See* Rule 18a–5 (paragraph (a)(1) (trade blotters); paragraph (a)(2) (general ledgers); paragraph (a)(3) (ledgers of customer and non-customer accounts); paragraph (a)(4) (stock record); paragraph (a)(5) (memoranda of proprietary orders); paragraph (a)(6) (confirmations); paragraph (a)(7) (accountholder information); paragraph (a)(8) (options positions); paragraph (a)(9) (trial balances and computation of net capital); paragraph (a)(10) (associated person's application); paragraph (a)(12) (Rule 18a–3 calculations); paragraph (a)(15) (unverified transactions); paragraph (a)(17) (compliance with business conduct standards)).

[2] *See* Rule 18a–5 (paragraph (a)(13) (compliance with Rule 18a–4 possession or control requirements); paragraph (a)(14) (Rule 18a–4 reserve account computations); and paragraph (a)(16) (political contributions)).

[3] *See* Rule 18a–5 (paragraph (b)(1) (trade blotters); paragraph (b)(2) (general ledgers); paragraph (b)(3) (stock record); paragraph (b)(4) (memoranda of brokerage orders); paragraph (b)(5) (memoranda of proprietary orders); paragraph (b)(6) (confirmations); paragraph (b)(7) accountholder information); paragraph (b)(8) (associated person's application); paragraph (b)(11) (unverified transactions); and paragraph (b)(13) (compliance with business conduct requirements)).

[4] *See* Rule 18a–5 (paragraph (b)(9) (possession or control requirements under Rule 18a–4); paragraph (b)(10) (customer reserve requirements under Rule 18a–4); and paragraph (b)(12) (political contributions)).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106754; File No. SR–CboeBZX–2026–086]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 11.1(a) To Adopt a Start Time Order Instruction

October 28, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 15, 2026, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (''BZX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (''Commission'' or ''SEC'') a proposed rule change to amend Rule 11.1(a) to adopt a Start Time order instruction, based on the Start Time instruction adopted by its affiliated exchange, Cboe EDGX Exchange, Inc. (''EDGX''). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (*https://www.sec.gov/rules/sro.shtml*), the Exchange's website (*https://www.cboe.com/us/equities/regulation/rule_filings/bzx/*), and at the principal office of the Exchange.

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 Rule 11.1(a) to adopt a ''Start Time'' order instruction that would permit a User to designate, in thirty-minute increments prior to the commencement

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

of Regular Trading Hours,[5] the time at which an order entered prior to Regular Trading Hours becomes eligible for execution. The proposed rule change is based on EDGX Rule 11.1(a)(2),[6] but the Exchange is proposing to adopt only the Start Time instruction and related provisions. The Exchange intends to implement the proposed rule change on December 7, 2026, in coordination with the implementation of the Start Time instruction on EDGX, so that Members have access to consistent order handling functionality across the Cboe-affiliated equities exchanges.

Current Rule

Under current Rule 11.1(a), Users may enter orders into the System from 2:30 a.m. until 8:00 p.m. Eastern Time (''ET'').[7] Orders entered between 2:30 a.m. and 4:00 a.m. are not eligible for execution until the start of the Early Trading Session,[8] Pre-Opening Session,[9] or Regular Trading Hours, depending on the Time in Force [10] selected by the User. The current rule provides for two fixed start times within the Early Trading Session. At the commencement of the Early Trading Session, orders entered between 2:30 a.m. and 4:00 a.m. become eligible for execution (a ''4:00 a.m. Start''), unless designated as eligible for execution during the Early Trading Session beginning at 7:00 a.m. (a ''7:00 a.m. Start''). Orders with a 7:00 a.m. Start designation may be entered between 2:30 a.m. and 7:00 a.m. At each start time, orders are handled in time sequence, beginning with the order with the oldest time stamp, and are placed on the BZX Book, routed, cancelled, or executed in accordance with the terms of the order.

Current Rule 11.1(a) also provides that the Exchange will not accept the following orders prior to 7:00 a.m.: BZX Post Only Orders,[11] ISOs,[12] BZX Market Orders [13] that are not Stop Orders [14] or Eligible Auction Orders as defined in Rule 11.23(a)(8), Minimum Quantity Orders [15] that also include a Time in Force of Regular Hours Only, and all orders with a Time in Force of IOC [16] or FOK.[17] The rule also contains a sentence providing that, at the commencement of the Early Trading Session, orders entered between 6:00 a.m. and 7:00 a.m. will be handled in time sequence and placed on the BZX Book, routed, cancelled, or executed in accordance with their terms. That sentence is inconsistent with the current 2:30 a.m. order entry window and is superseded by the 4:00 a.m. Start and 7:00 a.m. Start provisions described above.

Proposed Start Time Instruction

The Exchange proposes to delete the 4:00 a.m. Start and 7:00 a.m. Start designations, together with the superseded sentence relating to orders entered between 6:00 a.m. and 7:00 a.m., and to replace them with a flexible Start Time instruction. As proposed, in addition to the Time in Force, a User may also designate a start time for an order (''Start Time''). Start Times may be designated in thirty-minute increments and must be set to a time prior to the commencement of Regular Trading Hours; Start Times may not be designated during Regular Trading Hours. This language is substantively identical to the Start Time language in EDGX Rule 11.1(a)(2), which replaced EDGX's 4:00 a.m. Start and 7:00 a.m. Start designations with the same flexible and uniform framework. Because orders on the Exchange are not eligible for execution prior to the commencement of the Early Trading Session at 4:00 a.m., the earliest Start Time that will have practical effect is 4:00 a.m., and the latest permissible Start Time is 9:00 a.m.

The Exchange also proposes to provide that, at the commencement of the Early Trading Session and at each Start Time, orders will be handled in time sequence, beginning with the order with the oldest time stamp, and will be placed on the BZX Book, routed, cancelled, or executed in accordance with the terms of the order. This provision is consistent with the sequencing provision adopted by EDGX, which provides that, at each Start Time, orders will be handled in time sequence beginning with the oldest time stamp.[18] The Exchange proposes to retain the reference to the commencement of the Early Trading Session so that orders that are entered prior to the Early Trading Session without a Start Time designation continue to become eligible for execution, in time sequence, at the commencement of the Early Trading Session, as they do today.

For example, a User may enter an order at 5:15 a.m. with a Start Time of 8:00 a.m. That order would be accepted but would not be eligible for execution until 8:00 a.m., at which time it would be handled in time sequence with all other orders designated with an 8:00 a.m. Start Time, beginning with the order with the oldest time stamp, and would be placed on the BZX Book, routed, cancelled, or executed in accordance with its terms.

Order Acceptance Restrictions

The Exchange proposes to amend the order acceptance restrictions in Rule 11.1(a) so that they apply prior to 7:00 a.m. or, if later, prior to the order's designated Start Time. The Exchange is not proposing any change to the categories of orders subject to these restrictions, which will continue to be: BZX Post Only Orders, ISOs, BZX Market Orders that are not Stop Orders or Eligible Auction Orders as defined in Rule 11.23(a)(8), Minimum Quantity Orders that also include a Time in Force of Regular Hours Only, and all orders with a Time in Force of IOC or FOK. The Exchange is also retaining the existing 7:00 a.m. threshold. Under the proposal, an order in one of these categories designated with a Start Time later than 7:00 a.m. will not be accepted prior to its Start Time. The current restrictions are designed to limit certain order types that are not suitable for queueing to the period in which an order is eligible for execution and, in the case of the 7:00 a.m. Start, already apply until the time at which an order with a 7:00 a.m. Start designation becomes eligible for execution. Tying the restrictions to an order's designated Start Time applies that same rationale to the more flexible Start Time framework. EDGX similarly ties the same five categories of restrictions to the period before orders become eligible for execution, which on EDGX is the Order Acceptance Queueing Time.[19]

The Exchange is not proposing to change its order entry window, which will continue to begin at 2:30 a.m., or the Time in Force instructions available to Users. Orders entered prior to the Early Trading Session without a Start Time designation will continue to become eligible for execution at the start of the Early Trading Session, Pre-

[5] *See* Exchange Rule 1.5(w).

[6] *See* Securities Exchange Act Release No. 105587 (May 29, 2026), 91 FR 33238 (June 3, 2026) (SR–CboeEDGX–2026–019) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Amended by Amendment No. 1, To Extend the Exchange's Trading Hours to 23 Hours per Day, Five Days per Week) (''EDGX Approval Order'').

[7] *See* Exchange Rule 11.1(a). All times stated herein are in ET.

[8] *See* Exchange Rule 1.5(ff).

[9] *See* Exchange Rule 1.5(r).

[10] *See* Exchange Rule 11.9(b).

[11] *See* Exchange Rule 11.9(c)(6).

[12] *See* Exchange Rule 11.9(d).

[13] *See* Exchange Rule 11.9(a)(2).

[14] *See* Exchange Rule 11.9(c)(16).

[15] *See* Exchange Rule 11.9(c)(5).

[16] *See* Exchange Rule 11.9(b)(1).

[17] *See* Exchange Rule 11.9(b)(6).

[18] *See* EDGX Rule 11.1(a)(2); EDGX Approval Order, *supra* note 6.

[19] *See* EDGX Rule 11.1(a)(3); EDGX Approval Order, *supra* note 6. Because the Exchange does not operate an Overnight Trading Session or an Order Acceptance Queueing Time, the Exchange proposes to tie the restrictions to the existing 7:00 a.m. threshold and the order's designated Start Time.

Opening Session, or Regular Trading Hours, depending on the Time in Force selected by the User. Use of the Start Time instruction is optional.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[20] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[21] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed Start Time instruction removes impediments to and perfects the mechanism of a free and open market and a national market system because it replaces the fixed 4:00 a.m. Start and 7:00 a.m. Start designations with a flexible and uniform framework. Under that framework, Members may control the time at which their orders become eligible for execution prior to Regular Trading Hours. The Commission approved the same Start Time framework for EDGX, which replaced EDGX's 4:00 a.m. Start and 7:00 a.m. Start construct.[22] The Start Time instruction provides Members with additional flexibility to manage the timing of their order flow in the period before Regular Trading Hours. This includes aligning order eligibility with anticipated market conditions or with their own trading strategies, without requiring Members to manually enter orders at a particular time.

The Exchange believes the proposed time-sequencing provision promotes just and equitable principles of trade and protects investors because orders that become eligible at the commencement of the Early Trading Session or at a given Start Time will be handled in a transparent and objective manner, in time sequence beginning with the order with the oldest time stamp. This is the same manner in which orders are handled today at the commencement of the Early Trading Session and at each of the 4:00 a.m. Start and 7:00 a.m. Start, and it is consistent with the sequencing provision approved for EDGX.

The Exchange believes that tying the existing order acceptance restrictions to the later of 7:00 a.m. or the order's designated Start Time protects investors and the public interest. The proposal preserves the existing categories of restricted orders and the existing 7:00 a.m. threshold. It applies those restrictions consistently to orders that will not be eligible for execution until a later Start Time, ensuring that order types that are not suitable for queueing are not accepted before the order may execute. The proposed rule change does not loosen any existing restriction.

The proposed rule change also promotes consistency across the Cboe-affiliated equities exchanges, which reduces complexity for Members that access multiple Cboe-affiliated exchanges and fosters cooperation and coordination with persons engaged in facilitating transactions in securities. The proposed rule change does not permit unfair discrimination because the Start Time instruction will be available to all Members on the same terms, and its use is optional.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change will impose any burden on intramarket competition because the Start Time instruction will be available to all Members on an equal and non-discriminatory basis, and its use is optional. The Exchange does not believe the proposed rule change will impose any burden on intermarket competition because it is based on a rule that the Commission approved for EDGX, and it is designed to provide Members with consistent order handling functionality across the Cboe-affiliated equities exchanges rather than to address any competitive issue. Other exchanges are free to adopt similar functionality.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[23] and Rule 19b–4(f)(6)[24] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBZX–2026–086 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–CboeBZX–2026–086. 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

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

[22] *See* EDGX Approval Order, *supra* note 6.

[23] 15 U.S.C. 78s(b)(3)(A).

[24] 17 CFR 240.19b–4(f)(6).

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 filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBZX–2026–086 and should be submitted on or before November 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22262 Filed 10–30–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release 36372; File No. 812–16058]

Eldridge Dynamic Income Fund, et al.

October 28, 2026.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of application for an order under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain business development companies (''BDCs''), closed-end, and open-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

APPLICANTS: Eldridge Dynamic Income Fund, Eldridge Structured Credit Advisers, LLC, Eldridge Credit Advisers, LLC, Eldridge GP1 Advisers, LLC, Eldridge SME Advisers, LLC, and certain of their affiliated entities as described in Appendix A to the application.

FILING DATES: The application was filed on July 20, 2026, and amended on August 25, 2026, September 30, 2026, and October 8, 2026.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. The email should include the file number referenced above. Hearing requests should be received by the Commission by 5:30 p.m., Eastern time, on November 23, 2026, and should be accompanied by proof of service on the Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Meredith Dodd, *legal@eldridge.com,* Eldridge Capital Management, LLC, 767 Fifth Avenue, Floor 17, New York, NY 10153, Rajib Chanda, *rajib.chanda@stblaw.com,* Neesa Patel Sood, *neesa.sood@stblaw.com,* Matthew Micklavzina, *matthew.micklavzina@stblaw.com,* Simpson Thacher & Bartlett LLP, 900 G Street NW, Washington, DC 20001

FOR FURTHER INFORMATION CONTACT: Thomas Ahmadifar, Branch Chief or Toyin Momoh, Senior Counsel at (202) 551–6720 or *IMOCC@sec.gov* (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' third amended application, filed October 8, 2026, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *https://www.sec.gov/search-filings.* You may also call the SEC's Office of Investor Education and Assistance at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22250 Filed 10–30–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106758; File No. SR–MX2–2026–09]

Self-Regulatory Organizations; MX2 LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 11.23 Concerning the Resumption of Trading Following a Level 3 Market-Wide Circuit Breaker Halt in Connection With the Industry's Expansion of Trading Hours to 23 Hours per Day, 5 Days per Week

October 28, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on October 19, 2026, MX2 LLC (''MX2'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend Rule 11.23, (''Trading Halts Due to Extraordinary Market Volatility/Market-Wide Circuit Breakers'') concerning the resumption of trading following a Level 3 Market-Wide Circuit Breaker (''MWCB'') halt (''Level 3 Market Decline'') in connection with the industry's expansion of trading hours to 23 hours per day, 5 days per week (''23/5 Trading''). The text of the proposed rule change is provided in Exhibit 5 and is available on the Exchange's website at *https://info.memxtrading.com/regulation/rules-and-filings/.*

[25] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 Rule 11.23(b)(2) concerning the resumption of trading following a Level 3 Market Decline in connection with the industry's expansion of trading hours to 23/5 Trading. Some exchanges, including the Exchange's affiliate exchange, MEMX, LLC (''MEMX''), are planning to offer overnight trading,[3] and as a result, the uniform Level 3 Market Decline rules of each exchange are being modified, as explained further below.

Background

The MWCB mechanism under Rule 11.23 provides an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when U.S. securities markets experience extreme broad-based declines. All U.S. equity exchanges and FINRA (collectively, the self-regulatory organizations or ''SROs'') adopted uniform rules relating to the MWCB mechanism in 2012, which are designed to slow the effects of extreme price movement through coordinated trading halts across U.S. securities markets when severe price declines reach levels that may exhaust market liquidity.[4] Such market-wide circuit breakers provide for trading halts in all U.S. cash equity and equities options markets during a severe market decline as measured by a single-day decline in the S&P 500 Index during regular trading hours.

Pursuant to Rule 11.23, a market-wide trading halt will be triggered if the S&P 500 Index declines in price by specified percentages from the prior day's closing price of that index. Currently, the triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 halt after 9:30 a.m. ET and before 3:25 p.m. ET would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. ET would not halt market-wide trading. If a Level 3 Market Decline occurs at any time during the trading day, trading in all stocks will halt on the Exchange for the remainder of the trading day, and will resume the following trading day at 7:00 a.m. ET.

Proposal

The Exchange now proposes to amend Rule 11.23 to reflect extended trading hours under 23/5 Trading. On December 6, 2026, several exchanges, including MEMX, intend to offer new overnight trading sessions that would be available from 9:00 p.m. ET to 4:00 a.m. ET, significantly increasing their hours of operation in response to customer demand.

As discussed, consistent with the uniform rules in place across all SROs, current Rule 11.23(b)(2) provides that if a Level 3 Market Decline occurs at any time during the trading day, the Exchange shall halt trading in all stocks on the Exchange for the remainder of the trading day. Currently, that means that the earliest that any exchange would re-open trading after a Level 3 Market Decline is 4:00 a.m. ET the following day, since no SROs are open for trading before 4:00 a.m. ET.

Unless amended, when 23/5 Trading is launched, the current rule's reference to halting ''for the remainder of the trading day'' [5] would require SROs participating in 23/5 Trading to re-open trading at an earlier time, *i.e.,* 9:00 p.m. ET on the same calendar day, when those SROs' systems would generally become available for overnight trading. The Exchange does not believe that this is an expected or desired result and is therefore amending this rule in coordination with the other SROs such that trading on any SRO will not resume until 4:00 a.m. ET or later on the following trading day, consistent with current market practice. This proposed rule change is therefore not intended to make any substantive changes to the MWCB mechanism. Rather, the proposed rule change would preserve the current resumption time following a Level 3 Market Decline.

To effect this change, the Exchange proposes to delete the language in Rule 11.23(b)(2) that provides that trading in all stocks will halt on the Exchange ''for the remainder of the trading day'' if a Level 3 Market Decline occurs at any time during the trading day, and replace it with new language that explicitly provides that trading in all stocks would halt on the Exchange until 4:00 a.m. Eastern Time on the following trading day.

2. Statutory Basis

The Exchange believes the proposal is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The MWCB mechanism described in Rule 11.23 is an important, automatic mechanism that is invoked to promote stability and investor confidence during periods of significant stress when U.S. securities markets experience extreme broad-based declines. The proposed rule change, when applied uniformly by all SROs, would ensure that the current 4:00 a.m. ET resumption time following a Level 3 halt continues to apply under 23/5 Trading, notwithstanding current rule text implying that the resumption time would coincide with the start of overnight trading on SROs operating an overnight session.

Rather than leave the rule in place as is, which would result in an earlier resumption time than originally contemplated when the rule was adopted, the Exchange, the other U.S. equity exchanges, and FINRA met alongside industry representatives to determine the appropriate resumption time. Following those discussions, the collective decision was made to retain the 4:00 a.m. ET resumption time,

[3] *See e.g.,* Securities Exchange Act Release No. 106310 (September 9, 2026) 91 FR 58185 (September 14, 2026) (SR–MEMX–2026–28) (''MEMX 23/5 Filing''). The Exchange does not intend to implement 23/5 Trading at this time.

[4] *See* Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–BATS–2011–038; SR–BYX–2011–025; SR–BX–2011–068; SR–CBOE–2011–087; SR–C2–2011–024; SR–CHX–2011–30; SR–EDGA–2011–31; SR–EDGX–2011–30; SR–FINRA–2011–054; SR–ISE2011–61; SR–NASDAQ–2011–131; SR–NSX–2011–11; SR–NYSE–2011–48; SR–NYSEAmex2011–73; SR–NYSEArca–2011–68; SR–Phlx–2011–129) (''MWCB Approval Order'').

[5] *See* Rule 11.23(b)(2).

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

notwithstanding the fact that an earlier resumption time would be possible with the introduction of 23/5 Trading. The proposed rule change codifies this decision into the Exchange's rules. The Exchange understands that the other SROs have filed similar proposed rule changes. As a result, the market as a whole, including on- and off-exchange, will continue to be subject to harmonized rules for the resumption of trading following a Level 3 Market Decline.

While the SROs had previously decided to tie the resumption time following a Level 3 halt to the earliest SRO opening time, the upcoming transition to 23/5 Trading raises various concerns that warrant a change from the current approach.

First, the Exchange notes that the MWCB mechanism was designed to provide a cooling-off period where market participants would be provided with additional time to evaluate the market events that led to the decline before determining how to position their trading activity for the next day. With the introduction of 23/5 Trading and the start of overnight trading on some SROs at 9:00 p.m. ET, however, this cooling-off period could be materially shortened, reducing one of the key benefits that the MWCB mechanism was designed to provide in the first place. Rather than shorten the cooling-off period and risk this benefit, the Exchange believes the market would be better served by a change to the length of the associated trading halt that mirrors current market practice. Under the proposed rule, as is the case today, after a Level 3 halt, all SROs would re-open trading at 4:00 a.m. ET or later, and no SRO would offer an overnight trading session starting on the day of a Level 3 halt.

Second, overnight trading may be subject to different liquidity and participation considerations than the current pre-market sessions that start at or after 4:00 a.m. ET. Notably, while retail investors have expressed interest in overnight trading, the Exchange expects that institutional investors will take more time to transition to a round-the-clock model. However, such institutional participation may be of heightened importance following a Level 3 halt, as these investors are likely to have views on the underlying market events that led to the Level 3 Market Decline in the first place. The Exchange is concerned that opening during hours that such participants do not normally trade may impact the quality of price discovery at a time of significant market volatility. Waiting until 4:00 a.m. ET to resume trading would facilitate broader participation and therefore price discovery.

Finally, the Exchange notes that the Commission recently approved an amendment to the Plan to Address Extraordinary Market Volatility (''LULD Plan'') that would establish new price protections from 9:00 p.m. ET to 4:00 a.m. ET.[8] While these price bands would help to assure a fair and orderly market during normal market conditions, it is possible that they would instead prevent normal price discovery following a Level 3 Market Decline. Rather than allowing trading to resume with such price bands in effect, which would represent a change from the current trading reopening following a Level 3 Market Decline, the Exchange believes that requiring SROs to wait until 4:00 a.m. ET to resume trading would ensure that price discovery can occur unimpeded during pre-market trading, as it does today, which may further inform prices going into the opening auction and regular market hours trading following a Level 3 halt.

Given the factors discussed above, the Exchange believes that trading in all securities on the Exchange should not resume before 4:00 a.m. ET on the trading day after a Level 3 halt. This decision, which the Exchange understands will also be reflected in the rules of the other SROs, would promote a fair and orderly market at a time of significant market volatility, and thereby protect investors and the public interest. In addition, while the actual Level 3 resumption time would not be changing in practice—as proposed, the current resumption time and future resumption time would both be 4:00 a.m. ET at the earliest—the Exchange believes that it is appropriate to amend its rules to ensure that its rules reflect the upcoming changes due to 23/5 Trading. Without this change, market participants may mistakenly believe that the Exchange intends for trading to re-open on overnight trading exchanges at 9:00 p.m. ET following a Level 3 halt. The proposed rule change would therefore facilitate operational transparency while providing for a fair and orderly market.

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 because the proposal would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across U.S. securities markets. Further, the Exchange understands that the other SROs have filed proposed rule changes to ensure a consistent resumption time at 4:00 a.m. ET across markets. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and subparagraph (f)(6) of Rule 19b–4 thereunder.[10]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[8] *See* Securities Exchange Act Release No. 106042 (August 5, 2026), 91 FR 51515 (August 10, 2026) (Order Granting Approval of the Twenty-Seventh Amendment to the National Market System Plan to Address Extraordinary Market Volatility to Establish Temporary Price Band Protections in Overnight Trading).

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

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–MX2–2026–09 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–MX2–2026–09. 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 filing 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–MX2–2026–09 and should be submitted on or before November 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22264 Filed 10–30–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106753; File No. SR–CboeEDGA–2026–035]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 11.1(a)(1) To Adopt a Start Time Order Instruction

October 28, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 15, 2026, Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGA Exchange, Inc. (''EDGA'' or the ''Exchange'') is filing with the Securities and Exchange Commission (''Commission'' or ''SEC'') a proposed rule change to amend Rule 11.1(a)(1) to adopt a Start Time order instruction, based on the Start Time instruction adopted by its affiliated exchange, Cboe EDGX Exchange, Inc. (''EDGX''). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (*https://www.sec.gov/rules/sro.shtml*), the Exchange's website (*https://www.cboe.com/us/equities/regulation/rule_filings/edga/*), and at the principal office of the Exchange.

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 Rule 11.1(a)(1) to adopt a ''Start Time'' order instruction that would permit a User to designate, in thirty-minute increments prior to the commencement of Regular Trading Hours,[5] the time at which an order entered prior to Regular Trading Hours becomes eligible for execution. The proposed rule change is based on EDGX Rule 11.1(a)(2),[6] but the Exchange is proposing to adopt only the Start Time instruction and related provisions. The Exchange intends to implement the proposed rule change on December 7, 2026, in coordination with the implementation of the Start Time instruction on EDGX, so that Members have access to consistent order handling functionality across the Cboe-affiliated equities exchanges.

Current Rule

Under current Rule 11.1(a)(1), Users may enter orders into the System from 6:00 a.m. until 8:00 p.m. Eastern Time (''ET'').[7] Orders entered between 6:00 a.m. and 7:00 a.m. are not eligible for execution until the start of the Early Trading Session,[8] Pre-Opening Session,[9] or Regular Trading Hours, depending on the Time in Force[10] selected by the User. At the commencement of the Early Trading Session, orders entered between 6:00 a.m. and 7:00 a.m. are handled in time sequence, beginning with the order with the oldest time stamp, and are placed on the EDGA Book, routed, cancelled, or executed in accordance with the terms of the order. The current rule therefore provides a single, fixed point (the commencement of the Early Trading Session at 7:00 a.m.) at which orders entered prior to the Early Trading Session become eligible for execution, and does not permit a User to designate a later point prior to Regular Trading Hours at which an order becomes eligible.

Current Rule 11.1(a)(1) also provides that the Exchange will not accept the following orders prior to 7:00 a.m.: orders with a Post Only instruction,[11] ISOs,[12] Market Orders[13] other than those with a TIF instruction of Regular Hours Only or a Stop Price,[14] orders with a Minimum Execution Quantity[15] instruction that also include a TIF instruction of Regular Hours Only, and

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Exchange Rule 1.5(y).

[6] *See* Securities Exchange Act Release No. 105587 (May 29, 2026), 91 FR 33238 (June 3, 2026) (SR–CboeEDGX–2026–019) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Amended by Amendment No. 1, To Extend the Exchange's Trading Hours to 23 Hours per Day, Five Days per Week) (''EDGX Approval Order'').

[7] *See* Exchange Rule 11.1(a)(1). All times stated herein are in ET.

[8] *See* Exchange Rule 1.5(jj).

[9] *See* Exchange Rule 1.5(s).

[10] *See* Exchange Rule 11.6(q).

[11] *See* Exchange Rule 11.6(n)(4).

[12] *See* Exchange Rule 11.8(c).

[13] *See* Exchange Rule 11.8(a).

[14] *See* Exchange Rule 11.8(a)(1).

[15] *See* Exchange Rule 11.6(h).

all orders with a TIF instruction of IOC [16] or FOK.[17]

Proposed Start Time Instruction

The Exchange proposes to amend the time-sequencing provision so that it is no longer limited to orders entered between 6:00 a.m. and 7:00 a.m., and to adopt a flexible Start Time instruction. As proposed, in addition to the Time in Force, a User may also designate a start time for an order (''Start Time''). Start Times may be designated in thirty-minute increments and must be set to a time prior to the commencement of Regular Trading Hours; Start Times may not be designated during Regular Trading Hours. This language is substantively identical to the Start Time language in EDGX Rule 11.1(a)(2), which replaced EDGX's 4:00 a.m. Start and 7:00 a.m. Start designations with the same flexible and uniform framework. Because orders on the Exchange are not eligible for execution prior to the commencement of the Early Trading Session at 7:00 a.m., the earliest Start Time that will have practical effect is 7:00 a.m., and the latest permissible Start Time is 9:00 a.m.

The Exchange also proposes to provide that, at the commencement of the Early Trading Session and at each Start Time, orders will be handled in time sequence, beginning with the order with the oldest time stamp, and will be placed on the EDGA Book, routed, cancelled, or executed in accordance with the terms of the order. This provision is consistent with the sequencing provision adopted by EDGX, which provides that, at each Start Time, orders will be handled in time sequence beginning with the oldest time stamp.[18] The Exchange proposes to retain the reference to the commencement of the Early Trading Session so that orders that are entered prior to the Early Trading Session without a Start Time designation continue to become eligible for execution, in time sequence, at the commencement of the Early Trading Session, as they do today.

For example, a User may enter an order at 6:15 a.m. with a Start Time of 8:00 a.m. That order would be accepted but would not be eligible for execution until 8:00 a.m., at which time it would be handled in time sequence with all other orders designated with an 8:00 a.m. Start Time, beginning with the order with the oldest time stamp, and would be placed on the EDGA Book, routed, cancelled, or executed in accordance with its terms.

Order Acceptance Restrictions

The Exchange proposes to amend the order acceptance restrictions in Rule 11.1(a)(1) so that they apply prior to 7:00 a.m. or, if later, prior to the order's designated Start Time. The Exchange is not proposing any change to the categories of orders subject to these restrictions, which will continue to be: orders with a Post Only instruction, ISOs, Market Orders other than those with a TIF instruction of Regular Hours Only or a Stop Price, orders with a Minimum Execution Quantity instruction that also include a TIF instruction of Regular Hours Only, and all orders with a TIF instruction of IOC or FOK. The Exchange is also retaining the existing 7:00 a.m. threshold. Under the proposal, an order in one of these categories designated with a Start Time later than 7:00 a.m. will not be accepted prior to its Start Time. The current restrictions are designed to limit certain order types that are not suitable for queueing to the period in which an order is eligible for execution. Tying the restrictions to an order's designated Start Time applies that same rationale to the more flexible Start Time framework. EDGX similarly ties the same five categories of restrictions to the period before orders become eligible for execution, which on EDGX is the Order Acceptance Queueing Time.[19]

The Exchange is not proposing to change its order entry window, which will continue to begin at 6:00 a.m., or the Time in Force instructions available to Users. Orders entered prior to the Early Trading Session without a Start Time designation will continue to become eligible for execution at the start of the Early Trading Session, Pre-Opening Session, or Regular Trading Hours, depending on the Time in Force selected by the User. Use of the Start Time instruction is optional.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[20] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [21] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed Start Time instruction removes impediments to and perfects the mechanism of a free and open market and a national market system because it replaces the single fixed point at which orders entered prior to the Early Trading Session become eligible for execution with a flexible and uniform framework. Under that framework, Users may control the time at which their orders become eligible for execution prior to Regular Trading Hours. The Commission approved the same Start Time framework for EDGX, which replaced EDGX's 4:00 a.m. Start and 7:00 a.m. Start construct.[22] The Start Time instruction provides Members with additional flexibility to manage the timing of their order flow in the period before Regular Trading Hours. This includes aligning order eligibility with anticipated market conditions or with their own trading strategies, without requiring Members to manually enter orders at a particular time.

The Exchange believes the proposed time-sequencing provision promotes just and equitable principles of trade and protects investors because orders that become eligible at the commencement of the Early Trading Session or at a given Start Time will be handled in a transparent and objective manner, in time sequence beginning with the order with the oldest time stamp. This is the same manner in which orders are handled today at the commencement of the Early Trading Session, and it is consistent with the sequencing provision approved for EDGX.

The Exchange believes that tying the existing order acceptance restrictions to the later of 7:00 a.m. or the order's designated Start Time protects investors

[16] *See* Exchange Rule 11.6(q)(1).

[17] *See* Exchange Rule 11.6(q)(3).

[18] *See* EDGX Rule 11.1(a)(2); EDGX Approval Order, *supra* note 4.

[19] *See* EDGX Rule 11.1(a)(3); EDGX Approval Order, *supra* note 4. Because the Exchange does not operate an Overnight Trading Session or an Order Acceptance Queueing Time, the Exchange proposes to tie the restrictions to the existing 7:00 a.m. threshold and the order's designated Start Time.

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

[22] *See* EDGX Approval Order, *supra* note 4.

and the public interest. The proposal preserves the existing categories of restricted orders and the existing 7:00 a.m. threshold. It applies those restrictions consistently to orders that will not be eligible for execution until a later Start Time, ensuring that order types that are not suitable for queueing are not accepted before the order may execute. The proposed rule change does not loosen any existing restriction.

The proposed rule change also promotes consistency across the Cboe-affiliated equities exchanges, which reduces complexity for Members that access multiple Cboe-affiliated exchanges and fosters cooperation and coordination with persons engaged in facilitating transactions in securities. The proposed rule change does not permit unfair discrimination because the Start Time instruction will be available to all Members on the same terms, and its use is optional.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change will impose any burden on intramarket competition because the Start Time instruction will be available to all Members on an equal and non-discriminatory basis, and its use is optional. The Exchange does not believe the proposed rule change will impose any burden on intermarket competition because it is based on a rule that the Commission approved for EDGX, and it is designed to provide Members with consistent order handling functionality across the Cboe-affiliated equities exchanges rather than to address any competitive issue. Other exchanges are free to adopt similar functionality.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [23] and Rule 19b–4(f)(6) [24] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeEDGA–2026–035 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeEDGA–2026–035. 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 filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeEDGA–2026–035 and should be submitted on or before November 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22261 Filed 10–30–26; 8:45 am]

BILLING CODE 8011–01–P

[23] 15 U.S.C. 78s(b)(3)(A).

[24] 17 CFR 240.19b–4(f)(6).

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106759; File No. S7–2026–38]

Notice of Potential Change To Increase Maximum Fixed-Dollar Amount for Alternative Compliance Mechanism for Security-Based Swap Dealers That Are Registered as Swap Dealers and Have Limited Security-Based Swap Activities

October 28, 2026.

On October 26, 2026, Mizuho Capital Markets LLC (''MCM'') requested that the Securities and Exchange Commission (''Commission'') increase the maximum fixed-dollar amount of an security-based swap dealer's (''SBSD'') aggregate gross notional outstanding security-based swap (''SBS'') positions to qualify for Rule 18a–10's [1] alternative compliance mechanism (''ACM'') from $50 billion to $100 billion.[2] After considering the levels of SBS activity of SBSDs operating under Rule 18a–10, the Commission determines that it may be appropriate to change the maximum fixed-dollar amount for any SBSD eligible for Rule 18a–10 to $100 billion. Pursuant to Rule 18a–10(f)(2), the Commission is publishing this notice of the potential change to provide interested persons with an opportunity to comment.

I. Background

In 2019, the Commission adopted Rule 18a–1 and Rules 18a–3 through 18a–9 establishing capital, margin, segregation, recordkeeping, reporting, notification, and security count requirements applicable to SBSDs that are not banks and are not registered as broker-dealers (''stand-alone SBSDs'').[3]

[1] *See* 17 CFR 240.18a–10 (''Rule 18a–10'').

[2] The request is attached as an Appendix to this notice (''Request''). MCM is registered with the Commodity Futures Trading Commission (''CFTC'') as a swap dealer and is registered with the Commission as an SBSD.

[3] *See* Capital, Margin, and Segregation Requirements for Security-Based Swap Dealers and Major Security-Based Swap Participants and Capital and Segregation Requirements for Broker-Dealers, Securities Exchange Act (''Exchange Act'') Release No. 86175 (June 21, 2019), 84 FR 43872 (Aug. 22, 2019) (''Capital, Margin, and Segregation Release'') (adopting, among other things, 17 CFR 240.18a–1

The Commission also adopted Rule 18a–10, which establishes an ACM pursuant to which a stand-alone SBSD that is registered as a swap dealer and predominantly engages in a swaps business may elect to comply with the capital, margin, segregation, recordkeeping, and reporting requirements of the Commodity Exchange Act (''CEA'') and the CFTC's rules in lieu of complying with Rules 18a–1 and Rules 18a–3 through 18a–9.[4]

The Capital, Margin, and Segregation Release explains the rationale for the ACM as follows: ''In light of the differences between the rules of the Commission and the CFTC, the Commission believes it is appropriate to permit such firms to comply with the capital, margin, and segregation requirements of the CEA and the CFTC's rules, provided the firm's [SBS] business is not a significant part of the [SBS] market and predominantly involves dealing in swaps as compared to [SBS]. In this circumstance, the CFTC's regulatory interest in the firm will greatly exceed the Commission's regulatory interest given the relative size of its swaps business as compared to its [SBS] business.'' [5]

To qualify to operate pursuant to Rule 18a–10, the stand-alone SBSD must: (1) be registered as an SBSD pursuant to section 15F(b) of the Exchange Act and the rules thereunder, (2) be registered as a swap dealer pursuant to section 4s of the CEA and the rules thereunder, (3) not be registered as a broker or dealer pursuant to section 15 of the Exchange Act and the rules thereunder, and (4) meet the conditions to be exempt from paragraph (f) of Exchange Act rule 18a–4.[6] In addition to these other conditions, the aggregate gross notional amount of the firm's outstanding SBS positions must not exceed the lesser of a maximum fixed-dollar amount or 10% of the combined aggregate gross notional amount of the firm's SBS and swap positions.[7]

The maximum fixed-dollar amount was set at a transitional level of $250 billion for the first 3 years after the compliance date of the rule and then dropped to $50 billion thereafter unless the Commission issues an order: (1) maintaining the $250 billion maximum fixed-dollar amount for an additional period of time or indefinitely; or (2) lowering the maximum fixed-dollar amount to an amount between $250 billion and $50 billion.[8] In explaining the $50 billion fixed-dollar amount, the Commission stated its belief that ''a stand-alone SBSD with a gross notional amount of outstanding [SBS] of no more than $50 billion will not be a significant participant in the [SBS] market.'' [9] In contrast, the transitional $250 billion fixed dollar-amount was adopted to provide stand-alone SBSDs predominantly engaged in a swaps business ''with a substantial amount of leeway to develop their [SBS] business without managing the level of that business to the lower $50 billion threshold,'' as well as ''additional time to transition from the $250 billion threshold to the $50 billion threshold or another threshold.'' [10]

Since more than 3 years have passed since the compliance date for Rule 18a–10, the current maximum fixed-dollar amount is $50 billion. For context, the gross notional amount of SBS outstanding on December 26, 2025 was approximately $7,265.144 billion.[11] The Capital, Margin, and Segregation Release stated that ''[t]he Commission intends to analyze how significant . . . [SBSDs] are to the [SBS] market and broader securities markets based on their levels of their [SBS] activity. The analysis will consider the firm's individual and collective impact on the [SBS] market.'' [12] The Commission is considering increasing the maximum fixed-dollar amount in paragraph (f)(1) of Rule 18a–10 from $50 billion to $100 billion. Rule 18a–10(f)(2) provides that if, after considering the levels of SBS activity of the SBSDs operating under the ACM, the Commission determines that it may be appropriate to change the maximum fixed-dollar amount, the Commission will publish a notice of the potential change.[13]

II. Summary of the Request

In the Request, MCM asks the Commission to increase the maximum fixed-dollar amount of the aggregate gross notional outstanding SBS positions for any SBSD eligible for Rule 18a–10 from $50 billion to $100 billion.[14]

In support of its Request, MCM states that it is one of two stand-alone SBSDs operating pursuant to the ACM in Rule 18a–10. MCM represents that its SBS activity represents only a small fraction of its overall derivatives business. From 2022 to 2024, its SBS activity represented less than 0.25% of the firm's total gross notional across SBS and swaps, and only 1.47% of the total active trade count. MCM states that the substantial majority of MCM's derivatives activity is conducted through its swap dealing business, which deals principally in interest rate and foreign exchange derivatives. MCM conducts a significant amount of business with commercial end users not required to post margin to MCM. Only roughly $0.4 billion of MCM's total $2.0 billion tier 1 capital is currently allocated to support SBS activity.[15]

MCM provides the following reasons for increasing the maximum fixed-dollar amount in Rule 18a–10 to $100 billion: [16]

• *Consistent with the Design of Rule 18a–10 and the Commission's Reserved Discretion:* The Commission expressly built flexibility into Rule 18a–10 to adjust the maximum fixed-dollar amount between $50 billion and $250 billion after reviewing the levels of SBS activity of firms operating under the ACM. Granting MCM's request would be a straightforward exercise of that authority.

• *Minimal Impact on the Broader SBS Market:* Because only a small number of firms operate under the ACM, and because MCM's SBS activity is a small fraction of its overall derivatives business, increasing the fixed-dollar amount would not distort the broader SBS market. The relief would also reflect the premise underlying the ACM—that, for a firm predominantly engaged in a swaps business, the CFTC's regulatory interest greatly exceeds the Commission's.[17] While granting relief

(''Rule 18a–1'') (capital requirements), 17 CFR 240.18a–3 (''Rule 18a–3'') (margin requirements), and 17 CFR 240.18a–4 (segregation requirements)). *See* Recordkeeping and Reporting Requirements for Security-Based Swap Dealers, Major Security-Based Swap Participants, and Broker-Dealers, Exchange Act Release No. 87005 (Sept. 19, 2019), 84 FR 68550 (Dec. 16, 2019) (adopting, among other things, 17 CFR 240.18a–5 (record making requirements), 17 CFR 240.18a–6 (record preservation requirements), 17 CFR 240.18a–7 (reporting requirements), 17 CFR 240.18a–8 (notification requirements), and 17 CFR 240.18a–9 (''Rule 18a–9'') (security count requirements)).

[4] *See id. See also* 17 CFR 240.18a–10.

[5] *See* Capital, Margin, and Segregation Release, 84 FR at 43944.

[6] *See* 17 CFR 240.18a–10(a)(1)–(a)(4).

[7] *See* 17 CFR 240.18a–10(a)(5).

[8] *See* 17 CFR 240.18a–10(f)(1).

[9] *See* Capital, Margin, and Segregation Release, 84 FR at 43944–45.

[10] *See* Capital, Margin, and Segregation Release, 84 FR at 43945.

[11] *See* Commission, Report on Security-Based Swaps Pursuant to Section 13(m)(2) of the Securities Exchange Act of 1934 (June 26, 2026), *available at https://www.sec.gov/files/tm/report-security-based-swaps-062626.pdf* (adding $5,221,757 from the Depository Trust and Clearing Corporation Data Repository—gross notional amount outstanding table on page 3 of the report and $2,043,387 from the ICE Trade Vault—gross notional amount outstanding table from page 5 of the report).

[12] *See* Capital, Margin, and Segregation Release, 84 FR at 43945.

[13] *See* 17 CFR 240.18a–10(f)(2).

[14] *See* Request at 1.

[15] *See* Request at 4.

[16] *See* Request at 4–6.

[17] *Id.* at 44039.

will likely have a small impact on the market, choosing not to grant relief is likely to subject MCM to substantial costs that could further incentivize migration of SBS activities into an already smaller cluster of the market, leading to decreased choice for counterparties. Additionally, since much of MCM's SBS activity is related to hedging and internal risk management, it is likely that counterparties and MCM and its affiliates as a whole will face substantial costs and difficulties when mitigating counterparty and hedging risks.

• *Promotes Regulatory Comparability:* Permitting MCM to continue to comply through the CEA and the CFTC's rules advances the Dodd-Frank Act's goal, of establishing and maintaining comparable minimum capital requirements across the Commission, the CFTC, and the prudential regulators to the maximum extent practicable.[18] Rule 18a–10 provides a unique ability to ease a regulatory burden while fostering harmonization across the securities industry. Relief in this instance furthers regulatory consistency by expanding existing coverage for similar derivatives products in a manner that is inherently coherent.[19]

• *Preserves Safety, Soundness, and Liquidity While Reducing Duplicative Costs:* MCM would remain subject to the CFTC's comprehensive capital, margin, segregation, and risk management requirements, including its liquidity risk management requirements, so the relief would not compromise MCM's financial soundness. At the same time, the relief would spare MCM the cost and inefficiency of maintaining duplicative capital, margin, and segregation calculations under two regulatory regimes, reducing burdens on both MCM and the Commission's limited resources.[20]

III. Solicitation of Comments

The Commission requests and encourages any interested person to submit comments regarding the potential change, including whether the Commission should increase the maximum fixed-dollar amount of the aggregate gross notional outstanding SBS positions for any SBSD eligible for Rule 18a–10 from $50 billion to $100 billion. In particular, the Commission solicits comment on the following questions:

1. Do commenters agree with MCM's reasons described in the Request for increasing Rule 18a–10's maximum fixed-dollar amount to $100 billion? Please explain why or why not.

2. Would increasing Rule 18a–10's maximum fixed-dollar amount to $100 billion be consistent with paragraph (f)(2) of Rule 18a–10, which requires the Commission to consider the levels of SBS activity of SBSDs operating under the rule? Please explain why or why not.

3. If Rule 18a–10's maximum fixed-dollar amount was increased to $100 billion, how significant could SBSDs relying on the ACM be to the SBS market and broader securities markets based on their SBS activity levels? What would be the individual and collective impact of these firms on the SBS market? Please explain.

4. Is there a maximum fixed-dollar amount that is lower or higher than the amount in the Request that the Commission should adopt, that accounts for the factors the Commission should consider in changing the maximum fixed-dollar amount? If so, please identify the amount and explain why it is appropriate.

Comments should be received on or before December 2, 2026. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission's internet comment form (*https://www.sec.gov/comments/s7-2026-38/notice-potential-change-increase-maximum-fixed-dollar-amount-alternative-compliance-mechanism*); or

• Send an email to *rule-comments@sec.gov.* Please include File Number S7–2026–38 on the subject line.

Paper Comments

• Send paper comments to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number S7–2026–38. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method of submission. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules-regulations/public-comments/s7-2026-38*). 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.

For further information, you may contact Raymond A. Lombardo, Acting Associate Director, Michelle Danis, Acting Associate Director, or Valentina Minak Deng, Special Counsel, Office of Broker-Dealer Finances, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–7010.

By the Commission.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22272 Filed 10–30–26; 8:45 am]

BILLING CODE 8011–01–P

[18] 15 U.S.C. 78o–10(e)(3)(D)(ii); *see* Adopting Release at 44035, 44036 (describing the Commission's aim to promote a harmonized regulatory environment for SBSDs).

[19] Providing relief by increasing the maximum fixed-dollar amount is also consistent with the CFTC's and SEC's commitment to harmonization in areas of common regulatory interest. In a memorandum of understanding published in March 2026, the SEC and CFTC agreed to coordinate and collaborate between agencies to promote innovation with a ''minimum effective dose of regulation.'' Among those explicit areas of discussion was a commitment to remove regulatory obstacles and to generally enhance the derivatives market, with an aim at lowering compliance frictions and ensuring that the U.S. markets remain competitive. Memorandum of Understanding Between the Commission and the CFTC Regarding Harmonization in Areas of Common Regulatory Interest (Mar. 26, 2026), *available at https://www.sec.gov/newsroom/press-releases/2026-26-sec-cftc-announce-historic-memorandum-understanding-between-agencies.*

[20] *See* 17 CFR 23.600 (CFTC risk management program requirements for swap dealers, including requirements addressing liquidity risk).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106760; File No. SR–NYSEAMER–2026–95]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the NYSE American Options Fee Schedule To Waive the Maximum Combined Floor Broker Credits on QCC Trades and Rebates Paid Through the Manual Billable Rebate Program for October 2026

October 28, 2026.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on October 20, 2026, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE American Options Fee Schedule (''Fee Schedule'') to waive the maximum combined Floor Broker credits paid for QCC trades and rebates paid through the Manual Billable Rebate Program for the month of October 2026. The proposed rule change is available on the Exchange's website at *www.nyse.com* and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend the Fee Schedule to waive the maximum combined Floor Broker credits paid for QCC trades and rebates paid through the Manual Billable Rebate Program for the month of October 2026.

The Exchange imposes a limit on the maximum combined Floor Broker credits paid for QCC trades and rebates paid through the Manual Billable Rebate Program per month per Floor Broker firm (the ''Cap'').[4] In 2025, the combined limit was $3,000,000. However, based on continuing open outcry volumes on the Exchange throughout 2025, the Exchange increased the combined limit to $4,000,000.[5] Shortly thereafter, and for the same reason (*i.e.,* elevated open outcry volume), the Exchange waived the Cap for the months of January and February 2026.[6] Shortly thereafter, and again to address continued elevated open outcry volumes, the Exchange further increased the Cap to $5,500,000 in March 2026.[7]

Because open outcry volumes on the Exchange are again significantly elevated, the Exchange proposes to waive the Cap for the month of October 2026 and to use the period during which the Cap is waived to evaluate further adjustments to the amount of the Cap.[8] As with previous waivers, the proposed waiver is being adopted in anticipation of Floor Broker firms reaching the Cap before month's end and potentially redirecting their order flow away from the Exchange. In the absence of the proposed waiver, Floor Broker firms may choose to re-direct such order flow to a competing market. Accordingly, the purpose of the proposal is to encourage Floor Broker firms to continue to direct open outcry transactions to the Exchange, despite increasing industry volumes making it less difficult to reach the Cap (even at the most recently increased amount).

Although the Exchange cannot predict with certainty how many Floor Broker firms would be impacted by this change, the Exchange believes that the proposed changes would incent Floor Brokers to continue to direct their order flow to the Exchange, thus increasing liquidity to the benefit of all market participants.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[10] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [11]

There are currently 20 registered options exchanges competing for order flow. Based on publicly available information and, excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[12] Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in September 2026, the Exchange had 12.39% market share of executed volume of multiply-listed equity and ETF options order flow. In such a low concentrated and highly competitive market, no single options exchange possesses significant pricing power in the execution of option order flow.

The proposed waiver of the Cap is reasonable because it is designed to encourage the role performed by Floor Brokers in facilitating the execution of orders via open outcry, a function that the Exchange wishes to support for the benefit of all market participants, and would allow the Exchange time to evaluate further changes to the amount of the Cap. Absent the proposed waiver, the Exchange believes that as soon as

[4] *See* Fee Schedule, Sections I.F. and III.E.1 (providing, in relevant part, that Floor Broker credits paid for QCC trades and rebates paid through the Manual Billable Rebate Program shall not combine to exceed $5,5000,000 per month per Floor Broker firm).

[5] *See* Securities Exchange Act Release No. 104676 (January 23, 2026), 91 FR 3748 (January 28, 2026) (SR–NYSEAMER–2026–03) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify the NYSE American Options Fee Schedule To Modify the Market Maker Sliding Scale Qualification Tiers and Amend the Floor Broker Fixed Cost Prepayment Incentive Program).

[6] *See* Securities Exchange Act Release No. 104696 (January 27, 2026), 91 FR 4136 (January 30, 2026) (SR–NYSEAMER–2026–05) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify the NYSE American Options Fee Schedule To Waive the Combined Cap on Floor Broker Credits Paid for QCC Trades and Rebates Paid Through the Manual Billable Rebate Program for the Months of January and February 2026).

[7] *See* Securities Exchange Act Release No. 105132 (March 31, 2026), 91 FR 17020 (April 3, 2026) (SR–NYSEAMER–2026–25) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify the NYSE American Options Fee Schedule To Eliminate Certain Incentive Programs and Increase the Limit on the Maximum Combined Floor Broker Credits Paid on QCC Trades and Rebates Paid Through the Manual Billable Program).

[8] *See* proposed Fee Schedule, Sections I.F. and III.E.1.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

[11] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (''Reg NMS Adopting Release'').

[12] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available at: *https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.*

Floor Brokers reach the Cap, they are likely to re-direct order flow away from the Exchange, which may adversely impact other market participants trading on the Exchange. To the extent that the proposed waiver encourages Floor Brokers to facilitate transactions on the Exchange instead of on a competing market, all market participants participating on the Exchange would benefit from the increased liquidity. The Exchange believes the proposed waiver should continue to incent Floor Brokers to encourage market participants to aggregate their executions at the Exchange as a primary execution venue. To the extent that the proposed change achieves its purpose in attracting more volume to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution, thus improving market quality for all market participants.

The Exchange believes the proposed waiver of the Cap is an equitable allocation of its fees and credits and is not unfairly discriminatory because the proposal is based on the amount and type of business transacted on the Exchange. Floor Brokers are not obligated to execute manual transactions and QCCs to earn rebates and credits applied toward the Cap. However, the proposed waiver is designed to continue to encourage the role performed by Floor Brokers in facilitating the execution of orders via open outcry, a function that the Exchange wishes to support for the benefit of all market participants.

To the extent that the proposed waiver of the Cap continues to attract manual transactions and QCCs to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed waiver would improve market quality for all market participants on the Exchange and attract more order flow to the Exchange, thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [13]

Intramarket Competition. The proposed waiver of the Cap would apply equally to all similarly situated Floor Brokers. To the extent that there is an additional competitive burden on non-Floor Brokers, the Exchange believes that any such burden would be appropriate because Floor Brokers serve an important function in facilitating the execution of orders in open outcry and price discovery for all market participants.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the other 19 competing options exchanges if they deem the Exchange's fee levels to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[14] Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in September 2026, the Exchange had 12.39% market share of executed volume of multiply-listed equity and ETF options trades.[15]

The Exchange believes that the proposed waiver of the Cap reflects this competitive environment because it is designed to continue to incent Floor Brokers to direct manual and QCC transactions to the Exchange, to provide liquidity and to attract order flow. To the extent that Floor Brokers are encouraged to utilize the Exchange as a primary trading venue for all transactions, all Exchange market participants stand to benefit from the improved market quality and increased opportunities for price improvement. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [16] of the Act and subparagraph (f)(2) of Rule 19b–4 [17] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [18] of the Act to determine whether the proposed rule

[13] *See* Reg NMS Adopting Release, *supra* note 11, at 37499.

[14] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available at: *https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.*

[15] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, see id., the Exchange's market share in equity-based options increased from 8.89% for the month of September 2026 to 12.39% for the month of September 2026.

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(2).

[18] 15 U.S.C. 78s(b)(2)(B).

change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEAMER–2026–95 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–NYSEAMER–2026–95. 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 filing 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–NYSEAMER–2026–95 and should be submitted on or before November 23, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22265 Filed 10–30–26; 8:45 am]

BILLING CODE 8011–01–P

[19] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 13133]

Notice of Department of State Sanctions Actions

ACTION: Notice of sanctions action.

SUMMARY: On February 24, 2026, the Secretary of State Marco Rubio determined that each of Sergey Sergeyevich Zelenyuk, Matrix LLC, and Special Technology Services LLC FZ met the criteria for sanctions set forth in section 2(a)(1)(A) of the Protecting American Intellectual Property Act of 2022 (Pub. L. 117–336) (PAIPA) and, in consultation with the heads of other relevant agencies, as appropriate, selected the sanctions described in section 2(b)(1)(A), (D), (H), (I), and (J) to be imposed on the entities.

DATES: The Secretary of State's determinations and selection of certain sanctions to be imposed upon the entities and individuals identified in the **SUPPLEMENTARY INFORMATION** section were effective on February 24, 2026.

FOR FURTHER INFORMATION CONTACT: Andrew J. Weinschenk, Director, Office of Global Sanctions & Threat Finance, Bureau of Economic, Energy, and Business Affairs, Department of State, Washington, DC 20520, tel.: (202) 647–5763, email: *WeinschenkAJ@state.gov*

SUPPLEMENTARY INFORMATION: Acting pursuant to PAIPA and Presidential Memorandum of July 19, 2024 (''Delegation of Functions and Authorities Under the Protecting American Intellectual Property Act of 2022''), the Secretary of State determined that each of Sergey Sergeyevich Zelenyuk, Matrix LLC, and Special Technology Services LLC FZ met the criteria set forth in section 2(a)(1)(A) of PAIPA, as indicated below, and, in consultation with the heads of other relevant agencies, as appropriate, selected the sanctions described in section 2(b)(1)(A), (D), (H), (I), and (J) to be imposed on the entities. As a result, Sergeyevich Zelenyuk, Matrix LLC, and Special Technology Services LLC FZ are subject to the sanctions indicated below, effective February 24, 2026.

Individual

1. SERGEY SERGEYEVICH ZELENYUK (Cyrillic: ЗЕЛЕНЮК, Сергей Сергеевич) (a.k.a. ZELENYUK, Sergei Sergeevich; a.k.a. Zelenyuk, Sergey Sergeevich; a.k.a. ''MORTENOIR''; a.k.a. ''SRGSRGSRG111''), Rimsky-Korsakov Prospect, Building 109–111, Litera/Block A, Apartment 20, Saint Petersburg 190068, Russia; DOB 17 Mar 1994; POB Saint Petersburg, Russia; Nationality Russia; Gender Male; PAIPA Section 2 information: BLOCKING OF PROPERTY (individual). Sec.2(b)(2)(a); Tax ID No. 780223642330 (Russia) (individual) [PAIPA].

Identified pursuant to section 2(a)(1)(A)(i) of PAIPA for being a foreign person that has knowingly engaging in, or benefitted from, significant theft of trade secrets of United States persons, which occurred on or after January 5, 2023, and is reasonably likely to result in, or has materially contributed to, a significant threat to the national security, foreign policy, or economic health or financial stability of the United States.

Entities

1. Matrix LLC (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ МАТРИЦА) (a.k.a. LLC MATRITSA; a.k.a. MATRIX LIMITED; a.k.a. MATRIX LTD (Cyrillic: ООО МАТРИЦА); a.k.a. OPERATION ZERO; a.k.a. OPZERO), Sh. Petergofskoe, 73, Letter T, Office 26/1, Room 1, Municipal District Sosnovaya Polyana, Saint Petersburg 198206, Russia; website opzero.ru; PAIPA Section 2 information: BLOCKING OF PROPERTY (entity). Sec.2(b)(1)(A); alt. PAIPA Section 2 Information: LOANS FROM UNITED STATES FINANCIAL INSTITUTIONS. Sec.2(b)(1)(D); alt. PAIPA Section 2 Information: FOREIGN EXCHANGE. Sec.2(b)(1)(H); BANKING TRANSACTIONS. Sec.2(b)(1)(I); BAN ON INVESTMENT IN EQUITY OR DEBT OF SANCTIONED PERSON. Sec.2(b)(1)(J); Organization Established Date 27 Sep 2021; Tax ID No. 7807251301 (Russia) [PAIPA].

Identified pursuant to section 2(a)(1)(A)(i) of PAIPA, for being a foreign person that has knowingly engaged in, or benefitted from, significant theft of trade secrets of United States persons, which occurred on or after January 5, 2023 and is reasonably likely to result in, or has materially contributed to, a significant threat to the national security, foreign policy, or economic health or financial stability of the United States.

2. SPECIAL TECHNOLOGY SERVICES LLC FZ Meydan Grandstand, 6th Floor, Meydan Road, Nad Al Sheba, Dubai, United Arab Emirates; PAIPA Section 2 information: BLOCKING OF PROPERTY (entity). Sec.2(b)(1)(A); alt. PAIPA Section 2 Information: LOANS FROM UNITED STATES FINANCIAL INSTITUTIONS. Sec.2(b)(1)(D); alt. PAIPA Section 2 Information: FOREIGN EXCHANGE. Sec.2(b)(1)(H); BANKING TRANSACTIONS. Sec.2(b)(1)(I); BAN ON INVESTMENT IN EQUITY OR DEBT OF SANCTIONED PERSON. Sec.2(b)(1)(J); Organization Established Date 07 Dec 2024 [PAIPA]. (Linked To: ZELENYUK).

Identified pursuant to section 2(a)(1)(A)(iii) of PAIPA for being a foreign person that is owned or controlled by, or that has acted or purported to act for or on behalf of, directly or indirectly, Sergey Sergeyevich Zelenyuk.

Hugo Y. Yon,

Principal Deputy Assistant Secretary, Bureau of Economic, Energy, and Business Affairs, U.S. Department of State.

[FR Doc. 2026–22248 Filed 10–30–26; 8:45 am]

BILLING CODE 4710–07–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 290 (Sub-No. 426X)]

Norfolk Southern Railway Company—Abandonment Exemption—in Madison County, Ohio

Norfolk Southern Railway Company (NSR) filed a verified notice of exemption under 49 CFR 1152 subpart F—*Exempt Abandonments* to abandon approximately 0.96 miles of rail line located between milepost XD 24.73 +/− and milepost XD 25.69 +/− in Madison County, Ohio (the Line). The Line traverses U.S. Postal Service Zip Code 43140.

NSR has certified that: (1) no local traffic has moved over the Line for at least two years; (2) any overhead traffic on the Line can be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government on behalf of such user) regarding cessation of service over the Line is pending with either the Surface Transportation Board (Board) or any U.S. District Court or has been decided in favor of a complainant within the two-year period prior to the filing of the notice; and (4) the requirements at 49 CFR 1105.7(b) and 1105.8(c) (notice of environmental and historic reports), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to government agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received,[1] this exemption will be effective on December 2, 2026, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues[2] and formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2) and interim trail use/railbanking requests under 49 CFR 1152.29[3] must be filed by November 12, 2026. Petitions to reopen and requests for public use conditions under 49 CFR 1152.28 must be filed by November 23, 2026.

All pleadings, referring to Docket No. AB 290 (Sub-No. 426X), must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on NSR's representative, William A. Mullins, Mullins Law Group PLLC, 2001 L St. NW, Suite 720, Washington, DC 20036.

If the verified notice contains false or misleading information, the exemption is void ab initio.

NSR has filed a combined environmental and historic report that addresses the potential effects, if any, of the abandonment on the environment and historic resources. OEA will issue a Draft Environmental Assessment (Draft EA) by November 6, 2026. The Draft EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245–0294. If you require an accommodation under the Americans with Disabilities Act, please call (202) 245–0245. Comments on environmental or historic preservation matters must be filed within 15 days after the Draft EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/railbanking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), NSR shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by NSR's filing of a notice of consummation by November 2, 2027, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at *www.stb.gov.*

Decided: October 28, 2026.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2026–22256 Filed 10–30–26; 8:45 am]

BILLING CODE 4915–01–P

[1] Persons interested in submitting an OFA must first file a formal expression of intent to file an offer, indicating the type of financial assistance they wish to provide (*i.e.,* subsidy or purchase) and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[3] Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Performance Review Board Membership

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: This notice announces the Office of the United States Trade Representative (USTR) staff members selected to serve on the Senior Executive Service (SES) and Senior Level (SL) Performance Review Board (PRB). This notice supersedes all previous PRB membership notices.

DATES: The staff members in this notice will begin serving as PRB members on September 22, 2026.

FOR FURTHER INFORMATION CONTACT: Cassie Ender, Human Capital Specialist, Office of Human Capital and Services, at (202) 881–7782 or *Cassie.L.Ender@ustr.eop.gov.*

SUPPLEMENTARY INFORMATION: USTR is required (*see* 5 U.S.C. 4314(c)) to establish a PRB to review and make recommendations to the U.S. Trade Representative for final approval of the performance rating, performance-based pay adjustment, and performance award for each incumbent SES and SL. The following staff members have been selected to serve on USTR's PRB:

Member: Jospeh Barloon, Deputy U.S. Trade Representative for Geneva.

Chairperson: Jeffrey Goettman, Deputy U.S. Trade Representative.

Member: Sarah Ellerman, Assistant U.S. Trade Representative for Southeast Asia and Pacific.

Member: Kenneth Schagrin, Assistant U.S. Trade Representative for Services and Investments.

Member: Michael Starr, Deputy Chief of Staff.

Member: Arthur Tsao, Deputy General Counsel for Negotiations, Legislation & Administrative Law.

Fred Ames,

Assistant U.S. Trade Representative for Administration, Office of the United States Trade Representative.

[FR Doc. 2026–22251 Filed 10–30–26; 8:45 am]

BILLING CODE 3390–F4–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Transportation Project in Nebraska

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT)

ACTION: Notice of limitation on claims for judicial review.

SUMMARY: This notice announces actions taken by the FHWA, on behalf of the Nebraska Department of Transportation and Iowa Department of Transportation, that are final. The action(s) relate to the Decatur Bridge Project, located in Burt County, Nebraska and Monona County, Iowa. Those actions grant licenses, permits, and approvals for the project. The project involves improving the existing Nebraska Highway 51 (N–51)/ Iowa Highway 175 (IA–175) crossing of the Missouri River near Decatur, Nebraska. The FHWA's National Environmental Policy Act (NEPA) Finding of No Significant Impact (FONSI) provides details on the Selected Alternative for the proposed improvements.

DATES: A claim seeking judicial review of the Federal agency actions on the listed highway project will be barred unless the claim is filed on or before April 1, 2027. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT:

For FHWA: James Simerl, Division Administrator, Federal Highway Administration, 100 Centennial Mall North, Room 220, Lincoln, NE 68508, (402) 742–8460, *james.simerl@dot.gov.*

For NDOT: Kyle Keller, Project Development Engineer, 1500 Nebraska Parkway, Lincoln, NE 68502–4759, (402) 479–4795, *kyle.keller@nebraska.gov.*

For Iowa DOT: Angela L. Poole, Bureau Director, Location and Environment Bureau, 800 Lincoln Way, Ames, IA 50010, (515) 239–1798, *angela.poole@iowadot.us.*

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA has taken final agency actions within the meaning of 23 U.S.C. 139(l)(1) by issuing a NEPA FONSI for the Decatur Bridge Project, located in Burt County, Nebraska and Monona County, Iowa. The action(s) by FHWA and the laws under which such actions were taken, are described in the FONSI and the associated agency records. That information is available by contacting FHWA at the addresses provided above.

The purpose of the project is to provide a resilient river crossing connecting Decatur, Nebraska/N–51 and Onawa, Iowa/IA–175 that maintains access to regional commerce, employment, education, health care, and recreation facilities, maintains accessibility to and by emergency services, and provides infrastructure to support current and future travel demand. A FONSI for the project was signed on October 26, 2026.

Information about the FONSI and associated records are available from FHWA at the addresses provided above and can be found at: *https://dot.nebraska.gov/projects/environment/environmental-documents/* or obtained by contacting the individuals listed above. This notice applies to all Federal agency decisions related to the FONSI as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4347]; Federal-Aid Highway Act [23 U.S.C. 109].

2. *Air:* Clean Air Act, as amended [42 U.S.C. 7401–7671(q)].

3. *Land:* Section 6(f) of the Land and Water Conservation Fund Act of 1965 [16 U.S.C. 4601]; Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303].

4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and 1536]. Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]. Migratory Bird Treaty Act [16 U.S.C. 703–712]. Bald and Golden Eagle Protection Act [16 U.S.C. 668–668c]. Magnuson-Stevens Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801 *et seq.*].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archaeological and Historic Preservation Act [16 U.S.C. 469–469(c)];

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000d *et seq.*]; Farmland Protection Policy Act [7 U.S.C. 4201–4209].

7. *Wetlands and Water Resources:* Clean Water Act (Section 319, Section 401, Section 402, Section 404) [33 U.S.C. 1251–1377]. Safe Drinking Water Act [42 U.S.C. 300(f) *et seq.*].

8. *Executive Orders:* Executive Order 11990 Protection of Wetlands; Executive Order 11988 Floodplain Management; Executive Order 11593 Protection and Enhancement of Cultural Resources; Executive Order 13007 Indian Sacred Sites; Executive Order 13287 Preserve America; Executive Order 13175 Consultation and Coordination with Indian Tribal Governments; Executive Order 11514 Protection and Enhancement of Environmental Quality; Executive Order 13112 Invasive Species; Executive Order 13045 Protection of Children From Environmental Health Risks and Safety Risks.

Authority: 23 U.S.C. 139(l)(1).

James Simerl,

FHWA Division Administrator, Lincoln, NE.

[FR Doc. 2026–22331 Filed 10–30–26; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2026–0991]

Agency Information Collection Activities; Renewal of an Approved Information Collection Request: Hazardous Materials Safety Permits

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for review and approval. This ICR requires companies holding safety permits to develop communications plans that allow for the periodic tracking of the shipments. A record of communications that includes the time of the call and location of the shipment may be kept by either the driver (*e.g.,* recorded in the logbook) or the company. These records must be kept, either physically or electronically, for at least 6 months at the company's principal place of business or readily available to the employees at the company's principal place of business. No comments were received in response to the 60-day **Federal Register** notice.

DATES: Comments on this notice must be received on or before December 2, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be submitted within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Ms. Melissa Williams, Office of Safety, Hazardous Materials Division, DOT, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 366–4163; *melissa.williams@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Hazardous Materials Safety Permits.

OMB Control Number: 2126–0030.

Type of Request: Renewal.

Respondents: Motor carriers subject to the Hazardous Materials Safety Permit requirements in 49 CFR part 385, subpart E.

Estimated Number of Respondents: 1,142.

Estimated Time per Response: 5 minutes. The communication between motor carriers and their drivers must take place at least two times per day. It is estimated that it will take 5 minutes to maintain a daily communication record for each driver.

Expiration Date: November 30, 2026.

Frequency of Response: On occasion.

Estimated Total Annual Burden: 799,400 hours [9,592,800 trips × 5 minutes per record ÷ 60 minutes per hour = 799,400].

Background

The Secretary of Transportation is responsible for implementing regulations to issue safety permits for transporting certain hazardous materials (HM) in accordance with 49 U.S.C. 5101 *et seq.* The HM safety permit regulations (49 CFR part 385, subpart E) require initial or first time HM safety permit carriers to file using the Unified Registration System, Form MCSA–1. Update and renewal applications must be filed with FMCSA using the ''Combined Motor Carrier Identification Report and HM Permit Application'' (Form MCS–150B). The HM safety permit regulations also require carriers to have a security program. As part of the HM safety regulations, carriers are required to develop and maintain a route plan so that law enforcement officials can verify the correct location of the HM shipment. FMCSA requires companies holding permits to develop a communications plan that allows for the periodic tracking of the shipment that includes the time of the call and location of the shipment. The records may be kept by either the driver (*e.g.,* recorded in the logbook) or the company. These records must be kept, either physically or electronically, for at least 6 months at the company's principal place of business or readily available to employees at the company's principal place of business.

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 performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority of 49 CFR 1.87.

Jonathan Mueller,

Acting Associate Administrator, Office of Research and Registration.

[FR Doc. 2026–22277 Filed 10–30–26; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2026–1684]

Notice of Petition for Waiver of Compliance

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice; extension of comment period.

SUMMARY: This document extends the period for public comment regarding the CSX Transportation Inc. (CSXT) petition for relief from certain regulations concerning inspections performed by qualified mechanical inspectors (QMIs).

DATES: FRA must receive comments on the petition by December 2, 2026. FRA will consider comments received after that date to the extent practicable.

ADDRESSES:

Comments: Comments related to this docket may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number. All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Caleb Rogers, Railroad Safety Specialist, FRA Motive Power & Equipment Division, telephone: 202–493–6322, email: *caleb.rogers@dot.gov.*

SUPPLEMENTARY INFORMATION: On September 1, 2026, FRA published notice [1] that CSXT petitioned FRA for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 229 (Railroad Locomotive Safety Standards). FRA assigned the petition Docket Number FRA–2026–1684.

On September 9, 2026, the Transportation Trades Department, AFL–CIO (TTD) requested that FRA extend the comment period on this petition.[2] Through this notice, FRA is extending the comment period for an additional 30 days (until December 2, 2026).

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *https://www.regulations.gov.* Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. Communications received by December 2, 2026 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Privacy Act

Anyone can search the electronic form of any written communications and comments received into any of FRA's dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov.*

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2026–22336 Filed 10–30–26; 8:45 am]

BILLING CODE 4910–06–P

[1] *https://www.regulations.gov/document/FRA-2026-1684-0002.*

[2] *https://www.regulations.gov/comment/FRA-2026-1684-0003.*

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2026–1420]

Notice of Petition for Waiver of Compliance

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice; extension of comment period.

SUMMARY: This document extends the period for public comment regarding the Union Pacific Railroad Company (UPRR) petition for relief from certain regulations concerning inspections performed by qualified mechanical inspectors (QMIs).

DATES: FRA must receive comments on the petition by December 2, 2026. FRA will consider comments received after that date to the extent practicable.

ADDRESSES:

Comments: Comments related to this docket may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number. All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Caleb Rogers, Railroad Safety Specialist, FRA Motive Power & Equipment Division, telephone: 202–493–6322, email: *caleb.rogers@dot.gov.*

SUPPLEMENTARY INFORMATION: On September 1, 2026, FRA published notice [1] that UPRR petitioned FRA for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 229 (Railroad Locomotive Safety Standards). FRA assigned the petition Docket Number FRA–2026–1420.

On September 9, 2026, the Transportation Trades Department, AFL–CIO (TTD) requested that FRA extend the comment period on this petition.[2] Through this notice, FRA is extending the comment period for an additional 30 days (until December 2, 2026).

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov.* Interested parties are invited to participate in these proceedings by submitting written views, data, or comments.

Communications received by December 2, 2026 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Privacy Act

Anyone can search the electronic form of any written communications and comments received into any of FRA's dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacy-notice* for the privacy notice of *www.regulations.gov.*

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2026–22335 Filed 10–30–26; 8:45 am]

BILLING CODE 4910–06–P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: November 5, 2026, 12:00 p.m. to 3:00 p.m., Eastern time.

PLACE: The meeting will be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll), Meeting ID: 925 2084 5891, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is *https://kellen.zoom.us/meeting/register/SMAgiZOR3eJDl7CMw1y9g.*

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Enforcement Subcommittee (the ''Subcommittee'') will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Call to Order—UCR Enforcement Subcommittee Chair

The UCR Enforcement Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda and Setting of Ground Rules—UCR Enforcement Subcommittee Chair

For Discussion and Possible Subcommittee Action

The Subcommittee Agenda will be reviewed, and the Subcommittee will consider adoption.

Ground Rules

➢ Subcommittee action only to be taken in designated areas on agenda

IV. Review and Approval of Subcommittee Minutes from the October 28, 2025, Meeting—UCR Enforcement Subcommittee Chair

For Discussion and Possible Subcommittee Action

The draft minutes from the October 28, 2025, Subcommittee meeting will be reviewed. The Subcommittee will consider action to approve.

V. Enforcement Performance Snapshot Through Q3 2026—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

The UCR Enforcement Subcommittee Chair and UCR Enforcement Subcommittee Vice-Chair will present an overview of enforcement activity and compliance rates through the third quarter of 2026, highlighting trends and areas of focus.

[1] *https://www.regulations.gov/document/FRA-2026-1420-0002.*

[2] *https://www.regulations.gov/comment/FRA-2026-1420-0004.*

VI. Planning for 2027 Enforcement Awareness Initiatives—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

The UCR Enforcement Subcommittee Chair and UCR Enforcement Subcommittee Vice-Chair will lead a discussion on the proposed dates for the 2026 Enforcement Awareness Weeks: January 10–16 (aligned with 2027 schedule and avoids the MLK holiday); June 6–12 (scheduled to avoid Juneteenth observance).

VII. Expanding Jurisdictional Engagement—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

The UCR Enforcement Subcommittee Chair and UCR Enforcement Subcommittee Vice-Chair will lead a discussion on outreach efforts to additional jurisdictions to broaden enforcement collaboration.

VIII. FMCSA Registration and UCR Compliance Requirements—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

The UCR Enforcement Subcommittee Chair and UCR Enforcement Subcommittee Vice-Chair will lead a discussion regarding potential coordination with FMCSA to require UCR registration for interstate carriers during initial FMCSA registration and verification of continued UCR registration during biennial updates.

IX. SafeSpect UCR Violation Notifications—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

The UCR Enforcement Subcommittee Chair and UCR Enforcement Subcommittee Vice-Chair will lead a discussion regarding potential coordination with FMCSA to explore SafeSpect enhancements that would alert inspectors when an interstate carrier may be operating without current UCR registration, helping reduce missed UCR violations.

X. Enforcement Efficiency Standard—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

For Discussion and Possible Subcommittee Action

Discussion of the potential adoption of an Enforcement Efficiency standard for all participating states to supplement the existing Audit Compliance Initiatives and Annual State Audit Evaluation Criteria. The Enforcement Subcommittee may take action to recommend to the UCR Plan Board the adoption of an Enforcement Efficiency standard for all participating states.

XI. Other Business—UCR Enforcement Subcommittee Chair

The UCR Enforcement Subcommittee Chair will call for any other items Subcommittee members would like to discuss.

XII. Adjournment—UCR Enforcement Subcommittee Chair

The UCR Enforcement Subcommittee Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, October 27, 2026 at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2026–22276 Filed 10–29–26; 11:15 am]

BILLING CODE 4910–YL–P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: November 5, 2026, 10:30 a.m.–2:30 p.m., Eastern time.

PLACE: This meeting will be held at the Graduate by Hilton Providence, 11 Dorrance Street, Providence, RI 02903.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Governance Task Force (the ''Task Force'') will conduct a meeting to continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

PROPOSED AGENDA

I. Call to Order—UCR Plan Governance Task Force Chair

The UCR Governance Task Force Chair will welcome attendees, call the meeting to order, call roll for the task force, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Task Force Agenda and Setting of Ground Rules—UCR Plan Governance Task Force Chair

For Discussion and Possible Task Force Action

The Governance Task Force Agenda will be reviewed, and the Task Force will consider adoption.

Ground Rules

➢ Task Force action only to be taken in designated areas on agenda

IV. Approval of Minutes of the October 7, 2026, Task Force Meeting—UCR Governance Task Force Chair

For Discussion and Possible Task Force Action

Draft Minutes from the October 7, 2026 UCR Task Force meeting will be reviewed. The Task Force will consider action to approve.

V. Long-Term Strategic Planning for UCR Plan Partners—UCR Governance Task Force Chair

For Discussion and Possible Task Force Action

The UCR Governance Task Force Chair will lead a discussion regarding the long-term evolution of the UCR Plan's key vendor partnerships, including the Executive Director role, Seikosoft and the next iteration of the National Registration System, DSL's service model, Kellen, and other strategic partners. The Governance Task Force may take action by recommending to the UCR Plan Board development in these and other roles that identify opportunities for further evaluation, and future planning activities to support continuity, innovation, and the UCR Plan's evolving needs.

VI. Other Business—UCR Plan Governance Task Force Chair

The UCR Plan Governance Task Force Chair will call for any other business, old or new, from the floor, including items from the previous Task Force meeting.

VII. Adjournment—UCR Plan Governance Task Force Chair

The UCR Plan Governance Task Force Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, October 27, 2026 at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2026–22278 Filed 10–29–26; 11:15 am]

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FEDERAL REGISTER

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 107 and 184
Infant Formula Nutrient Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 107 and 184

[Docket No. FDA–2026–N–10832]

RIN 0910–AJ34

Infant Formula Nutrient Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) proposes to amend the regulations on nutrient specifications and labeling for infant formula as part of its phased, comprehensive review of infant formula nutrients. This action, if finalized, would amend the minimum and/or maximum levels of four required nutrients, change the unit of measure for certain nutrients, change the permitted source to meet one of the nutrient requirements, and amend the content of the required labeling. This action also includes a comprehensive assessment of four additional nutrients for which we conclude that the current required levels remain appropriate and reflect the best available scientific evidence on infant nutritional requirements and safe intake levels.

DATES: Either electronic or written comments on the proposed rule must be submitted by March 2, 2027.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 2, 2027. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–10832 for ''Infant Formula Nutrient Requirements.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

Docket: For access to the docket to read background documents, the plain language summary of the proposed rule of not more than 100 words as required by the ''Providing Accountability Through Transparency Act,'' or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: *With regard to the proposed rule:* Carrie Assar, Office of Critical Foods, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1453; or Barbara Little, Office of Regulation and International Programs, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378. *With regard to the information collection:* Christopher Colburn, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8758, *PRAStaff@fda.hhs.gov*.

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I. Executive Summary

A. Purpose and Coverage of the Proposed Rule

Under Operation Stork Speed, FDA is taking steps to enhance its efforts to ensure the ongoing quality, safety, nutritional adequacy, and resilience of the domestic infant formula supply (*https://www.fda.gov/food/infant-formula-homepage/operation-stork-speed*). As part of this effort, FDA conducted a scientific review of a subset of nutrient requirements for infant formula to ensure that infant formula provides adequate nutrition to support the growth and development of infants from birth through 12 months of age while avoiding excessive intakes that could pose health risks. This is the first comprehensive update and review of infant formula nutrients by the FDA since 1998 and part of FDA's strategic, phased approach to evaluating available scientific evidence for a comprehensive review of infant formula nutrients, as announced as part of Operation Stork Speed. This proposed rule assesses 8 of the 30 required nutrients in infant formula. The proposed rule, if finalized, would amend the minimum and/or maximum levels of four required nutrients—iodine, vitamin A, vitamin D, and manganese—and establish a maximum level for manganese. Additionally, the proposed rule, if finalized, would change the unit of measure for vitamin A and vitamin D, change the permitted source to meet the vitamin A requirement, and amend the content of the required labeling. This action also includes a comprehensive assessment of four additional nutrients—chloride, selenium, potassium, and sodium—for which we conclude that the current required levels remain appropriate. FDA intends to address the remaining infant formula nutrient specifications through subsequent proposed rules followed by one final rule covering all infant formula nutrient requirement changes. Lastly, the proposed rule, if finalized, would amend infant formula labeling requirements to change the unit of measure for vitamin A from International Units (IU) to microgram Retinol Activity Equivalents (µg RAE), and change the unit of measure for vitamin D from IU to micrograms (µg). The rule would also provide that vitamin A and vitamin D content may be voluntarily declared in IU in parentheses immediately following the declarations in µg RAE and µg, respectively.

Additionally, in accordance with the OMB ''Final Information Quality Bulletin for Peer Review'' (*https://www.federalregister.gov/documents/2005/01/14/05-769/final-information-quality-bulletin-for-peer-review*), FDA intends to conduct an external peer review on all influential scientific information used to inform development of any final rule.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule, if finalized, would:

- Increase the required minimum level of iodine in infant formula from 5 µg/100 kilocalories (kcal) to 15 µg/100 kcal and decrease the required maximum level of iodine from 75 µg/100 kcal to 50 µg/100 kcal;
- Change the unit of measure for vitamin A in infant formula from IU to µg RAE (1 IU retinol = 0.3 µg RAE);
- Decrease the required minimum level of vitamin A in infant formula from 250 IU/100 kcal (75 µg RAE/100 kcal) to 70 µg RAE/100 kcal (233 IU/100 kcal) and decrease the required maximum level from 750 IU/100 kcal (225 µg RAE/100 kcal) to 120 µg RAE/100 kcal (400 IU/100 kcal);
- Limit permitted forms of vitamin A that contribute to minimum and maximum vitamin A content from both preformed vitamin A and *beta*-carotene to preformed vitamin A only;
- Change the unit of measure for vitamin D in infant formula from IU to µg (1 IU = 0.025 µg);
- Increase the required minimum level of vitamin D in infant formula from 40 IU/100 kcal (1 µg/100 kcal) to 2 µg/100 kcal (80 IU/100 kcal) and increase the required maximum level from 100 IU/100 kcal (2.5 µg/100 kcal) to 3 µg/100 kcal (120 IU/100 kcal);
- Decrease the required minimum level for manganese in infant formula from 5 µg/100 kcal to 1 µg/100 kcal and establish a maximum level for manganese in infant formula of 50 µg/100 kcal.

C. Legal Authority

We are issuing this proposed rule consistent with our authority in sections 201(z), 403(j), 412(i), and 701(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(z), 343(j), 350a(i), and 371(e)).

D. Costs and Benefits

This proposed rule, if finalized, would update the nutrient specifications for infant formula to reflect the best available scientific evidence on infant nutritional requirements and safe intake levels. Vitamin D is a fat-soluble vitamin essential for calcium absorption, skeletal mineralization, and the prevention of rickets. Clinical symptoms of vitamin D deficiency include hypocalcemia (*i.e.,* low blood calcium levels), hypophosphatemia (*i.e.,* low blood phosphorus levels), tetany, and rickets. We quantify benefits to formula-fed infants from avoided healthcare costs associated with vitamin D deficiency-induced late-onset hypocalcemia. This approach captures the most severe and acute clinical manifestation of vitamin D deficiency and therefore represents a lower bound on the rule's total societal benefits. Additional benefits include reduced risk of inadequate iodine intake, excessive vitamin A exposure, and excessive manganese exposure in formula-fed infants; these benefits are described qualitatively. We quantify costs to infant formula manufacturers from relabeling, reformulation, and administrative costs associated with Before First Processing notification submissions. Additional costs would include FDA review costs associated with those submissions. We estimate that the annualized benefits over 10 years would range from $18.8 million to $171.7 million, with a primary estimate of $80.9 million, at a 7 percent discount rate and from $20.9 million to $191.0 million, with a primary estimate of $90.0 million, at a 3 percent discount rate. The annualized costs would range from $8.4 million to $31.7 million, with a primary estimate of $17.6 million, at a 7 percent discount rate and from $8.3 million to $31.6 million, with a primary estimate of $17.6 million, at a 3 percent discount rate.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
25(OH)D	25-hydroxy vitamin D.
AAP	American Academy of Pediatrics.
AI	Adequate Intake.
ALA	Alpha-linolenic acid.
AR	Average Requirement.
ARA	Arachidonic acid.
BMIC	Breast Milk Iodine Concentration.
BSSL	Bile-Salt-Stimulated Lipase.
CDRR	Chronic Disease Risk Reduction Intake.
CFR	Code of Federal Regulations.
CFSAN	Center for Food Safety and Applied Nutrition.
CI	Confidence Interval.
D–A–CH	German, Austrian, and Swiss Nutrition Societies.
DHA	Docosahexaenoic acid.
DRI	Dietary Reference Intake.
EAR	Estimated Average Requirement.
EFSA	European Food Safety Authority.
EFSA NDA Panel	EFSA Panel on Nutrition, Novel Foods and Food Allergens.
EPA	Eicosapentaenoic acid.
ESPGHAN	European Society for Paediatric Gastroenterology, Hepatology and Nutrition.
EU	European Union.
FAO	Food and Agricultural Organization.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FITS	Feeding Infants and Toddlers Study.
FR	**Federal Register**.
FSANZ	Food Standards Australia New Zealand.
GABA	Gamma-Aminobutyric Acid.
GUL	Guidance Upper Level.
HFP	Human Foods Program.
HHS	U.S. Department of Health and Human Services.
ICCIDD	International Council for Control of Iodine Deficiency Disorders.
iHMNutD	Interim Human Milk Nutrient Profile Data.
IOM	Institute of Medicine.
IQR	Interquartile range.
IU	International Unit.
Kcal	Kilocalorie.
Kg	Kilogram.
kJ	Kilojoule.
L	Liter.
LA	Linoleic acid.
LOAEL	Lowest Observed Adverse Effect Level.
LSRO	Life Sciences Research Office.
mEq	Milliequivalent.
mg	Milligram.
MILQ	Mothers, Infants, and Lactation Quality.
MIREC	Maternal-Infant Research on Environmental Chemicals.
mmol	Millimole.
MoH	Ministry of Health.
NASEM	National Academy of Sciences, Engineering, and Medicine.
ND	Not Determined.
NHANES	National Health and Nutrition Examination Survey.
NHMRC	National Health and Medical Research Council.
NOAEL	No Observed Adverse Effect Level.
Oz	Ounce.
PRA	Paperwork Reduction Act.
PRI	Population Reference Intake.
PRIA	Preliminary Regulatory Impact Analysis.
RAE	Retinol Activity Equivalents.
RDA	Recommended Dietary Allowance.
RE	Retinol Equivalents.
RfD	Reference Dose.
RFI	Request for Information.
RNI	Recommended Nutrient Intake.
Secretary	Secretary of HHS.
SE	Standard error.
TDS	Total Diet Study.
µg	Microgram.
UIC	Urinary Iodine Concentration.
UL	Tolerable Upper Intake Level.
UNICEF	United Nations Children's Fund.

Abbreviation/acronym	What it means
U.S.C.	United States Code.
USDA	U.S. Department of Agriculture.
VAD	Vitamin A Deficiency.
WHO	World Health Organization.
WIC	U.S. Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children.

III. Background

The Infant Formula Act of 1980 added section 412 of the FD&C Act, establishing requirements for infant formulas, including nutrient content requirements, and authorizing the Secretary of Health and Human Services (HHS) to revise these requirements. In the **Federal Register** of October 30, 1985 (50 FR 45106), FDA issued a final rule revising the infant formula nutrient requirements of the Infant Formula Act of 1980 (Pub. L. 96–359, 94 Stat. 1190), which was codified at § 107.100 (21 CFR 107.100). In 1995, FDA's Center for Food Safety and Applied Nutrition (CFSAN), now known as the Human Foods Program (HFP), contracted the Life Sciences Research Office (LSRO) of the American Society for Nutritional Sciences to provide evidence-based recommendations on compositional requirements for infant formula, with Health Canada serving as a cosponsor. The assessment was conducted in consultation with expert scientists and professional organizations. The 1998 LSRO Panel report represents our last comprehensive review of the required infant formula nutrients although comprehensive updates to the nutrient requirements were not proposed after the report (Ref. 1). In 2015, we updated the table in § 107.100 to add the mineral selenium to the list of required nutrients and to establish minimum and maximum levels of selenium in infant formula (80 FR 35834, June 23, 2015). The table in § 107.100 specifies that infant formulas must contain 30 nutrients; the table specifies minimum levels for each nutrient and maximum levels for 10 of the 30 nutrients.

On March 18, 2025, HHS and FDA announced ''Operation Stork Speed,'' a set of actions and initiatives to expand options for safe, reliable, and nutritious infant formula for American families, including a comprehensive infant formula nutrient review (*https://www.fda.gov/food/infant-formula-homepage/operation-stork-speed*).

On May 14, 2025, FDA issued a Request for Information (RFI) as a first step in the comprehensive nutrient review process (90 FR 20475, May 14, 2025). Specifically, the RFI sought information that would help us determine whether there is a need to revise the existing nutrient requirements in § 107.100, taking into consideration any new scientific data or information related to infant formula nutrients, including international infant formula standards. The comment period closed on September 11, 2025.

IV. Legal Authority

Section 412(i) of the FD&C Act establishes requirements for the nutrient content of infant formula. Section 412(i) of the FD&C Act contains a table listing the required infant formula nutrients with respective minimum and, as applicable, maximum required levels. Section 412(i)(2) of the FD&C Act authorizes the Secretary, and by delegation the Commissioner of Food and Drugs (Commissioner), to revise the list of required nutrients and to revise the level of any required nutrient. In addition, section 412(i)(1) of the FD&C Act, as amended by the Food and Drug Omnibus Reform Act of 2022 (commonly referred to as FDORA (Pub. L. 117–328)), requires the Secretary, and by delegation the Commissioner, to review the table of required nutrients ''every 4 years as appropriate,'' taking into consideration ''any new scientific data or information related to infant formula nutrients, including international infant formula standards.'' The table of required nutrients is codified at § 107.100.

The nutrition information labeling requirements for infant formula are codified at § 107.10 (21 CFR 107.10). If finalized, the proposed rule would amend the label required in § 107.10(a)(2) to change the unit of measure for vitamin A in infant formula from IU to µg RAE and to change the unit of measure for vitamin D in infant formula from IU to µg. The rule would also amend § 107.10(b)(1) to provide that vitamin A and vitamin D content may be voluntarily declared in IU in parentheses immediately following the declarations in µg RAE and µg, respectively. ''Infant formula'' is defined as a food for ''special dietary use'' under section 201(z) of the FD&C Act. Under sections 403(j) and 701(e) of the FD&C Act for foods for special dietary uses, the Secretary, and by delegation the Commissioner, may prescribe regulations requiring information concerning the vitamin and mineral content of the food to be provided on the label to fully inform purchasers as to the value of the food for such uses. Thus, FDA has the authority to revise the statement of the content of nutrients required for infant formula labeling in § 107.10 under sections 201(z), 403(j), 412(i), and 701(e) of the FD&C Act. If the proposed revisions to § 107.10 are finalized, FDA will provide an opportunity for filing objections and requests for a formal evidentiary public hearing under 21 CFR part 12.

V. Description of the Proposed Rule

A. Scope

The proposed rule, if finalized, would apply to products that meet the statutory definition of ''infant formula'' in section 201(z) of the FD&C Act. Section 201(z) of the FD&C Act defines infant formula as ''a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.'' FDA regulations define an ''infant'' as a person not more than 12 months of age (21 CFR 105.3(e) and 106.3).

B. Approach and Assumptions Used in Scientific Assessments

The proposed rule evaluates eight of the 30 required nutrients in infant formula. For each nutrient, FDA reviewed the physiological role and health consequences of deficiency or excess, relevant nutrient reference values from major expert bodies, human milk composition data, international regulatory standards, and recent scientific evidence. This nutrient-by-nutrient approach culminates in an evidence evaluation and rationale section that explains FDA's basis for either proposing changes to current minimum and/or maximum specifications or concluding that existing levels remain appropriate.

In sections V.C through V.J of this document, we present FDA's nutrient-specific evaluations, including the scientific basis for proposed changes to minimum and maximum specifications and the rationale for maintaining current specifications where appropriate. These nutrient-specific

evaluations are based on comprehensive nutrient-specific assessments, which we reference herein and have included in the docket. As required by section 412(i)(1) of the FD&C Act, FDA considered scientific information and data since the last comprehensive review of infant formula in 1998 as well as infant formula nutrient requirements in international standards. FDA also reviewed and considered comments submitted in response to the RFI.

FDA conducted a comprehensive evidence scan of peer-reviewed literature using the PubMed database to identify English-language publications regarding chloride, iodine, manganese, potassium, selenium, sodium, vitamin A, and vitamin D. Searches were individually constructed to account for the distinct characteristics of each nutrient. The queries utilized specific Medical Subject Headings (commonly referred to as MeSH) and keywords focused on general pharmacokinetics, nutritional requirements, deficiency, and toxicity for human infants 0 to 12 months of age. To capture updated evidence, search parameters targeted literature published from the end of the previous 1998 LSRO report review periods through May 2026. This corresponded to search start dates of 1989 for manganese; 1992 for vitamin D; 1995 for chloride, potassium, sodium, vitamin A, and iodine; and 2015 for selenium, which corresponds to FDA''s final rule, ''The Addition of Minimum and Maximum Levels of Selenium to Infant Formula and Related Labeling Requirements'' (80 FR 35834, June 23, 2015). FDA considered study design among other factors when prioritizing the literature reviewed, which included meta-analyses, randomized controlled trials, clinical trials, and observational studies. While, for example, traditional literature reviews and case reports were generally excluded from the primary evidence scan used to evaluate nutrient specifications, FDA notes that such literature was incorporated where necessary to provide clinical, historical, or toxicological context. The population of interest focused on healthy, full-term infants. This target population included infants with low birth weight or who were small for gestational age but excluded preterm infants and those with conditions requiring specialized formulas. Finally, the selected outcomes prioritized evidence regarding minimum dietary requirements, maximum safe levels, clinical signs of deficiency or toxicity, and adverse nutrient interactions.

To evaluate nutrient reference values, FDA considered recommendations from several expert bodies, including the National Academies of Science, Engineering, and Medicine (NASEM), the European Food Safety Authority (EFSA), the Australian National Health and Medical Research Council (NHMRC)/New Zealand Ministry of Health (MoH), and the German, Austrian, and Swiss nutrition societies (D–A–CH). These organizations, utilizing expert committees, develop nutrient reference values, including Dietary Reference Intakes (DRIs), which are science-based benchmarks used to assess and plan diets for healthy populations. Grounded in rigorous expert review across multiple countries and methodologies, these values serve as appropriate inputs for evaluating both the adequacy and safety of nutrient intakes in infant populations.

Nutrient reference values developed by these expert committees include several types of recommendations: Estimated Average Requirement (EAR), Recommended Dietary Allowance (RDA), Adequate Intake (AI), and Tolerable Upper Intake Level (UL). The EAR represents the average daily intake estimated to meet the needs of half of healthy individuals in each life stage. EFSA uses an equivalent term, Average Requirement (AR). The RDA is derived mathematically from the EAR (EAR plus two standard deviations) and is set to meet the needs of nearly all (97–98 percent) healthy individuals (Ref. 2); the Food and Agriculture Organization (FAO) of the United Nations/World Health Organization (WHO) and EFSA use equivalent terms: the Recommended Nutrient Intake (RNI) and Population Reference Intake (PRI), respectively (Refs. 3, 4). When insufficient scientific evidence exists to establish an EAR—and thus an RDA—an AI is established instead, based on experimentally derived intake levels or observed mean nutrient intakes in healthy populations (Ref. 2). The UL represents the highest average daily intake level likely to pose no risk of adverse health effects (Ref. 2). These reference values provide science-based benchmarks for assessing both the adequacy and safety of nutrient intakes in infant populations and are incorporated into each nutrient section if available.

FDA considered human milk composition data, where appropriate, as a primary source of evidence, recognizing that human milk serves as the gold standard for infant nutrition during, at minimum, the first 6 months of life, and that most nutrient AIs for infants are based on observed nutrient concentrations in human milk.[1] Mature human milk is the stage of lactation established approximately 2 weeks postpartum, following colostrum and transitional milk, and is characterized by a relatively stable nutrient composition compared with earlier phases (Ref. 5). For the purposes of FDA's review, human milk collected 21 days or more postpartum was considered mature. In addition, for the purposes of this review, FDA converted nutrient concentrations in human milk from per liter (L) to per 100 kcal using an assumed energy density of approximately 650 kcal/L for mature human milk. This value represents a well-supported midpoint estimate that is consistent with the range of values reported across multiple independent data sources and accounts for the natural variability in human milk energy content across lactation stages and populations (Refs. 6, 7, 8, 9, 10). FDA acknowledges that this value represents a midpoint within a range of plausible estimates and commits to updating this reference value as new, nationally representative data from North American populations become available. Therefore, FDA requests comment on the use of approximately 650 kcal/L in mature milk for calculations performed in this proposed rule including the references that were used to derive this value.

Two recent publications provide updated human milk nutrient composition data that were considered in this review, along with other relevant studies as discussed in the sections

[1] For the purposes of this notice of proposed rulemaking, FDA converted nutrient concentrations in human milk from per liter (per L) to per 100 kcal using an assumed energy density of approximately 650 kcal/L for mature human milk. This value represents a well-supported midpoint estimate that is consistent with the range of values reported across multiple independent data sources and accounts for the natural variability in human milk energy content across lactation stages and populations. The most directly applicable North American data are provided by the iHMNutD project, which reported a weighted mean energy density of 67.4 kcal per 100 grams (approximately 695 kcal/L) based on nine studies comprising 208 participants from the United States (Ref. 8). The MILQ study reported median energy density values that varied by lactation stage, with approximately 650 kcal/L at 18–31 days and stabilizing at approximately 597–602 kcal/L from 3–4 months onward, with a pooled median of approximately 607 kcal/L for 1–6 months (Ref. 10). A systematic review reported approximately 620 kcal/L for mature milk from exclusively breastfed infants aged 3–6 months (Ref. 9), and a probabilistic modeling study reported approximately 650 kcal/L for infants aged 1–3 months and approximately 617 kcal/L for infants aged 3–6 months (Ref. 6). The reference value of approximately 650 kcal/L is also consistent with the central reference value identified by EFSA, which served as the basis for EFSA's recommended permitted energy range for infant formula (Ref. 7). FDA acknowledges that this value represents a midpoint within a range of plausible estimates and commits to updating this reference value as new, nationally representative data from North American populations become available.

below. The Mothers, Infants and Lactation Quality (MILQ) study was designed to establish reference values for nutrient concentrations in human milk from well-nourished women with minimal nutrient supplementation and dietary fortification across geographically diverse populations. The study collected human milk samples from 1,242 women in Bangladesh, Brazil, Denmark, and The Gambia at multiple time points throughout the first 8.5 months of lactation (Ref. 11). Concentrations of macronutrients, water-soluble vitamins, fat-soluble vitamins, and minerals were quantified using validated analytical methods. Milk volume was measured simultaneously, enabling calculation of total nutrient transfer to the infant (Ref. 11). The other study developed interim human milk nutrient profile data (iHMNutD) for use in North American food composition databases through a literature synthesis of eligible North American data from three previously published systematic reviews covering the period 1980–2022 and one large Canadian biomonitoring study (Ref. 8). Data were restricted to mature milk from term-born infants collected within the first 6 months of lactation using nutrient-specific collection and analytical methods. Values were reviewed by subject matter experts and accompanied by data flags to communicate uncertainty where data were limited (Ref. 8).

FDA reviewed international infant formula standards and recommendations from Codex Alimentarius, the European Union (EU), Australia, New Zealand, Canada, and China, among others, to inform its assessment of appropriate nutrient specifications while also considering differences in methodology and regulatory philosophy. Codex Alimentarius and some non-U.S. countries use the term ''infant formula'' to refer to formula intended for infants 0–6 months of age and the term ''follow-on formula'' to refer to formula intended for infants 6–12 months of age. In the United States, there is not a regulatory distinction between formula intended for infants 0–6 months of age and formula intended for infants 6–12 months of age; both are considered ''infant formula,'' as defined in 21 CFR 106.3 and section 201(z) of the FD&C Act. We considered data on nutrient function and interactions, clinical outcomes associated with deficiency or excess intake, U.S. dietary intake data, and other evidence relevant to evaluating minimum and maximum nutrient levels in infant formula. Where relevant, FDA notes distinctions between maximums and guidance upper levels (GULs) established in some international standards. Unlike maximums, GULs apply to nutrients for which sufficient information for a science-based risk assessment is not available; rather, they are derived based on meeting nutritional requirements of infants and an established history of apparent safe use. In general, from a nutrition perspective, it is best that nutrient contents in infant formulas do not exceed GULs unless higher levels cannot be avoided (Ref. 12).

To estimate infant exposure to nutrients from infant formula, FDA assumed typical infant formula intakes of 0.78 L/day for infants 0–6 months of age and 0.6 L/day for infants 7–12 months of age, accounting for the introduction of complementary foods in the second half of infancy. These intake volumes are based on observed consumption patterns in breastfed infants and are consistent with the assumptions used by NASEM (Ref. 2) and similar to assumptions used by other expert bodies in establishing nutrient reference values. Assuming a standard infant formula energy density of 20 kcal/oz (676 kcal/L), these volumes correspond to approximately 527 kcal/day for infants 0–6 months of age and approximately 406 kcal/day for infants 7–12 months of age. FDA requests comment on all aspects of its assumptions to calculate the kcal consumed per day for infants 0–6 months of age and infants 7–12 months of age, including the assumption of the energy density of infant formula.

For certain nutrients, FDA also considered a high consumer scenario based on data from three cycles of the National Health and Nutrition Examination Survey (NHANES), using the 90th percentile of energy intake from infant formula among non-breastfed infants to evaluate potential nutrient exposures at the upper end of the consumption distribution (Refs. 13, 14, 15, 16, 17, 18). Evaluation of typical consumption scenarios (*i.e.,* mean, representing the average diet) informed the assessment of minimum specifications to ensure adequate nutrient intakes, while both typical and high-consumer scenarios informed the assessment of maximum specifications to ensure appropriate safety margins.

C. Chloride

The current requirements for chloride in infant formula are a minimum level of 55 milligrams (mg)/100 kcal and a maximum level of 150 mg/100 kcal (§ 107.100). Based on our analysis of scientific information and data since the 1998 comprehensive study of infant formula nutrients (LSRO Panel report), including infant formula chloride requirements in international standards, we conclude that the required chloride levels in § 107.100 remain appropriate.

1. Background

Chloride is an essential mineral that serves critical physiological functions in infants, including maintenance of acid-base balance, regulation of fluid and electrolyte homeostasis, and production of hydrochloric acid for digestion (Refs. 19, 20). Chloride works closely with sodium, potassium, and bicarbonate as electrically charged particles in body fluids to help regulate membrane electrical charge, facilitate nutrient absorption, and generate signals in muscles and nerves (Ref. 20). Chloride also helps keep mucus moist and fluid in the lungs and other organs through a process controlled by the Cystic Fibrosis Transmembrane Conductance Regulator channel; when this channel malfunctions, it causes cystic fibrosis (Ref. 20). Most dietary chloride intake comes from sodium chloride (*i.e.,* table salt) added to food during processing or at the table (Refs. 19, 20).

a. Health Consequences of Chloride Deficiency

A deficiency in chloride can result in metabolic alkalosis (*i.e.,* a condition in which blood becomes excessively alkaline) (Ref. 21). The most well-documented cases of chloride deficiency in the United States occurred during 1978–1979, when approximately 150 infants in the United States developed hypochloremic metabolic alkalosis after consuming improperly formulated soy protein-based infant formulas (Ref. 22). These formulas contained chloride levels as low as 1–2 milliequivalents (mEq)/L (approximately 5–11 mg/100 kcal) (Refs. 22, 23, 24), and symptoms were observed in some infants consuming formula with 5.1 mEq/L (approximately 27 mg/100 kcal) (Ref. 1). Infants with acute chloride deficiency exhibited a failure to thrive, lethargy, loss of appetite, and weakness. Other laboratory abnormalities included low blood and urine chloride levels with metabolic alkalosis, low blood potassium levels, and red blood cells in the urine (Refs. 24, 25). This public health incident helped lead to the enactment of the Infant Formula Act of 1980 (Pub. L. 96–359).

Long-term followup studies of the infants in the United States affected by the chloride deficiency crisis identified subtle neurodevelopmental effects in children who experienced severe

chloride deficiency during infancy, particularly affecting language skills (Refs. 22, 26).

b. Health Consequences of Excess Chloride Intake

Hyperchloremia is a condition in which blood chloride levels exceed the normal range. Hyperchloremia typically results from medical disorders or clinical treatments rather than dietary chloride intake, and excessive chloride consumption through infant formula or other food is unlikely to be a cause of hyperchloremia (Ref. 20).

In its 2005 assessment, NASEM found no research examining the consequences of chronic overconsumption of chloride in infants (Ref. 19). Available evidence regarding harmful effects of excess chloride consumption in infants remains sparse. FDA's review identified no significant new scientific evidence concerning adverse outcomes from excessive dietary chloride consumption during infancy since NASEM's 2005 report (Ref. 27).

2. Nutrient Reference Values

a. NASEM (United States)

NASEM established AIs for chloride for infants in 2005 as part of its comprehensive report, *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate* (Ref. 19). NASEM established an AI of 180 mg/day for infants 0–6 months of age and an AI of 570 mg/day for infants 7–12 months of age. NASEM established these AIs based on the sodium content of human milk, assuming chloride adequacy in equimolar amounts to sodium, because most dietary chloride is consumed as sodium chloride. The calculation for infants 7–12 months of age accounted for the introduction of complementary foods at this age.

b. European Food Safety Authority (EFSA)

The EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) published a comprehensive Scientific Opinion on dietary reference values for chloride in 2019 (Ref. 20), in which it established an AI of 300 mg/day for infants 7–11 months of age. EFSA did not establish an AI for chloride in infants 0–6 months of age, but, through a comprehensive review of human milk studies from others of term infants in Western populations, the EFSA Panel determined an approximate midpoint of chloride concentration in mature human milk to be 400 mg (11.3 millimole (mmol))/L and estimated infant intake of 320 mg/day from exclusive breastfeeding.

The EFSA Panel also reviewed a study that calculated physiological requirements of chloride in infants and that recommended an intake of 120 mg/day throughout the first year of life. EFSA noted that the amount of chloride provided by human milk during the first 6 months of life (approximately 320 mg/day) is substantially higher than this calculated physiological requirement, suggesting either that the approach underestimates actual needs or that human milk provides chloride beyond minimal physiological requirements (Ref. 20).

c. D–A–CH (Germany, Austria, Switzerland)

In 2017, D–A–CH established an AI for chloride of 300 mg/day for infants 0–4 months of age, and 450 mg/day for infants 4–12 months of age (Ref. 28). Because intake data from complementary foods were unavailable, the 4–12 months value was extrapolated from the 0–4-month group's values, adjusting for differences in average body weight.

d. UL

Establishing a UL requires evidence from studies that test multiple levels of intake and identify the point at which adverse effects begin to occur; however, available data were insufficient to support such a determination for chloride in infants (Ref. 19). Consequently, neither NASEM (Ref. 19) nor EFSA (Ref. 20) established a UL for chloride in infants. In its 2005 assessment, EFSA observed that chloride consumption levels in European populations surpassed the amounts needed for normal physiological function (Ref. 29). EFSA also recognized that higher consumption of chloride in the form of sodium chloride correlated with increased risk of high blood pressure (Refs. 20, 29). Nevertheless, EFSA determined that the available scientific evidence was inadequate to establish a specific numerical value for an upper limit (Ref. 20). Similarly, NASEM noted that ''as with other nutrients, an intake of sodium or chloride markedly above the AI is not warranted'' (Ref. 19).

e. Comparison of International Recommendations

Table 1 shows the chloride AIs established by NASEM, EFSA, and D–A–CH.

TABLE 1—ADEQUATE INTAKES AND TOLERABLE UPPER INTAKE LEVELS OF CHLORIDE

Organization	Year	Age range (months)	Adequate intake (mg/day)	Tolerable upper intake level
NASEM	2005	0–6	180	ND
		7–12	570	ND
EFSA	2019	7–11	300	ND
D–A–CH	2017	0–4	300	ND
		4–12	450	ND

ND: not determined.

The considerable variation in chloride recommendations across international expert bodies reflects fundamental differences in methodology and data sources (Ref. 27). Despite these methodological differences, all expert bodies used human milk composition as the primary basis for chloride AIs and assessed that there is insufficient evidence to establish a UL.

3. Human Milk Composition

Maternal diet and nutritional status do not affect how much chloride is present in human milk (Refs. 20, 30). Multiple studies have characterized chloride concentrations in mature human milk from mothers with term pregnancies. The direct measurements of chloride concentrations in mature human milk resulted in values ranging from 339 to 547 mg/L across individual study timepoints (Refs. 31, 32, 33, 34, 35) and a pooled weighted mean of 416 mg/L (n=5 studies and 139 participants) (Ref. 8) and reflect the natural variability observed in human milk.

The MILQ study (Ref. 36) provides comprehensive recent data on human milk mineral composition, from 1,242 women in Bangladesh, Brazil, Denmark, and The Gambia. The MILQ study

reported sodium concentrations, not chloride. In converting sodium to chloride on an equimolar basis, substantially lower values are obtained than with direct measurements of chloride in milk (Ref. 27).

The discrepancy suggests either that chloride and sodium may not be present in exactly equimolar amounts in human milk or that different analytical methods, study populations, or periods yield systematically different results. NASEM's approach of establishing chloride AIs based on equimolar conversion from sodium may underestimate actual chloride concentrations when based on sodium measurements alone (Ref. 27).

4. International Regulatory Standards for Infant Formula

Chloride specifications for infant formula vary among international regulatory bodies and expert organizations, though most align closely with Codex Alimentarius standards. The Codex Alimentarius Commission, a program that establishes internationally recognized standards, specifies a minimum of 50 mg/100 kcal and a maximum of 160 mg/100 kcal. These specifications apply to both infant formula (for 0–6 months of age) (Ref. 12) and follow-on formula (for 6–12 months of age) (Ref. 37). The EU, based on recommendations from EFSA (Ref. 7), specifies a minimum of 60 mg/100 kcal and a maximum of 160 mg/100 kcal (Ref. 38). The EU minimum assumes that infants 0–6 months of age consume 500 kcal/day and require 300 mg/day of chloride. Other countries have adopted or proposed to adopt specifications aligned with Codex Alimentarius, including Food Standards Australia New Zealand (Ref. 39), Health Canada (Ref. 40), and China (Ref. 41); however, China has different standards for follow-on formulas for infants 6–12 months of age (approximately 220 mg/100 kcal maximum for 6–12 months) (Ref. 42).

In its 1998 comprehensive review of infant formula nutrients, LSRO recommended a minimum of 50 mg/100 kcal and a maximum of 160 mg/100 kcal. The LSRO Panel based the minimum recommendation on the mean minus one standard deviation value for the chloride concentration of human milk, which was approximately 320 mg/L (48 mg/100 kcal) (Ref. 30), rounded up to 50 mg/100 kcal for the minimum specification. The LSRO Panel found no evidence to suggest that chloride is absorbed differently from infant formula compared to human milk, supporting the use of human milk composition data as the basis for the specification. For the maximum chloride content of 160 mg/100 kcal, the LSRO Panel based this on the 90th percentile of FDA analyses of infant formulas available at that time, rather than on safety concerns, as no evidence supported that excessive chloride intake caused adverse effects in children.

Table 2 shows the requirements and recommendations of these international regulatory bodies and organizations.

TABLE 2—INTERNATIONAL STANDARDS AND/OR RECOMMENDATIONS FOR CHLORIDE IN INFANT FORMULA

Organization	Age range (months)	Minimum (mg/100 kcal)	Maximum (mg/100 kcal)	Reference
U.S. Current Standards	0–12	55	150	21 CFR 107.100.
LSRO [1]	0–12	50	160	LSRO, 1998.
Codex Alimentarius	0–12	50	160	CXS 72–1981, CXS 156–1987.
EU	0–12	60	160	Commission Delegated Regulation (EU) 2016/127.
Australia [2]	0–12	50	159	FSANZ P1028.
Canada [3]	0–12	50	160	Health Canada, 2025.
China	0–6	50	159	GB 10765–2021.
	6–12	ND	218	GB 10766–2021.

[1] Recommended ranges.
[2] Values converted from per 100 kJ to per 100 kcal (1 kcal = 4.184 kJ).
[3] Reflects proposed compositional requirements for infant formula.

5. Recent Scientific Evidence on Chloride Intake

A 2006 analysis of electrolyte intake in infants from the 2002 Feeding Infants and Toddlers Study (FITS) reported mean chloride intakes of 290 mg/day for infants 4–5 months of age and 761 mg/day for infants 6–11 months of age based on equimolar conversion of sodium to chloride (Ref. 43). Mean intakes exceeded NASEM's AI for both age groups. For infants 6–11 months of age, chloride intakes ranged from approximately 50 percent of the AI at the 10th percentile (276 mg/day) to approximately 260 percent at the 90th percentile (1,493 mg/day). Although there are several limitations of the FITS study (Ref. 27), the FITS data nonetheless provide useful information demonstrating that most infants—whether breastfed or consuming infant formulas meeting current specifications—along with age-appropriate complementary foods, achieve chloride intakes that meet or exceed established AIs.

6. Evidence Evaluation and Rationale

Based on the review of available literature, NRVs, and international standards, we conclude that the current minimum level of 55 mg/100 kcal and maximum level of 150 mg/100 kcal for chloride in § 107.100 remain appropriate.

a. Maintaining the Minimum Specification of 55 mg/100 kcal

The current minimum required level of 55 mg/100 kcal of chloride provides a 2- to 11-fold margin above the deficiency-causing levels of 5–27 mg/100 kcal associated with the 1978–1979 chloride-deficiency crisis. Given the severity of the consequences of the chloride-deficiency crisis in 1978–1979 and the lack of functional biomarkers for chloride status (*i.e.,* early indicators of chloride inadequacy), we determine that the substantial margin is appropriate.

Although methodological variability exists in measuring chloride levels in human milk, human milk composition data support the current required minimum. The current minimum of 55 mg/100 kcal falls between and aligns well with direct chloride measurements in human milk (approximately 52 to 84 mg/100 kcal, with a pooled weighted mean of 64 mg/100 kcal) (Refs. 1, 8, 20, 28, 31 through 35). When chloride measurements are derived from converting sodium concentrations to chloride, the chloride measurements are far lower than direct chloride measurements, suggesting that chloride and sodium are not present in exactly equimolar amounts in human milk (Refs. 8, 27, 36). Given the uncertainty associated with chloride measurements

derived from converting sodium concentrations to chloride, the current minimum appropriately reflects direct chloride measurement data while providing a conservative safety margin.

The current minimum ensures that infant formula provides chloride intakes that pose low risk of deficiency relative to established AIs (Ref. 27). Our current specification of 55 mg/100 kcal falls within the international consensus range, and no compelling evidence from other jurisdictions suggests that lowering the minimum would provide any benefit. Doing so would reduce the safety margin above the established deficiency threshold without corresponding nutritional justification (Ref. 27).

b. Maintaining the Maximum Specification of 150 mg/100 kcal

The current maximum of 150 mg/100 kcal substantially exceeds the median human milk chloride content while maintaining a prudent upper limit for sole-source infant nutrition. No compelling evidence supports either raising or lowering this specification (Ref. 27).

Although expert bodies have not established a UL for chloride in infants due to limited data (Refs. 19, 20, 29), the absence of an established UL reflects insufficient dose-response data regarding adverse effects rather than confirmation that all intake levels are safe (Ref. 27).

The current maximum provides a substantial margin above the chloride content of human milk (Ref. 27). FDA's current maximum of 150 mg/100 kcal provides an additional conservative margin below both LSRO's recommendation and the international standard of approximately 160 mg/100 kcal.

History of use and available intake data support safety at the current maximum. The current maximum would provide 791 mg/day for a 0–6-month-old infant and 609 mg/day for a 6–12-month-old infant consuming typical daily infant formula intakes. These chloride amounts have not been associated with adverse effects in clinical use since the chloride requirements were established in the Infant Formula Act of 1980. An analysis of 2002 FITS data (Ref. 43) reported mean sodium intakes corresponding to estimated chloride intakes of 290 mg/day (4–5 months of age) and 761 mg/day (6–11 months of age), although these estimates included intake from all dietary sources, not solely infant formula.

We have considered whether raising the maximum to align with the international consensus of approximately 160 mg/100 kcal would be warranted and conclude that it is not necessary to ensure adequate infant nutrition. While such harmonization could provide modest additional manufacturing flexibility and align U.S. standards with international regulatory agencies, the difference between the current U.S. maximum and the international standard is relatively small (6.7% or 10 mg/100 kcal). No evidence suggests that the current maximum is inadequate, constrains appropriate formulation, or that chloride intakes between 150 and 160 mg/100 kcal provide nutritional advantages to infants beyond those achieved at the present maximum of 150 mg/100 kcal. Manufacturers have successfully met the current specification since the 1980s without reported difficulties. Therefore, we conclude that the slightly lower maximum provides an additional conservative margin without imposing undue manufacturing constraints (Ref. 27).

c. Consideration of the Evidence Base

We acknowledge several uncertainties in the evidence base that support maintaining the current specifications. There is wide variability in reported human milk chloride concentrations across studies (171–547 mg/L or approximately 26–84 mg/100 kcal for mature milk) primarily from discrepancies between direct chloride measurements and sodium-based estimates, lack of functional biomarkers for chloride status, and individual variability in infant requirements. Given these uncertainties, the serious consequences of dietary chloride deficiency, and the lack of evidence of adverse effects from current specifications, we believe a conservative approach is warranted and that the current required minimum level of 55 mg/100 kcal and maximum level of 150 mg/100 kcal should be retained (Ref. 27).

D. Selenium

At the time FDA initially established nutrient specifications for infant formula, selenium was not recognized as an essential nutrient and was not one of the nutrients required by statute in infant formula. However, in 1989, an RDA for selenium for infants 0–6 months of age was established (Ref. 44), and in 2000, AI levels and ULs were established for infants 0–6 and 7–12 months of age (Ref. 45). In 2015, FDA added selenium as a required nutrient in infant formula with a minimum of 2 µg/100 kcal and a maximum of 7 µg/100 kcal (see 80 FR 35834, June 23, 2015). Based on our analysis of the scientific information and data since the addition of minimum and maximum levels of selenium to the infant formula requirements in 2015, including infant formula selenium requirements in international standards, we conclude that the required selenium levels in § 107.100 remain appropriate.

1. Background

Selenium is an essential trace element for humans that functions largely through its incorporation into proteins known as selenoproteins. The known biological functions of selenium include defense against oxidative stress, regulation of thyroid hormone action, and regulation of the oxidation/reduction status of vitamin C and other molecules (Ref. 46). Selenium also provides protective effects against toxicity of certain elements—including arsenic, lead, cadmium, and mercury—by facilitating urinary excretion, reducing oxidative damage, and forming biologically inactive complexes with these elements (Refs. 45, 47, 48). Infant selenium status is influenced by geographic variation in the selenium content of soil and water, which shapes maternal selenium intake and, in turn, the selenium content of human milk. As a result, the selenium intake of breastfed infants varies by geographic location (Ref. 46).

a. Health Consequences of Selenium Deficiency

Keshan disease, a cardiomyopathy that occurs almost exclusively in children, has been associated with selenium deficiency. Keshan disease has been reported in areas of China where the population has severe selenium deficiency (Refs. 46, 49; 78 FR 22442 at 22443, April 16, 2013). Selenium deficiency has also been identified throughout the lifespan in those who receive long-term parenteral nutrition (*i.e.,* intravenous nutrition) not adequately supplemented with selenium. Deficiency signs and symptoms include macrocytosis, loss of skin and hair pigmentation, and, in severe cases, cardiomyopathy (Ref. 46).

b. Health Consequences of Excess Selenium Intake

Chronic selenium toxicity (selenosis) is rare but has been observed in adults consuming diets containing excess levels of selenium due to selenium supplementation (Ref. 46). Reported characteristics include hair and nail brittleness and loss, gastrointestinal upsets, skin rash, garlic breath odor, fatigue, irritability, and nervous system abnormalities. Acute selenium toxicity

is rare, and the few reports in the literature of acute fatal or near fatal selenium poisoning in adults occurred secondary to accidental ingestion of selenium (Ref. 45).

2. Dietary Reference Intakes

a. NASEM

In 2000, NASEM established AI and UL values for selenium for infants as part of its comprehensive report, *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids* (Ref. 45). NASEM did not find sufficient evidence to calculate an EAR for selenium for infants during the first year of life and, therefore, did not have a basis to set an RDA for selenium for infants. This contrasts with the 1989 Food and Nutrition board recommendation, which had established an RDA for infants extrapolated from adult values (Ref. 44). NASEM's 2000 report instead determined that, due to the lack of functional criteria of selenium status in infants to accurately reflect dietary intake, recommended intakes should be based on an AI reflecting observed mean intakes of infants fed principally with human milk.

NASEM established an AI of 15 µg/day for infants 0–6 months of age and an AI of 20 µg/day for infants 7–12 months of age. NASEM's basis for deriving an AI for the first 6 months of life was the average intake by full-term infants born to healthy, well-nourished mothers and exclusively fed human milk (Ref. 45). The AI for infants 7–12 months of age was derived from using the data of infants 0–6 months of age, extrapolated upward to account for increased body size and the introduction of complementary foods.

NASEM established a UL of 45 µg/day for selenium for infants 0–6 months of age by relying on the concentration of selenium in human milk, which is not associated with known adverse effects. The UL of 60 µg/day for infants 7–12 months of age was extrapolated to account for increased body size (Ref. 45).

b. EFSA

EFSA published dietary reference values for selenium in 2014 (AI) and 2023 (UL) (Refs. 50, 51). EFSA did not establish an AI for selenium in infants 0–6 months of age. For infants 7–11 months of age, EFSA established an AI of 15 µg/day (Ref. 49).

EFSA established ULs of 45 µg/day for infants 4–6 months of age and 55 µg/day for infants 7–11 months of age. EFSA acknowledged that there are no direct data to support derivation of a UL for infants; however, given that there is no evidence that infants are more susceptible to selenium toxicity than adults, the EFSA Panel considered it appropriate to extrapolate ULs from adults to infants (Ref. 51). The EFSA Panel noted that these ULs are consistent with human milk concentrations.

c. FAO/WHO

The joint FAO/WHO Consultation established RNI levels of 6 µg/day for infants 0–6 months of age and 10 µg/day for infants 7–12 months of age based on the selenium content of human milk from international surveys, which averaged 18.5 µg/L, combined with data on milk consumption by exclusively breastfed infants (Ref. 3).

d. D–A–CH (Germany, Austria, Switzerland)

In 2015, D–A–CH established an AI for selenium of 10 µg/day for infants 0–4 months of age, based on the selenium content of human milk. Values were adjusted for body weight to establish an AI of 15 µg/day for infants 4–12 months of age. No UL was determined (Ref. 52).

e. Australian NHMRC/New Zealand MoH

Australia and New Zealand established AIs and ULs in 2005 (Ref. 53). The AI of 12 µg/day for infants 0–6 months of age was calculated by multiplying the average intake of human milk (0.78 L/day) and the average selenium content in human milk of 15 µg/L based on several key studies (Refs. 54, 55, 56). The AI of 60 µg/day for infants 7–12 months of age was extrapolated from that of the younger infants on a metabolic weight basis, with considerations for the introduction of complementary foods.

The UL for young infants was based on the studies showing that a human milk concentration of 60 µg/L was not associated with adverse effects (Ref. 57). This gives a no observed adverse effect level (NOAEL) of 47 µg/day (7 µg/kg body weight).

f. Comparison of international recommendations

Table 3 shows the selenium AIs established by NASEM, EFSA, FAO/WHO, D–A–CH, and Australian NHMRC/New Zealand MoH.

TABLE 3—ADEQUATE INTAKES AND TOLERABLE UPPER INTAKE LEVELS OF SELENIUM

Organization	Year	Age range (months)	Adequate intake	Tolerable upper intake level
NASEM	2000	0–6	15 µg/day	45 µg/day.
		7–12	20 µg/day	60 µg/day.
EFSA	2014 (AI)	4–6	ND	45 µg/day.
	2023 (UL)	7–11	15 µg/day	55 µg/day.
FAO/WHO	2004	0–6	6 µg/day *	ND.
		7–12	10 µg/day *	ND.
D–A–CH	2015	0–4	10 µg/day	ND.
		4–12	15 µg/day	ND.
Australian NHMRC/New Zealand MoH	2005	0–6	12 µg/day	45 µg/day.
		7–12	15 µg/day	60 µg/day.

Values established are RNI levels.

The substantial variation in selenium recommendations across international expert bodies reflects fundamental differences in methodology and data sources (Ref. 49).

3. Human Milk Composition

a. Selenium Concentration in Human Milk

Maternal diet and nutritional status affect the amount of selenium present in human milk. The average selenium content of mature human milk sampled between 2- and 6-months lactation appears to be relatively constant within a population group. However, selenium content in human milk varies greatly based on maternal selenium intakes, including variability in selenium soil content (Ref. 45).

There is wide interindividual variation in the selenium content of human milk, and the selenium content of hind milk (*i.e.,* milk at the end of an infant feeding) is greater than that of the fore milk (*i.e.,* milk at the beginning of the feeding). Studies report average selenium concentrations of mature human milk of 10 to 23 µg/L (with a range of 6 to 39 µg/L) (Refs. 45, 49).

b. Recent Data

The MILQ study (Ref. 36) reported a pooled median selenium concentration of 9 µg/L in human milk collected from mothers of infants 1–6 months of age, representing only 50 percent of the NASEM reference concentration of 18 µg/L used to establish the current AI. The study suggested that the current NASEM AI may overestimate selenium concentrations in human milk from well-nourished populations and called for updated recommendations informed by these study data (Ref. 36). The iHMNutD study reported a pooled weighted mean selenium concentration which converted to approximately 20.4 µg/L (Ref. 8). A 2019 study (Ref. 58) measured milk selenium concentrations in lactating Chinese women across three regions with varying selenium status. Among mothers with optimal selenium intake, the Beijing milk concentration was 27.8 µg/L; combined with an average milk volume of 0.55 L/day, this yielded a calculated AI of 15.29 µg/day for Chinese infants 0–3 months of age, consistent with the current Chinese AI of 15 µg/day for infants 0–6 months of age.

4. International Regulatory Standards for Infant Formula

Selenium specifications for infant formula vary among international regulatory bodies and expert organizations (table 4). The Codex Alimentarius Commission specifies a minimum of 1 µg/100 kcal and a GUL of 9 µg/100 kcal for infant formula (0–6 months of age) (Ref. 12), and a minimum of 2 µg/100 kcal and GUL of 9 µg/100 kcal for follow-on formula (6–12 months of age) (Ref. 37). The EU specifies a minimum of 3 µg/100 kcal and a maximum of 8.6 µg/100 kcal (Ref. 38). Other countries have adopted or proposed to adopt specifications aligned with Codex Alimentarius, including Food Standards Australia New Zealand (FSANZ) (Ref. 39), Health Canada (Ref. 40), and China (Refs. 41, 42).

The 1998 LSRO Panel report recommended a minimum selenium requirement of 1.5 µg/100 kcal and a maximum of 5 µg/100 kcal. The minimum value approximated the estimated value for the mean minus one standard deviation for the selenium concentration in human milk in countries in which selenium deficiency has not been recognized in breastfed infants. This recommended minimum level would provide an estimated 7.5 µg/day of selenium for young infants exclusively fed infant formula, an amount below the 1989 RDA (10 µg/day). The LSRO Panel was aware that there were disparities between some of its recommendations for nutrient levels in infant formulas and the 1989 RDAs; however, the history of use for a large population in which selenium deficiency had not been reported was regarded as a reasonable basis for recommending a minimum value for selenium in infant formula (Ref. 1; 78 FR 22442 at 22443, April 16, 2013).

The 1998 LSRO Panel report recommended a maximum selenium level for infant formula of 5 µg/100 kcal (33.5 µg/L). This recommendation was based on the upper limit of the range of selenium in human milk, which was considered to represent a history of use for a large population in which selenium toxicity had not been reported. The LSRO Panel report also indicated that, on a body weight basis, this level is far below the intake associated with the development of selenosis in adults (Ref. 1; 78 FR 22442 at 22444–22445).

Table 4 shows the requirements and recommendations of these international regulatory bodies and organizations.

TABLE 4—INTERNATIONAL STANDARDS AND/OR RECOMMENDATIONS FOR SELENIUM IN INFANT FORMULA

Organization	Age range	Minimum (µg/100 kcal)	Maximum (µg/100 kcal)	References
U.S. Current Standards	0–12 (months)	2	7	21 CFR 107.100.
LSRO [1]	0–12 (months)	1.5	5	LSRO, 1998.
Codex Alimentarius	0–6 (months)	1	9 (GUL)	CXS 72–1981.
	6–12 (months)	2	9 (GUL)	CXS 156–1987.
EU	0–12 (months)	3	8.6	Commission Delegated Regulation (EU) 2016/127.
Australia [2]	0–12 (months)	2	9 (GUL)	FSANZ P1028.
Canada [3]	0–12 (months)	1	9	Health Canada, 2025.
China	0–6 (months)	3	8.6	GB 10765–2021.
	6–12 (months)	2	8.6	GB 10766–2021.

[1] Recommended ranges.
[2] Values converted from per 100 kJ to per 100 kcal (1 kcal = 4.184 kJ).
[3] Reflects proposed compositional requirements for infant formula.

5. Recent Scientific Evidence on Selenium Intake

A randomized dose-response trial of healthy term infants from birth to 16 weeks of age fed infant formula containing selenium at three different concentrations and a breastfed reference group found that infants fed the formula containing a selenium level of 1.9 µg/100 kcal received sufficient selenium to meet their nutritional needs and that much of the selenium above the level of 1.9 µg/100 kcal was eliminated from the body (Ref. 59). An analysis of a randomized controlled trial investigating maternal selenium status during pregnancy and lactation in relation to infant birth outcomes across

898 mother-infant dyads in Guatemala, India, and Pakistan concluded that maternal selenium supplementation did not impact serum selenium concentrations in populations at high risk for deficiency, suggesting that supplementation may not overcome the impact of low dietary intake and the high demands of pregnancy and early lactation (Ref. 60). However, the authors noted that larger studies in high-risk regions are needed to further clarify the relationship between maternal selenium deficiency and infant outcomes (Ref. 60).

6. Evidence Evaluation and Rationale

Based on our review of available scientific data, information, and international standards, we conclude that the current minimum of 2 µg/100 kcal and maximum level of 7 µg/100 kcal for selenium in § 107.100 remain appropriate.

a. Maintaining the Minimum Specification of 2 µg/100 kcal

The current minimum of 2 µg/100 kcal is based primarily on two sources of evidence. First, NASEM's AI of 15 µg/day for infants 0–6 months of age, converted to an energy basis assuming 100 kcal/kg body weight/day intake, yields approximately 2.1 µg/100 kcal. FDA rounded this to 2 µg/100 kcal for the minimum specification (Refs. 45, 49). The current minimum provides adequate selenium to meet established AIs. For a 0–6-month-old infant consuming a typical daily infant formula intake, infant formula at the minimum specification provides 10.5 µg/day, which represents 70 percent of the NASEM AI of 15 µg/day (Refs. 45, 49). While this percentage may appear modest, it is important to note that the AI is based on the mean intake from human milk and is intended to meet or exceed the needs of nearly all individuals in the population (Refs. 45, 49). Second, the randomized dose-response trial described in section V.D.5 of this document provides direct clinical evidence supporting this minimum level, demonstrating that 1.9 µg/100 kcal was sufficient to achieve selenium status indicators comparable to breastfed infants (Ref. 59). Additionally, the current minimum also aligns well with international standards (Ref. 49).

Moreover, recent evidence from the MILQ study suggests that the pooled median total selenium intake from human milk is 7.3 µg/day from 1 to 6 months postpartum, representing only 49 percent of the NASEM AI (Ref. 36). This finding raises questions about whether the NASEM AI may overestimate infant selenium requirements, as the MILQ study population of well-nourished mothers and healthy, normally developing infants showed no evidence of selenium deficiency despite intakes well below the established AI. However, the current minimum specification of 2 µg/100 kcal, providing 10.4 µg/day, exceeds the MILQ median intake by 42 percent, offering a conservative margin of safety.

The minimum specification also accounts for potential differences in bioavailability. The U.S. minimum was established as a level providing sufficient amounts to account for potential differences in bioavailability among various infant formula types, including a conservative estimate of 50 percent relative bioavailability of selenium from soy protein-based formulas compared to human milk (Ref. 1). This conservative approach ensures that all formula types, regardless of protein source, provide adequate selenium.

Human milk composition data support the current minimum. The current minimum of 2 µg/100 kcal exceeds the estimated median value of 1.3 µg/100 kcal from the MILQ study by approximately 54 percent, providing a safety margin to account for population variability and potential differences in bioavailability (Refs. 36, 49). The MILQ study authors noted that the substantially lower concentrations as compared with NASEM estimates suggested that the differences may be due to maternal dietary selenium intake, which varies with regional soil selenium content (Ref. 36). The lower MILQ study values as compared with other studies may reflect populations with lower selenium intake rather than indicating that lower concentrations are adequate (Refs. 8, 36, 49, 58). Data from other well-nourished populations (Refs. 8, 58) support selenium concentrations closer to the NASEM reference value. The wide geographic variability in human milk selenium concentrations underscores the importance of maintaining a minimum specification that ensures adequacy across diverse populations and accounts for the serious health consequences of selenium deficiency, including Keshan disease (Ref. 49).

b. Maintaining the Maximum Specification of 7 µg/100 kcal

The current maximum is based on safety considerations. NASEM established a UL of approximately 7 µg/kg/day for infants 0–6 months of age, which approximates 7 µg/100 kcal (Ref. 45). The UL is defined as ''the highest daily intake level that is likely to pose no risk of adverse health effects in almost all individuals in a life stage group'' (Ref. 45). NASEM established this UL by relying on data on the concentration of selenium in human milk, which is not associated with known adverse effects.

The current maximum substantially exceeds median human milk content while maintaining a prudent limit (Ref. 49). Although the current maximum is approximately 5.4 times the median human milk concentration from the MILQ study population, the studies conducted in mothers with optimal selenium intake (North American data) and from well-nourished populations (in China) reported reference values of approximately 3.1 µg/100 kcal and 4.2 µg/100 kcal, respectively (Refs. 8, 49, 58). Relative to these higher reference values from populations with optimal selenium intake, the current maximum of 7 µg/100 kcal represents approximately 2.3 times the North American median and 1.7 times the concentration in milk from optimally nourished Chinese mothers.

The current maximum is conservative compared to most international standards. The current maximum is lower than the Codex Alimentarius GUL, the FSANZ GUL, and the Health Canada, EU, and China maximums (Ref. 49). The LSRO recommendation of a maximum selenium level for infant formula of 5 µg/100 kcal was based on the upper limit of the range of selenium in human milk and represented a history of use for a large population in which selenium toxicity had not been reported. The current maximum is higher than the LSRO recommendation but aligns with the NASEM UL, reflecting a conservative approach based on safety considerations while providing additional manufacturing flexibility (Ref. 49).

History of use also supports safety at the current maximum. The current maximum has demonstrated safety in practice since the level went into effect in 2016. Manufacturers have successfully met the current specification since 2016 without reported difficulties, suggesting that the current maximum does not impose undue constraints.

c. Consideration of the Evidence Base

There is wide variability in reported human milk selenium concentrations across studies and geographic regions, reflecting differences in maternal selenium intake, which is highly dependent on regional soil selenium

content. There are limited recent data from U.S. populations specifically, methodological variability across studies, and uncertainty about bioavailability differences between infant formula types and human milk. Recent evidence suggests that populations at high risk of selenium deficiency may have higher needs during pregnancy and lactation that cannot be easily met through supplementation alone and that selenium status can decline substantially during lactation even with supplementation (Ref. 60). Given these uncertainties, the associated consequences of dietary selenium deficiency (*i.e.,* Keshan disease), the potential for selenium status to decline during lactation, and the lack of evidence of adverse effects from current specifications, we believe a conservative approach in maintaining the required minimum level of 2 µg/100 kcal and maximum level of 7 µg/100 kcal is warranted.

E. Iodine (Proposed § 107.100(a))

The current requirements for iodine in infant formula are a minimum level of 5 µg/100 kcal and a maximum level of 75 µg/100 kcal (§ 107.100). Based on our analysis of scientific information and data since the 1998 comprehensive study of infant formula nutrients (Ref. 1), including infant formula iodine requirements in international standards, we propose to amend § 107.100(a) to increase the required minimum to 15 µg/100 kcal and decrease the required maximum to 50 µg/100 kcal.

1. Background

Iodine is an essential micronutrient whose primary physiological role is as an essential component of the thyroid hormones that regulate protein synthesis, enzymatic activity, and metabolic processes critical to normal growth and development (Refs. 1, 61). In infants, thyroid hormones are particularly important for myelination of the central nervous system, which is most active in the perinatal period and during early postnatal development; iodine deficiency during this critical window can irreversibly impair neuromotor development (Ref. 62).

Iodine (I_2) refers to the elemental form, while iodide (I^-) is the reduced, ionic form that predominates in food, water, and the body. Most dietary iodine is rapidly converted to iodide in the gastrointestinal tract prior to absorption (Ref. 62). Infant formula and human milk contain iodine primarily in the iodide form. In regulatory and nutritional contexts, the term ''iodine'' is used conventionally to refer to total iodine intake regardless of chemical form, and this convention is followed throughout this document.

a. Health Consequences of Iodine Deficiency

Iodine deficiency disorders identified throughout the lifespan include intellectual disability, hypothyroidism, goiter, cretinism, and varying degrees of growth and developmental abnormalities resulting from inadequate thyroid hormone production (Ref. 62). Fetal iodine deficiency resulting in cretinism occurs in areas where endemic goiters exist, generally in association with iodine intakes less than 25 µg/day (Ref. 1). Infants are among the most vulnerable populations for iodine deficiency because their intrathyroidal iodine stores are small, daily thyroid hormone turnover rates per body weight are higher than at any other time of life, and they are entirely dependent on dietary iodine from human milk or infant formula (Refs. 61, 62). Deficiencies of vitamin A, selenium, or iron can exacerbate the effects of iodine deficiency (Refs. 61, 62).

b. Health Consequences of Excess Iodine Intake

High iodine intakes have been associated with thyroiditis, goiter, hypothyroidism, hyperthyroidism, and sensitivity reactions (Ref. 62). Excess iodine can be harmful to infants, particularly premature infants, because excretion mechanisms may be unable to accommodate high intake levels, potentially resulting in transient hypothyroidism (Refs. 1, 61).

2. Nutrient Reference Values

a. NASEM

NASEM established AI values for iodine for infants in 2001 based on the observed mean iodine intake of infants exclusively fed human milk (Ref. 62). NASEM established an AI of 110 µg/day for infants 0–6 months of age and an AI of 130 µg/day for infants 7–12 months of age. The AI for infants 7–12 months of age was extrapolated from the AI for younger infants using a metabolic weight ratio (Ref. 62). NASEM judged the UL to be not determinable for infants due to insufficient data on adverse effects and concern about the infant's ability to handle excess amounts (Ref. 62).

b. EFSA

EFSA published dietary reference values for iodine in 2014 (Ref. 63). EFSA did not establish an AI for iodine in infants 0–6 months of age, during which period exclusive breastfeeding is assumed to provide an adequate iodine supply. For infants 7–11 months of age, EFSA established an AI of 70 µg/day based on the urinary iodine concentration (UIC) threshold (100 µg/L) from school-age children, extrapolated to infants using age-adjusted urinary volumes and body weight. The EFSA Panel concluded that an iodine intake of 90 µg/day is adequate for the majority of infants, and, since there is no reason to assume that infants from birth to 6 months of age need more iodine than infants in the second half of the first year of life, an intake of 70 µg/day is adequate for the majority of infants from birth to 12 months of age (Ref. 63). EFSA did not establish a UL for iodine for infants.

c. WHO

WHO, together with the United Nations Children's Fund (UNICEF) and the International Council for Control of Iodine Deficiency Disorders (ICCIDD), established an RNI of 90 µg/day for children under 5 years of age (0–59 months) based on physiological evidence that positive iodine balance requires iodine intake of at least 15 µg/kg/day, approximating 90 µg/day for a 6-month-old infant weighing 6 kg (Refs. 64, 65). The recommended value supports normal thyroid hormone production without stressing the iodide trapping mechanism. While a UL for infants was not established, daily intakes exceeding 180 µg/day were not expected to provide additional health benefit and may be associated with impaired thyroid function. However, the Consultation set upper limits of probable safe intake for infants at 150 µg/kg/day (0–6 months of age) and 140 µg/kg/day (7–12 months of age) (Ref. 64).

d. D–A–CH (Germany, Austria, Switzerland)

D–A–CH established a reference value for daily iodine intake for infants of 80 µg/day for infants 0–12 months of age in 2025 (Ref. 66). This value represents a doubling of the previous D–A–CH reference value of 40 µg/day. According to the D–A–CH reference values, the updated iodine recommendation for infants differs methodologically from the previous reference value and allows the revised reference value to be expressed as a recommended intake rather than an estimated value (Refs. 61, 66). No UL was determined.

e. Australian NHMRC/New Zealand MoH

Australia and New Zealand established AIs for iodine in 2006 (Ref. 53). The AI for infants 0–6 months of age was calculated by multiplying the

average intake of human milk (0.78 L/day) by the average concentration of iodine in human milk (115 µg/L), consistent with the 2001 recommendation (Ref. 64), in addition to other studies, yielding an AI of 90 µg/day. The AI for infants 7–12 months of age was extrapolated from that of younger infants using a metabolic weight ratio, yielding an AI of 110 µg/day. No UL was determined (Ref. 53).

f. Comparison of International Recommendations

Table 5 shows the iodine AIs established by NASEM, EFSA, WHO, D–A–CH, and NHMRC/MoH.

TABLE 5—ADEQUATE INTAKES AND TOLERABLE UPPER INTAKE LEVELS OF IODINE

Organization	Year	Age range (months)	Adequate intake (µg/day)	Tolerable upper intake level
NASEM	2001	0–6	110	ND
		7–12	130	ND
EFSA	2014	7–11	70	ND
WHO	2001	0–12	*90	ND
D–A–CH	2025	0–12	80	ND
Australian NHMRC/New Zealand MoH	2006	0–6	90	ND
		7–12	110	ND

*Values established are RNI levels.

The variation in iodine recommendations across international expert bodies reflects differences in methodology, data sources, and the timing of each review (Ref. 61). A key methodological difference across all bodies is the degree to which human milk iodine data are used as the primary reference. Unlike many other minerals, iodine in human milk is not homeostatically regulated (*i.e.,* automatically kept at a consistent level by the body) but directly reflects maternal iodine status and population-level iodine exposure. Consequently, human milk iodine concentrations vary substantially across populations and over time, and the choice of reference population for human milk data has a direct and substantial effect on the resulting AI (Refs. 36, 61, 67).

3. Human Milk Composition

There is wide variability in milk iodine concentrations across populations, driven by differences in national salt iodization policies, dietary patterns, geographic variability, and dietary supplement use (Ref. 61). Consequently, no single human milk iodine concentration can be considered universally representative. The large, multi-country MILQ study ultimately chose not to generate pooled iodine reference values or percentile curves because of this between-country variability, unlike its approach to other minerals (Ref. 36).

4. International Regulatory Standards for Infant Formula

Iodine specifications for infant formula vary considerably among international regulatory bodies and expert organizations (see table 6). The current U.S. specification of 5 µg/100 kcal (minimum) to 75 µg/100 kcal (maximum) is an outlier relative to international standards. Specifically, the U.S. minimum falls below the current minimum thresholds established by major international regulatory frameworks, while the U.S. maximum exceeds their corresponding upper levels.

Across the international regulatory frameworks assessed, minimum iodine specifications range from 10 to 15 µg/100 kcal, while maximum levels or GULs range from 29 to 60 µg/100 kcal. Codex Alimentarius, FSANZ, and Health Canada share identical specifications (10 µg/100 kcal minimum; 60 µg/100 kcal maximum or GUL) (Refs. 12, 37, 39, 40). China also has a maximum of 60 µg/100 kcal with a higher minimum of 15 µg/100 kcal (Refs. 41, 42). The EU specifies the narrowest range, with a minimum of 15 µg/100 kcal and a maximum of 29 µg/100 kcal (Ref. 38). The EU minimum was derived from EFSA's 2014 scientific opinion, which determined that a minimum iodine content of 14 µg/100 kcal (rounded up to 15 µg/100 kcal) is necessary for an infant consuming approximately 500 kcal/day to achieve an adequate intake of 70 µg/day (Ref. 7).

The 1998 LSRO Panel report recommended a minimum of 8 µg/100 kcal and a maximum of 35 µg/100 kcal (Ref. 1). The LSRO minimum was based on the then-current RDA for iodine of 40 µg/day for infants 0–6 months of age, which translates to 8 µg/100 kcal for a 5 kg infant consuming 100 kcal/kg/day (Ref. 44). Human milk was not used as the reference standard. Data obtained from iodine balance studies further support this level, estimating the dietary requirement at no more than 8.6 µg/kg/day (Ref. 1). The LSRO recommended maximum of 35 µg/100 kcal represented approximately the 75th percentile of FDA analyses of marketed formulas and was considered the lowest feasible value at the time (Ref. 1). The LSRO Panel considered the U.S. maximum of 75 µg/100 kcal to be too high.

Table 6 shows the requirements and recommendations of these international bodies and organizations.

TABLE 6—INTERNATIONAL STANDARDS AND/OR RECOMMENDATIONS FOR IODINE IN INFANT FORMULA

Organization	Age range (months)	Minimum (µg/100 kcal)	Maximum (µg/100 kcal)	Reference
U.S. Current Standards	0–12	5	75	21 CFR 107.100.
LSRO [1]	0–12	8	35	LSRO, 1998.
Codex Alimentarius	0–12	10	60 (GUL)	CXS 72–1981, CXS 156–1987.
EU	0–12	15	29	Commission Delegated Regulation (EU) 2016/127.
Australia [2]	0–12	10	60 (GUL)	FSANZ P1028.
Canada [3]	0–12	10	60	Health Canada, 2025.
China	0–12	15	60	GB 10765–2021, GB 10766–2021.

[1] Recommended ranges.

[2] Values converted from per 100 kJ to per 100 kcal (1 kcal = 4.184 kJ).
[3] Reflects proposed compositional requirements for infant formula.

5. Recent Scientific Evidence on Iodine Intake

The most direct evidence on iodine requirements in early infancy comes from a 2016 balance study in formula-fed infants 2–5 months of age (Ref. 68). The study found that zero iodine balance was achieved at approximately 70 µg/day and found iodine retention to be linear up to 300 µg/day with no evidence of down-regulation (Ref. 68). These findings led the authors to propose an EAR of 72 µg/day and an RDA of 80 µg/day, suggesting the current AI of 110 µg/day for infants 0–6 months of age may be set too high. The study also proposed a urinary iodine concentration threshold of approximately 125 µg/L as indicative of adequacy, slightly above the WHO cutoff of 100 µg/L (Ref. 68). An additional study to evaluate iodine status in settings with universal salt iodization supports these estimates (Refs. 61, 69).

Moreover, a 2022 secondary analysis of a randomized controlled trial (Ref. 70) provided independent corroboration of the proposed EAR. Median UICs were greater than or equal to 100 µg/L at all ages from 1 to 12 months, and more than 98 percent of infants met the proposed EAR of 72 µg/day. These findings support the appropriateness of the lower estimated iodine requirement derived from the 2016 balance study (Refs. 61, 68, 70).

These newer estimates are broadly consistent with established reference values. WHO, together with UNICEF and ICCIDD, established an RNI of 90 µg/day for children under 5 years of age (0–59 months) and identified a UIC of greater than or equal to 100 µg/L as indicative of adequate iodine nutrition, while noting that daily intakes exceeding 180 µg/day are not expected to provide additional health benefit (Refs. 64, 65). A narrative review of the literature from 1960 to 2007 proposed an iodine requirement of greater than or equal to 15 µg/kg/day (≥90 µg/day) for full-term infants (Ref. 71). Further, the 2016 balance study suggests that the true AR may sit somewhat below the established RNI, though the difference between the proposed RDA (80 µg/day) and the established RNI (90 µg/day) is modest, and both fall below NASEM's current AIs of 110 and 130 µg/day.

Studies conducted in populations with high environmental iodine exposure have documented adverse thyroid outcomes in infants and young children at elevated iodine intakes. A cross-sectional study documented subclinical hypothyroidism in 7.4 percent and elevated thyroglobulin in 15.8 percent of participants 6–24 months of age in a population with high environmental iodine exposure (Ref. 72). An observational study found that high iodine intakes were associated with subclinical hypothyroidism in 9 percent of children and elevated thyroglobulin in 13 percent at 3-year followup (Ref. 73).

The excess iodine exposures represented in these studies arise primarily from environmental sources and supplementation rather than from infant formula, and, in some cases, involve intake levels far exceeding those achievable through formula feeding alone. The studies were also conducted in populations with iodine exposure profiles markedly different from typical U.S. infants, limiting direct generalizability. Nevertheless, the thyroid and growth outcomes observed across these populations provide useful context for understanding the biological consequences of sustained elevated iodine intake in early infancy, a period of particular vulnerability to disruption of thyroid function (Ref. 61).

6. Evidence Evaluation and Rationale

a. Rationale for Increasing the Minimum Specification to 15 µg/100 kcal

The current minimum specification of 5 µg/100 kcal has not been updated since 1985 (50 FR 45106, October 30, 1985) and is no longer supported by more recently available scientific evidence. At this level, an infant 0–6 months of age would receive only approximately 26 µg/day of iodine, representing 24 percent of the NASEM AI of 110 µg/day (Ref. 62) and 29 percent of the WHO RNI of 90 µg/day (Ref. 65) (see table 7). An infant 6–12 months of age would receive approximately 20 µg/day at the current minimum, representing 16 percent of the NASEM AI of 130 µg/day and 23 percent of the WHO RNI of 90 µg/day. Intakes at both age groups fall below even the experimentally derived EAR of 72 µg/day (Ref. 68), representing 37 percent and 28 percent of that threshold for infants 0–6 months and 6–12 months of age, respectively, the most conservative available estimate of average iodine requirement. The 1998 LSRO Panel also recommended a higher minimum of 8 µg/100 kcal based on the then-current RDA of 40 µg/day for infants 0–6 months of age (Ref. 1).

TABLE 7—ESTIMATED DAILY IODINE INTAKE AT THE CURRENT AND PROPOSED MINIMUM SPECIFICATIONS EXPRESSED AS A PERCENTAGE OF NUTRIENT REFERENCE VALUES

Typical infant formula intake [1]	Energy intake from infant formula (kcal/day)	Estimated iodine intake (µg/day)	% NASEM AI	% WHO RNI	% Balance study EAR	% Balance study RDA
Current Minimum Specification (5 µg/100 kcal)						
0–6 months	527	26.3	24	29	37	33
6–12 months	406	20.3	16	23	28	25
Proposed Minimum Specification (15 µg/100 kcal)						
0–6 months	527	79.1	72	88	110	99
6–12 months	406	60.9	47	68	85	76

Reference values used: NASEM AI: 110 µg/day (0–6 months of age) and 130 µg/day (6–12 months of age) (Ref. 62); WHO RNI: 90 µg/day (0–12 months of age) (Ref. 65); 2016 balance study EAR (proposed): 72 µg/day; and 2016 balance study RDA (proposed): 80 µg/day (Ref. 68).
[1] Typical intake based on assumed formula consumption of 0.78 L/day (0–6 months of age) and 0.60 L/day (6–12 months of age) at 676 kcal/L.

FDA acknowledges that, at typical intake volumes, the proposed minimum of 15 µg/100 kcal does not fully meet the NASEM AI or WHO RNI for either age group, reflecting a challenge of setting a minimum specification for a nutrient with varying nutrient reference values among expert bodies. The NASEM AIs are based on the mean intake from human milk and are intended to reflect observed intakes in healthy populations rather than a minimum requirement threshold. The proposed minimum is intended to ensure an adequate iodine provision consistent with the best available evidence on iodine requirements in infancy (Ref. 61).

The current U.S. minimum of 5 µg/100 kcal is the lowest of any major regulatory jurisdiction. All other major international regulatory frameworks have established minimums of 10 to 15 µg/100 kcal: Codex Alimentarius, FSANZ, and Health Canada specify a minimum of 10 µg/100 kcal, while the EU and China specify a minimum of 15 µg/100 kcal (table 6). The proposed minimum of 15 µg/100 kcal aligns with the standards from the EU and China and represents a scientifically supported improvement over the current U.S. minimum.

Since the 1998 LSRO Panel report (Ref. 1), the evidence base has expanded substantially (see Refs. 68, 69, 70, 74) and consistently supports a minimum above the current 5 µg/100 kcal (Ref. 61). Additionally, a few comments in response to FDA's 2025 RFI on nutrient requirements for infant formula express support for increasing the minimum iodine level (90 FR 20475, May 14, 2025).

b. Rationale for Decreasing the Maximum Specification to 50 µg/100 kcal

The current FDA maximum of 75 µg/100 kcal has not been revised since 1985 (50 FR 45106, October 30, 1985). At this level, an infant 0–6 months of age consuming a typical daily infant formula intake would receive approximately 396 µg/day of iodine, and an infant 6–12 months of age consuming a typical daily infant formula intake would receive approximately 305 µg/day. These levels substantially exceed upper levels of probable safe intake (Ref. 75), as well as estimated intakes associated with subclinical thyroid dysfunction in several applicable studies (Refs. 72, 73).

The limitations of the current maximum are further illustrated by NHANES-derived estimates of energy intake from infant formula among high consumers (Refs. 13, 14, 15, 16, 17, 18). At the 90th percentile of energy intake from infant formula (836 kcal/day for infants 0–6 months of age and 794 kcal/day for infants 6–12 months of age), the current maximum of 75 µg/100 kcal would provide iodine intakes of approximately 627 µg/day and 596 µg/day, respectively.

These findings reinforce the need for a significant downward revision of the maximum specification, particularly given the absence of a formal UL for infants and the linear iodine retention observed across intake levels (Ref. 69). Because no UL has been established for infants by any major international expert body (Ref. 62), the safety margin between the current maximum and any established toxicity threshold cannot be precisely quantified, a significant limitation that further underscores the need for a decrease (Ref. 61).

As discussed in section V.E.5 of this document, other major international regulatory frameworks have established GULs or maximums substantially below the current U.S. maximum of 75 µg/100 kcal: Codex Alimentarius, FSANZ, Health Canada, and China specify a GUL or maximum of 60 µg/100 kcal, and the EU specifies a maximum of 29 µg/100 kcal (table 6). In 1998, the LSRO Panel report explicitly concluded that the current maximum of 75 µg/100 kcal was too high and recommended a maximum of 35 µg/100 kcal based on the 75th percentile of FDA analyses of marketed formulas at the time (Ref. 1). The proposed maximum of 50 µg/100 kcal represents a substantial reduction from the current maximum and falls within international consensus and available scientific evidence to reduce risk of excessive exposure while allowing manufacturing flexibility.

Since the 1998 LSRO Panel report, several lines of evidence have emerged that support reducing the maximum specification. A Technical Consultation document noted that daily intakes exceeding 180 µg/day are not expected to provide additional health benefit and may be associated with impaired thyroid function (Ref. 75). Consistent with this, studies conducted in populations with high environmental iodine exposure have documented adverse thyroid outcomes in infants and young children at elevated iodine intakes (Refs. 72, 73). A balance study (Ref. 68) further found that iodine retention was linear across all intake levels up to 300 µg/day, with no evidence of homeostatic down-regulation (*i.e.,* the body's ability to automatically reduce absorption or increase excretion to prevent excess buildup) at higher intakes, suggesting that infants do not have robust mechanisms to limit iodine retention at high intakes and that higher formula iodine concentrations may result in proportionally higher retention with uncertain long-term consequences. FDA considers that these findings, while derived from populations with environmental iodine excess rather than formula-fed infants, provide the best available evidence for understanding the biological consequences of sustained elevated iodine intake in early infancy and collectively support a significant downward revision of the maximum (Ref. 61).

At 50 µg/100 kcal, an infant 0–6 months of age consuming a typical daily infant formula intake would receive approximately 264 µg/day of iodine, and an infant 6–12 months of age consuming a typical daily infant formula intake would receive approximately 203 µg/day of iodine. Among higher consumers, NHANES-derived estimates of energy intake from infant formula indicate that, at the 90th percentile of energy intake from infant formula (836 kcal/day for infants 0–6 months of age and 794 kcal/day for infants 6–12 months of age), the proposed maximum of 50 µg/100 kcal would permit iodine intakes of approximately 418 µg/day and 397 µg/day, respectively (Refs. 13, 14, 15, 16, 17, 18, 61).

FDA acknowledges that these intakes exceed 180 µg/day, the level above which additional health benefits are unlikely (Ref. 75); however, they are below the probable safe upper limits of 150 µg/kg/day for infants 0–6 months of age (reference weight: 6 kg) and 140 µg/kg/day for infants 7–12 months of age (reference weight: 8.9 kg). Using the reference weights identified in the report, these correspond to absolute upper limits of approximately 900 µg/day and 1,246 µg/day, respectively (Ref. 64). In populations with excess environmental exposure to iodine, reports of subclinical hypothyroidism in infants and young children have been documented (Refs. 72, 73). However, the evidence from these studies is derived from populations with environmental iodine excess rather than routine feeding of formula-fed infants, and the generalizability of these findings to U.S. formula-fed infants is uncertain. Because no UL has been established for infants, the percentage of UL at the proposed maximum cannot be calculated: a significant limitation that FDA acknowledges. The proposed maximum reflects a conservative approach based primarily on international regulatory alignment, rather than a formally derived safety margin (Ref. 61).

F. Potassium

The current requirements for potassium in infant formula are a minimum level of 80 mg/100 kcal and a maximum level of 200 mg/100 kcal (§ 107.100). Based on our analysis of scientific information and data since the 1998 LSRO Panel report (Ref. 1), including infant formula potassium requirements in international standards, we conclude that the required potassium levels in § 107.100 remain appropriate.

1. Background

Potassium is an essential nutrient that serves critical physiological functions in infants, including regulation of cell volume, membrane transport, cardiac conduction, nerve signaling, and muscle contraction (Ref. 76). Most of the potassium in the body is found inside cells; potassium and sodium are interrelated and function together across cell membranes to regulate cell volume and membrane transport. Potassium also plays a role in regulating water and acid-base balance in the blood and tissues (Ref. 76). Potassium metabolism is tightly controlled over a wide range of dietary intakes, primarily regulated via the kidneys. Assessing potassium status is difficult because most potassium in the body resides inside cells, and no sensitive biomarker exists that can characterize the distribution of potassium requirements in healthy populations (Refs. 76, 77).

a. Health Consequences of Potassium Deficiency

Hypokalemia (*i.e.,* low blood potassium; serum potassium ≤3.5 mmol/L) can result from inadequate intake, excessive losses, or transcellular shifts in potassium. Hypokalemia from dietary inadequacy alone is rare in healthy individuals because the kidney efficiently conserves potassium at low dietary intakes (Ref. 77). Potassium depletion studies conducted in adults over short periods have shown that very low intakes (0–390 mg/day) can lead to hypokalemia. Inadequate potassium intake may also contribute to impaired glycemic control (Ref. 78). However, in clinical settings, hypokalemia is more commonly caused by abnormal losses of potassium (renal or gastrointestinal) or medications promoting transcellular shifts (Ref. 76).

b. Health Consequences of Excess Potassium Intake

In healthy individuals with normal kidney function, excess potassium is efficiently excreted and toxicity from dietary sources is unlikely. Hyperkalemia (*i.e.,* high blood potassium) is of greater concern in individuals with chronic kidney disease, diabetes, heart failure, adrenal insufficiency, or those taking certain medications. In addition, there is no evidence that high intakes of potassium cause hyperkalemia or other adverse effects in adults with normal kidney function (Ref. 77).

2. Nutrient Reference Values

a. NASEM

NASEM published DRIs for water, potassium, sodium, chloride, and sulfate in 2005 and published an updated report specific to sodium and potassium in 2019 (Refs. 19, 76). Because no EAR could be established due to the absence of a sensitive biomarker of potassium status and limitations in available balance study data, the committee established AI values for potassium in infants based on estimated potassium intakes from human milk (Ref. 76). The AI for infants 0–6 months of age was set at 400 mg/day, derived by multiplying the average human milk intake (0.78 L/day) by the average human milk potassium concentration (515 mg/L) from a meta-analysis of 15 studies focusing on the first 6 months of lactation. The AI for infants 7–12 months of age was set at 860 mg/day, based on estimated intakes from human milk plus an estimated potassium intake from complementary foods of approximately 600 mg/day, derived from NHANES 2003–2010 and FITS 2016 data (Ref. 76). The AI for infants 0–6 months of age is unchanged from the 2005 DRI report, while the AI for infants 7–12 months of age was increased from 700 mg/day (2005) to 860 mg/day (2019), reflecting updated estimates of complementary food contributions (Refs. 19, 76).

No UL has been established for potassium in infants. The 2019 NASEM committee concluded that ''there is insufficient evidence of potassium toxicity risk within the apparently healthy population to establish a potassium Tolerable Upper Intake Level (UL)'' (Ref. 76).

b. EFSA

The EFSA Panel established an AI of 750 mg/day for infants 7–11 months of age, extrapolated from the adult AI using isometric scaling and a growth factor (Ref. 79). No AI was established for infants 0–6 months of age. The EFSA NDA Panel estimated an approximate midpoint potassium concentration in mature human milk of 500 mg/L based on data from multiple studies of women from Western countries (Ref. 79).

c. D–A–CH

The D–A–CH reference values established estimated values of 400 mg/day for infants 0–4 months of age and 600 mg/day for infants 4–12 months of age. The authors based the 0–4-month estimate on an average human milk intake of 750 mL/day and a mean potassium content of 500 mg/L. They calculated the 4–12-month estimate by extrapolating from the younger group's value and adjusting for differences in reference body weight (Ref. 80).

d. Australian NHMRC/New Zealand MoH

NHMRC/MoH (2006) (Ref. 53) derived the AI for infants 0–6 months of age as 400 mg/day, calculated by multiplying the average human milk intake (0.78 L/day) by the average human milk potassium concentration (500 mg/L). NHMRC/MoH derived an AI of 700 mg/day for infants 7–12 months of age, calculated by assuming an average 0.6 L/day of human milk intake plus 440 mg/day from complementary foods.

e. Comparison of International Recommendations

Table 8 shows AIs of potassium for NASEM, D–A–CH, EFSA, and NHMRC/MoH.

TABLE 5—ADEQUATE INTAKES AND TOLERABLE UPPER INTAKE LEVELS OF IODINE

Organization	Year	Age range (months)	Adequate intake (mg/day)	Tolerable upper intake level
NASEM	2019	0–6	400	ND
		7–12	860	ND
D–A–CH	2017	0–4	400	ND
		4–12	600	ND
EFSA	2016	7–11	750	ND

TABLE 5—ADEQUATE INTAKES AND TOLERABLE UPPER INTAKE LEVELS OF IODINE—Continued

Organization	Year	Age range (months)	Adequate intake (mg/day)	Tolerable upper intake level
Australian NHMRC/New Zealand MoH	2006	0–6	400	ND
		7–12	700	ND

There is consistency across international bodies in the AI established for young infants (0–6 months of age). Divergence in AIs for older infants (7–12 months of age) across international bodies is primarily attributable to methodological differences in estimating potassium intake from complementary foods. EFSA used a different approach entirely, extrapolating from the adult AI using isometric scaling rather than observed infant intake data.

3. Human Milk Composition

Maternal dietary intake does not strongly influence human milk potassium concentrations (Ref. 76). Human milk potassium concentrations decline over the course of lactation (Ref. 79). Four sources informed the analysis of potassium concentrations in human milk: the 2019 NASEM meta-analysis (Ref. 76), the 2016 EFSA NDA Panel review (Ref. 79), the iHMNutD study (Ref. 8), and the MILQ study (Ref. 36).

In 2019, NASEM conducted a meta-analysis of 15 longitudinal and cross-sectional studies (1980–2017) and estimated mean potassium concentrations of 515 mg/L (95 percent confidence interval (CI): 472.76–557.81 mg/L) for the 0–6-month interval and 437 mg/L (95 percent CI: 367.89–505.22 mg/L) for the 7–12-month interval (Ref. 76). The 2016 EFSA Panel reviewed data from eight studies (1982–2012) and derived an estimate of approximately 500 mg/L as the midpoint concentration (Ref. 79). The iHMNutD study identified 10 eligible North American studies (1980–2024; total n = 905) and estimated a weighted mean potassium concentration of 573 ± 75 mg/L (Ref. 8). Additionally, the MILQ study, the most comprehensive recent data, reported a pooled median of 542 mg/L (interquartile range (IQR): 485–609 mg/L) from 1 to 6 months of lactation (Ref. 36).

Across all four sources, central estimates of potassium concentration in mature human milk ranged from approximately 500 to 573 mg/L (Refs. 8, 36, 76, 79). The NASEM estimate for human milk potassium content for infants 7–12 months of age (437 mg/L) (Ref. 76) was notably lower than the estimate for younger infants, consistent with the expected decline in potassium concentration over the course of lactation. While estimates derived from NASEM, EFSA, and the iHMNutD study show a degree of consistency, this convergence should be interpreted with some caution, as the three analyses draw from an overlapping body of foundational literature, particularly studies conducted in North American populations during the 1980s and 1990s (Ref. 77). The MILQ study (Ref. 36) provides broader geographic evidence consistent with the range of concentrations observed in North American estimates.

4. International Regulatory Standards for Infant Formula

The current U.S. minimum requirement for potassium aligns with the EU and meets or exceeds the minimum levels set by most other international bodies. The U.S. maximum of 200 mg/100 kcal exceeds most international standards, with only China's standard for infants 6–12 months of age (225 mg/100 kcal) surpassing it (see table 9).

In its 1998 comprehensive review, the LSRO Panel recommended a potassium range of 60–160 mg/100 kcal for infants 0–12 months of age. The recommended minimum was derived from the mean minus one standard deviation of potassium concentrations in mature human milk, with no evidence identified to suggest differences in potassium bioavailability between human milk and infant formula. The recommended maximum of 160 mg/100 kcal was based on the 90th percentile of FDA analyses of commercially available infant formulas at the time (Ref. 1).

Table 9 shows the requirements and recommendations of these international regulatory bodies and organizations.

TABLE 9—INTERNATIONAL STANDARDS AND/OR RECOMMENDATIONS FOR POTASSIUM IN INFANT FORMULA

Organization	Age range (months)	Minimum (mg/100 kcal)	Maximum (mg/100 kcal)	Reference
U.S. Current Standards	0–12	80	200	21 CFR 107.100.
LSRO [1]	0–12	60	160	LSRO, 1998.
Codex Alimentarius	0–12	60	180	CXS 72–1981, CXS 156–1987.
EU	0–12	80	160	Commission Delegated Regulation (EU) 2016/127.
Australia [2]	0–12	60	180	FSANZ P1028.
Canada [3]	0–12	60	180	Health Canada, 2025.
China	0–6	70	180	GB 10765–2021.
	6–12	75	225	GB 10766–2021.

[1] Recommended ranges.
[2] Values converted from per 100 kJ to per 100 kcal (1 kcal = 4.184 kJ).
[3] Reflects proposed compositional requirements for infant formula.

5. Recent Scientific Evidence on Potassium Intake

Several U.S.-based national dietary surveys have assessed potassium intake in U.S. infants and toddlers, consistently demonstrating that most infants meet or exceed established AIs for potassium. Data are available primarily from three iterations of FITS (FITS 2002, 2008, and 2016) (Refs. 43, 81, 82, 83) and from NHANES 2009–2012 (Ref. 84).

Mean potassium intakes for infants 0–6 months of age generally met or exceeded the AI of 400 mg/day. Mean intakes ranged from approximately 570 to 700 mg/day across datasets. At the 10th percentile, intakes ranged from

approximately 387 to 414 mg/day across FITS 2008 and FITS 2016, close to the AI, suggesting that most infants in this age group had potassium intakes at or above the recommended level.

Mean potassium intakes for infants 7–12 months of age consistently exceeded the current AI of 860 mg/day and ranged from approximately 1,085 to 1,225 mg/day across three FITS iterations and NHANES 2009–2012. The 10th percentile of usual potassium intake ranged from approximately 650 to 791 mg/day across available studies, falling below the current AI of 860 mg/day. While most infants had adequate intakes, a small proportion had intakes near or below the AI.

Several methodological limitations should be considered. Potassium intake estimates rely on proxy-reported 24-hour dietary recalls subject to recall bias. Human milk volumes were not directly measured but estimated using standardized assumptions, and some analyses excluded the youngest infants from intake modeling. The available data do not include information on health outcomes associated with potassium intake levels. As such, the extent to which current intakes translate to clinical outcomes cannot be determined from these data alone (Ref. 77).

6. Evidence Evaluation and Rationale

Based on the review of available scientific data, information, and international standards, we conclude that the current minimum level of 80 mg/100 kcal and maximum level of 200 mg/100 kcal for potassium in § 107.100 remain appropriate.

a. Maintaining the Minimum Specification of 80 mg/100 kcal

The current minimum of 80 mg/100 kcal is consistent with human milk potassium concentrations and provides potassium intakes that meet or exceed established AIs when applied to typical formula consumption patterns. The most current estimates of human milk potassium concentration range from approximately 77 to 88 mg/100 kcal (derived from 500 to 573 mg/L at a typical energy density of 650 kcal/L) (Refs. 8, 36, 76, 77, 79). The current minimum falls within this range.

Applied to typical formula consumption patterns, the current minimum provides potassium intakes that meet or exceed NASEM (2019) AIs for both infant age groups. For an infant 0–6 months of age consuming a typical daily infant formula intake, the minimum specification of 80 mg/100 kcal provides approximately 422 mg/day, which is 105 percent of the AI of 400 mg/day. For an infant 7–12 months of age consuming a typical daily infant formula intake, the minimum provides approximately 324 mg/day from formula alone. When combined with the estimated complementary food contribution of approximately 600 mg/day (Ref. 76), total intake would be approximately 920 mg/day, which is 107 percent of the AI of 860 mg/day. These calculations demonstrate that the current minimum supports adequate potassium intake across the first year of life (Ref. 77).

Population intake data provide contextual support for maintaining the current minimum. Across several large national surveys, mean potassium intakes for infants 0–6 months of age ranged from approximately 570 to 700 mg/day, and for infants 6–12 months of age ranged from approximately 1,085 to 1,225 mg/day, with all mean estimates exceeding the respective AIs (Refs. 43, 81, 82, 83, 84).

The current U.S. minimum is consistent with or above international regulatory standards. FDA considered whether the minimum should be lowered to 60 mg/100 kcal to align with Codex Alimentarius, FSANZ, Health Canada, and LSRO; however, lowering the minimum to 60 mg/100 kcal would reduce the daily potassium intake from formula for infants 0–6 months of age to approximately 78 percent of the AI, reducing the margin of adequacy for infants consuming formula as their sole source of nutrition. Maintaining the current minimum of 80 mg/100 kcal is supported by human milk composition data and U.S. population intake data and falls within the range of minimums set by international standards. FDA has not identified evidence that the current minimum is nutritionally insufficient or presents manufacturing challenges.

b. Maintaining the Maximum Specification of 200 mg/100 kcal

The current maximum of 200 mg/100 kcal was originally established based on the potassium content of cow milk, which was considered to represent a significant but tolerable burden on the kidneys for healthy infants with normal renal function (Ref. 85). After reviewing the available scientific evidence, FDA concludes that this maximum remains appropriate (Ref. 77).

No authoritative body has established a UL for potassium in infants (Refs. 1, 76, 77, 79). However, the current maximum of 200 mg/100 kcal has been in effect since the 1980 Infant Formula Act was enacted without documented adverse effects attributable to potassium intake from infant formula in healthy infants (Ref. 77).

The current maximum of 200 mg/100 kcal provides a substantial margin above the potassium content of human milk (approximately 77–88 mg/100 kcal), positioned at approximately 227–260 percent of the mean mature human milk potassium content on a per-calorie basis (Ref. 77). Applied to typical infant formula daily consumption, the current maximum would provide approximately 1,054 mg/day for an infant 0–6 months of age and approximately 812 mg/day from formula alone for an infant 7–12 months of age. These intakes substantially exceed the AIs but remain well below the levels associated with adverse effects in healthy infants with normal renal function (Refs. 1, 77).

Internationally, maximum specifications range from 160 to 180 mg/100 kcal for infants 0–6 months of age and up to 225 mg/100 kcal for infants 6–12 months of age, with the U.S. maximum of 200 mg/100 kcal falling within the upper portion of this range (see table 9). FDA considered whether the maximum should be lowered to align with the international consensus range and concludes that such a change is not warranted at this time. No UL has been established for potassium in infants, no documented adverse effects from dietary potassium intake at the current maximum have been identified, and lowering the maximum would reduce manufacturing flexibility without a demonstrated safety benefit. The LSRO Panel's recommended maximum of 160 mg/100 kcal was based on the 90th percentile of FDA analyses of infant formulas on the market at that time, rather than on safety concerns (Ref. 1). FDA also considered whether the maximum should be raised and concludes this is not warranted. No evidence was identified suggesting that higher potassium levels in infant formula would provide nutritional benefits (Ref. 77).

c. Consideration of the Evidence Base

FDA acknowledges several uncertainties in the evidence base. No sensitive biomarker of potassium status has been identified that can be used to assess adequacy at the population level (Refs. 76, 79). The AIs for infants are derived from observed intake data rather than experimental determination of requirements, and the AI for infants 7–12 months of age is sensitive to assumptions about complementary food contributions. Human milk potassium concentrations vary across studies, stages of lactation, and populations. Population intake data are based on proxy-reported dietary recalls not linked to health outcomes. Given these limitations, FDA considers that

maintaining the current specifications, which have a demonstrated history of safe use, is appropriate in the absence of compelling evidence for change (Ref. 77).

G. Vitamin A (Proposed §§ 107.10(a)(2), (b)(1), and 107.100(a) and (g))

The current requirements for vitamin A in infant formula are a minimum level of 250 IU/100 kcal (75 µg RAE/100 kcal) and a maximum level of 750 IU/100 kcal (225 µg RAE/100 kcal) (21 CFR 107.100). Based on our analysis of scientific information and data since the 1998 LSRO Panel report (Ref. 1), including infant formula vitamin A requirements in international standards, we propose to decrease the required minimum to 70 µg RAE/100 kcal (233 IU/100 kcal) and decrease the maximum specification to 120 µg RAE/100 kcal (400 IU/100 kcal) for vitamin A in infant formula in § 107.100(a). We also propose changes to the unit of measure from IU to µg RAE in § 107.10(a)(2), (b)(1), and § 107.100(a). Finally, we propose to change which forms of vitamin A may contribute to the minimum and maximum vitamin A content calculations from both preformed vitamin A and *beta*-carotene to preformed vitamin A only in newly established § 107.100(g).

1. Background

Vitamin A is a fat-soluble vitamin and essential nutrient that supports vision, immune function, cell growth and differentiation, and embryonic development (Ref. 86). These functions are especially critical during infancy, a period of rapid growth and immune system development. The term ''vitamin A'' encompasses preformed vitamin A (*i.e.,* retinol and retinyl esters) and provitamin A carotenoids such as *beta*-carotene, which the body can convert to active vitamin A. Infants are born with limited hepatic vitamin A stores even when mothers are well-nourished during pregnancy, making adequate postnatal intake from human milk or infant formula essential (Refs. 62, 86, 87, 88).

a. Factors Affecting Absorption

Preformed vitamin A absorption efficiency is generally 70–90 percent (Refs. 62, 87). However, exclusively formula-fed infants may absorb vitamin A less efficiently than breastfed infants because bile-salt-stimulated lipase (BSSL), which is present in human milk but absent from infant formula, facilitates hydrolysis of retinyl esters. Formula-fed infants rely solely on endogenous digestive enzymes for this process (Ref. 1). Unlike preformed vitamin A, the absorption and conversion of provitamin A carotenoids such as *beta*-carotene are far more variable (5–65 percent), depending on factors such as the food source, genetics, vitamin A status, and health status. The extent to which infants can absorb and convert *beta*-carotene to active vitamin A remains poorly understood (Refs. 62, 87, 89).

b. Health Consequences of Vitamin A Deficiency

Vitamin A deficiency (VAD) is a major public health concern in low- and middle-income countries, affecting an estimated 190 million preschool-age children globally (Ref. 90). Xerophthalmia is a well-documented consequence of VAD, encompassing a spectrum of ocular manifestations from night blindness to corneal ulceration and blindness (Refs. 87, 88, 91). VAD is also associated with increased morbidity and mortality from infectious diseases and impaired iron mobilization contributing to anemia (Refs. 62, 87, 91). In the United States and other high-income countries, clinical VAD is uncommon in healthy term infants receiving adequate nutrition, though infants with fat malabsorption disorders (*e.g.,* cystic fibrosis, cholestatic liver disease) are at elevated risk (Ref. 91).

c. Health Consequences of Excess Vitamin A Intake

Vitamin A is fat soluble and is stored primarily in the liver (Refs. 62, 87). Excessive intake of preformed vitamin A can cause hypervitaminosis A, a toxic condition caused by having too much vitamin A in the body. Provitamin A carotenoids are not associated with toxicity, because their absorption and conversion are downregulated at high intakes (Ref. 89). Acute toxicity in infants may manifest as bulging fontanelle, vomiting, irritability, and headache (Ref. 86). Chronic toxicity symptoms may include fatigue, loss of appetite, hair loss, bone pain, skin changes, and, in serious cases, liver damage, decreased bone mineral density, and increased intracranial pressure. In young children, doses as low as 450 µg/kg/day have been reported to cause hypervitaminosis A (Refs. 62, 88, 92).

2. Nutrient Reference Values

a. NASEM

NASEM established AIs for vitamin A in infants in 2001 based on the mean vitamin A intake of infants fed human milk, as no functional criteria of vitamin A status reflecting dietary response in infants have been demonstrated. The AI for infants 0–6 months of age was set at 400 µg RAE/day, derived from an average milk intake of 0.78 L/day and average human milk vitamin A concentration of 485 µg/L during the first 6 months of lactation. The AI for infants 7–12 months of age was set at 500 µg RAE/day, based on extrapolation from the 0–6-month AI plus estimated contributions from human milk and complementary foods. NASEM did not consider contribution of carotenoids in human milk in meeting the vitamin A requirement of infants (Ref. 61). The UL was set at 600 µg RAE/day for infants 0–12 months of age, derived from case reports of hypervitaminosis A in infants, with a lowest observed adverse effect level (LOAEL) of 6,000 µg/day and an uncertainty factor of 10 to account for the extrapolation from a LOAEL to a NOAEL. NASEM acknowledged this UL was deliberately conservative (Ref. 62).

b. EFSA

The 2015 EFSA Panel derived dietary reference values for vitamin A using a factorial approach (*i.e.,* multiplying together a series of known biological parameters) with pediatric-specific adjustments for body weight, liver/body weight ratio, and growth, yielding a PRI of 250 µg retinol equivalents (RE)/day for infants 7–11 months of age (Ref. 87). In 2024, EFSA proposed a UL of 600 µg RE/day for all infants 4–11 months of age, derived by allometric scaling from the adult UL (Ref. 89). EFSA noted that a UL of 500 µg RE/day for infants 4–6 months of age would be overconservative given that human milk secretion of retinol is estimated at 424 µg RE/day (midpoint concentration: 530 µg/L × 0.8 L/day) during the first 6 months of lactation (Ref. 89).

c. Australian NHMRC/New Zealand MoH

NHMRC/MoH derived AIs for vitamin A in infants based on human milk composition from a single multinational study (Ref. 53). The AI for infants 0–6 months of age was set at 250 µg retinol/day (as retinyl esters), based on an average human milk intake of 0.78 L/day and a retinol concentration of 310 µg/L. The AI for infants 7–12 months of age was set at 430 µg RE/day, based on an average human milk intake of 0.6 L/day (approximately 186 µg RE/day), plus an estimated 244 µg RE/day from complementary foods (including vitamin A from retinol and carotenoids). The UL for infants 0–12 months of age was set at 600 µg RE/day, derived from case reports of hypervitaminosis A in infants (Ref. 53).

d. FAO/WHO

The joint FAO/WHO Consultation estimated vitamin A requirements for infants from observed retinol intakes of breastfed infants in communities with good nutrition and no signs of deficiency (Ref. 3). Notably, due to insufficient data to derive mean requirements for any age group, the Consultation provided ''recommended safe intakes'' rather than true RNIs. The recommended safe intake for infants 0–6 months of age was set at 375 µg RE/day, based on an average human milk retinol concentration of approximately 1.75 µmol/L (503 µg/L × 0.75 L/day). The recommended safe intake for infants 7–12 months of age was increased to 400 µg RE/day, accounting for a decline in average milk intake to 0.65 L/day and increased mortality risk in vitamin A-deficient populations from 6 months of age onward (Ref. 3).

e. Comparison of International Recommendations

Table 10 shows the vitamin A AIs established by NASEM, EFSA, NHMRC/MoH, and FAO/WHO.

TABLE 10—VITAMIN A NUTRIENT REFERENCE VALUES

Organization	Year	Type of reference intake	Age range (months)	Value (per day)	Type of reference intake	Age range (months)	Value (per day)
NASEM	2001	AI	0–6 7–12	400 µg RAE 500 µg RAE	UL	0–12	600 µg RAE.
EFSA	2015 (PRI) 2024 (UL)	PRI	4–6 7–11	ND 250 µg RE	UL	4–11	600 µg RE.
Australian NHMRC/ New Zealand MoH.	2006	AI	0–6 7–12	250 µg retinyl esters. 430 µg RE	UL	0–12	600 µg RE.
FAO/WHO	2004	Recommended Safe Intake.	0–6 7–12	375 µg RE 400 µg RE	UL		ND.

1 µg RE = 1 µg retinol + 6 µg ß-carotene + 12 µg other pro-vitamin A carotenoids.
1 µg RAE = 1 µg retinol + 12 µg ß-carotene + 24 µg other pro-vitamin A carotenoids.

Authoritative bodies differ fundamentally on whether infant vitamin A requirements should be derived from observed intakes from human milk or through a factorial approach. NASEM (Ref. 62), FAO/WHO (Ref. 3), and NHMRC/MoH (Ref. 53) all used human milk composition, but the wide variation in mean retinol concentrations across studies explains why these bodies arrived at different values despite using the same general approach. None of the bodies reviewed incorporated provitamin A carotenoid contributions from human milk into reference values for infants 0–6 months of age due to unknown bioconversion efficiency in this age group. With respect to ULs, NASEM, NHMRC/MoH, and EFSA converged on 600 µg RAE/day or 600 µg RE/day despite different derivation methods, strengthening confidence in this value for evaluating maximum levels (Ref. 86).

FDA believes the NASEM AIs are the most appropriate choice for assessing minimum vitamin A requirements in infant formula, as they represent the most conservative estimates and best ensure that infant nutritional needs are met (Ref. 86).

3. Human Milk Composition

Vitamin A in human milk is present almost exclusively as retinyl esters in the lipid fraction of the milk (Ref. 93). Retinol concentration is highly dependent on fat content, is substantially higher in colostrum than in mature milk, and reflects both maternal vitamin A status and recent dietary intake (Ref. 93).

Three primary data sources inform FDA's assessment of vitamin A concentrations in mature human milk. These sources were selected based on recent publication dates, robust study designs, validated analytical methods, and inclusion of healthy, full-term mother-infant dyads (Ref. 86). A 2022 meta-analysis pooled data from 76 studies that used high-performance liquid chromatography-based retinol measurements totaling 9,171 samples across 33 geographically diverse countries (Ref. 94). Studies involving vitamin A supplementation were excluded. Country was identified as a significant source of variance (Ref. 94). The authors proposed the mean early mature milk concentration of 402.4 µg/L as the reference concentration for DRI revision in infants up to 6 months of age (Ref. 94). The MILQ study (Ref. 95) provides the most comprehensive recent data on retinol concentrations in human milk using validated analytical methods from well-nourished, unsupplemented populations across four countries. Median milk retinol concentrations were highest in early lactation (886 µg/L) and stabilized from 3 months onward (450–460 µg/L) (Ref. 95). The iHMNutD study reported a pooled weighted mean of 36.09 µg/100 g (approximately 372 µg/L) (Ref. 8); however, this value was based on a limited number of studies and participants, introducing uncertainty (Ref. 8).

FDA acknowledges several limitations relevant to the estimates from human milk studies that introduce uncertainty in cross-study comparisons, including small sample sizes, geographic variability, inconsistent collection protocols, and the absence of milk fat adjustment for retinol concentrations (see Ref. 86). Notwithstanding this, FDA considers that these three sources support a plausible range of approximately 370–460 µg/L (approximately 57–71 µg RAE/100 kcal) as the best current estimate of vitamin A concentration in mature human milk, with higher concentrations observed in early mature milk. This range informs FDA's proposed minimum vitamin A specification in infant formula.

4. International Regulatory Standards for Infant Formula

Vitamin A specifications for infant formula vary among international regulatory bodies and expert organizations, though most have adopted or proposed to adopt specifications that generally align with Codex Alimentarius standards (see table 11). The Codex Alimentarius specifies a minimum of 60 µg RE/100 kcal and a maximum of 180 µg RE/100 kcal for infant formula (for infants 0–6 months of age) (Ref. 12). For follow-on formula (for infants 6–12 months of age), Codex Alimentarius specifies a higher minimum of 75 µg RE/100 kcal with the same maximum (Ref. 37).

FSANZ and Health Canada specify the same maximum as Codex

Alimentarius but do not specify a higher minimum for infants 6–12 months of age, maintaining 60 µg RE/100 kcal for infants 0–12 months of age (Refs. 39, 40). The EU and China have higher minimums and/or lower maximums than Codex Alimentarius. The EU, based on recommendations from EFSA (Ref. 7), specifies a minimum of 70 µg RE/100 kcal and a maximum of 114 µg RE/100 kcal, applicable to both infant formula and follow-on formula (Ref. 38). The EU minimum of 70 µg RE/100 kcal was set to ensure that infants consuming approximately 500 kcal/day receive at least 350 µg RE/day (Ref. 7). The EU reduced the maximum from 180 µg RE/100 kcal to 114 µg RE/100 kcal (Ref. 96), resulting in a daily vitamin A intake of approximately 570 µg RE/day (assuming 500 kcal/day), just under the UL of 600 µg RE/day. China also specifies a lower maximum of 150 µg RE/100 kcal for infant formula (Ref. 41), although the maximum for follow-on formula is consistent with Codex Alimentarius (Ref. 42).

The LSRO Panel report recommended a minimum preformed vitamin A content of infant formulas of 60 µg RE/100 kcal and a maximum of 150 µg RE/100 kcal (Ref. 1), noting that a minimum above the estimated vitamin A concentration in human milk (approximately 30 µg RE/100 kcal) was appropriate to account for lower absorption efficiency in formula-fed infants due to the absence of BSSL (Refs. 1, 86).

Table 11 shows the requirements and recommendations of these international bodies and organizations.

TABLE 11—INTERNATIONAL STANDARDS AND/OR RECOMMENDATIONS FOR VITAMIN A IN INFANT FORMULA

Organization	Age range (months)	Minimum (µg RE/100 kcal)	Maximum (µg RE/100 kcal)	Permitted sources	Reference
U.S. Current Standards [1] [2].	0–12	75 (250 IU)	225 (750 IU)	Preformed retinol: retinol, retinyl acetate, retinyl palmitate (21 CFR 184.1930). *Beta*-carotene may be used in infant formula as a source of vitamin A (21 CFR 184.1245).	21 CFR 107.100.
LSRO [3]	0–12	60	150	Preformed vitamin A	LSRO, 1998.
Codex Alimentarius	0–6	60	180	Preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.	CXS 72–1981.
	6–12	75	180		CXS 156–1987.
EU	0–12	70	114	Preformed vitamin A	Commission Delegated Regulation (EU) 2016/127.
Australia [4]	0–12	59	180	*Retinol:* vitamin A (retinol), vitamin A acetate (retinyl acetate), vitamin A palmitate (retinyl palmitate), retinyl propionate. *Provitamin A: beta*-carotene.	FSANZ P1028.
Canada [5]	0–12	60	180	Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A.	Health Canada, 2025.
China	0–6	60	150	Vitamin A only includes preformed retinol, and does not include any carotene components when vitamin A is calculated and claimed.	GB 10765–2021.
	6–12 months	75	180		GB 10766–2021.

[1] Values converted from international units (1 IU = 0.3 µg RAE). See Section V.G.6.a, "Rationale for Changing the Unit of Measure from IU to µg RAE," for additional information on RE and RAE conversions.
[2] Vitamin A content may also be declared on the label in units of µg RE—when these declarations are made, they shall appear in parentheses immediately following the declarations in IU (21 CFR 107.10(b)(1)).
[3] Recommended ranges.
[4] Values were converted from per 100 kJ to per 100 kcal (1 kcal = 4.184 kJ).
[5] Reflects proposed compositional requirements for infant formula.

5. Recent Scientific Evidence on Vitamin A Intake

Several U.S.-based national dietary surveys have assessed vitamin A intake in U.S. infants and toddlers, including the FITS (FITS 2008 and FITS 2016) and NHANES (NHANES 2009–2012 and NHANES 2015–2020) (Refs. 81, 82, 84, 86, 97). Mean intakes for infants 0–6 months of age ranged from approximately 582 to 637 µg RAE/day, and for infants 6–12 months of age from approximately 669 to 794 µg RAE/day. Preformed vitamin A constituted 88 percent of total vitamin A intake for infants 0–6 months of age and 74 percent for infants 6–12 months of age, with the remainder derived from provitamin A carotenoids (Ref. 97). The proportion of infants with vitamin A intakes exceeding the UL ranged from 21 to 39 percent depending on study and age group (Refs. 81, 82, 84).

Important methodological differences must be considered when interpreting these data. Treatment of human milk varies substantially across studies. NHANES-based analyses exclude or cannot quantify human milk contributions, while FITS-based analyses estimate them through imputation. Infant dietary supplement inclusion differs across studies, and supplement use was reported in 8.8–23 percent of infants (Refs. 81, 82). Finally, carotenoid-derived vitamin A is disaggregated from preformed vitamin A only in one available study (Ref. 97), limiting comparisons of retinol versus carotenoid contributions.

Overall, the available studies support the conclusion that current vitamin A intakes in U.S. infants are adequate and that a significant proportion have

intakes approaching or exceeding the UL. It should be noted, however, that the available dietary intake data do not include information on health outcomes associated with vitamin A intake levels (Ref. 86).

6. Evidence Evaluation and Rationale

Based on the review of available scientific data, information, and international standards, we propose to decrease the current minimum specification for vitamin A from 75 to 70 µg RAE/100 kcal and to decrease the current maximum specification for vitamin A from 225 to 120 µg RAE/100 kcal in § 107.100. We also propose a change to the unit of measure for vitamin A in §§ 107.10(a)(2) and (b)(1) and 107.100 from IU to µg RAE. Finally, we propose a change to the form of vitamin A that may be used to meet the minimum and maximum vitamin A specifications in § 107.100 from both preformed vitamin A and *beta*-carotene to preformed vitamin A only in § 107.100(g) (see table 11).

a. Rationale for Changing the Unit of Measure From IU to µg RAE

Expert scientific bodies recommend expressing vitamin A intake in µg RAE rather than IU, as these weight-based units more accurately reflect the differing bioavailability and bioconversion of preformed vitamin A and provitamin A carotenoids. This approach has been widely adopted in dietary reference values and infant formula vitamin A specifications (tables 10 and 11). In the United States, vitamin A was expressed in RE in the 1989 National Research Council Recommended Dietary Allowances (Ref. 44). An RE is a standardized unit that captures how much bioavailable vitamin A the body derives from dietary sources. The RAE unit was introduced by the U.S. DRI Committee on vitamin A (Ref. 62) to reflect updated evidence on the bioavailability of provitamin A carotenoids. Under the RE system, 6 µg of *beta*-carotene was considered equivalent to 1 µg of retinol; under the RAE system, 12 µg of *beta*-carotene is required to yield 1 µg of retinol, meaning that the vitamin A activity attributed to provitamin A carotenoids is half the amount obtained when expressed in µg RAE compared to µg RE. Because preformed retinol contributes equally under both systems (1 µg retinol = 1 µg RE = 1 µg RAE), the practical effect of this change is that total vitamin A intake estimates are lower when carotenoid contributions are calculated using µg RAE rather than µg RE. The IOM recommended expressing vitamin A requirements in µg RAE rather than µg RE or IU to more accurately reflect the bioavailability of vitamin A from mixed diets and, accordingly, established the AIs for infants in µg RAE (Ref. 86).

In the United States, when included voluntarily on food (other than infant formula) and dietary supplement labels, vitamin A is declared in µg RAE following the recommendation from the NASEM Labeling Committee that the units of measure be consistent with the DRI (81 FR 33742 at 33912, May 27, 2016); 21 CFR 101.9(c)(8)(iv)) (Ref. 98). We are therefore proposing to change the units of measure for vitamin A in infant formula from IU to µg RAE, for consistency with both the DRI and U.S. nutrition labeling regulations for other foods. We believe this proposed change will benefit consumers, as it aligns the unit of measure for vitamin A in infant formula with that already used for general food and dietary supplement labeling in the United States, as well as infant formula labeling outside the United States. The IU may be voluntarily declared in parentheses immediately following the declaration in µg RAE, providing infant formula manufacturers with flexibility and supporting continuity for consumers accustomed to IU-based labeling. This change would also be more aligned with international regulatory standards. If only preformed vitamin A is permitted to meet the vitamin A requirement in infant formula, the adoption of µg RAE would not create a discrepancy with international organizations that use µg RE, since 1 µg RAE = 1 µg RE = 1 µg all-*trans*-retinol. The three units are numerically equivalent when applied solely to preformed retinol. FDA has developed a guidance document that provides detailed instructions to assist manufacturers in converting from IU to µg RAE (Ref. 99).

b. Rationale for Allowing Only Preformed Vitamin A To Meet Vitamin A Specifications

Current U.S. regulation allows *beta*-carotene to be used in infant formula as a source of vitamin A (§ 184.1245 (21 CFR 184.1245)). Other international expert bodies, aside from FSANZ, allow only preformed vitamin A as a source of vitamin A in infant formula (table 11). In its 1998 assessment, the LSRO recommended using only preformed vitamin A to meet the minimum requirements in infant formula (Ref. 1). NASEM did not include *beta*-carotene contributions when establishing the AI for vitamin A for infants because the bioconversion of carotenoids in milk and in infants is not known (Ref. 62). Because the efficiency with which infants convert *beta*-carotene to active vitamin A is unknown, relying on *beta*-carotene as a source of vitamin A in infant formula may put infants at risk of vitamin A deficiency if the assumed conversion does not occur as expected. Additionally, only preformed retinols are considered when establishing the UL for vitamin A, as provitamin A carotenoids are not known to cause vitamin A toxicity (Ref. 62). Thus, excluding *beta*-carotene from the calculated vitamin A content of infant formula would not increase the risk of vitamin A toxicity (Ref. 1, 62, 86). Therefore, FDA is proposing to amend § 107.100 to specify that vitamin A minimum and maximum levels must be met through preformed vitamin A only. *Beta*-carotene, if used in infant formula, shall not be considered to contribute to the required minimum and maximum levels of vitamin A in infant formula (proposed § 107.100(g)).

The use of *beta*-carotene in infant formula is addressed in § 184.1245(c)(2). FDA proposes to amend § 184.1245(c)(2) to list infant formula among the foods in which *beta*-carotene may be used at levels not to exceed current good manufacturing practice.

c. Decreasing the Minimum Specification From 75 µg RAE/100 kcal to 70 µg RAE/100 kcal

The proposed minimum specification of 70 µg RAE/100 kcal is supported by DRIs, human milk composition data, bioavailability considerations, manufacturing feasibility, and international standards, and provides an appropriate margin of nutritional adequacy for formula-fed infants. FDA relies on NASEM AIs as the most appropriate and conservative reference values for vitamin A requirements in infant formula. Notably, the AI is not equivalent to a minimum requirement, but rather it represents an intake assumed to be adequate based on observed intakes in healthy, breastfed infants (Ref. 62). At the proposed minimum, an infant 0–6 months of age consuming a typical daily infant formula intake would receive 369 µg RAE/day (92 percent of the NASEM AI of 400 µg RAE/day). For infants 6–12 months of age consuming a typical daily infant formula intake, the proposed minimum would provide 284 µg RAE/day from formula. NASEM estimated that complementary foods provide approximately 244 µg/day, yielding a combined intake of approximately 528 µg/day (106 percent of the NASEM AI of 500 µg RAE/day). FDA considers this level of intake adequate to meet the vitamin A needs of formula-fed infants 0–12 months of age, with a low risk of deficiency (Ref. 86).

Human milk composition data from multiple studies (Refs. 8, 94, 95) support a plausible range of approximately 370 to 460 µg retinol/L in mature human milk, corresponding to approximately 57 to 71 µg RAE/100 kcal. The proposed minimum of 70 µg RAE/100 kcal falls at the upper end of this range, indicating that formula-fed infants consuming formula at the proposed minimum would receive vitamin A at concentrations consistent with mature human milk from well-nourished populations. The proposed minimum also exceeds the LSRO recommendation of 60 µg RE/100 kcal and provides a buffer to account for potentially lower vitamin A absorption from formula due to the absence of BSSL (Ref. 86).

Lowering the minimum from 75 to 70 µg RAE/100 kcal also responds to manufacturing feasibility considerations. Manufacturers must account for nutrient degradation over shelf life, lot-to-lot variability in raw material potency, and inherent variation in blending and manufacturing processes when formulating infant formulas. In conjunction with the proposed maximum of 120 µg RAE/100 kcal, a minimum of 75 µg RAE/100 kcal would create an allowable manufacturing range of only 45 µg RAE/100 kcal. Reducing the minimum to 70 µg RAE/100 kcal widens this range to 50 µg RAE/100 kcal without compromising nutritional adequacy, reducing the risk of unintentional noncompliance during manufacturing (Ref. 86).

The proposed minimum of 70 µg RAE/100 kcal aligns with the EU minimum of 70 µg RE/100 kcal (Ref. 38); exceeds the Codex Alimentarius minimum for infant formula, the FSANZ minimum, the Health Canada proposed minimum, and the LSRO recommendation (all 60 µg RE/100 kcal) (Refs. 1, 12, 39, 40); and falls modestly below the Codex Alimentarius minimum for follow-on formula (75 µg RE/100 kcal) (Ref. 37). FDA's use of the NASEM AI as the primary reference value for assessing minimum requirements is consistent with the higher U.S. minimum relative to some international standards (Ref. 86).

FDA assesses that 70 µg RAE/100 kcal is consistent with available data on nutritional adequacy and appropriate as a minimum specification. At this level, estimated intakes for infants 0–6 months of age represent approximately 92 percent of the NASEM AI, within the 15 percent margin below the AI that has been used by other regulatory bodies to indicate low risk of nutritional inadequacy (Ref. 100).

d. Decreasing the Maximum Specification From 225 to 120 µg RAE/100 kcal

FDA's evaluation of the maximum is guided by the NASEM UL of 600 µg RAE/day for infants 0–12 months of age (Ref. 62), which is also supported by EFSA (Ref. 89) and NHMRC/MoH (Ref. 53). The NASEM UL was derived by applying an uncertainty factor of 10 to a LOAEL of 6,000 µg/day, identified from case reports of hypervitaminosis A in infants receiving supplemental preformed vitamin A.

At the current maximum of 225 µg RAE/100 kcal, estimated vitamin A intakes from infant formula substantially exceed the UL across all intake scenarios evaluated. U.S. dietary intake data from multiple national surveys consistently show that mean vitamin A intakes approach or exceed the UL and that 21–39 percent of infants have intakes above the UL (Refs. 81, 82, 84, 97). The current maximum also exceeds that of all other international regulatory standards, none of which permit a maximum above 180 µg RE/100 kcal.

FDA initially considered a maximum of 180 µg RAE/100 kcal, consistent with the Codex standard. However, at typical intake volumes, a maximum of 180 µg RAE/100 kcal would still result in estimated intakes from infant formula alone reaching 158 percent and 122 percent of the UL for infants 0–6 and 7–12 months of age, respectively, and as high as 251 percent and 238 percent of the UL among high consumers (90th percentile of energy intake from infant formula) (Refs. 13, 14, 15, 16, 17, 18). EFSA found that regular consumption of infant formula at the previously permitted maximum of 180 µg RE/100 kcal would result in intakes exceeding the UL (Ref. 7). In the interest of maintaining an adequate safety margin, particularly for high consumers of infant formula, FDA proposes a lower maximum of 120 µg RAE/100 kcal.

At the proposed maximum of 120 µg RAE/100 kcal, estimated vitamin A intakes from infant formula at typical volumes represent 106 percent and 81 percent of the UL for infants 0–6 and 7–12 months of age, respectively. Among high consumers (90th percentile of energy intake) (Refs. 13, 14, 15, 16, 17, 18), estimated intakes from infant formula alone reach 167 percent and 159 percent of the UL for the 0–6-month and 7–12-month age groups, respectively. While intakes exceed the UL under higher intake scenarios, the safety margin relative to the LOAEL improves substantially from approximately 2.9- to 3.2-fold at the current maximum to approximately 4.9- to 9.5-fold at the proposed maximum.

FDA acknowledges that no available data suggest that routine intake of infant formula at current vitamin A levels is associated with adverse events, and that U.S. dietary intake studies did not assess health outcomes associated with vitamin A intake levels (Refs. 81, 82, 84, 86, 97). Nevertheless, FDA considers it appropriate to limit unnecessary exposure to preformed vitamin A above the UL, particularly among high consumers.

The proposed maximum of 120 µg RAE/100 kcal falls within the range of international maximum specifications, which extend from 114 µg RE/100 kcal (EU) to 180 µg RE/100 kcal (Codex Alimentarius, Health Canada, and FSANZ) (Refs. 12, 37, 39, 40) and is below the LSRO recommendation of 150 µg RE/100 kcal (Ref. 1). The proposed maximum of 120 µg RAE/100 kcal is higher than the corresponding EU specification of 114 µg RE/100 kcal. This range is intended to provide manufacturers with sufficient operational flexibility to account for manufacturing overages, nutrient losses during processing, and shelf-life variability while ensuring appropriate vitamin A intakes across the U.S. infant population. FDA acknowledges that, despite a reduction of more than 46 percent from the current maximum, estimated vitamin A intakes among high consumers of infant formula may continue to exceed the UL at the proposed maximum. The safety margin relative to the LOAEL ranges from approximately 4.9- to 9.5-fold across intake scenarios evaluated (Ref. 86).

FDA acknowledges several important uncertainties in the evidence base underlying the proposed specifications for vitamin A in infant formula. The NASEM AI and UL were each derived from a limited number of studies with few participants, and the UL was deliberately set conservatively using a LOAEL rather than a NOAEL (Ref. 62). Human milk retinol concentrations vary substantially across studies, reflecting the influence of lactation stage, milk fat content, maternal vitamin A status, and geographic differences in diet and supplementation practices. The efficiency of vitamin A absorption from infant formula relative to human milk has not been precisely quantified, and the bioconversion efficiency of *beta*-carotene in infants remains unknown (Refs. 62, 95). Finally, none of the available U.S. dietary intake studies assessed health outcomes associated with vitamin A intake levels, limiting the ability to assess health outcomes at current intake levels. Given these

uncertainties, FDA has taken a conservative approach by only slightly decreasing the current minimum to preserve the margin of nutritional adequacy and implementing a large reduction in the maximum that is supported by the available safety evidence and falls within the range of current international maximum specifications (Ref. 86).

H. Sodium

The current requirements for sodium in infant formula are a minimum level of 20 mg/100 kcal and a maximum level of 60 mg/100 kcal (§ 107.100). Based on our analysis of scientific information and data since the 1998 comprehensive study of infant formula nutrients, including infant formula sodium requirements in international standards, we conclude that the required sodium levels in § 107.100 remain appropriate.

1. Background

Sodium is an essential nutrient. It plays a critical role in regulating extracellular fluid volume and blood pressure homeostasis, and it is important for the absorption of amino acids, small peptides, and monosaccharides (Refs. 76, 101, 102). Together with chloride and potassium, sodium maintains osmotic and acid-base balance between intracellular and extracellular compartments and is necessary for transporting solutes across membranes and generating electrical signals in the musculoskeletal and nervous systems (Refs. 101, 102, 103). Sodium also interacts with calcium, as increasing sodium intake has been shown to increase urinary calcium excretion, which may negatively affect bone health (Refs. 76, 101, 102). Approximately 95 percent of total body sodium is extracellular, and the body absorbs approximately 98 percent of dietary sodium consumed across a wide range of intakes (Refs. 76, 101, 102). There is no sensitive or specific biomarker for sodium status, as blood sodium concentrations are tightly controlled by homeostatic mechanisms (Refs. 76, 101, 102).

a. Health Consequences of Sodium Deficiency

Hyponatremia, defined as a sodium concentration in the blood less than or equal to 135 mmol/L, is rarely due to dietary sodium intake; rather, it is typically due to disturbances in free water balance and the hormonal regulation of that balance (Refs. 76, 101, 102). Low dietary sodium intakes are rare in healthy populations because sodium chloride and other sodium salts are ubiquitous in the food supply. Sodium intakes of infants who participated in the 2002 FITS exceeded the AIs (Ref. 43). There are also adaptive physiological mechanisms that reduce sodium losses in urine, feces, and sweat at low intakes, and the term-newborn kidney has sufficient renal absorption and excretion capabilities to minimize obligatory sodium losses (Refs. 1, 76, 101, 102).

b. Health Consequences of Excess Sodium Intake

Hypernatremia, defined as a blood sodium concentration greater than 145 mmol/L, is typically a consequence of dehydration rather than excessive sodium intake (Ref. 76). In adults, excessive sodium intake has been linked to elevated blood pressure and increased risk of cardiovascular disease (Refs. 76, 101, 102). It has been suggested that sodium intake during infancy may influence future blood pressure and taste preferences for sodium; however, the current evidence is insufficient to establish an upper limit of intake for this age group, and more research is needed (Refs. 76, 101, 102).

2. Nutrient Reference Values

a. NASEM

NASEM updated AIs for sodium in infants in its 2019 report, *Dietary Reference Intakes for Sodium and Potassium* (Ref. 76). The AI for infants 0–6 months of age was set at 110 mg/day, based on an estimated mean human milk sodium concentration of 140 mg/L and an assumed average consumption of 0.78 L/day. The AI for infants 7–12 months of age was set at 370 mg/day, based on approximately 70 mg/day from human milk (at 110 mg/L and 0.6 L/day) plus an estimated 300 mg/day from complementary foods. No UL was established for sodium in infants. In 2019, NASEM expanded its DRI model toward establishing DRIs based on chronic disease risk reduction intakes (CDRRs); however, NASEM was unable to establish a CDRR for infants. The absence of a sodium UL reflects an evolution in the DRI model's approach to characterizing risk rather than a change in the evidence regarding risks associated with excessive sodium intake (Refs. 76, 102).

b. EFSA

EFSA published a comprehensive scientific opinion on dietary reference values for sodium in 2019 (Ref. 101). Because insufficient data existed from which an AR could be derived, EFSA established an AI of 200 mg/day for infants 7–11 months of age based on upward extrapolation of the estimated sodium intake of exclusively breastfed infants during the first 6 months of life (midpoint sodium concentration of 150 mg/L and assumed milk transfer of 0.8 L/day = 120 mg/day), adjusted using the ratio of average energy requirements for infants 3 and 9 months of age. EFSA did not establish an AI for infants 0–6 months of age due to insufficient data. No UL was established for sodium in infants (Ref. 101).

c. D–A–CH

In 2017, D–A–CH established estimated values for sodium intake of 130 mg/day for infants 0 to under 4 months of age based on a mean mature human milk sodium concentration of 170 mg/L and an assumed average daily intake of 750 mL of human milk. For infants 4 months to under 12 months of age, the estimated value of 200 mg/day was derived from the 0–4-month value adjusted for differences in average body weight, as complementary food intake data from Germany were unavailable. No UL was established for sodium in infants (Ref. 28).

d. Comparison of International Recommendations

Table 12 shows the sodium AIs established by NASEM, EFSA, and D–A–CH.

TABLE 12—ADEQUATE INTAKES AND TOLERABLE UPPER INTAKE LEVELS OF SODIUM

Organization	Year	Age range (months)	Adequate intake (mg/day)	Tolerable upper intake level
NASEM	2019	0–6	110	ND.
		7–12	370	ND.
EFSA	2019	7–11	200	ND.

TABLE 12—ADEQUATE INTAKES AND TOLERABLE UPPER INTAKE LEVELS OF SODIUM—Continued

Organization	Year	Age range (months)	Adequate intake (mg/day)	Tolerable upper intake level
D–A–CH	2017	0–4	130	ND.
		4–12	200	ND.

All three expert bodies used human milk composition as the primary basis for infant sodium reference values, and none established a UL for sodium in infants (see table 12). The substantially higher NASEM AI for infants 7–12 months (370 mg/day) compared to EFSA (200 mg/day) and D–A–CH (200 mg/day) reflects a key methodological difference: NASEM incorporated estimates of sodium intake from complementary foods, while EFSA and D–A–CH applied body weight scaling or lacked complementary food intake data. All expert bodies acknowledged wide variability in reported human milk sodium concentrations across studies and populations, which complicates the derivation of precise reference values and underscores shared uncertainty in this area (Ref. 102).

3. Human Milk Composition

a. Sodium Concentration in Mature Human Milk

There is no clear correlation between maternal dietary sodium intake and human milk sodium concentrations (Ref. 104). Direct measurements of sodium concentrations in mature human milk across individual study timepoints ranged from approximately 82 to 297 mg/L, reflecting natural variability in human milk (Ref. 102).

b. Recent Data

The iHMNutD study, based on literature synthesis covering mature milk from 21 to 180 days postpartum, included 12 studies with 924 participants with applicable sodium data (Ref. 8). The pooled weighted mean sodium concentration was 14.73 ± 6.99 mg/100 g, which converts to approximately 152 ± 72 mg/L. Eleven of the 12 studies overlap with sources reviewed by EFSA (Ref. 101) and NASEM (Ref. 76) and are drawn from U.S. data sources. All studies with sodium data except the Maternal-Infant Research on Environmental Chemicals (MIREC) study were conducted before 2000, which was identified as a data limitation (Ref. 8).

The MIREC Study (Ref. 105) provides additional recent data from a large Canadian cohort. Samples were collected from 2007 through 2011, from 3.5 to 10 weeks postpartum. The geometric mean sodium concentration for the full sample set (n = 770) was 151 ± 70 mg/L, and for the DRI variable subset (n = 660) was 153 ± 71 mg/L. This study was included among the 12 studies evaluated in the iHMNutD study (Refs. 8, 105).

The MILQ study (Ref. 36) provides the most comprehensive recent data on human milk mineral composition. Median sodium concentrations were 140 mg/L at 1–2 months of age, 111 mg/L at 3–4 months of age, and 97 mg/L at 5–6 months of age, with a pooled 1–6-month median of 111 mg/L (IQR: 87–156 mg/L). Total daily median sodium intake from 1 to 6 months of age was 96.5 mg/day based on measured milk volumes (Ref. 36).

The pooled weighted mean of 152 mg/L reported by the iHMNutD study (Ref. 8) is broadly consistent with values from the MIREC study (151–153 mg/L) (Ref. 105) and converts to approximately 23 mg/100 kcal. The MILQ study pooled median of 111 mg/L corresponds to approximately 17 mg/100 kcal. Together, these values suggest a central reference range of roughly 17–23 mg/100 kcal as reflective of typical mature human milk composition (Ref. 102).

4. International Regulatory Standards for Infant Formula

Sodium specifications for infant formula are generally aligned among international regulatory bodies and expert organizations, and most are closely aligned with Codex Alimentarius standards. The Codex Alimentarius Commission specifies a minimum of 20 mg/100 kcal and a maximum of 60 mg/100 kcal for both infant formula (0–6 months of age) (Ref. 12) and follow-on formula (6–12 months of age) (Ref. 37). The EU, based on recommendations from EFSA (Ref. 7), specifies a minimum of 25 mg/100 kcal and a maximum of 60 mg/100 kcal (Ref. 38). Other countries that have adopted or proposed specifications aligned with Codex Alimentarius include FSANZ (20–59 mg/100 kcal) (Ref. 39) and Health Canada (20–60 mg/100 kcal) (Ref. 40). China specifies 30–59 mg/100 kcal for infants 0–6 months of age (Ref. 41) but has different standards for follow-on formula (6–12 months of age; see table 13) (Ref. 42).

In its 1998 comprehensive review, the LSRO Panel recommended a minimum of 25 mg/100 kcal and a maximum of 50 mg/100 kcal (Ref. 1). The LSRO Panel based the minimum on the 1989 RDA of 120 mg/day for infants less than 6 months of age, which for a 5-kg infant consuming 100 kcal/kg/day equates to 24 mg/100 kcal (rounded to 25 mg/100 kcal). The LSRO Panel was reluctant to use the mean minus one standard deviation approach typically applied to other nutrients due to high coefficients of variation in reported human milk sodium values. The recommended maximum of 50 mg/100 kcal was based on the 90th percentile of FDA analyses of infant formulas available at that time (Ref. 1).

Table 13 shows the requirements and recommendations of these international regulatory bodies and organizations.

TABLE 13—INTERNATIONAL STANDARDS AND/OR RECOMMENDATIONS FOR SODIUM IN INFANT FORMULA

Organization	Age range (months)	Minimum (mg/100 kcal)	Maximum (mg/100 kcal)	Reference
U.S. Current Standards	0–12	20	60	21 CFR 107.100.
LSRO [1]	0–12	25	50	LSRO, 1998.
Codex Alimentarius	0–12	20	60	CXS 72–1981, CXS 156–1987.
EU	0–12	25	60	Commission Delegated Regulation (EU) 2016/127.
Australia [2]	0–12	20	59	FSANZ P1028.
Canada [3]	0–12	20	60	Health Canada, 2025.

TABLE 13—INTERNATIONAL STANDARDS AND/OR RECOMMENDATIONS FOR SODIUM IN INFANT FORMULA—Continued

Organization	Age range (months)	Minimum (mg/100 kcal)	Maximum (mg/100 kcal)	Reference
China	0–6	30	59	GB 10765–2021.
	6–12	ND	84	GB 10766–2021.

[1] Recommended ranges.
[2] Values converted from per 100 kJ to per 100 kcal (1 kcal = 4.184 kJ).
[3] Reflects proposed compositional requirements for infant formula.

5. Recent Scientific Evidence on Sodium Intake

Reported sodium intakes in U.S. infants 0–12 months of age consistently met or exceeded the NASEM AIs across datasets reviewed, including two iterations of FITS (FITS 2008 and FITS 2016) and one cycle of NHANES (NHANES 2009–2012) (Refs. 81, 82, 84). For infants 0–5.9 months of age, FITS 2016 reported a mean usual sodium intake of 214 mg/day (10th–90th percentile: 107–347 mg/day), and FITS 2008 reported a mean of 175 mg/day for 0–5 months of age (10th–90th percentile: 138–240 mg/day), both exceeding the NASEM AI of 110 mg/day. For infants 6–11.9 months of age, mean usual sodium intakes were higher across all three surveys: FITS 2016 reported a mean of 400 mg/day (10th–90th percentile: 207–634 mg/day), FITS 2008 reported 528 mg/day (10th-90th percentile: 165–1,104 mg/day), and NHANES 2009–2012 reported 497 mg/day (10th-90th percentile: 163–946 mg/day), all exceeding the NASEM AI of 370 mg/day. In FITS 2016, approximately 49 percent of older infants exceeded the AI, and the wide 10th-to-90th percentile ranges observed across all surveys, particularly for the 6–11-month age group, indicate substantial variability in sodium exposure across the infant population.

Several methodological considerations must be factored in when interpreting these data. Human milk sodium content is relatively low and fixed by imputed volume rather than directly measured, so there may be limited precision when estimating sodium intakes in breastfed infants. All three studies rely on proxy-reported 24-hour dietary recalls, subject to recall bias. The statistical methods used to estimate usual intake distributions differ slightly across studies, though the approaches are designed to remove within-person variation and are broadly comparable. Additionally, the AI for sodium in infants is derived from estimated mean intakes from human milk in healthy, exclusively breastfed infants rather than from experimental dose-response data; consequently, exceeding the AI does not necessarily indicate risk of adverse health effects. Taken together, the data indicate that mean sodium intakes in U.S. infants meet or exceed the NASEM AIs across both age subgroups.

6. Evidence Evaluation and Rationale

Based on our review of available scientific data, information, and international standards, we conclude that the current minimum level of 20 mg/100 kcal and maximum level of 60 mg/100 kcal for sodium in § 107.100 remain appropriate.

a. Maintaining the Minimum Specification of 20 mg/100 kcal

The current minimum specification of 20 mg/100 kcal is supported by human milk composition data, intake-based reference value approaches, and international regulatory standards. Recent North American data from the MIREC study (Ref. 105) and the iHMNutD study (Ref. 8) converge on a central estimate of approximately 23 mg/100 kcal, while the multinational MILQ study (Ref. 36) suggests a somewhat lower value of approximately 17 mg/100 kcal, together defining a central reference range of approximately 17–23 mg/100 kcal for mature human milk sodium content. The reaffirmed minimum of 20 mg/100 kcal falls within this range. Applying the current NASEM AI of 110 mg/day using the same intake-based approach used by the LSRO yields an estimate of 22 mg/100 kcal, consistent with the North American central estimate and further supporting the current minimum (Refs. 1, 76, 102).

The current minimum requirement ensures that infant formula provides sodium intakes that pose a low risk of inadequacy relative to established AIs. For an infant 0–6 months of age consuming a typical daily infant formula intake, formula at the minimum specification provides 105 mg/day of sodium, which is 96 percent of the NASEM AI of 110 mg/day for infants 0–6 months of age. For an infant 0–4 months of age, this consumption level provides 81 percent of the D–A–CH AI of 130 mg/day for that age subset. For a 6–12-month-old infant consuming a typical daily intake of infant formula, the minimum specification provides 81 mg/day from formula, which is 22 percent of the NASEM AI of 370 mg/day, 40 percent of the EFSA AI of 200 mg/day for 7–11-month-old infants, and 40 percent of the D–A–CH AI of 200 mg/day for 4–12-month-old infants. However, for infants 7–12 months of age, estimated sodium intake from complementary foods of approximately 300 mg/day (Ref. 76) would contribute substantially to total sodium intake, bringing the total daily intake to approximately 381 mg/day, which is 103 percent of the NASEM AI (Ref. 102).

The current minimum aligns with international standards. The U.S. minimum of 20 mg/100 kcal is the same as Codex Alimentarius, FSANZ, and Health Canada but lower than the EU minimum of 25 mg/100 kcal as well as China's minimum of 30 mg/100 kcal. The current U.S. specification of 20 mg/100 kcal falls within this international consensus range, and no compelling evidence from other jurisdictions suggests that changing the minimum would provide any benefit (Ref. 102).

b. Maintaining the Maximum Specification of 60 mg/100 kcal

The current maximum provides a substantial margin above the central estimates of sodium content of mature human milk (approximately 17–23 mg/100 kcal) (Refs. 8, 36, 105). The LSRO Panel's 1998 recommendation of 50 mg/100 kcal as a maximum, although lower than the current specification, was based on the 90th percentile of sodium content in infant formulas available at that time, rather than on safety concerns, as the LSRO Panel found no evidence that excessive sodium intake caused adverse effects at these levels (Ref. 1). Finally, it is unclear if the difference between 50 and 60 mg/100 kcal reflects any functional significance, and the current maximum is aligned with international standards (Ref. 102).

History of use and available intake data also support safety at the current maximum. At typical daily infant formula intake volumes, the current maximum would provide approximately 316 mg/day for an infant 0–6-months of

age and 244 mg/day for an infant 6–12 months of age. Findings from the 2016 FITS reported mean sodium intakes of 214 mg/day (0–6 months of age) and 400 mg/day (6–11 months of age) (Ref. 82), although these estimates included intake from all dietary sources, including infant formula and complementary foods (Ref. 102).

Further, no upper limit or CDRR has been established for infants, and the current specification has not been associated with documented adverse effects in contemporary populations since 1980 when the Infant Formula Act was enacted. The evidence base for characterizing sodium intake-response relationships in infants remains limited, and findings derived from adult populations were extrapolated to children but not to infants (Ref. 76). This indicates that the current maximum level is sufficient to ensure nutritional adequacy in U.S. infants without adverse effects. The specifications are well-positioned within international regulatory consensus, and we find no compelling new evidence demonstrating functional benefits of modification or documented adverse effects at current levels (Ref. 102).

c. Consideration of the Evidence Base

We acknowledge several uncertainties in the evidence base that supports maintaining the current specifications. There is variability in reported mature human milk concentrations for sodium across studies (82 to 297 mg/L), lack of a sensitive or specific biomarker of sodium status and intake, and individual variability in infant requirements (Ref. 102). Nevertheless, FDA concludes that the totality of available evidence, including contemporary human milk composition data, alignment with international standards, and the longstanding history of use without documented safety concerns, supports maintaining the current minimum and maximum sodium specifications.

I. Vitamin D (Proposed §§ 107.10(a)(2), (b)(1), and 107.100(a))

The current requirements for vitamin D in infant formula are a minimum level of 40 IU/100 kcal (1 µg/100 kcal) and a maximum level of 100 IU/100 kcal (2.5 µg/100 kcal) (§ 107.100). Based on our analysis of scientific information and data since the LSRO Panel's 1998 comprehensive study of infant formula nutrients (Ref. 1), including infant formula vitamin D requirements in international standards, we propose to increase the required minimum to 2 µg/100 kcal (80 IU/100 kcal) and to increase the required maximum to 3 µg/100 kcal (120 IU/100 kcal) in § 107.100. We also propose to change the primary unit of measure from IU to µg in §§ 107.10(a)(2) and (b)(1) and 107.100.

1. Background

Vitamin D is a fat-soluble vitamin and essential nutrient important for calcium absorption, skeletal mineralization, and the prevention of rickets. The two major forms are vitamin D_2 (ergocalciferol), derived from plants and fungi, and vitamin D_3 (cholecalciferol), found in select animal-derived foods and synthesized in the skin with sunlight exposure. Both forms are also found in dietary supplements and fortified foods (Refs. 91, 106, 107). Vitamin D is generally present at low levels in human milk (Refs. 95, 106, 107, 108).

Vitamin D is recognized as a prohormone, as it undergoes two reactions before becoming biologically active. The first, occurring in the liver, produces 25-hydroxyvitamin D (25(OH)D; calcidiol), the major circulating form of vitamin D. The second, occurring in the kidney, converts 25(OH)D to 1,25-dihydroxyvitamin D ($1,25(OH)_2D$; calcitriol), the metabolically active form (Refs. 91, 106). The main function of calcitriol is to increase plasma calcium and phosphate, which are required for the mineralization of bone and the development and maintenance of skeletal health (Ref. 106). Calcitriol also regulates gene expression in a wide range of tissues throughout the body through binding to the vitamin D receptor (Ref. 106).

Serum 25(OH)D concentration is an indicator of total vitamin D exposure, which includes vitamin D intake from food and supplements, as well as synthesis from sun exposure (Ref. 106). The 2011 DRI report for calcium and vitamin D notes that while serum 25(OH)D cannot be considered a validated health outcome surrogate, it allows comparison of intake or exposure with health outcomes (Ref. 106). The DRI committee's review of data suggested that relative to bone health, individuals are at risk of deficiency at serum 25(OH)D concentrations below 30 nmol/L (12 ng/mL); some, but not all, individuals are potentially at risk for inadequacy at serum 25(OH)D concentrations between 30 and 50 nmol/L (12 and 20 ng/mL); practically all individuals are sufficient at serum 25(OH)D concentrations of at least 50 nmol/L (20 ng/mL); and there may be reason for concern with serum 25(OH)D concentrations above 125 nmol/L (50 ng/mL) (Ref. 106). Consistent with NASEM's framework, the American Academy of Pediatrics (AAP) and the Pediatric Endocrine Society endorse a target serum 25(OH)D of greater than or equal to 50 nmol/L (20 ng/mL) for vitamin D adequacy (Ref. 91). Deficiency is generally defined as a concentration below 30 nmol/L (12 ng/mL) and insufficiency as 30–49 nmol/L (13–19 ng/mL) (Refs. 91, 106).

a. Health Consequences of Vitamin D Deficiency

Vitamin D deficiency results in inadequate skeletal mineralization. Clinical manifestations include hypocalcemia (*i.e.*, low blood calcium), hypophosphatemia (*i.e.*, low blood phosphorus), tetany (*i.e.*, involuntary spasms, muscle cramps, and twitching), rickets (a metabolic bone disease characterized by widening at the ends of long bones), rachitic rosary (a clinical and x-ray finding of bead-like swellings at the joints where the ribs meet the costal cartilage), skeletal deformities, lower limb deformities, and muscle weakness and pain (Refs. 91, 106). Because the periods of infancy and childhood represent critical windows of skeletal development, ensuring adequate vitamin D intake during these stages is essential to prevent these clinical outcomes, underscoring the importance of appropriate vitamin D in infant formula and early childhood nutrition. Serum 25(OH)D concentrations below 27–30 nmol/L are associated with increased risk of rickets when calcium intakes are limited (Refs. 106, 109, 110). No reports of clinical deficiency have been documented in infants receiving 400 IU/day of vitamin D, and this intake level generally maintains serum 25(OH)D above 50 nmol/L (Refs. 106, 108). Vitamin D deficiency may also manifest as hypocalcemic seizures. Although most commonly reported in breastfed infants, case reports have documented this outcome in formula-fed infants when compounding risk factors are present, including limited sun exposure, poor maternal vitamin D status during pregnancy, and low formula intake volumes (Refs. 108, 111, 112).

Populations at heightened risk for vitamin D deficiency include exclusively breastfed infants, infants with dark skin pigmentation, preterm infants, and infants with dietary fat malabsorption (Refs. 91, 106). Additional risk factors include reduced sunlight exposure, maternal vitamin D deficiency, sex, and having a mother who has given birth more than two times (Refs. 113, 114). A co-occurrence of multiple risk factors may substantially amplify risk (Ref. 113).

b. Health Consequences of Excess Vitamin D Intake

Excess vitamin D dietary intake can lead to hypervitaminosis D (*i.e.,* a toxic condition resulting from excessive vitamin D). In contrast, toxic levels of vitamin D do not occur from prolonged sun exposure, as thermal activation of previtamin D3 in the skin gives rise to multiple non-vitamin D forms that limit the formation of vitamin D (Ref. 106). Hypervitaminosis D leads to hypercalcemia (*i.e.,* high blood calcium) and hypercalciuria (*i.e.,* high urine calcium) and can eventually cause soft tissue calcification and renal and cardiovascular damage (Refs. 91, 106, 107). Symptoms of hypervitaminosis D in children are similar to those of hypercalcemia, including feeding difficulties, excessive or abnormal thirst and urine production, diarrhea, irritability, poor weight gain, and increased deep tendon reflexes (Ref. 1). In infants, excess intake for greater than 6 months may adversely affect linear growth (Refs. 106, 108).

c. Vitamin D_2 and Vitamin D_3: Bioavailability Considerations

Both vitamin D_2 and D_3 are permitted for use in infant formula. The structural difference between the two forms does not affect intestinal absorption or the reaction required for activation to calcitriol, the biologically active form of vitamin D (Ref. 106). The available scientific literature on the relative bioavailability and potency of vitamin D_2 compared with vitamin D_3 in humans presents mixed findings. The 2011 NASEM DRI report concluded that ''firm conclusions about different effects of the two forms of vitamin D cannot be drawn,'' while observing that ''it would appear that at low doses, D_2 and D_3 are equivalent, but at high doses, D_2 is less effective than D_3,'' in terms of raising the serum 25(OH)D concentration (Ref. 106). Data comparing the effects of vitamin D_2 and vitamin D_3 specifically in infants are limited. The EFSA NDA Panel, in its 2018 scientific opinion on the UL for vitamin D in infants, reviewed the available infant-specific evidence and concluded that ''the limited data available on infants . . . do not allow a conclusion to be drawn on whether there is a difference between vitamin D_2 and D_3 as regards their impact on serum 25(OH)D concentrations in infants'' (Ref. 115).

2. Nutrient Reference Values

a. NASEM

The 2011 NASEM DRI report established an AI for vitamin D of 400 IU (10 µg)/day for both infants 0–6 months of age and infants 6–12 months of age, as available data were insufficient to support derivation of an EAR for infants under 12 months of age (Ref. 106). This AI assumes minimal sun exposure contributing to vitamin D synthesis as well as adequate calcium intakes. Calcium and vitamin D are physiologically interdependent with respect to bone health outcomes, and an inadequacy in one may alter the body's handling of or response to the other (Ref. 106). Clinical studies have demonstrated that an intake of 400 IU (10 µg)/day is generally consistent with maintaining serum 25(OH)D concentrations above 50 nmol/L in infants, and no cases of clinical vitamin D deficiency have been reported at this level (Ref. 106).

The vitamin D AI for infants could not be derived from the nutrient content of human milk, as human milk does not provide a meaningful amount of vitamin D. Instead, the AI was based on evidence indicating that serum 25(OH)D ''above 30 nmol/L, and more likely closer to 50 nmol/L, appears to cover adequately the needs of the majority of the infants and support normal bone accretion'' (Ref. 106).

NASEM established separate ULs of 1,000 IU (25 µg)/day for infants 0–6 months of age and 1,500 IU (38 µg)/day for infants 6–12 months of age. The indicator selected for establishing these ULs was decreased linear growth. These ULs were derived from an NOAEL of approximately 1,800 IU (45 µg)/day established from mean intakes in a 1966 study, with an uncertainty factor of approximately 0.5 applied for infants 0–6 months of age to account for smaller body weight, and a 500 IU (12.5 µg)/day upward adjustment for infants 6–12 months of age to reflect their greater body mass and organ maturation (Ref. 116). NASEM acknowledged that decreased linear growth is a relatively insensitive endpoint and that dose-response relationships for adverse outcomes in infants are not well characterized (Ref. 106).

b. EFSA

In 2016, the EFSA NDA Panel established an AI for vitamin D of 10 µg/day for infants 7–11 months of age based on several trials conducted in mostly breastfed infants (Ref. 107). Two studies showed that supplementation with 10 µg/day of vitamin D_3 for at least 15 weeks led to achieved mean or median serum 25(OH)D concentrations of at least 80 nmol/L. This finding was consistent with conclusions from NASEM (Ref. 106) and recent trials that demonstrated that 10 µg/day of vitamin D_3 in primarily breastfed infants was adequate to achieve plasma/serum 25(OH)D concentrations of at least 50 nmol/L (Refs. 106, 107).

In 2018, EFSA revised the ULs for vitamin D in infants, establishing 25 µg/day for infants up to 6 months of age and 35 µg/day for infants 6 to less than 12 months of age. The EFSA Panel's systematic literature review of studies on four adverse health outcomes, specifically hypercalciuria, hypercalcemia, nephrocalcinosis (*i.e.,* abnormal deposits of calcium in the kidney tissue), and abnormal growth patterns, concluded that the available evidence on these endpoints was insufficient to derive a UL. The EFSA Panel instead used serum 25(OH)(D) concentration as an endpoint and concluded that a serum 25(OH)(D) concentration of 200 nmol/L or below is unlikely to pose a risk of adverse health outcomes in healthy infants. This value was not regarded as a toxicity threshold but rather as a conservative reference point from which the UL could be derived. The EFSA Panel estimated the proportion of infants expected to exceed this threshold at various intakes. The updated ULs apply to both vitamin D_2 and D_3, though the dose-response analysis was based predominantly on vitamin D_3 supplementation data (Ref. 115).

c. Australian NHMRC/New Zealand MoH

NHMRC/MoH established an AI for vitamin D of 5 µg/day for infants 0–12 months of age. This recommendation assumes little to no sunlight exposure. The AI is based on the lowest dietary intake of vitamin D that is associated with a mean serum 25(OH)D concentration above 27.5 nmol/L. While a minimal intake of 2.5 µg/day may be sufficient to prevent rickets in infants 0–6 months of age, the AI was set at 5 µg/day to provide an additional margin of adequacy, as many infants at the lower intake level may still present with 25(OH)D concentrations within the range associated with rickets when sunlight exposure is absent. NHMRC/MoH noted that several studies have demonstrated that 5 µg/day is adequate for older infants and for formula-fed infants (Ref. 53).

The UL for vitamin D for infants 0–12 months of age was set at 25 µg/day, based on a NOAEL of 45 µg/day with an uncertainty factor of 1.8. The uncertainty factor reflects the small sample sizes and the relative insensitivity of the endpoint used (linear growth) in the studies informing the NOAEL (Ref. 53).

d. FAO/WHO

The joint FAO/WHO Consultation established a RNI of 5 µg/day for vitamin D for infants 0–6 months and 7–12 months of age (Ref. 3). This value was derived using plasma 25(OH)D as the primary indicator of vitamin D status, with the goal of maintaining concentrations above 27 nmol/L, the threshold associated with normal bone health. The Consultation did not establish a UL for infants (Ref. 3).

e. Comparison of International Recommendations

Table 14 shows the vitamin D AIs established by NASEM, EFSA, NHMRC/MoH, and FAO/WHO.

TABLE 14—ADEQUATE INTAKES AND TOLERABLE UPPER INTAKE LEVELS OF VITAMIN D

Organization	Year	Age range (months)	Adequate intake	Tolerable upper intake level
NASEM	2011	0–6	400 IU (10 µg)	1,000 IU (25 µg).
		6–12	400 IU (10 µg)	1,500 IU (38 µg).
EFSA	2016 (AI)	7–11	10 µg.	
	2018 (UL)	0–<6		25 µg.
		6–12		35 µg.
Australia NHMRC/New Zealand MOH	2006	0–6	5 µg	25 µg.
		7–12	5 µg	25 µg.
FAO/WHO	2004	0–6	5 µg*	ND.
		7–12	5 µg*	ND.

* Values established are RNI levels.

With respect to adequate intake, NASEM (Ref. 106) and EFSA (Ref. 107) both arrived at 10 µg/day (400 IU/day), while NHMRC/MoH (Ref. 53) and FAO/WHO (Ref. 3) established lower values of 5 µg/day. NASEM based its AI on evidence that serum 25(OH)D concentrations of approximately 50 nmol/L are sufficient to meet the needs of most infants (Ref. 106). EFSA similarly targeted 50 nmol/L as a minimum threshold but derived its AI from supplementation trials demonstrating achieved concentrations of at least 80 nmol/L at 10 µg/day and applied the value only to infants 7–11 months of age, without establishing a separate AI for younger infants (Refs. 107). By contrast, NHMRC/MoH and FAO/WHO both used a lower 25(OH)D threshold of 27–27.5 nmol/L to derive their respective values (Refs. 3, 53). With respect to ULs, NASEM (25–38 µg/day), EFSA (25–35 µg/day), and NHMRC/MoH (25 µg/day) all established infant ULs at or above 25 µg/day. Despite differing methodologies, all bodies that established a UL arrived at values within a similar range (Ref. 108).

3. Human Milk Composition

It is well established that human milk is generally not a meaningful source of vitamin D for infants. The MILQ study reported a pooled median antirachitic activity (*i.e.,* vitamin D activity to prevent or cure rickets) of 30.6 IU/L (approximately 0.765 µg/L; excluding Bangladesh, n = 1,461) in mature milk, representing only 61–77 percent of NASEM's estimated human milk vitamin D concentration of 40–50 IU/L (Ref. 95). The corresponding pooled median total infant intake from 1 to 6 months of age was 24.4 IU/day (0.61 µg/d), approximately 6 percent of the NASEM AI of 400 IU/day (Ref. 95). No eligible North American studies for total vitamin D in mature human milk were identified by the iHMNutD study. Only a single eligible North American study for 25(OH)D was identified (n = 21; mean: 0.13 µg/100 g; approximately 1.3 µg/L using the specific gravity of human milk of 1.031 g/mL). The authors cautioned that this 25(OH)D value is based solely on data from one study (Ref. 8). Globally, a 2026 systematic review similarly identified vitamin D as ''the nutrient most vulnerable to inadequacy among exclusively breastfed infants'' (Refs. 108, 117).

4. International Regulatory Standards for Infant Formula

International standards for vitamin D in infant formula are generally aligned with a minimum of 1 µg/100 kcal, with the exceptions of the EU and China (Refs. 38, 41, 42), which set higher minimums of 2 µg/100 kcal. Maximum specifications show somewhat greater variation, with the United States, Codex Alimentarius, the EU, and Canada sharing a common maximum of 2.5 µg/100 kcal for infants 0–6 months of age, while Codex Alimentarius, the EU, Australia, and Canada permit a higher maximum of 3 µg/100 kcal for older infants 6–12 months of age (Refs. 12, 37, 38, 39, 40, 118). China specifies a notably higher maximum of 5 µg/100 kcal for infants 0–12 months of age. Where rationale is provided, the allowance of a higher maximum for older infants reflects their greater tolerability for vitamin D, as evidenced by higher ULs established by NASEM for this age group, as well as their higher calcium requirements relative to younger infants (Refs. 40, 108).

In 1998, the LSRO Panel recommended a minimum of 40 IU (1 µg)/100 kcal and a maximum of 100 IU (2.5 µg)/100 kcal, based on long-standing use of the minimum in industrialized countries, elimination of nutritional rickets in formula-fed infants, and the 90th percentile of vitamin D content in commercially available formulas at the time (Ref. 1). In 2018, EFSA evaluated the safety of infant formula containing a maximum vitamin D content of 3 µg/100 kcal, the value established under Commission Delegated Regulation (EU) 2016/127 (Ref. 38). EFSA found that some high-consuming infants under 4 months of age could receive intakes approaching or exceeding the UL of 25 µg/day from infant formula alone. Following the assessment, the European Commission lowered the maximum vitamin D level for infant formula for infants 0–6 months of age from 3 µg/100 kcal back to 2.5 µg/100 kcal (Refs. 115, 118).

Table 15 shows the requirements and recommendations of these international bodies and organizations.

TABLE 15—INTERNATIONAL STANDARDS AND/OR RECOMMENDATIONS FOR VITAMIN D IN INFANT FORMULA

Organization	Age range (months)	Minimum (µg/100 kcal)	Maximum (µg/100 kcal)	Reference
U.S. Current Standards [1] [2]	0–12	1 (40 IU)	2.5 (100 IU)	21 CFR 107.100.
LSRO [3]	0–12	1	2.5	LSRO, 1998.
Codex Alimentarius	0–6	1	2.5	CXS 72–1981.
	6–12	1	3	CXS 156–1987.
EU	0–6	2	2.5	Commission Delegated Regulation (EU) 2019/828, amending Delegated Regulation (EU) 2016/127.
	6–12	2	3	Commission Delegated Regulation (EU) 2016/127.
Australia [4]	0–6	1	2.6	FSANZ P1028.
	6–12	1	3	
Canada [5]	0–6	1	2.5	Health Canada, 2025.
	6–12	1	3	
China	0–12	2	5	GB 10765–2021, GB 10766–2021.

[1] Values converted from international units (40 IU = 1 µg).
[2] Vitamin D may also be declared on the label content in units of µg cholecalciferol. When these declarations are made, they shall appear in parentheses immediately following the declarations in IU (21 CFR 107.10(b)(1)).
[3] Recommended ranges.
[4] Values converted from per 100 kJ to per 100 kcal (1 kcal = 4.184 kJ).
[5] Reflects proposed compositional requirements for infant formula.

5. Recent Scientific Evidence on Vitamin D Intake

A 2020 systematic review evaluating the effect of vitamin D supplementation in healthy, breastfed infants found evidence from six studies (n=334) indicating that supplementation at 400 IU/day was associated with a mean increase in serum 25(OH)D of 22.63 nmol/L (95 percent CI: 17.05 to 28.21) and a statistically significant reduction in the incidence of vitamin D insufficiency (serum 25(OH)D <50 nmol/L) (Risk ratio 0.57; 95 percent CI: 0.41 to 0.80) compared to placebo or no treatment (Ref. 119). The certainty of the evidence was rated as low to very low. This systematic review concluded that the evidence was insufficient to determine whether supplementation at this dose reduces deficiency (25(OH)D <30 nmol/L), improves bone mineral content, reduces the incidence of nutritional rickets, or affects growth (Refs. 108, 119).

A 2024 systematic review and individual participant data meta-analysis (120 studies; 5,412 participants), sought to identify a minimum serum 25(OH)D threshold associated with reduced risk of nutritional rickets in children under 4 years of age (Ref. 110). A key contribution of this analysis was its ability to account for the confounding effect of dietary calcium intake on the risk of rickets. When analyses were restricted to children with adequate calcium intake, the serum 25(OH)D threshold at which sensitivity and specificity for rickets were simultaneously maximized was approximately 28 nmol/L. When the full dataset was considered, this threshold increased to 40 nmol/L, reflecting the elevated vitamin D requirement in the presence of inadequate dietary calcium. The authors concluded that a minimum serum 25(OH)D concentration of approximately 28 nmol/L represents a low risk of nutritional rickets for most children with adequate calcium intake, a finding consistent with the positions of NASEM (Ref. 106) and other agencies in the development of vitamin D dietary reference values (Refs. 108, 110).

A 2024 meta-regression analysis examined the relationship between total dietary vitamin D intake and serum 25(OH)D concentrations in children under 4 years of age (Ref. 120). The analysis used a multilevel, multivariable dose-response approach and included 31 randomized controlled trials enrolling healthy children who received vitamin D supplements or fortified foods. Studies were excluded if they enrolled premature/low birth weight infants or children with conditions such as rickets (Ref. 120). The trials covered a wide range of total vitamin D intakes (0.6 to 57 µg/day), with a median of 11 µg/day. To translate the dose-response model into population-level intake recommendations, the authors simulated 100,000 individual serum 25(OH)(D) responses at each vitamin D intake level. The modeling demonstrated that a total daily vitamin D intake of 10 µg/day (400 IU/day) would maintain serum 25(OH)D above 28 nmol/L in 97.3 percent of young children, and that an intake of 35 µg/day (1,400 IU/day) would result in fewer than 1.5 percent of individuals exceeding a serum 25(OH)D concentration of 200 nmol/L, a NOAEL with respect to hypercalcemia and hypercalciuria. The authors acknowledged that the overall certainty of evidence was rated as low (Ref. 120).

U.S. dietary intake data indicate that inadequate vitamin D intake is common among infants across feeding types. Analysis of NHANES data found that only approximately 27 percent of U.S. infants met AAP guidelines for vitamin D between 2009 and 2016 (Ref. 121). Data from the 2016 FITS indicate that vitamin D was one of only two nutrients for which mean total intakes (including supplements) did not exceed the AI. Mean intakes were approximately 260 IU/day (6.5 µg/day) for infants 0–5.9 months of age and 296 IU/day (7.4 µg/day) for infants 6–11.9 months of age, with only 17 percent and 24 percent of infants in these respective age groups meeting the AI (Ref. 82). A longitudinal study of infants enrolled in the U.S. Department of Agriculture's (USDA) Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) found that despite the higher vitamin D intakes associated with formula feeding compared to breastfeeding, the proportion of formula-fed infants meeting the vitamin D AI ranged from only approximately 16–43 percent across time points (Ref. 122). Vitamin D supplementation was reported in only 4–5 percent of formula-fed infants.[2] Overall, only 16–36 percent of all WIC-enrolled infants, including those across all feeding types, met the vitamin D recommendation at any given time point (Ref. 122).

[2] WIC Program funds may not be used to purchase or issue dietary supplements, including vitamin D supplements.

6. Evidence Evaluation and Rationale

a. Rationale for Changing the Unit of Measure From IU to µg

Expert scientific bodies and international regulatory standards increasingly express vitamin D content in weight-based units (µg) rather than IU. Vitamin D specifications for infant formula currently must be expressed in IU (§ 107.10(a)(2)). In FDA's 2016 final rule revising the Nutrition and Supplement Facts labels, FDA replaced IUs with weight-based units for vitamin D on labels for conventional foods and dietary supplements, citing changes in understanding of vitamin activity and consistency with IOM DRI report units (81 FR 33742 at 33912). FDA considers that the same scientific rationale supports expressing vitamin D specifications for infant formula in µg, consistent with current labeling regulations, NASEM DRI values, and international infant formula standards. The conversion factor of 40 IU = 1 µg is universally accepted. FDA proposes to amend § 107.10(a)(2) to require that vitamin D specifications be expressed in µg with voluntary declaration of IU equivalents provided parenthetically, supporting continuity for healthcare providers and caregivers accustomed to IU-based expressions (Ref. 108). FDA also proposes to amend the table at § 107.100(a) to reflect the unit of measurement for vitamin D as µg rather than IU.

FDA proposes to express vitamin D specifications and label declarations for infant formula in micrograms of vitamin D, µg, encompassing both vitamin D_2 (ergocalciferol) and vitamin D_3 (cholecalciferol), rather than in micrograms of cholecalciferol alone. Currently, § 107.10(b)(1) specifies that vitamin D may be voluntarily declared on the label in units of µg cholecalciferol parenthetically following the declaration in IUs. Both vitamin D_2 and vitamin D_3 are currently permitted for use in infant formula individually or in combination (21 CFR 184.1950). Permitting declaration solely in µg of cholecalciferol would not accurately reflect the total vitamin D content of infant formulas containing vitamin D_2, either alone or in combination with vitamin D_3. As noted in section I.1.c of this document, the available scientific evidence of intake levels consistent with typical formula consumption does not demonstrate statistically significant differences in serum 25(OH)D response between vitamin D_2 and vitamin D_3, consistent with the conclusion of the 2011 NASEM report that ''it would appear that at low doses, D_2 and D_3 are equivalent'' (Ref. 106).

Accordingly, FDA considers that expressing vitamin D content as total µg vitamin D is scientifically appropriate, as it represents the combined antirachitic activity provided to the infant. This approach is also consistent with international infant formula standards, which specify and declare vitamin D content in terms of total vitamin D rather than by individual form (table 15), and with current U.S. nutrition labeling regulations for conventional foods and dietary supplements, which similarly declare vitamin D on a total basis in µg. Therefore, FDA proposes to amend § 107.10(a)(2) to require that vitamin D be expressed in µg. FDA also proposes to amend § 107.10(b)(1) to permit voluntary declaration in IU in parentheses following the declaration in µg, and to remove the option of expressing vitamin D in µg cholecalciferol.

b. Rationale for Increasing the Minimum Specification to 2 µg (80 IU)/100 kcal

Multiple independent assessments support 10 µg (400 IU)/day as an appropriate vitamin D intake for infants. NASEM established an AI of 10 µg/day for infants 0–12 months of age, EFSA independently arrived at the same AI for infants, and dose-response modeling predicted that this intake level would maintain serum 25(OH)D above 28 nmol/L in 97.3 percent of young children (Ref. 120). These independent assessments using different methodological approaches all support 10 µg (400 IU)/day as the basis for the minimum vitamin D specification in infant formula (Ref. 108).

U.S. dietary intake data suggest risk for inadequate vitamin D intake among U.S. infants (Refs. 82, 108, 121, 122). Although dietary intake data carry inherent measurement limitations, findings across these studies, conducted in both WIC and non-WIC populations using different methodologies, are consistent in suggesting that a substantial proportion of U.S. infants, including those who are formula-fed, are at risk of vitamin D intakes below the AI (Ref. 108).

At the current minimum of 1 µg (40 IU)/100 kcal, an infant 0–6 months of age consuming a typical daily infant formula intake would receive approximately 5.3 µg (211 IU)/day from infant formula, representing 53 percent of the NASEM AI of 10 µg (400 IU/day). To achieve the full AI at the current minimum, an infant would need to consume approximately 1,000 kcal/day from formula, a volume substantially exceeding typical intake for this age group. For infants 6–12 months of age consuming typical daily infant formula intakes, vitamin D intake at the current minimum would be approximately 4.1 µg (163 IU)/day, representing only 41 percent of the AI. FDA considers these intakes insufficient to reliably meet vitamin D needs in either age group.

In contrast, at the proposed minimum of 2 µg (80 IU)/100 kcal, an infant 0–6 months of age consuming a typical daily intake of infant formula would receive 10.5 µg (422 IU)/day from infant formula, representing 105 percent of the NASEM AI. For infants 6–12 months of age consuming a typical daily intake of infant formula, vitamin D intake at the proposed minimum would be approximately 8.1 µg (324 IU)/day, representing approximately 81 percent of the AI from formula alone. FDA considers this level of intake from infant formula to be sufficient to support meeting the AI when accounting for the typical patterns of formula feeding as well as complementary food contributions in older infants.

The proposed minimum of 2 µg (80 IU)/100 kcal aligns with or exceeds international standards (table 15). Both the EU and China specify a minimum of 2 µg/100 kcal for infant formula. Codex Alimentarius, Australia, Canada, and the LSRO Panel specify a minimum of 1 µg/100 kcal. The LSRO Panel noted that the 1 µg (40 IU)/100 kcal minimum had eliminated nutritional rickets in formula-fed infants and, noting that the RDA for vitamin D was 300 IU/day at that time, found no scientific justification to recommend a change (Ref. 1). The NASEM AI and the available U.S. dietary intake data indicate that the current minimum does not reliably support attainment of the AI across the range of typical infant formula consumption volumes. FDA considers that the proposed minimum of 2 µg (80 IU)/100 kcal more appropriately supports infants in meeting current nutrient reference values.

c. Rationale for Increasing the Maximum Specification to 3 µg (120 IU)/100 kcal

FDA's evaluation of the maximum is guided by the NASEM ULs of 25 µg (1,000 IU)/day for infants 0–6 months of age and 38 µg (1,500 IU)/day for infants 6–12 months of age. As discussed in section V.I.2.a of this document, NASEM used an endpoint of decreased linear growth (Ref. 106). NASEM noted that this endpoint is relatively insensitive and that newer data have not emerged to better characterize dose-response relationships or hypercalcemia risk in infants, representing a source of ongoing uncertainty (Ref. 106). EFSA established concordant ULs of 25 µg/day

for infants under 6 months of age and 35 µg/day for infants 6 to less than 12 months of age (Ref. 115). The modeling study similarly found that a daily intake of 35 µg/day would result in fewer than 1.5 percent of young children (under 4 years of age) exceeding serum 25(OH)D of 200 nmol/L (Ref. 120). The authors rated the overall certainty of evidence as low (Ref. 120). The convergence of assessments around similar ULs, despite differing methodologies, provides a consistent framework for evaluating the safety of the proposed maximum specification (Ref. 108).

i. Estimated Vitamin D Intakes at the Current and Proposed Maximum

At the current maximum of 2.5 µg (100 IU)/100 kcal, estimated vitamin D intakes from typical infant formula volumes represent approximately 53 percent and 27 percent of the ULs for infants 0–6 months of age and 7–12 months of age, respectively. Under a high-consumption scenario (*i.e.,* 90th percentile of energy intake from infant formula based on NHANES data from 2015–2023), these estimates increase to 84 percent and 52 percent of the ULs for the same age groups, respectively, from infant formula alone. At the proposed maximum of 3 µg (120 IU)/100 kcal, estimated vitamin D intakes at typical consumption volumes represent approximately 63 percent and 32 percent of the ULs for infants 0–6 months of age and 7–12 months of age, respectively (table 16). For high consumers, estimated intakes at the proposed maximum reach approximately 100 percent and 63 percent of the ULs for infants 0–6 months of age and 7–12 months of age, respectively. When complementary foods are also considered for infants 7–12 months of age, total estimated vitamin D intake reaches approximately 68 percent of the UL. Across all scenarios evaluated, estimated vitamin D intakes at the proposed maximum do not appreciably exceed the UL for either age group (Ref. 108).

TABLE 16—COMPARISON OF ESTIMATED VITAMIN D INTAKES FROM INFANT FORMULA ACROSS MAXIMUM SPECIFICATION LEVELS FOR INFANTS 0–6 MONTHS OF AGE AND 7–12 MONTHS OF AGE

Parameter	Current maximum (2.5 µg/100 kcal)	Proposed maximum (3 µg/100 kcal)
Infants 0–6 months of age		
Typical Intake Volumes		
Infant formula intake assumption	0.78 L/day at 676 kcal/L (527 kcal/day).	
Vitamin D from infant formula	13.2 µg/day	15.8 µg/day.
% of UL (25 µg/day)	53%	63%.
NHANES Data—High Consumers [1]		
90th percentile energy intake from infant formula	836 kcal/day.	
Vitamin D from infant formula	20.9 µg/day	25.1 µg/day.
% of UL (25 µg/day)	84%	100.3%.
Infants 7–12 months of age		
Typical Intake Volumes		
Infant formula intake assumption	0.6 L/day at 676 kcal/L (406 kcal/day).	
Vitamin D from infant formula	10.1 µg/day	12.2 µg/day.
% of UL (38 µg/day): Formula only	27%	32%.
NHANES Data—High Consumers [1]		
90th percentile energy intake from infant formula	794 kcal/day.	
Vitamin D from infant formula	19.9 µg/day	23.8 µg/day.
% of UL (38 µg/day): Formula only	52%	63%.
Vitamin D from complementary foods [2]	1.6 µg/day	1.6 µg/day.
Total vitamin D intake	21.5 µg/day	25.4 µg/day.
% of UL: Total intake	57%	68%.

[1] NHANES exposure estimates are based on the 90th percentile of energy intake from infant formula among non-breastfed infants aged 0–6 months (n = 235) and 7–12 months (n = 205), using NHANES data (Refs. 13, 14, 15, 16, 17, 18). Infants at the 90th percentile of energy intake from infant formula represent a high-consumption scenario and are used here to estimate upper-bound exposure to vitamin D from formula.

[2] Estimated vitamin D intake from complementary foods is incorporated into the 7–12-month exposure estimates only, reflecting the mean of reported complementary food intake among infants in this age group from the same NHANES cycles (Refs. 13, 14, 15, 16, 17, 18).

ii. Comparison With International Regulatory Standards

FDA's proposed maximum of 3 µg (120 IU)/100 kcal for vitamin D in infant formula is consistent with most international regulatory standards for follow-on formula for infants 6–12 months of age but exceeds most international standards for formula intended for infants 0–6 months of age. Codex Alimentarius, Australia, Canada, and the EU all permit a maximum of 3

µg/100 kcal for older infants (6–12 months of age), reflecting that age group's greater tolerability for vitamin D. The EU reduced its maximum for formula intended for infants 0–6 months of age from 3 µg/100 kcal to 2.5 µg/100 kcal following an EFSA safety assessment finding that some high-consuming infants in that age group may exceed the UL at the higher maximum. China specifies a notably higher maximum of 5 µg/100 kcal for all infants 0–12 months of age. The LSRO Panel's 1998 recommendation of 2.5 µg (100 IU)/100 kcal was based on the 90th percentile of vitamin D content in commercially available infant formulas at the time (Ref. 108).

Unlike most international frameworks, U.S. regulations do not distinguish between infant formula for infants 0–6 months of age and follow-on formula for infants 6–12 months of age. In the United States, all infant formulas must meet the nutrient specifications in § 107.100 and be suitable for infants from birth through 12 months of age. Accordingly, the proposed maximum of 3 µg/100 kcal would apply across the full infant age range, including younger infants 0–6 months of age who have a lower UL (25 µg/day) than older infants 7–12 months of age (38 µg/day) (Ref. 108).

iii. Safety Considerations for Younger Infants

EFSA's intake assessment for infants aged 0 to less than 4 months of age used high formula consumption values multiplied by median reference body weights, yielding estimated vitamin D intakes of approximately 19–25 µg/day at 1 month of age and 23–29 µg/day at 4 months of age. EFSA's approach, designed to characterize intake among high consumers in the context of European feeding practices, differs from FDA's exposure analysis, which is based on the 90th percentile of energy intake from infant formula among U.S. infants. EFSA's 2018 UL evaluation used a serum 25(OH)D concentration of 200 nmol/L as a conservative reference point rather than a toxicity threshold, predicting that 0–4 percent of infants under 6 months of age would exceed this level at intakes of 20–25 µg/day. FDA estimates that vitamin D intake among high-consuming U.S. infants 0–6 months of age at the proposed maximum is approximately 25.1 µg/day, which is at the NASEM UL. FDA considers this safety margin acceptable for younger infants, noting that the NASEM UL was derived from a relatively insensitive endpoint using a conservative uncertainty factor and that NASEM acknowledged limitations in the underlying evidence (Ref. 108). FDA is not aware of evidence of adverse effects at or near this level under current conditions of use. Nevertheless, FDA acknowledges residual uncertainty due to limited data on the dose-response relationship for adverse outcomes in infants 0–6 months of age and invites comment on whether a more conservative maximum should be considered for this age group.

iv. Manufacturing and Analytical Feasibility

The proposed maximum of 3 µg/100 kcal, paired with a proposed minimum of 2 µg/100 kcal, provides a manufacturing operating range of 1 µg (40 IU)/100 kcal. A 1 µg/100 kcal operating range between the minimum and maximum is intended to provide manufacturers sufficient flexibility to account for processing and shelf-life considerations while maintaining vitamin D intakes within a nutritionally appropriate and safe range across the U.S. infant population. Comments received in response to FDA's 2025 RFI on infant formula nutrient requirements support these manufacturing feasibility concerns (90 FR 20475). Multiple comments from industry stakeholders highlighted that vitamin D is a sensitive nutrient, since it degrades easily under certain conditions, with one reporting that it is less stable in the presence of protein hydrolysates or free amino acids, and that manufacturing variability and shelf-life losses necessitate formulating above the label claim, supporting the need for an adequate operating range between the minimum and maximum. Several of these comments recommended increasing the U.S. maximum to 3 µg (120 IU)/100 kcal, noting that the current U.S. maximum of 2.5 µg (100 IU)/100 kcal has proven insufficient to support manufacturing flexibility while reliably meeting the minimum label claim.

FDA's proposed range is also informed by considerations of analytical method performance and the ability to reliably verify regulatory compliance. A 2022 statistical assessment re-evaluated performance data from the multi-laboratory validation study of AOAC Method 2016.05/ISO 20636:2018, the current state-of-the-art analytical method for determining vitamin D content in infant formula. That study found that the narrower EU regulatory range of 2 to 2.5 µg/100 kcal presents significant compliance verification challenges: even when formula is accurately manufactured at the midpoint of that range (2.25 µg/100 kcal), approximately 18 percent of test results would be expected to indicate noncompliance due solely to analytical method variability (Ref. 123). In contrast, the Codex Alimentarius range of 1 to 2.5 µg/100 kcal was associated with a predicted noncompliance rate of less than 1 percent at the regulatory midpoint (Ref. 123). These findings indicate that maintaining the current maximum of 2.5 µg/100 kcal while raising the minimum to 2 µg/100 kcal is not analytically feasible using current validated methods (Ref. 123).

Applying the statistical methodology of the 2022 assessment previously discussed to the proposed 2 to 3 µg/100 kcal range, FDA estimates a predicted noncompliance rate of approximately 1.6 percent at the regulatory midpoint of 2.5 µg/100 kcal, assuming an average method reproducibility of 8.2 percent reproducibility relative standard deviation (Refs. 108, 123). FDA considers this to support the analytical feasibility of the proposed range and invites comment and data on analytical performance within the proposed range.

These manufacturing constraints also have direct nutritional implications. The AAP noted that, given manufacturing variability, shelf-life losses, and label claim requirements, it has proven difficult for infants to meet the full AI of 10 µg (400 IU)/day through typical infant formula intakes under the current allowable range, which the AAP characterized as too narrow. With label declarations commonly set at approximately 1.5 µg (60 IU) or 1.75 µg (75 IU)/100 kcal, manufacturers have difficulty ensuring that the label claim is maintained through end of shelf life without approaching or exceeding the current maximum of 2.5 µg (100 IU)/100 kcal, leaving only 25 to 40 IU/100 kcal of headroom for manufacturing overages (Ref. 91).

FDA acknowledges that the proposed range of 2 to 3 µg/100 kcal spans the same absolute width of 1 µg (40 IU)/100 kcal as the range the AAP described as insufficient. However, FDA considers that the proposed range addresses this concern not by widening the range, but by raising the minimum to 2 µg/100 kcal, which shifts the entire operating band upward, better positioning manufacturers to achieve label claims consistent with meeting the AI at typical consumption volumes. FDA invites comment on whether the proposed minimum-to-maximum range of 2 to 3 µg (80–120 IU)/100 kcal is sufficient to ensure that infants consuming typical volumes of infant formula can reliably meet the AI of 10 µg (400 IU)/day while addressing manufacturing variability and shelf-life losses. Specifically, FDA requests data and information on: (1)

whether the proposed 1 µg (40 IU)/100 kcal operating range is adequate to accommodate typical manufacturing overages and nutrient degradation over shelf life; (2) whether an alternative minimum or maximum should be considered, and if so, what scientific, technical, or operational data support such an alternative; and (3) whether the proposed maximum of 3 µg (120 IU)/100 kcal poses a risk of excessive vitamin D intake for infants 0–6 months of age (Ref. 108).

d. Consideration of the Evidence Base

FDA acknowledges significant uncertainties in the evidence base underlying its proposed vitamin D specifications for infant formula. The NASEM ULs were derived from a limited number of older studies using decreased linear growth, which it acknowledged as a relatively insensitive endpoint, and the dose-response relationship between vitamin D intake and adverse outcomes in infants is not well characterized (Refs. 106, 108). Additionally, differing consumption assumptions between FDA and EFSA led EFSA, but not FDA, to find that high-consuming infants under 4 months of age may exceed the UL at the proposed maximum of 3 µg/100 kcal. Exposure estimates do not account for vitamin D from sunlight. This is a conservative assumption with respect to the minimum specification, as any cutaneous vitamin D synthesis would supplement formula intake and reduce the risk of inadequacy. However, it is not conservative with respect to the maximum, as appreciable UV–B exposure would contribute to serum 25(OH)D concentrations beyond those estimated from formula intake alone.

Additionally, the estimates do not account for concurrent vitamin D supplementation. Currently, the AAP recommends that infants consuming less than 1,000 mL/day of infant formula receive routine vitamin D supplementation (Ref. 91). Thus, infants receiving both formula at or near the proposed maximum plus a vitamin D supplement could have total intakes that approach or exceed the UL, particularly among younger infants (Ref. 108). As an example, an infant 0–6 months of age consuming infant formula at the proposed maximum of 3 µg/100 kcal at approximately 780 mL/day would receive an estimated 15.8 µg/day from formula alone, and when combined with a standard 10 µg supplement, total intake would reach approximately 25.8 µg/day, marginally exceeding the UL of 25 µg/day (Ref. 108). FDA acknowledges this co-exposure scenario as a source of residual uncertainty and invites comment and associated data on the prevalence of concurrent formula feeding and vitamin D supplementation at volumes below the AAP threshold, and on whether additional labeling or guidance measures should be considered to address this scenario.

J. Manganese (Proposed § 107.100(a))

The current requirement for manganese in infant formula is a minimum level of 5 µg/100 kcal (21 CFR 107.100). There is no maximum level established. Based on our analysis of scientific information and data since the 1998 comprehensive study of infant formula nutrients (Ref. 1), including infant formula manganese requirements in international standards, we propose to decrease the required minimum level for manganese to 1 µg/100 kcal and establish a maximum level for manganese in infant formula of 50 µg/100 kcal in § 107.100.

1. Background

Manganese is an essential trace mineral found in all tissues and is required for normal amino acid, lipid, protein, and carbohydrate metabolism. Manganese functions as a cofactor for key metalloenzymes, including arginase, glutamine synthetase, pyruvate carboxylase, and manganese superoxide dismutase, supporting antioxidant defense, energy production, immune function, and neurological activity (Refs. 124, 125, 126). Manganese is integral to the synthesis of neurotransmitters, including dopamine, glutamate, and gamma-aminobutyric acid (GABA), that are essential for neural signaling and survival (Refs. 126, 127). During fetal and infant development, manganese is also essential for skeletal and connective tissue formation, as well as for carbohydrate, protein, and lipid metabolism during periods of rapid growth (Refs. 126, 127, 128).

Manganese concentrations and bioavailability differ substantially across infant feeding sources. Human milk contains relatively low manganese levels (approximately 3–10 µg/L), cow milk-based formulas contain intermediate concentrations (approximately 30–50 µg/L), and soy protein-based formulas contain the highest levels (approximately 200–300 µg/L)—up to 100 times that of human milk (Refs. 125, 126, 127). In infant formulas, manganese is present in the divalent form (*i.e.,* an oxidation state that allows for chemically bonding with two other atoms or groups), in contrast to human milk, in which it is predominantly in trivalent form, (*i.e.,* an oxidation state which can chemically bond with three other atoms or groups), resulting in less controlled absorption from infant formula (Refs. 126, 127). Iron status modulates manganese uptake, as both minerals share common transporters. Iron deficiency, the most clinically significant driver of manganese excess in infants, increases the amount of these shared intestinal transporters produced in cells and increases manganese absorption, while adequate iron stores reduce manganese uptake (Refs. 124, 126, 128, 129, 130, 131). Route of exposure also significantly influences manganese absorption, distribution, and tissue retention (Refs. 126, 132). The scientific literature lacks consensus on optimal biomarker selection for assessing manganese status (Refs. 126, 133).

a. Health Consequences of Manganese Deficiency

Acquired manganese deficiency in human infants is considered extremely rare given the manganese concentrations present in human milk, infant formula (Refs. 126, 127), and food, with no reported cases in the scientific literature to date (Refs. 125, 126). Animal models on manganese deficiency have documented impaired growth, skeletal abnormalities, neonatal ataxia (*i.e.,* an irreversible congenital defect characterized by a lack of normal coordination of movements and loss of equilibrium), impaired glucose tolerance, altered lipid and carbohydrate metabolism, and compromised immunity, as well as low red blood cell count, hemoglobin, and hematocrit (*i.e.,* the percentage of total blood volume made up of red blood cells) (Refs. 62, 126, 134, 135, 136, 137).

b. Health Consequences of Excess Manganese Intake

Although manganese deficiency data in humans are largely derived from animal studies, the primary concern for infants and children centers on the well-documented toxic effects of manganese excess (Refs. 126, 138). The developing brain is especially vulnerable to manganese imbalances, as manganese preferentially accumulates in the basal ganglia, and disruptions during critical neurodevelopmental windows can produce lasting alterations in dopamine and GABA metabolism (Refs. 126, 127). This vulnerability is compounded in neonates (*i.e.,* early infancy) by immature biliary excretion, the primary route of manganese elimination, limiting the infant's capacity to clear excess manganese. Potential adverse effects of excess manganese exposure

are discussed further, below, in section J.5 of this document.

2. Nutrient Reference Values

a. NASEM

NASEM established AI values for manganese for infants in 2001 (Ref. 62). For infants 0–6 months of age, NASEM established an AI of 3 µg/day based on the manganese content of human milk from well-nourished mothers (3.5 µg/L) and typical milk consumption patterns (0.78 L/day) and rounding, reflecting that no cases of manganese deficiency have been observed in full-term infants exclusively breastfed in the United States or Canada. The higher AI of 600 µg/day for infants 7–12 months of age accounts for complementary foods containing higher manganese concentrations than human milk (Refs. 62, 126).

b. EFSA

Due to insufficient evidence to establish an AR and, by extension, a PRI, the EFSA NDA Panel proposed an AI. For infants 7–11 months of age, the EFSA Panel determined an AI range of 0.02–0.5 mg/day (20–500 µg/day) (Ref. 139). This range accounts for the broad spectrum of manganese intake levels that appear to support adequate nutrition and is informed by several sources: upward extrapolation from manganese intakes in exclusively breastfed infants, observed manganese consumption in infants at 6 and 12 months of age, and values derived from extrapolating the adult AI through isometric scaling (Ref. 139). EFSA did not establish an AI for younger infants (Ref. 139).

c. Australian NHMRC/New Zealand MoH

NHMRC/MoH established an AI of 3 µg/day for infants 0–6 months of age, calculated by multiplying the average human milk intake (0.78 L/day) by the average manganese concentration in human milk (3.5 µg/L) and rounding. For infants 7–12 months of age, NHMRC/MoH established an AI of 0.6 mg/day (600 µg/day), which was derived using two methods. The first method used consumption estimates for infants at 6 and 12 months of age (0.071 and 0.08 mg/kg, respectively) (Ref. 140), which, applied to reference weights of 7 and 9 kg, yielded total manganese intakes of 0.5 and 0.72 mg/day (from human milk and complementary food). The second method used body weight adjustment to extrapolate from adult data, producing an estimate of 0.567 mg/day. As noted above, the AI for the 7–12-month age group is significantly higher than that for the 0–6-month group because human milk contains lower concentrations of manganese than the complementary foods introduced into older infants' diets (Refs. 53, 126).

d. UL

NASEM was unable to determine ULs in infants because of the lack of data on adverse effects in infancy and concern about infants' ability to handle excess amounts (Ref. 62). Similarly, NHMRC/MoH did not set ULs, noting that the gap between the oral exposure levels known to cause effects in humans and animals and the estimated intake from food is narrow (Ref. 53).

In 2023, the EFSA NDA Panel conducted an updated scientific opinion on the UL for manganese and concluded that a UL for manganese could not be established (Ref. 141). In the absence of adequate data to establish a UL, EFSA derived safe levels of intake based on observed dietary intakes among high consumers (95th percentile) as an indication of the highest level of intake at which there is reasonable confidence in the absence of adverse effects. For infants, EFSA adopted a conservative approach because of insufficient data to determine when manganese homeostatic processes become fully mature, calculating the average of all available 95th percentile estimates across countries for infants 4 months to less than 12 months of age. This yielded a ''safe level of intake'' of 2 mg/day (2,000 µg/day) for manganese intake from all dietary sources, including fortified foods and food supplements, for this age group. EFSA noted that this safe level of intake is more limited in application than a UL because the intake level at which the risk of adverse effects begins to increase is not defined (Ref. 141).

e. Comparison of International Recommendations

Table 17 shows the manganese AIs established by NASEM, EFSA, and NHMRC/MoH.

TABLE 17—ADEQUATE INTAKES AND TOLERABLE UPPER INTAKE LEVELS OF MANGANESE

Organization	Year	Age range (months)	Adequate intake (µg/day)	Tolerable upper intake level
NASEM	2001	0–6	3	ND.
		7–12	600	ND.
EFSA	2017	7–11	20–500	ND.
Australian NHMRC/New Zealand MoH	2006	0–6	3	ND.
		7–12	600	ND.

For the 0–6-month age group, NASEM and NHMRC/MoH assessed the manganese content of human milk combined with typical infant milk intakes and arrived at aligned AI values. EFSA did not establish a separate AI for this youngest age group based on the available information. All three bodies acknowledged that manganese deficiency has not been clinically observed in healthy, full-term, exclusively breastfed infants, which supports the human milk-based approach (Ref. 126).

For the 7–12-month age group, NASEM and NHMRC/MoH again converged on the same AI of 600 µg/day. EFSA used a different approach from NASEM and NHMRC/MoH, drawing on multiple methodologies, and proposed a range of 20–500 µg/day. EFSA's range-based approach reflects acknowledged uncertainty and captures the broad spectrum of intakes observed to support adequate nutrition, though its upper bound of 500 µg/day does not reach the 600 µg/day AI established by NASEM and NHMRC/MoH. The dramatic increase in AI values from the 0–6-month to the 7–12-month age group reflects the substantially higher manganese concentrations found in complementary foods relative to human milk (Ref. 126).

3. Human Milk Composition

Multiple studies have characterized manganese concentrations in mature human milk from mothers with term pregnancies. Across most study populations largely conducted outside of North America, reported manganese concentrations generally ranged from approximately 2 to 16 µg/L (Refs. 126, 142). One data source reported substantially higher manganese concentrations: a 1991 Philippines subcohort study reported approximately

39.55 µg/L (Ref. 143), which may have reflected either a positive bias in reported manganese concentrations or environmental contamination. FDA does not consider this dataset to be representative of the physiological range of manganese in human milk from the broader population (Ref. 126).

More recently, the 2024 MIREC study reported manganese concentrations in mature human milk from a Canadian pregnancy cohort, which is the largest published study of human milk mineral composition from a high-income country using methods meeting eligibility criteria for reference value development (Ref. 105). The average (±standard deviation) manganese concentration in human milk was approximately 1.99 ± 2.93 µg/L in the full dataset and 1.96 ± 1.74 µg/L in the subset of participants who met the DRI applicability criteria. These values were calculated as geometric means and converted to a volume-based measure using the density of human milk (1.032 g/mL). FDA considers these data to be a substantially stronger evidentiary basis for characterizing the physiological range of manganese in human milk from a North American population, as compared to the broader data set described above, based on sample size and population/location. Accordingly, FDA intends to rely primarily on these data to inform the minimum and maximum specifications for manganese in infant formula (Ref. 126).

4. International Regulatory Standards for Infant Formula

International regulatory bodies are largely aligned on manganese specifications for infant formula (table 18). Codex Alimentarius specifies a minimum of 1 µg/100 kcal and a GUL of 100 µg/100 kcal, applicable to both infant formula (0–6 months of age) and follow-on formula (6–12 months of age) (Refs. 12, 37). The EU specifies a minimum of 1 µg/100 kcal and a maximum of 100 µg/100 kcal (Ref. 38). Australia, Canada, and China have adopted or proposed specifications aligned with Codex, with the exception that China specifies a higher minimum of 3 µg/100 kcal for infant formula for infants 0–6 months of age (Refs. 39, 40, 41, 42). In 2005, the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) International Expert Group recommended a minimum of 1 µg/100 kcal and a lower maximum of 50 µg/100 kcal, citing infants' underdeveloped excretory capacity and the risk of bioaccumulation (Ref. 144). In 1998, the LSRO Panel recommended a minimum of 1 µg/100 kcal and a maximum of 100 µg/100 kcal.

TABLE 18—INTERNATIONAL STANDARDS AND/OR RECOMMENDATIONS FOR MANGANESE IN INFANT FORMULA

Organization	Age range (months)	Minimum (µg/100 kcal)	Maximum (µg/100 kcal)	Reference
U.S. Current Standards	0–12	5	ND	21 CFR 107.100
LSRO [1]	0–12	1	100	LSRO, 1998
Codex Alimentarius	0–12	1	100 (GUL)	CXS 72–1981, CXS 156–1987
EU	0–12	1	100	Commission Delegated Regulation (EU) 2016/127
Australia [2]	0–12	1	100 (GUL)	FSANZ P1028
Canada [3]	0–12	1	100	Health Canada, 2025
China	0–6	3	100	GB 10765–2021.
	6–12	1	100	GB 10766–2021.
ESPGHAN [1]	0–12	1	50	ESPGHAN International Expert Group, 2005

[1] Recommended ranges.
[2] Values converted from per 100 kJ to per 100 kcal (1 kcal = 4.184 kJ).
[3] Reflects proposed compositional requirements for infant formula.

5. Recent Scientific Evidence on Manganese Intake

a. Evidence of Toxicity (Neurotoxicity)

There are two distinct exposure frameworks that often occur simultaneously or over extended periods: (1) aggregate exposure, which involves a single chemical received through multiple routes or pathways simultaneously; and (2) cumulative exposure, which involves multiple chemicals acting on the same target system (Ref. 145). In the case of infant manganese exposure, both frameworks are relevant. Exposure routes include infant formula, drinking water, prenatal transfer, and airborne sources (Ref. 126). Neurodevelopmental effects are modified by co-exposures to other metals and nutrients such as selenium, lead, arsenic, and iron (Refs. 130, 146, 147, 148, 149).

Manganese becomes neurotoxic at elevated levels, and infants represent a uniquely vulnerable population due to their immature biliary excretion, higher intestinal absorption rates, and developing blood-brain barrier (Refs. 124, 127, 147, 150). Evidence from multiple prospective cohort studies, reviews (Refs. 133, 146, 147, 148, 151, 152, 153, 154, 155), and risk assessments (Refs. 156, 157) consistently demonstrate that excess prenatal and postnatal manganese exposure is associated with deficits in cognitive, motor, language, and social-emotional development in children (Ref. 158). Both manganese deficiency and manganese excess impair neurodevelopment, making it challenging to define a single, universal toxicity threshold (Ref. 126). The threshold at which manganese transitions from beneficial to harmful varies across studies but has been identified at approximately 24–28 µg/L in maternal blood at delivery for psychomotor outcomes (Ref. 152) and at cord serum manganese concentrations greater than 9.1 µg/L for neonatal neurobehavioral deficits (Ref. 148).

Regulatory and health-based thresholds for manganese exposure in infants have been established or proposed across studies and vary widely (Ref. 126). All current thresholds carry significant uncertainty, as they are largely extrapolated from animal studies or adult dietary data, and no threshold has been specifically validated for human infants across the full range of exposure routes and co-exposure conditions encountered in real-world settings.

Available evidence indicates that full neurological recovery from excess manganese exposure is unlikely when exposure is prolonged or occurs during critical periods of brain development (Refs. 126, 127, 133, 147, 159).

In addition to the limitations noted above regarding information about manganese toxicity, additional

limitations exist, such as study designs that preclude causal inference, the lack of a single validated biomarker, the potential for residual confounding by co-exposures, and inconsistent findings across studies and populations (Ref. 126).

b. Manganese Intakes From Water

Manganese occurs naturally in rocks, soil, groundwater, and surface water, with certain geographical regions in the United States exhibiting higher levels of manganese in the water (Ref. 160). Water manganese content is a significant consideration for formula-fed infants because water is used to reconstitute powdered and concentrated liquid infant formulas, and the total manganese intake reflects the contribution from water sources and infant formula. Powdered infant formulas, which represent most formula consumed by infants, require more water per unit volume than concentrated liquids, resulting in proportionally greater water-derived manganese intake. In a 2019 study, investigators analyzed data from 43,334 wells in the United States and estimated that 12.9 percent of groundwater samples exceeded the U.S. Environmental Protection Agency's Health Reference Level of 300 µg/L for manganese (Ref. 160). These findings were corroborated in a 2021 study at the state level, assessing water concentrations in Minnesota community public water systems, noting that 13 percent of U.S. groundwater samples exceeded this same threshold (Ref. 157). In the same 2021 paper, two additional international benchmarks applicable to the manganese content of water were highlighted: Canada's drinking water standard of 120 µg/L (Ref. 161) and a proposed WHO health-based guideline value of 80 µg/L (Ref. 162).

c. Manganese Intakes From Infant Formula

In 2019, a group of investigators measured manganese concentrations in infant formulas marketed in the United States and found ranges of 230–430 µg/L (36–65 µg/100 kcal) in cow milk-based formulas and 420–790 µg/L (64–120 µg/100 kcal) in soy protein-based formulas (Ref. 163). Researchers analyzing public drinking water in Minnesota and powdered infant formula samples also reported manganese concentrations of 69.8–291 µg/L and 306–531 µg/L for cow milk-based and soy protein-based infant formulas, respectively. Notably, the single amino acid-based formula included in the analysis contained the highest concentration at approximately 110 µg/100 kcal (Ref. 157). Based on these analyses, certain soy and amino acid-based formulas already exceeded the maximum specification of 100 µg/100 kcal set by other expert bodies (Ref. 126).

An important consideration is the combined exposure to manganese from both infant formula and drinking water used for reconstitution. When soy protein or amino acid-based formulas were reconstituted with water at the 95th percentile of Minnesota community water concentrations (562 µg/L), central tendency manganese intake estimates reached 156 percent and 213 percent, respectively, of the Minnesota Department of Health neonatal-based Reference Dose (RfD) (83 µg/kg/day) (Ref. 157). Upper-end estimates for all formula types, including cow milk-based formula, exceeded the RfD when reconstituted with water at the 95th percentile concentration (Ref. 157).

d. Manganese Intake

To characterize routine dietary manganese intakes among U.S. infants, FDA used food consumption data from the What We Eat in America/NHANES study covering 2017 to March 2020 (n = 332 infants 0–12 months of age) in conjunction with manganese concentration data from FDA's Total Diet Study (TDS) for fiscal years (FY) 2018–2020 (Refs. 164, 165, 166). Among infants 0–6 months of age (n = 169), the mean estimated daily manganese intake using mean TDS concentrations was 234 µg/day (10th percentile: 73 µg/day; 90th percentile: 601 µg/day). Among infants 7–12 months of age (n = 163), the mean estimated intake was 1,123 µg/day (10th percentile: 251 µg/day; 90th percentile: 1,991 µg/day) (Ref. 126).

6. Evidence Evaluation and Rationale

Based on the review of available scientific data, information, and international standards, we propose to decrease the current minimum specification for manganese in infant formula to 1 µg/100 kcal and to establish a maximum specification of 50 µg/100 kcal in § 107.100.

a. Rationale for Decreasing the Minimum Specification to 1 µg/100 kcal

At the current minimum manganese level, 5 µg/100 kcal, typical infant formula intakes provide approximately 26 µg/day and 20 µg/day for infants 0–6 months of age and 7–12 months of age, respectively. This represents 867 percent of the NASEM AI for infants 0–6 months of age (3 µg/day) and 3.3 percent of the AI for infants 7–12 months of age (600 µg/day). At the proposed minimum of 1 µg/100 kcal, the typical intake from infant formula is estimated to be 5.3 µg/day and 4.1 µg/day for infants 0–6 months of age and 7–12 months of age, respectively. These intakes exceed the AI for infants 0–6 months (176 percent AI) and would remain well below the AI for infants 7–12 months (0.7 percent AI). The notable discrepancy in AIs across the two age groups reflects variations in dietary exposure patterns (*i.e.,* older infants consuming complementary foods, which have higher concentrations of manganese) rather than a markedly distinct physiological requirement. Thus, FDA considers that manganese intakes at the proposed minimum of 1 µg/100 kcal are unlikely to present a risk of inadequacy for formula-fed infants in the 7–12-month age group (Ref. 126).

Manganese deficiency is rare in infants and has not been documented in healthy infants under normal dietary conditions. Cases of manganese deficiency are largely drawn from animal studies and rare genetic disorders affecting manganese transport. FDA considers that this limited evidence of deficiency under current intake conditions further supports the proposed reduction in the minimum specification (Ref. 126).

Central estimates of mature human milk manganese concentrations range from approximately 1.4 to 16 µg/L with recent North American data reflecting a mean concentration of 1.96 ± 1.74 µg/L (Ref. 105). Assuming an energy density of human milk of 650 kcal/L, the manganese content of human milk is approximately 0.3 µg/100 kcal based on the MIREC study (Ref. 105) mean, with the broader range of concentrations reported across studies corresponding to approximately 0.2 to 2.5 µg/100 kcal. The proposed minimum of 1 µg/100 kcal exceeds the mean manganese concentration of human milk on a per-kcal basis and remains within the range of concentrations reported across studies, providing a conservative margin above mean human milk concentrations (Ref. 126).

The current minimum of 5 µg/100 kcal exceeds all international standards assessed. The proposed minimum would align the U.S. minimum with international infant formula standards as well as recommendations from the LSRO Panel and ESPGHAN International Expert Group (table 18). Furthermore, the proposed decrease is supported by several comments recommending reducing or eliminating the minimum manganese requirement in response to FDA's 2025 RFI on nutrient requirements for infant formula (90 FR 20475, May 14, 2025).

b. Rationale for Establishing a Maximum Specification of 50 µg/100 kcal

Expert bodies, including NASEM and EFSA, have not established ULs for manganese in infants, citing insufficient dose-response data in human infant populations (Refs. 62, 141). Nevertheless, a substantial and growing body of evidence indicates that excess manganese exposure during infancy poses risks to neurodevelopment, and FDA considers that the weight of this evidence, along with the unique physiological vulnerabilities of infants and the aggregate nature of manganese exposure, supports establishing a maximum specification for manganese in infant formula (Ref. 126).

Manganese becomes neurotoxic at elevated levels, and infants represent a uniquely vulnerable population due to their immature biliary excretion, higher intestinal absorption rates, and developing blood-brain barrier (Refs. 125, 127). Evidence from multiple prospective cohort studies and reviews consistently demonstrates that excess prenatal and postnatal manganese exposure is associated with deficits in cognitive, motor, language, and social-emotional development in children (Refs. 133, 146, 147, 148, 151, 152, 153, 154, 155). FDA acknowledges that the dose-response relationship is complex and non-linear, that current health-based reference doses are largely extrapolated from neonatal animal studies rather than direct human infant data, and that causal inference from epidemiological literature remains limited by methodological constraints (Refs. 133, 156, 157). Nevertheless, FDA assesses that the consistency of associations across several independent cohorts, the biological plausibility based on manganese's known neurotoxic mechanisms, and the limited potential for full recovery from manganese-induced neurodevelopmental effects support a conservative approach to limiting manganese intake in infants.

Formula-fed infants may be exposed to manganese through several concurrent pathways, including infant formula, drinking water used to reconstitute powdered or concentrated liquid formulas, prenatal transfer, and inhalation (Refs. 147, 167). FDA considers that evaluating manganese intake from infant formula in isolation underestimates the total manganese burden experienced by formula-fed infants. As discussed in section V.J.5.b of this document, manganese occurs naturally in U.S. groundwater at variable concentrations (Ref. 160). Additionally, smaller community water systems, which comprise 97 percent of U.S. systems, have been shown to have significantly higher manganese concentrations than larger systems (Ref. 157). When infant formula is reconstituted with manganese-containing water, various combined contributions can result in total manganese intakes exceeding health-based reference doses (Refs. 126, 142, 155, 160).

At the proposed maximum of 50 µg/100 kcal, estimated manganese intakes from typical intake volumes of infant formula alone are approximately 264 µg/day and 203 µg/day for infants 0–6 months of age and 7–12 months of age, respectively, prior to any contribution from water or other sources (see table 19). Under a high-consumption scenario, defined here as the 90th percentile of energy intake from infant formula based on data from three NHANES cycles (Refs. 13, 14, 15, 16, 17, 18), these estimates increase to approximately 418 µg/day and 397 µg/day for the same age groups, respectively, representing approximately 139-fold and 66 percent of the respective AI values (see table 19). The proposed maximum continues to provide manganese well above adequacy thresholds while substantially reducing the formula-derived contribution to aggregate exposure.

TABLE 19—COMPARISON OF ESTIMATED MANGANESE INTAKES FROM INFANT FORMULA ACROSS MINIMUM AND MAXIMUM SPECIFICATION LEVELS FOR INFANTS 0–6 MONTHS AND 7–12 MONTHS OF AGE

Intake scenario	Estimated energy intake (kcal/day)	Proposed minimum (1 µg/100 kcal) (µg/day)	Proposed maximum (50 µg/100 kcal) (µg/day)	Codex alimentarius GUL (100 µg/100 kcal) (µg/day)
Infants 0–6 months of age				
Typical intake volume (0.78 L/day at 676 kcal/L)	527	5.3	264	527
NHANES 90th percentile	836	8.4	418	836
Infants 7–12 months of age				
Typical intake volume (0.60 L/day at 676 kcal/L)	406	4.1	203	406
NHANES 90th percentile	794	7.9	397	794

NHANES exposure estimates are based on the 90th percentile of energy intake from infant formula among non-breastfed infants 0–6 months (n = 235) and 7–12 months (n = 205) of age, using NHANES data (Refs. 13, 14, 15, 16, 17, 18). Infants at the 90th percentile of energy intake from infant formula represent a high-consumption scenario and are used here to estimate upper-bound exposure to manganese from infant formula.

Also, data from NHANES (2017–March 2020) and the TDS (2018–2020) suggest that infants may be routinely exposed to manganese at levels that substantially exceed the respective AIs for both age groups. This exposure accounts for all food sources, including complementary foods, infant formula, and human milk. FDA acknowledges that these estimates are subject to methodological limitations (Ref. 166) yet considers these intake data as contextual evidence in support of the proposed maximum.

Most major international regulatory bodies, including Codex Alimentarius, the EU, Australia, Canada, and China, have established a maximum or GUL of 100 µg/100 kcal (table 18). The LSRO Panel similarly recommended 100 µg/100 kcal (Ref. 1). FDA acknowledges this international consensus. However, FDA is concerned that this level may not fully account for aggregate infant exposure, particularly from drinking water used to reconstitute formula, or for the potentially higher absorption and retention of manganese in infants compared to the adults on whom adverse effect levels were based. FDA notes that the ESPGHAN International Expert Group reached a similar conclusion, recommending a maximum of 50 µg/100 kcal on the grounds that higher concentrations should be avoided given infants' immature

excretion mechanisms and the associated risk of bioaccumulation (Ref. 144).

Establishing a maximum specification for manganese in infant formula introduces manufacturing considerations that differ by protein source. Soy (*e.g.,* soy protein isolate) naturally contains high amounts of manganese, resulting in consistently higher manganese concentrations in soy protein-based formulas relative to cow milk-based formulas (Ref. 163). FDA acknowledges that the proposed maximum of 50 µg/100 kcal may represent the lowest technologically achievable level for soy protein-based formulas while maintaining adequate protein content. For cow milk-based formulas, which contain lower inherent manganese and for which manganese is typically added as a discrete ingredient (*e.g.,* manganese sulfate), greater formulation flexibility exists, and FDA does not expect that cow milk-based formulas would require formulation at or near the proposed maximum to meet nutritional requirements. It is also common for amino acid-based formulas to add manganese as a discrete ingredient, and FDA does not anticipate technological barriers to reformulation. FDA seeks comment on this proposed maximum, including data or information bearing on the feasibility of achieving lower manganese levels in soy protein-based infant formulas, which may include access to alternate sources of soy protein with lower manganese content.

c. Consideration of the Evidence Base

FDA acknowledges several important uncertainties in the evidence base supporting the proposed maximum. These include the absence of a validated UL for manganese in infants, the reliance on health-based reference doses extrapolated from neonatal animal studies, the lack of a single validated biomarker that captures total manganese body burden, the methodological limitations that preclude definitive causal inference regarding neurodevelopmental outcomes, variability in reported human milk manganese concentrations across studies, and the complexity of the dose-response relationship (Ref. 126). Despite these uncertainties, FDA is proposing to establish a lower maximum specification of 50 µg/100 kcal for manganese in infant formula (compared to 100 µg/100 kcal). FDA's recommendation is based on the weight of the available scientific evidence, including the consistency of associations between excess manganese exposure and adverse neurodevelopmental outcomes across independent cohorts, the unique physiological vulnerabilities of infants, and the aggregate nature of manganese exposure from multiple concurrent pathways, which together support a conservative approach to limiting manganese intake in this population.

VI. Proposed Effective/Compliance Dates

We intend that any final rule resulting from this rulemaking become effective 60 days after the date of the final rule's publication in the **Federal Register**. We propose a compliance date of 3 years after the effective date of the final rule completing our phased, comprehensive infant formula nutrient review to provide industry time to reformulate and relabel infant formula while recognizing the importance of updating the infant formula nutrient specifications. We invite comment on the proposed compliance date.

VII. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct us to assess all benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. Rules are economically significant under section 3(f)(1) of Executive Order 12866 if they have an annual effect on the economy of $100 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The Office of Information and Regulatory Affairs has determined that this proposed rule is a significant regulatory action under section 3(f)(1) of Executive Order 12866.

Executive Order 14192 requires that any new incremental costs associated with certain significant regulatory actions ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.'' This proposed rule, if finalized as proposed, is expected to be an Executive Order 14192 regulatory action.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we cannot determine with certainty the magnitude of reformulation costs that small infant formula manufacturers would incur under this proposed rule, we find that the proposed rule may have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (Section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current threshold after adjustment for inflation is $193 million, using the most current (2025) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits, Costs, and Transfers

This proposed rule, if finalized, would update the nutrient specifications for infant formula to reflect the best available scientific evidence on certain infant nutritional requirements and safe intake levels. If finalized, the proposed changes to the nutrient specifications would generate benefits primarily through (1) reducing the risk of vitamin D deficiency in formula-fed infants and (2) reducing the risk of inadequate iodine intake, excessive vitamin A exposure, and excessive manganese exposure across the formula-fed infant population. The primary quantified benefit is avoided healthcare costs from vitamin D deficiency-induced late-onset hypocalcemia, with a primary annualized estimate of $80.93 million at a 7 percent discount rate and $90.04 million at a 3 percent discount rate. If finalized as proposed, benefits of this rule would begin accruing in 2031, following the proposed 3-year compliance period. Additional benefits from iodine, vitamin A, and manganese specification changes are described qualitatively. The primary present value of quantified benefits is $568.43 million at a 7 percent discount rate and $768.08 million at a 3 percent discount rate.

Costs are one-time and borne by domestic and foreign infant formula manufacturers in the compliance year. The primary annualized cost estimate is $17.64 million at a 7 percent discount rate and $17.57 million at a 3 percent

discount rate. The primary present value of costs is $123.86 million at a 7 percent discount rate and $149.86 million at a 3 percent discount rate.

This proposed rule is not expected to generate transfers. Table 20 presents the ROCIS summary of benefits, costs, and distributional effects of the proposed rule. All monetary values in table 20 are expressed in 2025 dollars.

TABLE 20—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

[Millions of 2025 dollars]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized ($millions/year)	$80.93	$18.79	$171.65	2025	7	2027–2036	
	90.04	20.90	190.98	2025	3	2027–2036	
Annualized Quantified	.....	.....	.....	.....	.....	.....	
	.....	.....	.....	.....	.....	.....	
Qualitative.							
Costs:							
Annualized Monetized ($millions/year)	17.64	8.35	31.70	2025	7	2027–2036	
	17.57	8.31	31.58	2025	3	2027–2036	
Annualized Quantified	.....	.....	.....	.....	.....	.....	
	.....	.....	.....	.....	.....	.....	
Qualitative.							
Transfers:							
Federal Annualized Monetized ($millions/year)	.....	.....	.....	.....	7	.....	
	.....	.....	.....	.....	3	.....	
	From:			To:			
Other Annualized Monetized ($millions/year)	.....	.....	.....	.....	7	.....	
	.....	.....	.....	.....	3	.....	
	From:			To:			

Effects:
State, Local or Tribal Government:
Small Business:
Wages:
Distributional: Benefits are expected to accrue disproportionately to WIC-enrolled infants, who represent approximately 50 percent of formula-fed infants in the United States and are more likely to be exclusively formula-fed. Costs are borne by manufacturers.

In line with Executive Order 14192, in table 21, we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon. We estimate that this proposed rule would generate $7.08 million in 2024 dollars in annualized net costs at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

TABLE 21—EXECUTIVE ORDER 14192 SUMMARY TABLE

[Millions of 2024 dollars, discounted over a perpetual time horizon relative to year 2024 at a 7 percent discount rate]

	Primary estimate	Low estimate	High estimate
Present Value of Costs	$101.11	$47.85	$181.76
Present Value of Cost Savings	.....	.....	.....
Present Value of Net Costs	101.11	47.85	181.76
Annualized Costs	7.08	3.35	12.72
Annualized Cost Savings	.....	.....	.....
Annualized Net Costs	7.08	3.35	12.72

We request comment on our estimates of benefits, costs, and transfers of this proposed rule.

We have developed a Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 168) and at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(n) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). Collection of information includes any request or

requirement that persons obtain, maintain, retain, or report information to the Agency, or disclose information to a third party or to the public (44 U.S.C. 3502(3) and 5 CFR 1320.3(c)). The title, description, and respondent description of the information collection are shown under this section with an estimate of the annual reporting, recordkeeping, and/or third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Infant Formula Nutrient Requirements.

Description: Finalization of this rule to amend regulations in 21 CFR part 107 for nutrient products would revise OMB control number 0910–0256 with regard to the scope of activity applicable to labeling of these products. At the same time, consistent with 5 CFR 1320.3(b)(1)(v), we estimate a de minimis one-time burden for *[a]djusting the existing ways to comply with any previously applicable instructions and requirements.*

Specifically, the proposed rule includes a mandatory unit change for vitamin A (from IU to µg RAE) and vitamin D (from IU to µg) that applies to all infant formula products regardless of whether nutrient levels change, such that all 326 UPCs would be subject to relabeling. We detail our estimates for this one-time reformulating cost here and in the PRIA. We note that we do not expect this to cause an ongoing increase in PRA burden above the current labeling requirements, but we seek comment on this assumption.

Relabeling costs were estimated using FDA's Labeling Cost Model (Ref. 169), updated to 2025 dollars. The model estimates per-UPC costs across labor, materials, inventory, and recordkeeping activities associated with a label change. All proposed label changes in this analysis are classified as minor changes, that is, changes confined to the Nutrition Facts panel that do not require multi-color redesign or modification of the principal display panel. The proposed changes, including updating declared values for vitamin D, vitamin A, iodine, and manganese and converting vitamin A and vitamin D declarations from IU-based to weight-based units, satisfy this definition.

The model distinguishes between coordinated and uncoordinated label changes. A coordinated change occurs when a manufacturer aligns a required regulatory label change with a planned voluntary relabeling cycle, avoiding prepress, design, and plate costs that would have been incurred regardless. An uncoordinated change occurs when a manufacturer must make a required label change outside of its normal voluntary cycle, incurring the full cost independently. Consistent with the model's empirical data showing that most products are voluntarily relabeled on a two-to-five-year cycle, we assume all label changes in this analysis are coordinated. Even under a coordinated change, manufacturers still incur administrative and recordkeeping costs associated with understanding the regulation, determining their response, and tracking the required change throughout the labeling process.

The estimated cost of a label change is $836 per UPC, with a 90 percent confidence interval between $226 and $1,942. We assume domestic and foreign entities incur the same per-UPC cost. Table 22 shows total estimated labeling costs by domestic and foreign origin.

TABLE 22—TOTAL LABELING COSTS

[2025$]

	Number of UPCs	Low	Primary	High
Domestic	291	$65,696	$243,392	$565,145
Foreign	35	7,902	29,274	67,973
Total	326	73,598	272,666	633,118

Domestic UPCs estimated as 89.2% of total UPCs, consistent with the ratio of domestic to total formulations.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that 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. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, or the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. FDA solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. Request for Comments

We invite all interested persons to submit comments on any aspect of the proposed rule. In particular, we invite comment on the proposed changes to the minimum and/or maximum levels for iodine, vitamin A, vitamin D, and manganese; the proposal to establish a maximum level for manganese; the proposed changes to the unit of measure for vitamin A and vitamin D; the proposed change to the permitted source to meet the vitamin A requirement; and the proposed changes to the content of the required labeling. FDA also requests comment on maintaining the current required minimum and maximum levels in infant

formula for chloride, selenium, potassium, and sodium. Additionally, we invite comment on the following to further inform our phased, comprehensive infant formula nutrient review:

1. FDA is considering whether to require the inclusion of docosahexaenoic acid (DHA) and arachidonic acid (ARA) in infant formula. We invite comments supporting or opposing formal requirements for DHA and ARA, recommended minimum levels, ratios (*e.g.,* DHA:ARA ratio, amounts per 100 kcal), and any age- or formula type-specific considerations, along with scientific evidence supporting those recommendations.

2. FDA is considering whether alpha-linolenic acid (ALA) should be added as a required nutrient in infant formula given its role as an essential omega-3 fatty acid and precursor to longer-chain fatty acids such as DHA and eicosapentaenoic acid (EPA). If ALA were required, its ratio to linoleic acid (LA) would also need to be considered, as the two fatty acids compete for the same metabolic enzymes. We invite comments on the scientific evidence supporting or opposing a formal requirement for ALA and its ratio to LA, including any relevant clinical, epidemiological, or alternative data.

3. FDA is considering the minimum and/or maximum iron levels currently required in infant formula and will review emerging evidence regarding iron's role in neurodevelopment, gut microbiome development, and potential risks at higher intake levels. We invite comments on whether current levels should be maintained, increased, or reduced and on the scientific literature or international standards supporting those positions.

4. FDA is considering whether iron requirements in formula should differ for specific populations of infants (*e.g.,* infants 0–6 vs. 7–12 months of age, infants with socioeconomic and nutritional risk factors). We invite comments on evidence supporting differentiated iron requirements for these groups and how FDA should approach establishing population-specific standards.

5. FDA is considering whether L-carnitine should be required in infant formula given its role in fatty acid oxidation and energy metabolism. We invite comments on the current state of the science regarding L-carnitine's essentiality in infant nutrition and what evidence would support or oppose establishing a formal requirement.

6. FDA is considering whether the proposed minimum and/or maximum nutrient specifications for infant formula present any manufacturing, reformulation, or analytical feasibility challenges for manufacturers, and invites submission of any supporting data or information relevant to this determination.

7. FDA invites data and information on the variability of nutrient levels in tap water and bottled water in the U.S. and how such variability should be considered in establishing minimum and maximum standards for nutrients in infant formula, such as chloride.

8. FDA invites comment on our proposal to change the unit of measure from IU to µg RAE for vitamin A and from IU to µg for vitamin D, and on the potential impact of these changes on consumers' understanding of infant formula labeling.

XIII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

*1. Raiten, D.J., J.M. Talbot, and J.H. Waters, ''LSRO Report: Assessment of Nutrient Requirements for Infant Formulas,'' *Journal of Nutrition,* 128(11):2059S–2293S, 1998. Available at *https://jn.nutrition.org/action/showPdf?pii=S0022-3166%2823%2902391-X.*

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List of Subjects

21 CFR Part 107

Food labeling, Infants and children, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

21 CFR Part 184

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 107 and 184 be amended as follows:

PART 107—INFANT FORMULA

■ 1. The authority citation for part 107 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 350a, 371.

■ 2. Amend § 107.10 by:

■ a. In paragraph (a)(2):

■ i. Designating the table as table 1 to paragraph (a)(2); and

■ ii. In newly designated table 1, under ''Vitamins'' revising the entries for ''Vitamin A'', ''Vitamin D'', and ''Vitamin E''; and

■ b. Revising paragraph (b)(1).

The revisions read as follows:

§ 107.10 Nutrient information.

(a) * * *

(2) * * *

TABLE 1 TO PARAGRAPH (a)(2)

Nutrients	Unit of measurement
* * * * *	
Vitamins	
Vitamin A	Microgram Retinol Activity Equivalents.
Vitamin D	Micrograms.
Vitamin E	International Units.
* * * * *	

(b) * * *

(1) Vitamin A content may also be declared on the label in International Units, vitamin D content in International Units, vitamin E content in units of milligram alpha-tocopherol equivalents, and sodium, potassium, and chloride content in units of millimoles, micromoles, or milliequivalents. When these declarations are made, they shall appear in parentheses immediately following the declarations in microgram retinol activity equivalents for vitamin A, International Units for vitamin E, and micrograms for sodium, potassium, chloride, and vitamin D.

* * * * *

■ 3. Amend § 107.100 by:

■ a. In paragraph (a):

■ i. Designating the table as table 1 to paragraph (a); and

■ ii. In newly designated table 1, under the heading ''Vitamins'', revising the entries for ''Vitamin A'', ''Vitamin D'', ''Vitamin E'', and under the heading ''Minerals'' revising the entries for ''Manganese'', and ''Iodine''; and

■ b. Adding paragraph (g).

The revisions and addition read as follows:

§ 107.100 Nutrient specifications.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Nutrients	Unit of measurement	Minimum level	Maximum level
	* * * * *		
Vitamins			
Vitamin A	Microgram Retinol Activity Equivalents	70	120
Vitamin D	Micrograms	2	3
Vitamin E	International Units	0.7	
	* * * * *		
Minerals			
	* * * * *		
Manganese	Micrograms	1	50
	* * * * *		
Iodine	Do	15	50
	* * * * *		

* * * * *

(g) Vitamin A minimum and maximum levels shall be met through preformed vitamin A only. *Beta*-carotene, if used in infant formula, shall not be considered to contribute to the required minimum and maximum levels of vitamin A in infant formula.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

■ 4. The authority citation for part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

■ 5. Amend § 184.1245 by revising paragraph (c)(2) to read as follows:

§ 184.1245 *Beta*-carotene.

* * * * *

(c) * * *

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: dairy product analogs as defined in § 170.3(n)(10) of this chapter; fats and oils as defined in § 170.3(n)(12) of this chapter; processed fruits and fruit juices as defined in § 170.3(n)(35) of this chapter; and infant formula.

* * * * *

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–22273 Filed 10–29–26; 11:15 am]

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Part III

Department of Labor

Employee Benefits Security Administration

29 CFR Part 2550
Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure; Final Rule

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2550

RIN 1210–AB37

Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Final rule.

SUMMARY: The Department is issuing a final regulation that will require providers of pharmacy benefit management services and affiliated providers of brokerage and consulting services to disclose information about their compensation to fiduciaries of large, self-insured group health plans subject to the Employee Retirement Income Security Act (ERISA). Pharmacy spending is a major driver of overall healthcare costs for employers and is growing faster than medical and surgical spending. These disclosure requirements apply for purposes of ERISA's statutory prohibited transaction exemption for service arrangements under section 408(b)(2). These disclosures are needed so that fiduciaries can assess the reasonableness of contracts or arrangements with these service providers, including the reasonableness of the service providers' compensation. As directed in section 12 of President Trump's Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First*, the Department is issuing this rule to improve employer health plan transparency into the direct and indirect compensation received by pharmacy benefit managers. This final rule will affect sponsors and other fiduciaries of large, self-insured group health plans and certain service providers to such plans.

DATES: This regulation is effective January 4, 2027. This regulation is applicable to plan years beginning on or after July 1, 2027.

FOR FURTHER INFORMATION CONTACT: Stephen Sklenar, Office of Regulations and Interpretations, Employee Benefits Security Administration, Department of Labor, at 202–693–1000 ext. 18554, or Saliha Moore, Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Department of Labor, at 202–693–1000 ext. 12913. These are not toll-free numbers.

Customer service information: Individuals interested in obtaining general information from the Department of Labor concerning Title I of ERISA may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department's website (*www.dol.gov/agencies/ebsa*).

SUPPLEMENTARY INFORMATION:

A. Executive Summary

In Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First*, President Trump instructed the Department to propose regulations under ERISA section 408(b)(2) to improve employer health plan transparency into the direct and indirect compensation received by pharmacy benefit managers.[1] Businesses that provide pharmacy benefit management services (''PBMs,'' unless otherwise specified) to ERISA-covered self-insured group health plans have acquired significant influence over prescription drug costs in recent years. By addressing the influence of PBMs and promoting transparent pricing, President Trump's Executive Order aims to create a fairer and more competitive prescription drug market that lowers costs and ensures accountability across the entire healthcare system.[2] This final rule responds to Executive Order 14273 and is a part of the Trump Administration's larger initiative to address rising healthcare costs for Americans.[3]

ERISA section 408(b)(2) is a statutory exemption from ERISA's prohibited transaction rules applicable to contracts or arrangements for services. ERISA section 406(a)(1)(C) provides that the furnishing of goods, services, or facilities between employee benefit plans (including group health plans) and parties in interest to the plans is a prohibited transaction.[4] A person providing services to the plan is a ''party in interest'' to the plan.[5] To satisfy the conditions of the exemption, ERISA section 408(b)(2)(A) provides that the service contract or arrangement must be reasonable, the services must be necessary for the establishment or operation of the plan, and no more than reasonable compensation may be paid for the services. In addition, under recent amendments to ERISA section 408(b)(2)(B) as part of the Consolidated Appropriations Act, 2026 (CAA, 2026), a broad group of service providers to group health plans including PBMs must provide specified disclosures to the group health plan for the services contract or arrangement to meet the reasonableness condition of the exemption.[6] This final rule implements ERISA section 408(b)(2)(B) for PBMs and affiliated brokers and consultants, with respect to the covered plans described in the final rule.

PBMs are the ''middlemen'' in the pharmaceutical supply chain.[7] For ERISA-covered self-insured group health plans, PBMs perform a wide range of services including, but not limited to, organizing pharmacy networks, negotiating pharmacy reimbursement amounts and drug rebates,[8] establishing drug formularies,[9] processing claims, and managing utilization. In connection with these services, PBMs receive compensation from self-insured group health plans as

[1] 90 FR 16441 (Apr. 18, 2025).

[2] *See* Fact Sheet: President Donald J. Trump Announces Actions to Lower Prescription Drug Prices (Apr. 15, 2025) (''The [Executive] Order builds off [the Administration's] critical work and reevaluates the role of middlemen by: Improving disclosure of fees that pharmaceutical benefit managers (PBMs) pay to brokers for steering employers to utilize their services . . .''), available at *https://www.whitehouse.gov/fact-sheets/2025/04/fact-sheet-president-donald-j-trump-announces-actions-to-lower-prescription-drug-prices/*.

[3] *See, e.g.*, Department of Labor News Release, *Departments of Labor, Health and Human Services, Treasury Announce Move to Strengthen Healthcare Price Transparency*, available at *https://www.dol.gov/newsroom/releases/ebsa/ebsa20250522* (May 22, 2025); Executive Order 14221, ''Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information,'' which directs the Secretaries of Treasury, Labor, and Health and Human Services to build on the groundbreaking transparency regulations launched during President Trump's first term. E.O. 14221 (Feb. 25, 2025); Executive Order 13877, ''Improving Price and Quality Transparency in American Healthcare to Put Patients First'' (June 24, 2019); Executive Order 13813, ''Promoting Healthcare Choice and Competition Across the United States'' (Oct. 12, 2017).

[4] *See* 29 U.S.C. 1106(a)(1)(C). *See also Cunningham* v. *Cornell University*, 604 U.S. 693, 697 (2025) (ERISA section 406 ''supplements the fiduciary's general duty of loyalty to the plan's beneficiaries . . . by categorically barring certain transactions deemed 'likely to injure the pension plan.' '') (citations omitted). If the conditions of an exemption are not satisfied, responsible plan fiduciaries entering into service arrangements with parties in interest to self-insured group health plans, and the parties in interest themselves, may be subject to enforcement action by the Department and the imposition of a civil penalty under ERISA section 502. *See* 29 U.S.C. 1132.

[5] ERISA section 3(14)(B).

[6] Section 6702 of Title VII of Division B of the Consolidated Appropriations Act, 2026, amending definition of ''covered service provider'' in ERISA section 408(b)(2)(B).

[7] *See, e.g.*, Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*.

[8] As discussed below in section B.3.2 of this preamble, rebates are discounts on drugs offered by the pharmaceutical manufacturer in return for preferred placement on a self-insured group health plan's formulary.

[9] A formulary is a list of drugs covered by the plan.

well as from other sources in the pharmaceutical supply chain. Responsible plan fiduciaries of self-insured group health plans (including plan sponsors and other fiduciaries who are responsible for prudently selecting and monitoring service providers) [10] also commonly rely on brokers or consultants to help them with advice, recommendations, and referrals regarding pharmacy benefit management services. The brokers or consultants may, in some cases, be affiliated with a PBM. They also may receive compensation from sources other than group health plans.

Concerns have existed for many years that PBMs, including in their capacities as brokers and consultants with respect to pharmacy benefit management services, are not fully disclosing their compensation to the responsible plan fiduciaries. These concerns prompted the ERISA Advisory Council to recommend that the Department consider extending its service provider disclosure regulation to require specific disclosures by PBMs.[11] Congress took that step by amending ERISA section 408(b)(2) to specify disclosure requirements for PBMs and other covered service providers to group health plans.[12] Additionally, Congress has provided that effective for plan years beginning on or after August 3, 2028, PBMs must pass through rebates, fees, alternative discounts, and other remuneration received from drug manufacturers and other entities to the group health plans that the PBMs are providing services to (or to health insurance issuers on behalf of the plans).[13] A new ERISA section 726, added to part 7 of ERISA, will require additional, retrospective disclosures by providers of pharmacy benefit management services regarding drug spending and drug utilization under the group health plan, effective for plan years beginning on or after August 3, 2028.[14]

The Department's final rule implementing ERISA section 408(b)(2)(B) is intended to provide much needed transparency into contracts and arrangements with PBMs and affiliated brokers and consultants, so that the responsible plan fiduciaries of large ERISA-covered self-insured group health plans can fulfill their statutorily mandated role to determine whether these service contracts or arrangements are reasonable. Under the Department's final rule, these service providers must furnish detailed disclosures to responsible plan fiduciaries of large self-insured group health plans describing their compensation for such services, and advance disclosure of compensation they reasonably expect to receive. The final rule also includes audit provisions designed to ensure that the responsible plan fiduciaries of large self-insured group health plans can verify the accuracy of the disclosures. The responsible plan fiduciaries will be able to use the disclosures in their process of selecting a provider of pharmacy benefit management services, engaging an affiliated broker or consultant, and monitoring these service providers' operations and compliance with contractual obligations.

B. Background

1. Group Health Plan Prescription Drug Coverage

Approximately 136 million Americans receive health coverage through their employers (or their family members' employers) in group health plans covered by ERISA.[15] Group health plans provide healthcare benefits such as hospitalization, sickness, prescription drugs, vision, and dental. Group health plans provide these benefits by purchasing insurance [16] or by self-funding [17] (also known as self-insured) benefits from the employer's general assets or from a funded trust.

Employer pharmacy spending is increasing faster than medical and surgical expenses, representing a growing concern for employers and workers about affordability and adherence. Retail prescription drug spending in the U.S. amounted to nearly $495 billion in 2024 and is projected to grow 7 percent in 2025, but to grow more slowly from 2026 to 2033.[18] Against this backdrop, employers anticipate an 11 to 12 percent increase in pharmacy costs in 2025 into 2026.[19]

For employer-sponsored group health plans, the cost of prescription drugs is usually shared between the group health plan and the individual participant, where the participant pays a fixed amount (copayment), a percentage of the drug's cost (coinsurance), or the full cost of the drug up to the amount of the annual deductible, if the group health plan applies a deductible. The group health plan's drug formulary identifies the drugs that are covered and organizes the drugs into tiers, with different cost-sharing requirements imposed on

[10] It is well established that plan sponsors as defined in ERISA section 3(16)(B)(i) often wear two hats—a settlor hat and a fiduciary hat. *See, e.g., McKee Foods Corp.* v. *BFP Inc.*, 173 F.4th 242, 256 (6th Cir. 2026); *Reetz* v. *Aon Hewitt Inv. Counseling, Inc.*, 74 F.4th 171, 179–80 (4th Cir. 2023); *Bennett* v. *Conrail Matched Savings Plan Admin. Comm.*, 168 F.3d 671, 679 (3d Cir. 1999). Yet it is equally well established that ''ERISA does require, however, that the fiduciary with two hats wear only one at a time, and wear the fiduciary hat when making fiduciary decisions.'' *Pegram* v. *Herdrich*, 530 U.S. 211, 225 (2000). Under this principle, a contract or arrangement with a covered service provider necessary for the establishment or operation of the self-insured group health plan does not evade the requirements of this proposed regulation merely because it is signed by a plan sponsor.

[11] *See* Advisory Council on Employee Welfare and Pension Benefit Plans (ERISA Advisory Council), *PBM Compensation and Fee Disclosure* at 20 (Nov. 2014) available at *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf* (''Plan sponsors uniformly testified about the difficulties in obtaining the disclosure of PBM compensation, and how this interfered with their efforts to negotiate and monitor PBM contracts.'').

[12] Section 6702 of Title VII of Division B of the Consolidated Appropriations Act, 2026 amended subparagraph (b)(2)(B) of ERISA section 408.

[13] Section 6702 of Title VII of Division B of the Consolidated Appropriations Act, 2026 added subparagraph (b)(2)(C) to ERISA section 408.

[14] ERISA section 726, added by section 6701 of Title VII of Division B of the Consolidated Appropriations Act, 2026. Section 6701 also added parallel provisions in Public Health Service Act section 2799A–11 and Internal Revenue Code section 9826.

[15] U.S. Department of Labor, *Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2023 Annual Social and Economic Supplement to the Current Population Survey* at 6 (Aug. 30, 2024), available at *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2023.pdf*.

[16] In a fully insured plan, the employer pays a fixed monthly premium to an insurance carrier that assumes all risk for paying claims. Premiums are generally fixed for a year, providing high budget predictability. Under this model, employers have more limited design flexibility, since plans are standardized by the insurance carrier. For fully insured plans, the insurer manages all claims processing, network management, and regulatory compliance and must adhere to both federal and state-mandated insurance and coverage regulations. The fully insured model may appeal more to smaller, risk-averse firms.

[17] In a self-insured plan, the employer assumes the financial risk for providing health benefits to employees, rather than paying a fixed premium to an insurance carrier. Additionally, the employer pays for claims as they are incurred. While this can save on premiums and administrative costs, it exposes the employer to volatility; thus, employers often buy ''stop-loss'' coverage to protect against high-cost, catastrophic claims. Under self-funding, employers have more control over the plan design, allowing them to customize coverage to employee needs. Benefits are typically managed by a Third-Party Administrator (TPA), and the plan is subject to federal ERISA regulations, but exempt from many state-mandated benefits.

[18] Centers for Medicare & Medicaid Services, *National Health Expenditure Projections 2025–2034*, available at *https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf* (''From 2025–27, average growth is projected to slow to 5.6 percent due to decreasing Marketplace enrollment and slower anti-obesity medication uptake. For 2028–33, growth is projected to average 4.7 percent.'').

[19] Business Group on Health, *2026 Employer Health Care Strategy Survey: Executive Summary*, (Aug. 19, 2025), available at *https://www.businessgrouphealth.org/resources/2026-employer-health-care-strategy-survey-executive-summary*.

participants. The tiers often distinguish between generic drugs and brand-name drugs, and plans may have one or more separate tiers for ''specialty drugs.'' [20]

Managing a group health plan's prescription drug coverage is exceedingly complex due to the vast number of drugs available on the market and the large number of drug manufacturers and pharmacies, among other reasons. Further, the pharmaceutical supply chain involves multiple entities—including drug manufacturers, drug wholesalers, pharmacies, PBMs, payors (*e.g.*, group health plans), and participants—that interact with each other in arrangements that can be quite opaque.[21]

Due to the complexity of the pharmaceutical supply chain and the myriad players involved, responsible plan fiduciaries of group health plans often outsource pharmacy benefit management services. When group health plan benefits are obtained through insurance, pharmacy benefit management services are often integrated with the insurance contract. When group health plans are self-insured, however, the responsible plan fiduciaries may engage a PBM directly, or they may obtain pharmacy benefit management services through a third-party administrator (TPA) or other entity.

2. Pharmacy Benefit Managers' Services Provided to Self-Insured Group Health Plans

PBMs perform numerous services related to self-insured group health plans' prescription drug coverage, including identifying the prescription drugs that will be covered by a plan and negotiating prices with various entities in the pharmaceutical supply chain.[22]

2.1. Formulary Development and Design

PBMs develop a self-insured group health plan's prescription drug formulary,[23] which is a list of drugs (brand, generic, and specialty) that the self-insured group health plan will cover. A variety of different, tiered cost-sharing requirements may apply to the drugs in the formulary, either through coinsurance (a percentage off list price) or copayments (a fixed price not tied to list price).[24] Formularies generally balance access to prescription drugs with managing costs, and their development is similar across PBMs in that they often follow a multi-step process involving several distinct committees.[25] For example, a pharmacy and therapeutics (P&T) committee is often used as an external body of experts who ''evaluate clinical and medical literature to select the most appropriate medications for individual disease states and conditions.'' [26] These committees are staffed with healthcare providers including physicians, pharmacists, and patient representatives. Following their analyses, the P&T committee makes recommendations for the PBM's template formulary or for an individual client's custom formulary.[27] Notably, this is only one of several possible PBM committees that may have influence over formulary design.[28] There are also formulary review and value assessment committees which review P&T committee recommendations to make formulary placement decisions and trade relations committees which negotiate and approve rebate agreements with drug manufacturers.[29]

In connection with formulary development, PBMs and their affiliates enter into rebate contracts with drug manufacturers and negotiate for rebates and fees on prescription drugs and other remuneration in return for preferred formulary placement.[30] PBMs use the large number of participants across multiple self-insured group health plans to negotiate with drug manufacturers based on ''covered lives,'' primarily

[20] Generic drugs are ''medication[s] created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quantity, performance characteristics, and intended use.'' U.S. Food & Drug Administration, *Generic Drugs: Questions & Answers* (June 8, 2026), available at *https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers#q1*. Specialty drugs do not have a standard definition, but some characteristics that may identify specialty drugs are special handling requirements or high costs. Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 17–18 (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*.

[21] *See* Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 1 (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf* (''PBM business practices and their effects remain extraordinarily opaque.''); United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 65, available at *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf*. Many sources that discuss the pharmaceutical supply chain find it useful to include a chart to map out the parties involved. *See, e.g.*, U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 9 (GAO–24–106898, Mar. 2024), available at *https://www.gao.gov/assets/gao-24-106898.pdf*.

[22] *See* National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* (2025), available at *https://content.naic.org/sites/default/files/pmbwhitepap.pdf;* U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* (GAO–24–106898, Mar. 2024), available at *https://www.gao.gov/assets/gao-24-106898.pdf*; Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit* Managers (Apr. 2025), available at *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*; United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (2021); available at *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf*; Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* (Nov. 2014), available at *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf*.

[23] Some formularies are open—covering virtually all drugs—while others are more restrictive. There has been a growing trend over the last decade, however, in usage of more restrictive formularies, excluding more drugs. United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, at 71, available at *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf*; Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* 66–67 (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*.

[24] Tasmina Hydery & Vimal Reddy, Journal of Managed Care & Specialty Pharmacy, *A Primer on Formulary Structures and Strategies, Journal of Managed Care & Specialty Pharmacy* (Feb. 3, 2024), available at *https://www.jmcp.org/doi/10.18553/jmcp.2024.30.2.206*.

[25] *Id.*

[26] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 18 (2025), available at *https://content.naic.org/sites/default/files/pmbwhitepap.pdf*.

[27] United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 35 (2021), *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf*.

[28] *Id.* at 36.

[29] *Id.* at 36, 38.

[30] Federal Trade Commission, Interim Staff Report, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 10–11 (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 8 (GAO–24–106898, Mar. 2024), available at *https://www.gao.gov/assets/gao-24-106898.pdf*; National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 19 (2025), available at *https://content.naic.org/sites/default/files/pmbwhitepap.pdf*.

where there are competing therapeutic alternatives.[31] Rebates are paid to the PBM periodically after the prescriptions are filled and may be passed through to the self-insured group health plan to the extent required by the services contract.[32]

While PBMs historically have negotiated these contracts directly with drug manufacturers, PBM-affiliated group purchasing organizations (GPOs), also known as rebate aggregators, have taken over much of the rebate negotiation function for commercial health plans in return for incremental fees, or for a portion of the rebate that is then shared with the PBM and the self-insured group health plan, pursuant to contractual terms.[33] Each of the three largest PBMs is part of a vertically integrated entity which owns and controls such GPO subsidiaries. These GPOs are affiliates of their respective PBMs and perform the role of rebate aggregator, and two of these GPOs are currently headquartered outside of the United States.[34]

2.2. Drug Utilization Management

PBMs provide a range of utilization management services—such as prior authorization, step therapy, and quantity limits—to promote medication use, improve clinical outcomes, and control drug costs.[35] While formularies act as the ''menu'' of drugs the self-insured group health plan will cover, utilization management techniques dictate the ''how'' a participant may access drugs prescribed by their healthcare provider. As illustrated above, formularies typically sort drugs into tiers of cost-sharing requirements. Additionally, PBMs may require providers to obtain approval before a drug can be dispensed, a process known as prior authorization. Step therapy, on the other hand, requires participants to try and fail on a less expensive drug first before progressing to another, more expensive option. PBMs may also implement quantity limits that cap the amount of a drug a participant can receive for a particular condition within a given period.

2.3. Pharmacy Contracting and Network Design

PBMs develop pharmacy networks for self-insured group health plans which can be divided into three types of dispensing formats: retail, mail-order, and specialty.[36] Retail pharmacies, which may be part of a pharmacy chain or independent, purchase prescription drugs from drug manufacturers and drug wholesalers and make them available to self-insured group health plan participants.[37] Mail-order pharmacies dispense and deliver prescriptions directly to participants and are often utilized for prescription drugs that are taken regularly.[38] Specialty drugs that meet certain characteristics such as special handling needs or high cost may be provided through a separate pharmacy.[39]

Pharmacy networks can be open (which includes most pharmacies as in-network and apply uniform cost-sharing) or restrictive (which limit in-network status to a narrow group of pharmacies). An open network allows participants to fill prescriptions at nearly any licensed pharmacy nationwide, offering broad convenience and access. This wider access, however, often comes with higher costs for both the plan and its participants, as broader networks may reduce a plan's leverage to negotiate lower reimbursement rates. Recent analysis by the Federal Trade Commission (FTC), Congress, and others have highlighted that the largest PBMs utilize restrictive networks to steer participants to their own vertically integrated or PBM-affiliated pharmacies, even when another pharmacy may provide the same or better pricing, raising concerns about diminished competition and potential conflicts of interest.[40]

In developing pharmacy networks, PBMs negotiate reimbursement rates and post-sale adjustment provisions that determine the amount the pharmacy is ultimately reimbursed. The reimbursement rate is typically determined using the lowest price among various indices using the ''lesser of'' logic, for example, the lesser of: (1) Average Wholesale Price, (2) Wholesale Acquisition Cost, (3) Usual and Customary Price, (4) Submitted Costs, or (5) Maximum Allowable Costs (MAC).[41] MAC lists represent the amount that a group health plan will pay for generics and, in some cases, brand name drugs with generic equivalents.[42] MAC lists are often proprietary and are created, maintained, and updated by PBMs exclusively.

[31] Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 8 (April 2025), available at *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*; United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 29 (2021), available at *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf*. ''Covered lives'' means the total number of eligible members covered under a benefit plan. Truveris, *The Truveris Pharmacy Benefits Glossary of Terms* (Feb. 6, 2022), *https://truveris.com/pharmacy-benefits-glossary/*).

[32] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 19 (2025), available at *https://content.naic.org/sites/default/files/pmbwhitepap.pdf*; United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 39 (2021), available at *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf*.

[33] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 21 (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*; United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 83 (2021), available at *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf*.

[34] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 24 (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*.

[35] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 12 (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 8 (GAO–24–106898, Mar. 2024), available at *https://www.gao.gov/assets/gao-24-106898.pdf*.

[36] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 11 (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 8 (GAO–24–106898, March 2024), available at *https://www.gao.gov/assets/gao-24-106898.pdf*.

[37] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 17 (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*.

[38] *Id.*

[39] *Id.* at 17–18.

[40] *Id.* at 11.

[41] *Id.*; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 26 (Apr. 2025), available at *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*.

[42] U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 13 (GAO–24–106898, March 2024), *https://www.gao.gov/assets/gao-24-106898.pdf*.

2.4. Claims Administration and Other Services

Finally, PBMs also perform prescription drug claims administration services, which like the other services, are important to a self-insured group health plan's pharmacy benefit program. Claims processing may involve the determination of ''(1) whether an individual was an eligible participant: (2) whether the prescribed drug was covered by the plan; (3) whether the participant met his or her deductible; and (4) what the participant's co-payment would be if required by the plan.'' [43] PBMs have developed systems to transmit prescription information between themselves and pharmacies, permitting the rapid processing of claims as prescriptions are being filled.[44] Other services include adjudicating appeals, plan recordkeeping and regulatory compliance.[45]

3. PBM Contracts and Arrangements With Self-Insured Group Health Plans

When engaging in a request for proposal process, responsible plan fiduciaries of self-insured group health plans receive bids to contract directly with a PBM for services, or they may contract for services with a TPA or other entity (examples discussed herein) that agrees to provide pharmacy benefit management services to the self-insured group health plan.[46] Some responsible plan fiduciaries also join coalitions or cooperatives that negotiate with PBMs on behalf of a group of employer-sponsored self-insured group health plans.[47]

Negotiating a pharmacy benefit contract is a complex process that requires specialized expertise. Responsible plan fiduciaries, especially those without internal expertise and practices to manage drug benefits, often work with a separate consultant or broker to select and negotiate a direct contractual agreement with the PBM. As a best practice, the Department is of the view that large employers should ensure that strategic financial leaders, including the company's Chief Financial Officer or similarly situated individual(s), both lead and collaborate closely with internal teams in selecting, designing, and engaging in procurement for employee health benefits. This will ensure alignment of health benefits with the company's overall strategic financial plan and assist in addressing rising healthcare costs, improving benefits, and reducing administrative burdens.

Consultant or broker services can include requests for proposals (RFPs), PBM oversight, and PBM audit services.[48] In some cases, the consultants and brokers receive indirect compensation (*i.e.*, compensation from the PBMs or other sources other than the self-insured group health plan) that create a conflict of interest with respect to their self-insured group health plan customers.[49] Consulting firms and brokerages reportedly may receive payments on a per prescription or per covered employee basis, or they may share in rebates earned by PBMs.[50] Consultants may have preferred relationships with certain PBMs which may impact their recommendations.[51]

In addition to the complexity of the negotiations, PBM contracts themselves are complex and responsible plan fiduciaries often lack knowledge of how PBMs operate and how they receive compensation.[52] For example, PBM contracts may be for one year or multiple years, and may be amended at any point during the contract period if the formulary changes. The contracts may also allow for interim ''market checks.'' [53] As described by one source, this involves ''a comparison of the aggregate program pricing terms with the market access product types/distribution channels, administrative fees, allowances, other financial guarantees, and rebates to determine if the plan sponsor is receiving competitive market rates.'' [54] The contracts also address the ability of the responsible plan fiduciary to audit the PBM's compliance with the contract.[55] PBMs often limit a self-insured group health plan's audit rights, however, providing only a sample of records relating to contractual performance,

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[43] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 9 (Nov. 2014), available at *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf*.

[44] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 13 (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit* Managers at 11 (April 2025), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*.

[45] U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 8 (GAO–24–106898, Mar. 2024), available at *https://www.gao.gov/assets/gao-24-106898.pdf*; Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 6 (Nov. 2014), available at *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf*.

[46] *See* Matthew Fiedler, Loren Adler, & Richard G. Frank, *A Brief Look at Current Debates about Pharmacy Benefit Managers*, The Brookings Institution (Sept. 7, 2023), available at *https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/*.

[47] Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 19–20, 59 (Apr. 2025), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*.

[48] Milliman, Pharmacy Benefits Consulting, available at *https://www.milliman.com/en/services/pharmacy-benefits-consulting*.

[49] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 3 (Nov. 2014), available at *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf*. Deidre S. Gifford, Connecticut Health Strategy, *Report of Pharmacy Benefit Manager Practices* at 34 (Feb. 2025), available at *https://portal.ct.gov/-/media/ohs/reports/ohs-report-of-pharmacy-benefit-manager-practices-pa-23-171-s7.pdf?rev=01a4809a4795421e890970d8cd5f2fc1*.

[50] Bob Herman, *'It's beyond unethical': Opaque conflicts of interest permeate prescription drug benefits* (June 20, 2023), available at *https://www.statnews.com/2023/06/20/pbms-consulting-firms-investigation/*.

[51] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 21 (Nov. 2014), available at *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf*.

[52] Congress has prohibited plans and issuers from entering into contracts with healthcare providers, networks or association of providers, third-party administrators, or other service providers offering access to a network of providers that would prohibit them from electronically accessing de-identified claims and encounter information or data, including financial information, such as the allowed amount, or any other claim-related financial obligations included in the provider contract; however, such provisions do not affirmatively provide disclosure to responsible plan fiduciaries. *See* ERISA section 724; Code section 9824(a)(1)(B); PHS Act section 2799A–9.

[53] Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 60 (Apr. 2025), available at *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*; Alex Johnson & Brian N. Anderson, *PBM Best Practices Series, RFP Process;* Milliman White Paper at 4 (Sept. 2016), available at *https://edge.sitecorecloud.io/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/Articles/Best-practices-PBM-RFP-process.pdf*.

[54] Alex Johnson & Brian N. Anderson, *PBM Best Practices Series, RFP Process;* Milliman White Paper at 4 (September 2016), available at *https://edge.sitecorecloud.io/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/Articles/Best-practices-PBM-RFP-process.pdf*.

[55] Scott McEachern & Patrick Cambel, *PBM Contracts: Understand then Optimize;* Milliman White Paper (Aug. 2020), available at *https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize* (''PBMs normally define all audit rights and limitations in the PBM contract and plan sponsors must initiate the audit.''); Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 24 (Nov. 2014), available at *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf*.

requiring that the auditor be approved by the PBM, or that the audit be conducted on-site at a facility chosen by the PBM.

3.1. Administrative Fees and Spread Pricing

PBM compensation arrangements with self-insured group health plans may have multiple components, but the compensation models are sometimes described as falling into two general categories: pass through pricing and spread pricing.[56]

In a pass-through pricing model, self-insured group health plans may pay the PBM the average wholesale price (AWP) for a drug minus a negotiated discount (also referred to as the negotiated rate) plus an administrative fee, which may be structured on a per claim basis, per participant basis, flat rate, or other mechanism.[57] In a spread pricing model, self-insured group health plans may pay AWP or AWP minus a smaller negotiated discount than in a pass-through model, but will either not pay or pay only a reduced administrative fee.[58] The PBM will instead retain the spread between the price reimbursed to the pharmacy, which might be based on MAC or a different formula, and the negotiated rate with self-insured group health plans.[59]

The spread pricing model does not utilize an agreed upon AWP for a given drug. Accessing AWP data may be costly, and AWP providers use proprietary, hard-to-verify data sources and methodologies.[60] Additionally, PBMs typically have not disclosed to the responsible plan fiduciaries either the reimbursement amount paid to pharmacies or the pharmacies' acquisition costs.[61] Even where a price guarantee is included in a PBM contract, this guarantee may apply on an aggregate basis where PBMs may use periodic true-ups to show compliance with the price guarantee, rather than ensuring each individual prescription is billed at or below the guaranteed price.[62] One testimony to the ERISA Advisory Council indicated that PBMs may also use complex pricing algorithms in aggregate calculations, which can involve including or excluding certain claims in ways that affect the calculations used to measure the fulfillment of price guarantees.[63]

Some responsible plan fiduciaries may view the spread pricing model as providing potential benefits such as smoothing fluctuations in drug costs, which could reduce unpredictability, compared to models where the full drug costs are passed through to the self-insured group health plan, without applying a price smoothing mechanism.[64] However, the spread pricing model may be less transparent to responsible plan fiduciaries if there are no disclosures of the differences between the amounts the PBM paid to pharmacies and the amounts charged to the self-insured group health plan, or if pricing guarantees are verified only in the aggregate. Comparatively, in the pass-through model, PBMs charge the plan the same amount they reimburse pharmacies, and compensation is more plainly identified, which some responsible plan fiduciaries characterize as a more ''transparent'' arrangement.[65] Some PBMs that offer pass-through pricing also have business models that provide customers with frequent audit

[56] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 13 (2025), available at *https://content.naic.org/sites/default/files/pmbwhitepap.pdf*; House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 7 (2024), available at *https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf*; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 2 (Apr. 2025), available at *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*.

[57] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 13 (2025), available at *https://content.naic.org/sites/default/files/pmbwhitepap.pdf*; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 142–43 (Oct. 2024), available at *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*.

[58] Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 119 (Apr. 2025), available at *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*.

[59] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 13 (2025), available at *https://content.naic.org/sites/default/files/pmbwhitepap.pdf*; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 7–8 (GAO–24–106898, Mar. 2024), available at *https://www.gao.gov/assets/gao-24-106898.pdf*.

[60] AWP is ''an estimate of the price wholesalers charge for drugs.'' National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 12 (2025), available at *https://content.naic.org/sites/default/files/pmbwhitepap.pdf*. AWP prices are available from third-party vendors. Andrew W. Mulcahy & Vishnupriya Kareddy, Prescription Drug Supply Chains: An Overview of Stakeholder Relationships, RAND Corporation at 30 (2021), available at *https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf*. The Department reviewed the publicly available information on the websites of AWP providers and found no methodology documents, quality control practices, or sample price lists or analysis that could validate the accuracy of the AWP.

[61] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 21 (2025) (''Pharmacy pricing is complex, and the process is not transparent. Plan sponsors are often unaware of the difference between the amount they are billed and the pharmacy reimbursement.''), available at *https://content.naic.org/sites/default/files/pmbwhitepap.pdf*; Eastern Research Group, *An Examination of Pharmaceutical Supply Chain Intermediary Margins in the U.S. Retail Chain* at ii (Sept. 27, 2024), available at *https://aspe.hhs.gov/sites/default/files/documents/db1adf86053b1fda8ae9efd01c10ddc8/Pharma%20Supply%20Chains%20Margins%20Report_Final_2024.09.27_Clean_508.pdf*.

[62] Scott McEachern & Patrick Cambel, *PBM Contracts: Understand then Optimize*, Milliman White Paper (Aug. 2, 2020), available at *https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize* (''Contracts with PBMs typically involve guarantees in a number of pricing areas. The PBM may guarantee individual pricing by dispensing channel (retail, mail order, and specialty) as well as by drug type (brand or generic). The PBM might commit to these pricing metrics such that overall, at the end of the year, the aggregate pricing within each channel and drug type will be at least as good as the guarantees outlined in the contract. In the case that a PBM has not met a guarantee, the PBM would issue a true-up payment to the plan sponsor to make up for any deficiencies. However, some contracting language may allow the PBM to cover its underperformance by using any overperformance from other channels.'').

[63] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 22 (Nov. 2014), available at *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf*.

[64] Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit* Managers at 34 (Apr. 2025), available at *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*.

[65] House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 26 (2024), available at *https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf*; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit* Managers at 142 (Apr. 2025), available at *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*.

opportunities and minimal limitations on access to PBM data.[66]

Additionally, as discussed in greater detail later in the Regulatory Impact Analysis, the largest PBMs have become vertically integrated with health insurance companies, pharmacies, drug manufacturers, and other entities.[67] PBMs sometimes operate affiliated pharmacies and require plan participants to use these affiliated pharmacies for certain prescriptions such as mail-order and/or specialty drugs.[68] In some ways, the vertically integrated structure can be efficient and cost-effective, but it may affect price competition when participants are required to use a PBM-affiliated pharmacy for certain prescriptions.[69] With respect to specialty drugs, which are an increasing source of drug spending, the FTC found in a recent study that the three largest PBMs ''reimbursed their affiliated pharmacies at a higher rate than unaffiliated pharmacies on nearly every specialty generic drug examined.'' [70]

3.2. Payments From Drug Manufacturers

Payments from drug manufacturers are another component of PBM compensation. These types of payments include, but are not limited to, rebates, administrative fees, price protection fees, and so on. These payments are often defined by reference to list price, which incentivizes PBMs to choose high-list price, high-rebate drugs when creating a self-insured group health plan's formulary.[71]

Rebates are discounts on drugs offered by the pharmaceutical manufacturer in return for preferred placement on a self-insured group health plan's formulary; and the extent to which rebates are retained by the PBM or passed through to the self-insured group health plan is negotiated by the parties.[72] PBMs also earn administrative fees from drug manufacturers when prescriptions are filled based on the utilization of the drugs and plan design decisions made by plan sponsors, including formulary and utilization management strategies.[73] Price protection fees are an additional rebate that a manufacturer pays the PBM if list prices rise faster than inflation or another agreed upon amount.[74]

To the extent rebates, fees, and other sources of remuneration are passed through to the self-insured group health plan, such amounts can help defray the cost of the healthcare benefits being provided.[75] However, even if there are contracted obligations requiring that rebates, fees, and other sources of remuneration be passed through to the plans, the responsible plan fiduciaries may benefit from more transparent disclosures to ensure that such amounts are passed through as agreed to under the contract with the PBM, in part due to evolving terminology used in the contracts and or re-routing or recharacterizing of the amounts.[76] The role of rebate aggregators adds complexity to drug pricing and transparency for disclosure of rebates owed to group health plans.[77]

The rebate payment structure would also benefit from more transparent disclosure for other reasons. One commonly cited concern is that PBMs have an incentive to select certain drugs with high-list prices over others for group health plan formularies due to the size of the rebate payments from drug manufacturers.[78] In addition to

[66] House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 26 (2024), available at *https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf*.

[67] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 1–2 (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*.

[68] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 12 (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*; Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 11 (Nov. 2014), *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf*.

[69] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 23 (2025), available at *https://content.naic.org/sites/default/files/pmbwhitepap.pdf*; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 18 (Apr. 2025), available at *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*.

[70] Federal Trade Commission, *Second Interim Staff Report, Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Mangers* at 2 (Jan. 2025), *https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf*.

[71] *See* Federal Trade Commission, *FTC Secures Landmark Settlement with Express Scripts to Lower Drug Costs for American Patients* (Feb 4. 2026), available at *https://www.ftc.gov/news-events/news/press-releases/2026/02/ftc-secures-landmark-settlement-express-scripts-lower-drug-costs-american-patients* (''The complaint alleges that this system pushed insulin manufacturers, among others, to compete for preferred formulary coverage based on the size of rebates off the list price rather than net price, which ultimately benefitted the PBMs, including ESI, which keep a portion of the inflated rebates.'').

[72] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 19 (2025), available at *https://content.naic.org/sites/default/files/pmbwhitepap.pdf*.

[73] United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 8 (2021), available at *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf*; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 13 (Apr. 2025), available at *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*.

[74] United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 9 (2021), available at *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf*; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 13 (Apr. 2025), available at *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*.

[75] For example, rebates passed through to a trust established to fund a self-insured group health plan would be required to be used for the exclusive purposes of providing benefits to the plan's participants and beneficiaries and defraying reasonable expenses of administering the plan. *See* ERISA section 403(c)(1). *See also Deidre S. Gifford, Report of Pharmacy Benefit Manager Practices* at 38 (2025) (''From the plan sponsor's perspective, rebates are a valuable tool in keeping plan premiums low as most plans use rebate value to directly offset plan liability and do not share rebate value with members at the point of sale.''), available at *https://portal.ct.gov/-/media/ohs/reports/ohs-report-of-pharmacy-benefit-manager-practices-pa-23-171-s7.pdf?rev=01a4809a4795421e890970d8cd5f2fc1*.

[76] Joanna Shepherd, *Pharmacy Benefit Mangers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, Yale L. & Pol'y Rev. at 382 (2020), available at *https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content* (''PBMs rarely disclose the rebates they receive from manufacturers, and in situations in which they've agreed to share rebate information, the PBMs may recategorize rebates as fees to circumvent disclosure obligations.''); Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 22 (Nov. 2014), *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf*.

[77] Eric Percher, *Trends in Profitability and Compensation of PBMs & PBM Contracting Entities*, Nephron Research at 2 (Sept. 18, 2023), available at *https://cdn.ymaws.com/www.wsparx.org/resource/resmgr/legislative_session/2024/pbm_campaign/nephron_pbm.pdf*.

[78] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 20 (2025), available at *https://content.naic.org/sites/default/files/pmbwhitepap.pdf https://content.naic.org/sites/default/files/pmbwhitepap.pdf https://content.naic.org/sites/default/files/pmbwhitepap.pdf* (''The existence of rebates alone is not a problem. However, the PBM's ability to retain a percentage of the rebate creates a concern,

providing PBMs with an incentive to select higher priced drugs for the formularies, drug manufacturers offer higher rebates to PBMs to exclude competing products from the formulary.[79] Disclosure of rebates and other payments from drug manufacturers will enable responsible plan fiduciaries to evaluate the way the PBM has designed the formulary, the extent to which its composition might be influenced by financial incentives, and to determine whether the impacts of these incentives require mitigation to ensure the reasonableness of the contract or arrangement.

Rebates and related PBM formulary practices have also been shown to correspond to increases in the manufacturers' drug list prices.[80] Drug manufacturers often raise list prices to accommodate rebate demands to secure preferred formulary placement to protect market share, profits, or to recoup the costs for research and development.[81] While increases in list prices have a marginal impact on self-insured group health plans, as they generally pay a lower price due to rebates and other discounts negotiated by the PBMs, they can be detrimental to participants.[82]

To offset rising drug prices, employers are increasingly shifting towards cost-sharing structures that make participants more sensitive to list prices. Participants in self-insured group health plans often pay the full cost of the drug up to the amount of their annual deductible and a portion of prescription drug costs after the deductible is satisfied, typically in the form of coinsurance. In many self-insured group health plans, coinsurance is often based on list price, resulting in higher out-of-pocket costs for participants.[83]

3.3. Payments From Pharmacies

PBMs receive payments from pharmacies in several different circumstances. If a participant's copay is higher than the total reimbursement owed to the pharmacy, a PBM may ''claw-back'' the overpayment amount.[84] For example, if a participant's copayment for a generic drug is $15 dollars, but the PBM has agreed to pay the pharmacy $5, the PBM will ''claw-back'' the excess $10. In such cases, it is not clear whether such overpayments are generally or ever reimbursed to the self-insured group health plan (or participant).[85]

PBMs also reportedly recoup amounts paid to pharmacies for other reasons, including ''network participation fees, fees for non-compliance or lower performance with quality measures, and reimbursement reconciliation.'' [86] A relatively new PBM practice is ''effective rate reconciliation,'' in which the contractual reimbursement rate paid by a PBM to a pharmacy for dispensing a drug is determined by an aggregate effective rate, typically expressed as a percentage discount from AWP.[87] The PBM periodically reconciles the payments made to pharmacies at the point of sale with the specified effective rate and will adjust future reimbursement to the pharmacy to account for the difference between the amount paid at the point of sale and the effective rate following the reconciliation.[88] In addition to generic

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as they are also commonly in charge of formulary design. These two factors give PBMs a financial incentive to prioritize drugs in the formulary based on the highest rebate instead of the lowest total cost to the plan sponsor or consumer.''); House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 7 (2024), available at *https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf*; Shepherd, *Pharmacy Benefit Mangers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, Yale L. & Pol'y Rev. at 360 (2020), *https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content*; T. Joseph Mattingly II, David A Hyman, Ge Bai, *Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy*, available at *https://pubmed.ncbi.nlm.nih.gov/37921745/*.

[79] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 4 (July 2024) (''We share evidence that PBMs and brand pharmaceutical manufacturers sometimes enter agreements to exclude generic drugs and biosimilars from certain formularies in exchange for higher rebates from the manufacturer.''), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*; United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 8 (2021), available at *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf*.

[80] Neeraj Sood, Rocio Ribero, Martha Ryan, & Karen Van Nuys, *The Association Between Drug Rebates and List Prices* at 3, U.S.C. Schaeffer (Feb. 2020), available at *https://schaeffer.usc.edu/wp-content/uploads/2024/10/SchaefferCenter_RebatesListPrices_WhitePaper-1.pdf* (''Our finding that increased rebates are positively associated with increased list prices supports the notion that PBMs' demand for rebates is at least partly responsible for increasing list prices.''); United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 80 (2021), *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf*.

[81] *See* Joanna Shepherd, *Pharmacy Benefit Mangers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, Yale L. & Pol'y Rev. at 362 (2020), available at *https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content*.

[82] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Report to Congress: Prescription Drug Spending, Pricing Trends, and Premiums in Private Health Insurance Plans* at 4 (Nov. 2024), available at *https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/2024-report-to-congress-prescription-drug-spending.pdf* (noting that ''[f]or many drugs, however, list prices are not the prices ultimately paid to manufacturers; payers or pharmacy benefit managers (PBMs) negotiate with manufacturers over formulary placement in exchange for discounts in the form of rebates off the list price,'' and that ''[a]s used throughout this report, the term 'rebates' includes rebates, fees, and other remuneration transferred to PBMs from drug manufacturers and pharmacies.'').

[83] Neeraj Sood, Rocio Ribero, Martha Ryan, & Karen Van Nuys, *The Association Between Drug Rebates and List Prices* at 5, U.S.C. Schaeffer (Feb. 2020), available at *https://schaeffer.usc.edu/wp-content/uploads/2024/10/SchaefferCenter_RebatesListPrices_WhitePaper-1.pdf* (''We find that rebates and list prices are positively related, with an increase in rebates associated with a roughly dollar-for-dollar increase in list price. This suggests that reducing or eliminating rebates could result in lower list prices, thereby decreasing out-of-pocket costs for uninsured patients and for insured patients with deductibles or coinsurance.''); Joanna Shepherd, *Pharmacy Benefit Mangers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, Yale L. & Pol'y Rev. at 362–63 (2020), available at *https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content*; T. Joseph Mattingly II, David A Hyman, & Ge Bai, *Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy*, available at *https://pubmed.ncbi.nlm.nih.gov/37921745/*.

[84] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 21 (2025), available at *https://content.naic.org/sites/default/files/pmbwhitepap.pdf*. Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 23 (Nov. 2014), available at *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf*.

[85] Some self-insured plans have benefit-design edits that make copayments the ''lesser of'' the copayment amount and the acquisition cost to prevent overpayment and therefore claw-backs.

[86] Deidre S. Gifford, *Report of Pharmacy Benefit Manager Practices* at 17 (2025) (''Brokers earn revenues in several ways that may not be apparent to the plan sponsor, such as commissions, bonuses, fees, TPA fees paid by PBMs, per prescription fees, etc.''), available at *https://portal.ct.gov/-/media/ohs/reports/ohs-report-of-pharmacy-benefit-manager-practices-pa-23-171-s7.pdf?rev=01a4809a4795421e890970d8cd5f2fc1*. Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 11 (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf*.

[87] Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains: An Overview of Stakeholder Relationships,* RAND Corporation at 19 (2021), available at *https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf*.

[88] U.S. Senate Committee on Finance, *Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers,* Written testimony of Jonathan Levitt (2023), available at *https://www.finance.senate.gov/imo/media/doc/Jonathan%20Levitt%20Testimony%20US%20Senate%20Committee%20on%20Finance%20-%20Frier%20Levitt%20-%20March%202023_Redacted1.pdf*.

effective rate and brand effective rate, the PBM may also include a ''dispensing fee effective rate'' for the administrative cost charged by a pharmacy to dispense a drug.[89]

C. Service Provider Arrangements Under ERISA

1. Prohibited Transaction Framework

Responsible plan fiduciaries of group health plans must determine that service provider relationships involving the group health plan meet certain conditions to avoid constituting a prohibited transaction under ERISA. Specifically, unless an exemption applies, the furnishing of goods, services, or facilities between a group health plan and a party in interest to the plan is a prohibited transaction under ERISA section 406(a)(1)(C). A person providing services to the group health plan is defined by ERISA section 3(14)(B) to be a ''party in interest'' to the group health plan.

ERISA section 408(b)(2) exempts certain arrangements between ERISA-covered plans (including group health plans) and service providers that otherwise would constitute prohibited transactions under ERISA section 406. Section 408(b)(2) provides relief from ERISA's prohibited transaction rules for service contracts or arrangements between a plan and a party in interest if the contract or arrangement is reasonable, the services are necessary for the establishment or operation of the plan, and no more than reasonable compensation is paid for the services.

The Department's regulation under ERISA section 408(b)(2) clarifies the exemption's ''necessary service,'' ''reasonable contract or arrangement,'' and ''reasonable compensation'' conditions.[90] The regulation also clarifies that the exemption in ERISA section 408(b)(2) does not extend to acts described in ERISA section 406(b) relating to fiduciary conflicts of interest and provides examples illustrating this principle.[91]

In 2012, the Department amended its regulation under ERISA section 408(b)(2) to require parties who are ''covered service providers'' with respect to pension plans to disclose specified information to a responsible plan fiduciary, in order for certain services contracts or arrangements to be reasonable.[92] The amended regulation generally requires covered service providers to provide initial disclosure of: the services to be provided; the status of the covered service provider, an affiliate, or a subcontractor as a fiduciary, if applicable; the direct and indirect compensation reasonably expected to be received by the covered service provider, their affiliates and their subcontractors; as well as allocations of compensation reasonably expected to be made among the covered service providers and its affiliates and subcontractors. The amended regulation also establishes ongoing disclosure obligations in the event of a change in the information required to be provided in the initial disclosures and disclosures to be provided upon the written request of the responsible plan fiduciary as needed for the plan to comply with the reporting and disclosure requirements of title I of ERISA. The amended regulation also carries over a provision from the initial regulation regarding termination of the contract or arrangement.[93]

The amended regulation defines a responsible plan fiduciary as a fiduciary with authority to cause the plan to enter into, or extend or renew, a contract or arrangement for the provision of services to the plan.[94] The Department's amended regulation is accompanied by an administrative class exemption for responsible plan fiduciaries, codified at paragraph (c)(1)(ix), which provides prohibited transaction relief for responsible plan fiduciaries in the event a covered service provider fails to disclose information as required under the regulation. In the absence of an exemption providing otherwise, the service provider's failure to comply with the regulation will result in a prohibited transaction by the responsible plan fiduciary.[95]

In the final rule amending its regulation, the Department reserved paragraph (c)(2) for future guidance on disclosure with respect to welfare plans (including self-insured group health plans). The Department concluded that there were significant differences between service and compensation arrangements for welfare plans and those involving pension plans, and that those differences supported the development of specifically tailored disclosure requirements for welfare plans.[96]

In 2014, the ERISA Advisory Council studied PBM fee disclosures and recommended that the Department should ''consider making Section 408(b)(2) Regulations applicable to welfare plan arrangements with PBMs, and thereby deem such arrangements reasonable only where PBMs disclose direct and indirect compensation, including compensation paid among related parties such as subcontractors, in a manner consistent with current Section 408(b)(2) Regulations.'' [97]

The report included several findings related to this recommendation, including:

- ''Plan sponsors of group health plans who testified at the Council hearings were unanimous in their view that they face many challenges managing pharmacy benefits on a cost-effective basis. However, plan sponsors uniformly testified that PBM services are a valuable part of this effort.''
- ''Testimony submitted to the Council revealed that drug pricing methodologies and PBM compensation are complex and evolving, including rebates, price spreads, discounts, and other payments from retail pharmacy chains and manufacturers. Substantial evidence was submitted to the Council

[89] Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers, U.S. Senate Committee on Finance, 118th Cong. (2023) (Written testimony of Jonathan Levitt); Elevate Provider Network, *What are GERs/BERs/DFERs?,* available at *https://www.alliantrx.com/wp-content/uploads/2020/05/GER-Explainer-Document.pdf* Last accessed July 17, 2026.

[90] 29 CFR 2550.408b–2(b), (c), (d).

[91] 29 CFR 2550.408b–2(e).

[92] Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure, 77 FR 5632 (Feb. 3, 2012) (codified at 29 CFR 2550.408b–2(c)).

[93] 29 CFR 2550.408b–2(c)(3) (''No contract or arrangement is reasonable within the meaning of section 408(b)(2) of the Act and paragraph (a)(2) of this section if it does not permit termination by the plan without penalty to the plan on reasonably short notice under the circumstances to prevent the plan from becoming locked into an arrangement that has become disadvantageous. A long-term lease which may be terminated prior to its expiration (without penalty to the plan) on reasonably short notice under the circumstances is not generally an unreasonable arrangement merely because of its long term. A provision in a contract or other arrangement which reasonably compensates the service provider or lessor for loss upon early termination of the contract, arrangement, or lease is not a penalty. For example, a minimal fee in a service contract which is charged to allow recoupment of reasonable start-up costs is not a penalty. Similarly, a provision in a lease for a termination fee that covers reasonably foreseeable expenses related to the vacancy and reletting of the office space upon early termination of the lease is not a penalty. Such a provision does not reasonably compensate for loss if it provides for payment in excess of actual loss or if it fails to require mitigation of damages.'').

[94] 29 CFR 2550.408b–2(c)(1)(viii)(E).

[95] *See* ERISA section 406(a)(1) (''Except as provided in [section 408] . . . [a] fiduciary with respect to a plan shall not cause the plan to engage in a transaction, if he knows or should know that such transaction constitutes a direct or indirect . . . furnishing of goods, services, or facilities between the plan and a party in interest.'').

[96] 77 FR at 5649. The Department held a public hearing on December 7, 2010, to explore operational, disclosure, and fee transparency issues concerning welfare benefit plans. *See https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments/1210-AB37.*

[97] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 3 (Nov. 2014), available at *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.*

from ERISA plan sponsors and others that many PBMs do not fully disclose compensation in a manner which is readily understandable to even the most sophisticated plan sponsors and consultants.''

• ''Testimony before the Council indicated that some forms of PBM compensation have the potential for creating conflicts of interest. Sponsors of ERISA health plans may or may not be aware of these potential conflicts.''

• ''ERISA group health plans that contract directly with PBMs frequently use consultants to assist in negotiations with the PBM. Testimony was submitted to the Council that it is common for consultants to receive indirect compensation. The payment of indirect compensation to consultants who are advising plan sponsors in negotiations with the PBM may create the potential for conflicts of interest that may be adverse to the plan sponsor. Sponsors of ERISA health plans may or may not be informed of such indirect compensation.''

• ''Plan sponsors testified that disclosure of PBM compensation would better enable them to comply with their obligations to determine reasonable compensation under Section 408(b)(2). Nondisclosure creates the potential for impediments to plan sponsors' ability to comply with 408(b)(2).''

The second recommendation of the ERISA Advisory Council related to audits of a PBM's compliance with its contract with the welfare plan.[98] Specifically, the Council recommended that the Department should ''consider issuing guidance to assist plan sponsors in determining whether to and how to conduct a PBM audit of direct and indirect compensation.'' [99]

Findings related to this recommendation included identification of the following problem areas, among others:

• ''The exclusion of auditors who the PBM believes hold hostile views.''

• ''On-site audits are required at PBM headquarters.''

• ''PBMs limit the auditor to transcribing notes of documents.''

• ''Confidentiality agreements can be overly broad and put unnecessary burdens on the parties when they prohibit disclosure of information by an auditor to its client plan.''

• ''PBMs will not disclose documents requested by some auditors such as PBM contracts with retail pharmacies and drug manufacturers.''

• ''Access to claims data is restricted.''

• ''Audit rights restricted to limited periods (such as 2 years).''

• ''Some necessary data sources such as AWP pricing are not public and access is expensive . . . and disclosure is limited.''

2. Consolidated Appropriations Act, 2021 408(b)(2) Amendment

In the Consolidated Appropriations Act (CAA), 2021, Congress amended the ERISA section 408(b)(2) statutory exemption to add a new paragraph (B) applicable to certain services arrangements with group health plans, effective December 27, 2021.[100] As part of the amendment, Congress designated the pre-existing text as ERISA section 408(b)(2)(A).[101] The requirements in ERISA section 408(b)(2)(B) as originally enacted applied to a group of covered service providers, defined as persons or entities who provide ''brokerage services'' or ''consulting'' to group health plans with respect to a list of sub-services including pharmacy benefit management services.[102]

ERISA section 408(b)(2)(B) closely tracks the Department's regulation for pension plan arrangements. It requires disclosure of: the services to be provided; the status of the covered service provider, an affiliate, or a subcontractor as a fiduciary, if applicable; the direct and indirect compensation reasonably expected to be received by the covered service provider, their affiliates and their subcontractors; as well as allocations of compensation reasonably expected to be made among the covered service providers and its affiliates and subcontractors. It also establishes ongoing disclosure obligations in the event of a change in the information required to be provided in the initial disclosures and disclosures to be provided upon the written request of the responsible plan fiduciary as needed for the plan to comply with the reporting and disclosure requirements of title I of ERISA.

In December 2021, the Department provided a guidance and temporary enforcement policy addressing questions about ERISA section 408(b)(2)(B).[103] In general, the policy provided that, pending future guidance or rulemaking, covered service providers and responsible plan fiduciaries would be expected to implement the ERISA section 408(b)(2)(B) requirements using a good faith, reasonable interpretation of the law.

With respect to the terms ''brokerage services'' and ''consulting'' as used in the definition of a covered service provider, the Department noted that neither term was defined and the categories may overlap in some circumstances, but that the fact that a service provider did not call itself a broker or consultant would not be dispositive. Instead, the Department's enforcement policy would apply to parties who reasonably and in good faith determined their status as a covered service provider. The Department expressed that ''service providers who reasonably expect to receive indirect compensation from third parties in connection with *advice, recommendations,* or *referrals* regarding any of the listed sub-services . . . should be prepared, if the Department is auditing their 408(b)(2)(B) compliance, to be able to explain how a conclusion that they are not covered service providers is consistent with a reasonable good faith interpretation of the statute.'' [104]

[98] The Council noted this audit should not be confused with the requirement under ERISA section 103(3)(A).

[99] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure,* at 5 (Nov. 2014), available at *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.*

[100] Section 202 of Title II of Division BB of the Consolidated Appropriations Act, 2021.

[101] ERISA section 408(b)(2)(A) now provides an exemption for ''[c]ontracting or making reasonable arrangements with a party in interest for office space, or legal, accounting, or other services necessary for the establishment or operation of the plan, if no more than reasonable compensation is paid therefor.''

[102] Specifically, as originally enacted ERISA section 408(b)(2)(B)(ii)(I)(bb)(AA) defined a covered service provider as one who provides *brokerage services* ''provided to a covered plan with respect to selection of insurance products (including vision and dental), recordkeeping services, medical management vendor, benefits administration (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness services, transparency tools and vendors, group purchasing organization preferred vendor panels, disease management vendors and products, compliance services, employee assistance programs, or third party administration services.'' ERISA section 408(b)(2)(B)(ii)(I)(bb)(BB) as originally enacted defined a covered service provider as one who provides *consulting services* ''related to the development or implementation of plan design, insurance or insurance product selection (including vision and dental), recordkeeping, medical management, benefits administration selection (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness design and management services, transparency tools, group purchasing organization agreements and services, participation in and services from preferred vendor panels, disease management, compliance services, employee assistance programs, or third party administration services.''

[103] Field Assistance Bulletin No. 2021–03 (Dec. 30, 2021), available at *https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03.*

[104] *Id.* (emphasis added). In addition to the ERISA section 408(b)(2)(B), in 2019, Congress added a distinct statutory exemption in ERISA section 408(h) for the provision of pharmacy benefit services, although in a limited context. The

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D. Consolidated Appropriations Act, 2026

1. ERISA Amendments

The Department issued a proposed rule entitled Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure on January 30, 2026.[105] On February 3, 2026, Congress made further changes to ERISA in the CAA, 2026. Among other things, the CAA, 2026 amended subparagraph (B) of ERISA section 408(b)(2), added a new subparagraph (C) to ERISA section 408(b)(2), and added a new section 726 to ERISA entitled ''Oversight of Entities that Provide Pharmacy Benefit Management Services.''

1.1. Amendments to ERISA Section 408(b)(2)

In subparagraph (B) of ERISA section 408(b)(2), the CAA, 2026 revised the definition of covered service provider to remove the words ''brokerage services'' and ''consulting.'' This change clarified that providers of pharmacy benefit management services (as well as a broad range of other service providers to group health plans, including third party administrators) are covered service providers and are required to make the disclosures under the statute to rely on the prohibited transaction exemption. Additionally, new language was added to subparagraph (B) stating that a service provider for pharmacy benefit management services that contracts with a health insurance issuer in connection with health insurance coverage for a group health plan is considered an indirect provider of services to the plan and a party in interest under ERISA. This language clarified that providers of pharmacy benefit management services that provide services to fully insured plans through an insurance contract are considered parties in interest that must comply with an exemption to avoid participating in a prohibited transaction. The CAA, 2026 amendments also specified that the Department has authority to issue regulations addressing the time, manner, and content of the disclosures identified in subparagraph (B). The amendments to subparagraph (B) were effective on February 3, 2026, upon enactment of the CAA, 2026.

New subparagraph (C) of ERISA section 408(b)(2) focuses solely on providers of pharmacy benefit management services. Under that subparagraph, which is effective for plan years beginning on or after August 3, 2028, providers of pharmacy benefit management services are required to remit to group health plans (or to the insurance company on behalf of the plan) ''100% of rebates, fees, alternative discounts, and other remuneration'' received from ''any applicable entity'' related to the utilization of drugs or drug spending under the plan.[106] Applicable entities are defined in new ERISA section 726 and generally include: drug manufacturers, rebate aggregators, affiliated group purchasing organizations; affiliates of the plan, health insurance issuer, PBM, or drug manufacturers; and other entities that the Secretary specifies in rulemaking. Subparagraph (C) includes related disclosure and audit provisions.

1.2. New ERISA Section 726

ERISA section 726 provides that certain group health plans must receive a report from providers of pharmacy benefit management services every six months (or, at the plan's request, quarterly) containing detailed information about drug spending under the plan. Relatedly, applicable entities must agree by contract with plans and providers of pharmacy benefit management services (i) not to limit or delay disclosure of information in such a manner as to prevent the provider from making the required reports and (ii) to supply the required information. ERISA section 726 is applicable to plan years beginning on or after August 3, 2028, and the Department, along with the Secretaries of the Treasury and of Health and Human Services, has authority to issue regulations necessary to implement it.

Under ERISA section 726, the report is required for self-insured plans of ''specified large employers'' (generally with at least 100 employees) and self-insured ''specified large plans'' (generally with at least 100 participants).[107] Employers with fully insured plans that meet these size specifications can opt in to receive the report.[108] Under ERISA section 726, all group health plans regardless of size must also receive certain information from the entity providing pharmacy benefit management services on behalf of the group health plan. All group health plans must receive a summary document of the information required to be provided for self-insured plans of specified large employers and self-insured specified large plans, as specified by the Secretary through guidance, program instruction, or otherwise.[109] ERISA section 726 also requires that all group health plans regardless of size receive a summary document that plans can provide to participants and beneficiaries upon request by the participant or beneficiary.[110] Further, ERISA section 726 provides for a limited form of report to be defined by the Secretary for any group health plan established by a plan sponsor that is, or is affiliated with, a drug manufacturer, drug wholesaler, or any other participant in the drug supply chain, ''to prevent anti-competitive behavior.''[111]

The required reports for the self-insured group health plans of specified large employers and self-insured specified large plans include a list of drugs for which a claim was filed and related information about costs, compensation, and distribution channel, including information on spread compensation received by the provider of pharmacy benefit management services as well as the total amount received, or expected to be received, by the provider of pharmacy benefit management services from applicable entities in rebates, fees, alternative discounts or other remuneration.[112] The report must also include a list of each therapeutic class for which a claim was filed and related information about costs, utilization, and formulary placement; for any drug for which gross spending exceeded $10,000 during the reporting period (or the 50 drugs with the highest spending if gross spending exceeded $10,000 during the reporting period with respect to fewer than 50 drugs), information about other drugs in

exemption is available to ''an entity described in [ERISA section 3(37)(G)(vi)]'' or any related organization or subsidiary, provides pharmacy benefit services to a group health plan sponsored by the entity or any other group health plan sponsored by a regional council, local union, or other labor organization affiliated with such entity, see Section 1302 of Division P of the Further Consolidated Appropriations Act, 2020. The Department is aware that the United Brotherhood of Carpenters and Joiners of America takes the position that it is a 501(c)(5) organization, tax exempt under Section 501(a) of the Code, and was established in Chicago, Illinois, on August 12, 1881, as referenced in ERISA section 3(37)(G)(vi). *See* Exemption from Certain Prohibited Transaction Restrictions Involving the United Brotherhood of Carpenters and Joiners of America, 90 FR 2748 n. 3 (Jan. 13, 2025).

[105] 91 FR 4348.

[106] ERISA section 408(b)(2)(C)(vi) provides that ''[n]othing in this subparagraph shall be construed to—(I) prohibit reasonable payments to entities offering pharmacy benefit management services for bona fide services using a fee structure not described in this subparagraph, provided that such fees are transparent and quantifiable to group health plans and health insurance issuers; [and] (II) require a third-party administrator of a group health plan or covered service provider for pharmacy benefit management services under such health plan or health insurance coverage to remit bona fide service fees to the group health plan . . .''

[107] ERISA section 726(e)(8), (9).

[108] ERISA section 726(b)(3).

[109] ERISA section 726(b)(2)(B)(i)

[110] ERISA section 726(b)(2)(B)(ii).

[111] ERISA section 726(b)(4)(G).

[112] ERISA section 726(b)(2)(A)(i).

the same therapeutic class, rationale for formulary placement and any change in the formulary placement compared to prior year; and for plans, issuers, and providers of pharmacy benefit management services with affiliated pharmacies, information about benefit design that encourages/requires use of mail order, specialty or retail pharmacies, percentage of prescriptions dispensed by such pharmacies, and a list of drugs dispensed along with amount charged to the plan and comparative cost information from other pharmacies.[113]

2. Comments on Interaction With the Department's Rule

Upon enactment of the CAA, 2026, the Department published a notice in the **Federal Register** drawing the public's attention to the new amendments to ERISA and extending the comment period on the proposed rule by an additional 15 days to allow interested persons to address ''whether the rule should be adjusted in light of the CAA, 2026 amendments to ERISA, and if so, what adjustments are needed.'' [114]

Many commenters responded to the Department on the interaction of the proposed rule and the CAA, 2026, amendments to ERISA. These commenters generally touched on whether the Department should move forward to a final rule or withdraw its proposal, as well as ways that the Department should align provisions of its regulation with the CAA, 2026 amendments.

On the topic of whether the Department should move forward to a final rule or withdraw the proposal, commenters weighed in on both sides. A few commenters advocated for withdrawal of the Department's proposal based on their view that in the CAA, 2026, Congress established a disclosure framework for PBM transparency that rendered the Department's regulatory project unnecessary, or even outside its regulatory authority. Commenters said the CAA, 2026 amendments address the transparency issues that motivated the Department's rulemaking, and the Department should focus its efforts on implementing the CAA, 2026 framework under ERISA section 726 with the Departments of Treasury and Health and Human Services. Some commenters noted the Department could then evaluate whether additional regulation is warranted.

Some commenters also expressed a related concern that if the Department proceeded to a final rule at this time, the rule could end up being duplicative or even conflict with requirements under the CAA, 2026 amendments to ERISA that will become effective several years from now, resulting in compliance inefficiencies and difficulties and confusion for plan fiduciaries. One commenter said that implementing the Department's rule only to later make changes to satisfy the CAA, 2026 amendments would impose operational and financial burdens on the healthcare system. One commenter said these types of compliance burdens would particularly impact mid-market PBMs. Several commenters suggested the Department should at least repropose its rule to ensure its provisions are consistent with the CAA, 2026 amendments.

A few commenters also recognized that providers of pharmacy benefit management services are now clearly covered service providers under ERISA section 408(b)(2)(B) and expressed concern that such service providers would be required to comply with three sets of disclosure obligations: the statutory provisions of ERISA section 408(b)(2)(B), the Department's rule, and ERISA section 726. Another commenter opposed the Department proceeding with a regulation under the prohibited transaction framework because of the potential for penalties such as excise taxes for covered service providers as well as equitable remedies which the commenter said could disrupt the provision of pharmacy benefit management services.

Many more commenters expressed strong support for the proposal and urged the Department to finalize it. Commenters expressed particular support for the proposal's focus on transparency and accountability for providers of pharmacy benefit management services. Commenters also supported supplying plan fiduciaries with disclosures necessary to assess contracts with these providers and to satisfy the fiduciaries' obligations under ERISA. Some commenters expressed the view that the proposal represented an important protection of group health plan participants' interests.

One commenter who supported finalizing the rule noted that the CAA, 2026 provision that amended ERISA to add section 726 did not contain any preemptive language, did not rescind or prohibit rulemaking under ERISA section 408(b)(2), and did not state that the section 726 provisions are exclusive. Commenters also highlighted the distinct purpose of ERISA section 408(b)(2) as a statutory prohibited transaction exemption that requires group health plan fiduciaries to determine the reasonableness of services contracts or arrangements as a reason for the Department to proceed to a final rule. Some commenters identified the initial disclosures in particular as helpful to fiduciaries in discharging this obligation at the time they are entering into a contract and noted there is no counterpart in ERISA section 726. A few commenters also described how certain specific disclosures in the proposed rule would complement, not conflict with, those in ERISA section 726. For example, one commenter said that the pre-contract disclosure of spread pricing at the formulary level in the Department's proposed rule along with the post-transaction drug level reporting on spread under ERISA 726 would work together to allow for prospective fiduciary review as well as retrospective transaction verification. One commenter said the Department's adoption of a final rule at this time would provide impacted parties the opportunity to implement and gain experience with the disclosures in preparation for implementation of the CAA, 2026 amendments.

Regardless of their views on whether the Department should withdraw its proposal or proceed to a final rule, there was consensus among many commenters that if the Department determined to proceed to a final rule, it should align with the CAA, 2026 amendments to the extent possible. Many such commenters focused on alignment with the ERISA section 726 disclosures, including areas of scope, definitions, and timing.

Commenters also discussed the impact of the new subparagraph (C) of ERISA section 408(b)(2) on service provider arrangements. As that provision will require covered service providers to pass through to the group health plans ''100% of rebates, fees, alternative discounts, and other remuneration'' received from ''any applicable entity,'' commenters asserted that some of the contractual practices disclosed under the Department's rule would no longer persist after subparagraph (C)'s effective date. One commenter suggested sunsetting some of the disclosures while leaving in place robust audit rights to ensure that compensation is not recharacterized or shifted to avoid the pass-through

[113] ERISA section 726(b)(2)(A)(ii)–(iv).

[114] Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure: Extension of the Comment Period, 91 FR 10033 (Mar. 2, 2026). In the notice, the Department also specifically sought comment on ''whether specific provisions of the rule should be revised or whether new provisions should be added, in order to minimize complexity or align with the new statutory provisions, while continuing to fulfill the stated transparency goals of the proposal.'' *Id.* at 10034.

requirements. Other commenters suggested disclosures would still be needed with respect to any compensation not passed through to the group health plan. One commenter said that the definition of ''applicable entity'' does not specifically include pharmacies and therefore—unless the Department (with the Departments of Treasury and Health and Human Services) uses its regulatory authority to include them within the definition—revenue streams from pharmacies would continue to exist after the rebate-pass through provision takes effect.

3. The Department's Responses

The Department has carefully considered the interaction of its proposal with the CAA, 2026 amendments to ERISA, as well as comments urging withdrawal of the rule, but has determined that it would not be appropriate or prudent to withdraw its proposal in favor of a disclosure regime based solely on ERISA section 726. In making this determination, the Department acknowledges that the disclosures required under new ERISA section 726 have areas of overlap with the disclosures the Department had proposed under ERISA section 408(b)(2). However, the Department believes that, for many of the reasons cited by supportive commenters, it is appropriate to proceed to a final rule on its proposal.

Chiefly, the Department believes that the ERISA section 408(b)(2) disclosures serve a function that is distinct from those in ERISA section 726. First and foremost, the Department's regulation is designed to improve transparency in large self-insured group health plan contracting practices involving providers of pharmacy benefit management services. It will ensure responsible plan fiduciaries can determine the reasonableness of the contract or arrangement by providing them a description of each pharmacy benefit management service to be provided to the covered plan and disclosure of the direct and indirect compensation that service providers contracting for pharmacy benefit management services receive. This is achieved through initial disclosures, at the time of contracting, extension or renewal, as well as semiannual disclosures and audit rights that will support the fiduciaries' ongoing monitoring of the services contract or arrangement. Section 726, on the other hand, is a retrospective disclosure containing detailed information about drug spending and drug utilization under the group health plan that goes beyond the disclosure requirements of the Department's final rule.

Congress' amendments to ERISA section 408(b)(2)(B) clarified that providers of pharmacy benefit management services are covered service providers, and the legislation also provided specific authority to the Department to issue regulations addressing time, manner, and content of the disclosures. The fact that Congress added disclosure obligations for providers of pharmacy benefit management to both ERISA section 408(b)(2) and new ERISA section 726 in a single piece of legislation detailing separate, albeit related, disclosure regimes compels the conclusion that Congress meant for both disclosure regimes to coexist. In the Department's view, these two regimes complement each other.

In sum, the Department issues this final rule to implement disclosure obligations under ERISA section 408(b)(2)(B) with respect to the covered service providers and covered plans described in the rule, thus satisfying the provisions of section 408(b)(2)(B) for those covered service providers and responsible plan fiduciaries. The Department is operating under the authority granted in section 408(b)(2)(B) to regulate the time, manner, and content of those disclosures, applying the statutory framework. The Department has added a provision to the regulation in paragraph (a) to confirm this position.

The Department also acknowledges, as some commenters noted, that the new subparagraph (C) of ERISA section 408(b)(2) requiring pass-through to group health plans of ''100% of rebates, fees, alternative discounts, and other remuneration'' received from ''any applicable entity'' is likely to result in changes to pharmacy benefit manager compensation arrangements. The Department considered whether to sunset related disclosure obligations but, as discussed in greater detail below, determined that it would be preferable to retain the disclosure obligations generally as proposed to ensure transparency regarding how the payments are being handled. In this regard, the Department notes that, once in effect, ERISA section 408(b)(2)(C) will require the rebates, fees, alternative discounts, and other remuneration not only to be passed through to the group health plan but also to be fully disclosed to such plan.[115]

Overall, the Department concurs with commenters who stressed the importance of aligning with the CAA, 2026 amendments to avoid inefficiencies and potential confusion on the part of plan fiduciaries. The Department has made a number of changes to the text of the rule to achieve alignment. These changes, which are discussed in greater detail below, include:

- *Limitation to large self-insured group health plans:* The final rule applies only to self-insured plans of specified large employers and self-insured specified large plans, defined in the same way that such plans are defined in ERISA section 726. This is consistent with the approach in ERISA section 726(b)(2) in which the detailed information about drug spending will be provided to these plans.
- *Disclosure period:* The final rule provides for disclosures on a semiannual basis or, at the request of the group health plan, quarterly, for consistency with the reporting period in ERISA section 726(b)(1).
- *Manufacturer payments:* The final rule's disclosures regarding payments from drug manufacturers use the terminology ''rebate[s], fee[s], alternative discount[s], or other remuneration'' for consistency with the reporting obligation in ERISA section 726(b)(2)(A)(i)(X) and (XI).
- *Spread compensation:* The final rule's disclosures regarding spread compensation define spread compensation consistently with ERISA section 726(b)(2)(A)(i)(I)–(III).
- *Drug pricing methodology:* The final rule's disclosures regarding drug pricing methodology use terminology from ERISA section 726(b)(2)(A)(i)(VII).

The Department sought and received thoughtful comments on the extent to which this rule should align with the CAA, 2026. Comments on legal arguments regarding the Department's authority to issue the final rule in light of the CAA, 2026 are discussed along with the Department's responses, in section E.14 of this preamble.

The Department has not aligned the effective date of this final rule with the August 3, 2028 effective date of the CAA, 2026 amendments, as some commenters requested. The Department concurs with commenters who expressed concern about unduly delaying the introduction of much needed transparency in the area of group health plans' contracts with providers of pharmacy benefit management services. Implementing this final rule without delay will benefit responsible plan fiduciaries of self-insured group health plans by providing timely access to the more detailed information required to be disclosed. It will also provide timely guidance to

[115] ERISA section 408(b)(2)(C)(ii)(I)(bb).

covered service providers regarding their compliance with ERISA section 408(b)(2)(B), as amended effective February 3, 2026, who may use the guidance in this final rule to determine their own disclosure obligations.

Furthermore, as noted earlier in this preamble, the addition of new subparagraph (C) of ERISA section 408(b)(2) and the addition of section 726 of ERISA under the CAA, 2026 do not take effect until 30 months after the date of enactment. In contrast, Congress' amendments to ERISA section 408(b)(2)(B), establishing statutory disclosure requirements for pharmacy benefit management service providers wishing to take advantage of the exemption, became effective upon enactment of the CAA, 2026 on February 3, 2026. In the Department's view, this indicates Congress' intent that responsible plan fiduciaries should have the required disclosures to evaluate the contracts or arrangements with pharmacy benefit management service providers on an earlier timetable. The provisions in this final rule implement the statutory disclosure requirements in section 408(b)(2)(B), dictating against delaying applicability longer than necessary to allow parties to develop compliance structures. Accordingly, the Department has made the final rule effective January 4, 2027, and applicable to plan years beginning after July 1, 2027.

4. ERISA Section 408(b)(2)(B) Compliance

Several commenters urged the Department to acknowledge and highlight that the amendments to ERISA section 408(b)(2)(B) are in effect currently. The Department concurs with these commenters that the broader range of service providers to group health plans must make the disclosures outlined in the statute to rely on the exemption, for contracts or arrangements, extensions or renewals, effective as of February 3, 2026. As specified in ERISA section 408(b)(2)(B), as amended, covered service providers include, in addition to providers of brokerage services and consulting, providers of: pharmacy benefit management services, third-party administration services, insurance services and insurance product selection services (including vision and dental), recordkeeping services, and others.[116]

This final rule implements the requirements of ERISA section 408(b)(2)(B), as amended, for the covered service providers and covered plans identified herein. Although the statutory provisions apply to all ERISA-covered group health plans, the Department believes the detailed descriptions of compensation streams and arrangements in this rule that are tailored to the pharmaceutical supply chain will provide particularly valuable information to responsible plan fiduciaries of large, self-insured group health plans. Furthermore, to demonstrate alignment with the statutory disclosures as appropriate following the CAA, 2026 amendments, and in response to commenters requesting additional clarity regarding the application of the disclosure obligations to indirect compensation, the Department has revised the rule to categorize the disclosures in the final rule as either ''direct'' or ''indirect'' compensation.[117]

Some commenters asked the Department to offer an enforcement policy for all covered service providers identified in the amended ERISA section 408(b)(2)(B), which was effective as of February 3, 2026, as these providers work to come into compliance with the statutory disclosure obligations. Commenters also asked for safe harbors for responsible plan fiduciaries who demonstrate good faith efforts to comply with their obligations with respect to determining the reasonableness of the service contract or arrangement.

The Department concurs that enforcement relief under ERISA section 408(b)(2)(B) is appropriate as parties develop mechanisms to comply with obligations that became effective when the CAA, 2026 was enacted on February 3, 2026, and believes the appropriate period for a temporary enforcement policy should end on the final rule's applicability date of plan years beginning on or after July 1, 2027. This temporary enforcement policy will apply to all covered service providers and responsible plan fiduciaries of covered plans, each as defined in ERISA section 408(b)(2)(B), regardless of whether they are covered service providers and plan fiduciaries of covered plans addressed in this final rule. Accordingly, from the period from February 3, 2026 to the applicability date of the final rule, the Department will not treat a covered service provider as defined in ERISA section 408(b)(2)(B) as having failed to make the required disclosures to a responsible plan fiduciary under ERISA section 408(b)(2)(B) as long as the covered service provider made disclosures in accordance with a good faith interpretation of ERISA section 408(b)(2)(B), as amended. Further, prior to the applicability date of the final rule, the Department will not treat a responsible plan fiduciary of a covered plan as defined in ERISA section 408(b)(2)(B) as having engaged in a prohibited transaction in entering into a contract or arrangement with a covered service provider as long as the fiduciary acted in accordance with a good faith interpretation of their obligations under ERISA to determine the reasonableness of the contract or arrangement.

E. Description of the Final Rule

1. Scope of the Final Rule

1.1. General—Paragraph (a)

As discussed above in section C of this preamble, ERISA section 408(b)(2)

[116] *See* ERISA section 408(b)(2)(B)(ii)(I)(bb) (''The term 'covered service provider' means a service provider that enters into a contract or arrangement with the covered plan and reasonably expects $1,000 (or such amount as the Secretary may establish in regulations to account for inflation since December 27, 2020, as appropriate) or more in compensation, direct or indirect, to be received in connection with providing one or more of the following services, pursuant to the contract or arrangement, regardless of whether such services will be performed, or such compensation received, by the covered service provider, an affiliate, or a subcontractor: (AA) Services (including brokerage services), for which the covered service provider, an affiliate, or a subcontractor reasonably expects to receive indirect compensation or direct compensation described in item (dd), provided to a covered plan with respect to selection of insurance products (including vision and dental), recordkeeping services, medical management vendor, benefits administration (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness services, transparency tools and vendors, group purchasing organization preferred vendor panels, disease management vendors and products, compliance services, employee assistance programs, or third party administration services. (BB) Other services, for which the covered service provider, an affiliate, or a subcontractor reasonably expects to receive indirect compensation or direct compensation described in item (dd), including any of the following: plan design, insurance or insurance product selection (including vision and dental), recordkeeping, medical management, benefits administration selection (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness design and management services, transparency tools, group purchasing organization agreements and services, participation in and services from preferred vendor panels, disease management, compliance services, employee assistance programs, or third-party administration services, or consulting services related to any such services.'').

[117] *See* ERISA section 408(b)(2)(B)(iii)(III) and (IV) (''A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary addressing time, manner, and content of such disclosures) . . . (III) A description of all direct compensation, either in the aggregate or by service, that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with the services . . . [and] (IV)(aa) A description of all indirect compensation that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with the services . . .'').

provides an exemption for services contracts and arrangements with ERISA-covered plans, provided that the contracts or arrangements are reasonable, the services are necessary for the establishment or operation of the plan, and no more than reasonable compensation is paid. Paragraph (a) of the final rule [118] provides that no contract or arrangement for services between a ''covered plan'' and a ''covered service provider,'' nor any extension or renewal, is reasonable unless the requirements of ERISA section 408(b)(2)(B) are satisfied.[119] Paragraph (a) includes additional language that was not in the proposal, specifying that this final rule implements ERISA section 408(b)(2)(B) with respect to the covered service providers defined herein, and further that a contract or arrangement between a covered plan and a covered service provider, as defined in the final rule, that satisfies the requirements of the final rule also satisfies the requirements of ERISA section 408(b)(2)(B). These sentences were added to clarify the relationship between the statutory exemption and the final rule.

1.2. Covered Plan—Paragraph (b)

As provided in paragraph (b) of the final rule,[120] covered plans are generally defined to include large ERISA-covered self-insured group health plans. Specifically, a covered plan for purposes of this rule is a group health plan as defined in ERISA section 733(a) that is offered by a specified large employer or that is a specified large plan, each as defined in paragraph (m) of the final rule, with two exceptions. One is a group health plan in which all of the benefits are provided exclusively through a contract or policy of insurance issued by a health insurance issuer as defined in 29 CFR 2590.701–2. The second is a group health plan established by a plan sponsor that is *in the drug supply chain,* as discussed in further detail in section E.1.2.4 of this preamble. The definition of covered plans includes excepted benefits, such as limited scope dental and vision plans.[121] ERISA section 733(a)(1) expressly excludes qualified small employer health reimbursement arrangements from the definition of group health plan, and therefore such arrangements are not covered plans under the final rule.

While the proposed rule applied to all self-insured group health plans, the final rule further limited the scope to large self-insured group health plans and included a new exception for group health plans established by a plan sponsor that is, or that is affiliated with, a drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), as discussed in the next sections of the preamble.

1.2.1. Limitation to Large, Self-Insured Group Health Plans

The final rule applies only to self-insured group health plans offered by ''specified large employers'' and self-insured group health plans that are ''specified large plans.'' These terms are defined in paragraph (m) [122] and are generally consistent with those terms in ERISA section 726. A specified large employer means, in connection with a group health plan established or maintained by a single employer, with respect to a calendar year, an employer who employed an average of at least 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the calendar year. For purposes of counting employees to determine whether an employer is a specified large employer, employees must be counted in accordance with the rules for counting employees and employer aggregation under section 4980H of the Internal Revenue Code and its implementing regulations at 26 CFR 54.4980H. A specified large plan means a group health plan established or maintained by a plan sponsor described in ERISA section 3(16)(B)(ii) or (iii) that had an average of at least 100 participants on business days during the preceding plan year. Whether a group health plan is a specified large plan is determined by taking the sum of the total number of participants (not including beneficiaries) for each calendar month in the preceding plan year, and dividing by 12. The result, if not a whole number, is then rounded to the next lowest whole number. Self-insured group health plans that are not described in those definitions are not covered plans for purposes of the final rule, but they are covered plans for purposes of the application of the statutory exemption in ERISA section 408(b)(2)(B) to entities providing pharmacy benefit management services. Accordingly, covered service providers not addressed in this rule must provide the generalized compensation disclosures specified in the statute to rely on the prohibited transaction exemption.

The Department determined to limit the scope of the final rule in response to several different types of comments. First, commenters asked the Department to align the covered plan definition with ERISA section 726. Under ERISA section 726, the larger group health plans (*i.e.,* offered by a specified large employer or a specified large plan) receive a report with detailed information about drug spending while smaller group health plans will receive a summary document that includes information ''that the Secretary determines useful to group health plans for purposes of selecting pharmacy benefit management services, such as an estimated net price to group health plan and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary.'' [123] In the Department's view, aligning the definition of a covered plan so that only the larger self-insured group health plans receive the detailed disclosures under this final rule is responsive to those comments and is consistent with the Secretary's authority to specify the time, manner and content of the section 408(b)(2)(B) disclosures. Based on that same authority, the Secretary has determined that the smaller self-insured group health plans should receive the generalized compensation disclosures pursuant to ERISA section 408(b)(2)(B).

Limiting the detailed disclosures under the final rule to large, self-insured group plans is also responsive to other comments on the proposal. Commenters expressed the view that smaller employers with limited resources may

[118] 29 CFR 2550.408b–22(a).

[119] Title I of ERISA sets forth various requirements for covered plans, which, subject to certain specific exceptions, ''apply to any employee benefit plan if it is established or maintained . . . by any employer . . . or . . . by any employee organization . . . or . . . by both.'' ERISA section 4(a); 29 U.S.C. 1003(a). However, Title I of ERISA specifically does ''not apply to any employee benefit plan if . . . such plan is a governmental plan.'' ERISA section 4(b); 29 U.S.C. 1003(b). ''Governmental plan'' is defined for purposes of this exclusion as ''a plan established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision thereof, or by any agency or instrumentality of any of the foregoing.'' ERISA section 3(32); 29 U.S.C. 1002(32).

[120] 29 CFR 2550.408b–22(b).

[121] *See* Field Assistance Bulletin No. 2021–03, Q&A 3, available at *https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03* (''ERISA section 733(c)(2) provides that certain benefits are not subject to certain requirements of Part 7 of ERISA if offered separately, including limited scope dental or vision benefits. . . . The view of the Department is that limited scope dental and vision plans, although excepted from certain requirements in Part 7 of ERISA, are 'covered plans' subject to the requirements of ERISA section 408(b)(2)(B). The definition of a ''covered plan'' in ERISA section 408(b)(2)(B) refers to ERISA section 733(a), without any indication that the definition is further limited by ERISA section 733(c)(2).'').

[122] 29 CFR 2550.408b–22(m).

[123] ERISA section 726(b)(2)(B).

face substantial challenges analyzing the detailed disclosures in the proposal, and having received the detailed disclosures, may face increased litigation risk second guessing their disclosure-related decisions. Other commenters said that providing the detailed disclosures in the proposal would unduly burden smaller providers of pharmacy benefit management services who commonly serve smaller employers.

The Department believes that increased transparency in the area of pharmacy benefit management services is critical but it recognizes that, as a practical matter, the detailed disclosures required under the final rule may be most useful to responsible plan fiduciaries of larger employers, who are more likely to have compliance staff and sufficient resources to analyze the disclosures and take appropriate action. Proceeding with the more limited scope in the final rule is intended to avoid unintended negative consequences for smaller employers as described by some commenters while ensuring they receive disclosures under the statute to determine the reasonableness of the contracts or arrangements, including their covered service providers' compensation.[124]

This approach will not result in the smaller self-insured group health plans receiving no disclosures to assist them in selecting a provider of pharmacy benefit management services. These group health plans are covered plans under the statutory exemption in ERISA section 408(b)(2)(B) and would receive the disclosures required under the statute from covered service providers—including providers of pharmacy benefit management services—wishing to take advantage of the exemption. The disclosures are required at the time of the initial contract or arrangement and any extension or renewal, and include, for example, the services to be provided; the status of the covered service provider, an affiliate, or a subcontractor as a fiduciary, if applicable; and the direct and indirect compensation reasonably expected to be received by the covered service provider, their affiliates and their subcontractors. The statute also provides for disclosure in the event of a change in the information required to be provided in the initial disclosures and for disclosures to be provided upon the written request of the responsible plan fiduciary, as needed for the plan to comply with the reporting and disclosure requirements of Title I of ERISA. Simply put, the covered service providers of these smaller self-insured group health plans, alongside those that serve fully-insured entities through a health insurance issuer, will not be required to provide the disclosures described in the final rule, which are more specific, prescriptive, and detailed with respect to the compensation streams than the disclosure provisions in the statute, but they will still need to follow the statute. As such, after considering comments, the Department believes that these more detailed disclosures are appropriately directed to the responsible plan fiduciaries of larger self-insured group health plans.

1.2.2. Fully Insured Plans

The definition of ''covered plan'' in the final rule excludes fully insured group health plans because the Department is reserving for future action more detailed regulatory disclosure obligations with respect to these plans. However, these group health plans remain covered plans under ERISA section 408(b)(2)(B) and therefore covered service providers serving fully insured plans that wish to rely on the statutory prohibited transaction exemption are required to provide the generalized statutory disclosures.

In the proposal, the Department had reserved regulatory disclosure obligations with respect to fully insured group health plans for future action based on the preliminary view that responsible plan fiduciaries may focus on different considerations when contracting with an insurance company for health insurance coverage that integrates prescription drug coverage, as opposed to self-insuring medical care and contracting for pharmacy benefit management services. Specifically, the Department questioned whether responsible plan fiduciaries would find the specific disclosures proposed in the regulation useful when negotiating a fully insured arrangement as to justify the costs associated with the detailed disclosures (both to the covered service provider providing the disclosures and the responsible plan fiduciary reviewing and analyzing the disclosures). The Department also noted its understanding that, in some instances, other relevant reporting and disclosure requirements may apply under State law to the health insurance issuer, either independently under the applicable insurance code, or as part of the issuer's routine form filing review.

In the proposal, the Department sought comments on the relevance of the proposed disclosures to responsible plan fiduciaries of fully insured group health plans. In these arrangements in which services are fully bundled with insurance, the Department assumed that responsible plan fiduciaries discharged their obligation to ensure that the contract or arrangement is reasonable by focusing on premiums, covered benefits, coverage limits, exclusions, and cost-sharing requirements. The proposal further assumed that responsible plan fiduciaries would not, in these circumstances, benefit from the specific disclosures required under the proposal because when the pharmacy benefit management services are fully bundled with insurance, the responsible plan fiduciary has a clearer understanding of the total compensation paid for the services.

Some commenters supported the Department's proposed exclusion of fully insured group health plans as covered plans under the regulation. Commenters said a contract of insurance is different from the services arrangements involving self-insured plans and involves state insurance law oversight (*i.e.*, Medical Loss Ratio requirements). A few commenters also took the position that extending the proposed disclosures to responsible plan fiduciaries of fully insured group health plans would not be legally supportable. One commenter said that, in the case of a fully insured group health plan, the provider of pharmacy benefit management services is a vendor to the insurer and therefore does not have a contractual relationship with the plan. This commenter further argued that, in a fully insured group health plan, the insurer (not the plan) assumes financial risk, administers the benefits, and is responsible for all components of the insurance product. The same commenter also suggested that Congress addressed the mechanisms for fully insured arrangements to receive prescription drug reporting under ERISA section 726.

Many other commenters on the proposal said the Department should extend disclosure obligations under the final rule to covered service providers of fully insured group health plans. Many of these commenters said that excluding fully insured plans would leave fiduciaries without the benefit of the disclosures in the rule despite those fiduciaries having an obligation under ERISA to assess the reasonableness of contractual arrangements. Further, commenters believed that a consistent approach to transparency across self-insured plans and fully insured plans

[124] Providing at least some disclosures is important for smaller employers because, as one commenter highlighted, their average deductible for individual coverage is $2,631—significantly higher than the $1,670 average deductible for larger employers—and half of the nation's smallest employers do not offer health insurance at all.

was desirable. Some commenters specifically referenced concerns about transparency in connection with the vertical integration of the largest PBMs and health insurance issuers. Other commenters noted that fully insured plans that are offered by specified large employers or that are specified large plans can receive the detailed report required under ERISA section 726 (although such plans must specifically opt in to do so). One commenter said the Department's stated rationale for excluding fully insured plans—which was based on integration with a health insurance contract—was not compelling, on the basis that the rule would apply to other cases where the commenter believed that pharmacy benefits are integrated with medical services, such as in arrangements offered by TPAs.

A few commenters who supported extending disclosure obligations to covered service providers of fully insured group health plans asked the Department to conduct a future rulemaking for these products, acknowledging the differences between fully insured and self-insured contracts and arrangements. One commenter said the Department would have flexibility to tailor disclosures to reflect differences in the fully insured group health plan context. A commenter opposing the expansion of this rule to include fully insured group health plans also expressed the view that fiduciaries making decisions about an insurance contract would not act on the particular disclosures in the Department's proposal.

The Department has carefully considered comments encouraging the Department to extend the final rule's disclosure obligations to covered service providers with respect to fully insured plans. In the Department's view, some of these commenters argued for disclosures to be made to fully insured plans as a matter of policy, without addressing whether the proposed disclosures would be meaningful for responsible plan fiduciaries of fully insured group health plans. The Department believes that arrangements in which pharmacy benefit services are bundled with insurance are distinct from self-insured arrangements offered by TPAs in which pharmacy benefit management services are integrated with medical services, as referenced by one commenter. The bundling with health insurance raises different issues because of the insurance guarantees. When an employer self-insures a group health plan, the employer bears the financial risk of paying claims and managing the plan. To assist with managing the plan, these employers often contract with service providers such as TPAs to process claims and provide other plan administration services. For a fully insured plan, generally the employer purchases a pre-packaged insurance product where the issuer bears the financial risk of covering costs. These differences in financial risk and plan management require a different approach for developing meaningful disclosures for plan fiduciaries of fully insured plans. The Department is persuaded by the commenters who believe further work would need to be done before developing a framework for disclosures to responsible plan fiduciaries of fully insured group health plans.

The Department notes however that, contrary to an assertion by one commenter, providers of pharmacy benefit management services that contract with health insurers providing coverage to fully insured plans are in fact parties in interest and covered service providers, as clarified by the CAA, 2026.[125] Accordingly, these covered service providers have disclosure obligations under the statute that must be satisfied if they wish to rely on the exemption set forth in ERISA section 408(b)(2).

1.2.3. Other Types of Group Health Plans

Some commenters asked the Department to exclude excepted benefits such as limited scope dental and vision plans from the definition of covered plan. The commenters said that including excepted benefits is inconsistent with the CAA, 2026 amendments to ERISA. A few commenters also asked the Department to clarify whether the rule would apply to Taft-Hartley plans or welfare benefit plans under ERISA section 3(1).

The final rule applies to covered plans which are defined as group health plans under ERISA section 733(a) that are offered by a specified large employer or that are specified large plans, each as defined in paragraph (m), other than a group health plan in which all of the benefits are provided exclusively through a contract or policy of insurance issued by a health insurance issuer. Although excepted benefits are not subject to certain requirements in Part 7 of ERISA, such benefits are ''covered plans'' subject to the requirements of ERISA section 408(b)(2)(B) to the extent that such benefits satisfy the definition of ''group health plan'' under ERISA § 733(a)(1). The Department notes that in accordance with ERISA section 732(b) and (c), the market requirements of part 7 of ERISA do not apply to a group health plan or a health insurance issuer in the group or individual market in relation to the provision of excepted benefits described in ERISA section 733(c). However, ERISA section 408(b)(2)(B) provides that covered plan means a group health plan as defined in ERISA section 733(a). Under ERISA section 733(a) a group health plan is defined as ''an employee welfare benefit plan to the extent that the plan provides medical care . . . to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.'' Section 733(a)(1) of ERISA specifically excludes qualified small employer health reimbursement arrangements.

The definition of a group health plan in ERISA section 733(a) does not exclude excepted benefits, which are defined under ERISA section 733(c)(2). Therefore, excepted benefits are not excluded from the disclosure requirements under this final rule. To the extent that a covered service provider enters a contract or arrangement with an excepted benefit plan, the disclosure obligations required to qualify for a prohibited transaction exemption may apply. Similarly, the definition of group health plan does not exclude Taft-Hartley plans, and such plans are covered plans under ERISA section 408(b)(2)(B) and this regulation if they meet the size criteria.

1.2.4. Group Health Plans of Sponsors in the Drug Supply Chain

A few commenters raised the potential for anticompetitive harm associated with detailed disclosures to responsible plan fiduciaries of self-insured group health plans sponsored by drug manufacturers or other employers in the drug supply chain. Commenters pointed to a special provision in ERISA section 726 directing the Secretary (along with the Secretaries of Treasury and Health and Human Services) to define through rulemaking a limited form of report for any group health plan established by a plan sponsor that is, or is affiliated with,

[125] *See* ERISA section 408(b)(2)(B)(i) (''For purposes of applying section 1106(a)(1)(C) of this title with respect to a transaction described under this subparagraph or subparagraph (C), a contract or arrangement for services between a covered plan and an entity providing services to the plan, including a health insurance issuer providing health insurance coverage in connection with the covered plan, in which such entity contracts, in connection with such plan, with a service provider for pharmacy benefit management services, shall be considered an indirect furnishing of goods, services, or facilities between the covered plan and the service provider for pharmacy benefit management services acting as the party in interest.'').

a drug manufacturer, drug wholesaler, or other direct participant in the drug supply chain, ''to prevent anti-competitive behavior.'' [126] The commenters said the Department should include a similar limited initial disclosure and semiannual disclosure for these group health plans.

No commenters articulated why plan fiduciaries of self-insured group health plans sponsored by drug manufacturers or other employers in the drug supply chain should receive detailed disclosures under this final rule. Commenters highlighted that, in recent years, multiple cases have been brought by plan participants claiming that their plan fiduciaries did not fulfill their fiduciary responsibilities regarding PBM services by incurring excessive fees, failing to negotiate better pricing terms for prescription drugs, and not behaving prudently when selecting the plan's PBM.[127] One of these cases involved a pharmaceutical manufacturer, highlighting that employers in the drug supply chain are also expected to scrutinize the agreements they enter into with PBMs.

Although the disclosures under the final rule would assist employers in the drug supply chain in satisfying their fiduciary obligations, the Department is persuaded that Congress' inclusion of this special provision in CAA, 2026 reflects a deliberate judgement that anticompetitive harm could result from those with a direct financial stake in the drug supply chain receiving detailed disclosures. Therefore, the definition of covered plan in the final rule was revised from the proposal to exclude group health plans established by a plan sponsor that is, or that is affiliated with, a drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates). Plan sponsors that are considered direct participants in the drug supply chain for purposes of exclusion under this final rule include but are not limited to drug manufacturers, market authorization holders (if different than the manufacturer) that retain control over the drug's list price; distributors or wholesalers, pharmacy benefit managers; rebate aggregators, including GPOs; and affiliated pharmacies, including retail, mail-order, and specialty pharmacies. While group health plans of these sponsors would not receive disclosures under this final rule, they would receive the disclosures required under ERISA section 408(b)(2)(B) from those wishing to take advantage of the exemption as well as ERISA section 726 once the Secretaries define through rulemaking a limited form report.[128]

1.3. Covered Service Providers—Paragraph (c)

Paragraph (c) of the final rule [129] defines the entities that are covered service providers under the final rule and therefore have disclosure and related audit obligations. The final rule identifies two types of covered service providers: (i) providers of pharmacy benefit management services (as defined in paragraph (d) of the final rule) and (ii) providers of advice, recommendations, or referrals regarding pharmacy benefit management services who are themselves providers of pharmacy benefit management services or their affiliates.[130] In each case, to be a covered service provider, the entity must reasonably expect to receive $1,000 [131] or more in compensation, direct or indirect, in connection with providing the services.[132] These provisions in the definition of covered service provider in the final rule are consistent with the definition in the Department's proposal.

Some commenters asked the Department to clarify whether the $1,000 threshold figure would be calculated on a per claim basis or based on total aggregate earnings within a year. Commenters also asked whether the threshold applies to any combination of the services identified in the definition of pharmacy benefit management services. In response, the Department confirms the $1,000 is measured against total aggregate earnings within the year and applies to any combination of the pharmacy benefit management services.

1.3.1. Other Types of Service Providers

In the proposal, the Department noted that it was focusing on pharmacy benefit managers in response to President Trump's Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First*, which instructed the Department to propose regulations to improve employer health plan transparency into the direct and indirect compensation received by pharmacy benefit managers. However, the Department recognized that self-insured group health plans have other service providers that were not covered by the proposal. These service providers include TPAs, health insurers, and others involved in the administration of self-insured group health plans' medical claims, such as for hospital stays, surgeries, and chronic treatment, but whose services are unrelated to pharmacy benefit management. Stakeholders had indicated that group health plan fiduciaries may not have access to all claims data, payments to providers, and fee and pricing data that could enable negotiation for cost savings to group health plans and participants.[133] The Department sought comment on whether it should expand the proposed disclosures to cover additional service providers beyond providers of pharmacy benefit management services; and if so, which service providers should be covered. Additionally, the Department sought comment on whether the disclosures in the proposal would be sufficient to bring transparency into arrangements with those additional service providers or whether additional disclosures would be needed, such as claims data, payments to providers, and other fee and pricing data.

As discussed in section D. of this preamble, shortly after the Department published its proposed rule, Congress amended ERISA section 408(b)(2)(B) in the CAA, 2026, which in part clarified which service providers are covered service providers for purposes of the prohibited transaction exemption. The phrase ''Brokerage services'' was removed and replaced with ''Services (including brokerage services),'' in subparagraph (AA) of section 408(b)(2)(B)(ii)(I)(bb). The term ''Consulting'' was removed and replaced with ''Other services'' in subparagraph (BB) of section 408(b)(2)(B)(ii)(I)(bb). Additionally, in subparagraph (BB) of section 408(b)(2)(B)(ii)(I)(bb), the phrase

[126] ERISA section 726(b)(4)(G).

[127] *See Knudsen* v. *MetLife Grp., Inc.*, 117 F.4th 570 (3d Cir. 2024); *Navarro* v. *Wells Fargo & Co.*, No. 24–cv–3043 (LMP/DTS), 2025 WL 897717, (D. Minn. Mar. 24, 2025); *Lewandowski* v. *Johnson & Johnson*, No. CV 24–671 (ZNQ) (RLS), 2025 WL 288230 (D.N.J. Jan. 24, 2025).

[128] ERISA section 726(b)(4)(G).

[129] 29 CFR 2550.408b–22(c).

[130] Non-affiliated brokers and consultants remain subject to the ERISA section 408(b)(2)(B) disclosures.

[131] This $1,000 threshold is consistent with the thresholds in the statute (ERISA section 408(b)(2)(B)(ii)(I)(bb)) and the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)(1)(iii)).

[132] Under proposed paragraph (m)(3), compensation is defined as ''anything of monetary value but does not include any item or service valued at $250 or less, in the aggregate, during the term of the service contract or arrangement.'' The $250 threshold in this context is consistent with the definitions in the statutory provision (ERISA 408(b)(2)(B)(ii)(I)(dd)(AA)) and the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)(1)(viii)(B)).

[133] *See* letter to The Honorable Donald J. Trump from Cynthia A. Fisher, PatientRightsAdvocate.org (November 25, 2025), available at *https://www.patientrightsadvocate.org/lettertopresidentonaffordabilityandhealthcare.*

''related to the development or implementation of'' and the list of services that followed were removed and replaced with ''including any of the following'' and an updated list of services that includes consulting services.

In response to the CAA, 2026, the Department extended the comment period for the proposed rule to allow stakeholders to address how to harmonize the proposed rule with the new statutory requirements.[134] Many commenters said the Department should expand the definition of covered service provider to include additional types of service providers. They mentioned TPAs, independent brokers and consultants, insurers, and network vendors, for example. Commenters said the need for transparency was not limited to the context of pharmacy benefit management services, with some commenters also stating that arrangements with other service providers also suffered from undisclosed conflicts of interest, misaligned incentives, and indirect compensation streams that may not be known by the responsible plan fiduciaries. A few commenters said that the compensation flows among various group health plan service providers are inseparable, especially due to vertical integration of service providers and expressed concern that failure to expand the definition of covered service provider would allow parties to evade disclosure obligations and undermine the transparency goals of the rulemaking. Some commenters noted expansion to other types of service providers would be consistent with Congress' action clarifying the broader definition of covered service provider in ERISA section 408(b)(2)(B).

Some commenters provided information on the types of disclosures that should be required should the Department expand the final rule to include other covered service providers, especially TPAs with respect to medical claims. Commenters mentioned compensation retained on provider reimbursements; shared savings or gainsharing arrangements; network access or discount fees; repricing or claims-editing fees; and many others. Commenters raised the point that TPAs often receive compensation from network lessors, specialty vendors, and utilization management companies by routing business through those entities, for the plans the TPA serves. These indirect sources of compensation may not be known to plan sponsors as they are not always identified in the contracts between TPAs and plans. Commenters also identified brokers and consultants who advise plans on service provider selection and may receive compensation from selected providers.

Other commenters said the Department should not expand the definition of covered service providers to other types of service providers beyond providers of pharmacy benefit management services. One commenter said that TPA and claims administration services are fundamentally different from pharmacy benefit management services and disclosure issues would not be able to be addressed by expanding the disclosures in the Department's rule which had been developed for providers of pharmacy benefit management services. Another commenter noted that TPAs are included in the proposed rule to the extent they provide pharmacy benefit management services. Commenters also said that Congress had made clear that there is a broader set of covered service providers in the statutory exemption but did not single them out for detailed disclosure obligations.

The Department concurs with commenters who said that broader transparency encompassing additional covered service providers to group health plans would be beneficial and consistent with law. As discussed above, a broad range of covered service providers are now covered service providers for purposes of the statutory exemption in ERISA section 408(b)(2)(B), including TPAs. Commenters identified multiple types of service providers that contract with group health plans to provide a wide array of services with multiple sources of direct and indirect compensation that group health plan service providers, such as TPAs, may utilize. However, based on the comments identifying the compensation streams that should be disclosed, the Department believes disclosures for the expanded group of covered service providers would best be addressed in a separate regulatory or subregulatory guidance project tailored to those other types of service providers, and will consider adding this project to a future regulatory agenda.

For now, although not covered by this final rule, the Department expects this expanded group of covered service providers to make a good-faith effort to comply with their disclosure obligations under ERISA section 408(b)(2)(B), in line with the Department's temporary enforcement policy announced herein, in order to rely on the exemption. For example, a TPA providing services to a group health plan for medical management should disclose, pursuant to ERISA section 408(b)(2)(B), direct and indirect compensation. This includes direct or indirect compensation such as administrative fees, per-employee-per-month fees, or 340B-related income; provider and network compensation; affiliate, subcontractor, and vertically integrated compensation; data monetization compensation; and payment and recovery compensation.

1.3.2. Compensation of Individuals Who Are Officers, Directors, Employees or Partners

Some commenters noted that the definition of an ''affiliate'' includes officers, directors, employees, and partners of the covered service provider. These commenters said the final rule should not require disclosure of any individual's compensation in connection with providing pharmacy benefit management services. The Department agrees that compensation of individuals is not the focus of this regulatory project and notes that ERISA section 408(b)(2)(B) specifically provides that the requirement to disclose indirect compensation does not extend to compensation received by an employee from an employer on account of work performed by the employee.[135] The Department has added a similar provision in paragraph (c) of the final rule that specifies that the regulation does not require disclosure of the compensation of individuals who are officers, directors, employees and partners.

1.4. Providers of Pharmacy Benefit Management Services—Paragraph (c)(1)(i)

Paragraph (c)(1)(i) of the final rule defines, as covered service providers, service providers who enter into a contract or arrangement with a covered plan to provide pharmacy benefit management services. Like the proposed rule, the final rule clarifies that this would be the case regardless of whether the services will be performed by the covered service provider, an affiliate, an agent, or a subcontractor.[136] Thus, the

[134] Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure: Extension of the Comment Period, 91 FR 10033 (Mar. 2, 2026). In the notice, the Department also specifically sought comment on ''whether specific provisions of the rule should be revised or whether new provisions should be added, in order to minimize complexity or align with the new statutory provisions, while continuing to fulfill the stated transparency goals of the proposal.''

[135] ERISA section 408(b)(2)(B)(iii)(IV)(aa)(BB).

[136] The definition of pharmacy benefit management services in paragraph (d) of the final rule is discussed in the next subsection of this preamble. The terms affiliate, agent, and subcontractor are defined in paragraph (m) of the final rule and are discussed in the following subsection of this preamble.

final rule recognizes that the pharmacy benefit management services may be performed by the covered service provider, or they may be performed by an affiliate, an agent, or a subcontractor of the covered service provider. Likewise, the final rule recognizes that compensation in connection with the services may be received by the covered service provider or it may be received by an affiliate, an agent, or a subcontractor of the covered service provider.

Under this framework, paragraph (c)(1)(i) of the final rule focuses on the entity that has a contract or arrangement with the covered plan to provide any pharmacy benefit management services to that plan—that party is the covered service provider. The Department believes that the service provider directly responsible to the covered plan for the provision of pharmacy benefit management services is the appropriate party to ensure that the required disclosures under the regulation are made. This approach is consistent with ERISA section 408(b)(2)(B) as well as the Department's service provider regulation applicable to pension plans (29 CFR 2550.408b–2(c)(1)).[137]

In this regard, the Department understands that responsible plan fiduciaries to covered plans may take a number of different approaches in identifying and selecting a provider of pharmacy benefit management services. The covered plan may ultimately contract directly with the entity that will perform the services, or it may enter into a contract with a different entity that agrees to provide the services to the covered plan through an affiliate, an agent, or a subcontractor. It is common, for example, for responsible plan fiduciaries to work with a consultant or broker to conduct a request for proposal and to assist in negotiations with the providers of pharmacy benefit management services. In that case, the covered plan will enter a contract directly with the PBM.

On the other hand, the Department understands that TPAs may contract directly with covered plans to provide a range of health-care related services, such as creating networks of healthcare providers, negotiating payments rates, and processing and paying health claims. One component of these services may be pharmacy benefit management services. If the TPA contracts with the covered plan to provide pharmacy benefit management services, the TPA would be a covered service provider under this regulation, even if it intends to rely on another provider to perform those services. In that event, the TPA would be responsible for making the disclosures to the responsible plan fiduciary required under the final rule and therefore must be able to obtain information from the provider performing the pharmacy benefit management services necessary for those disclosures.

Covered plans may access pharmacy benefit management services through other similar types of arrangements, where the provider may or may not refer to itself as a TPA. For example, it is common for group health plans to enter level-funded arrangements that have stop-loss policies to emulate characteristics of fully insured arrangements, such as predictable spending, but that are actually self-funded arrangements. These arrangements commonly include pharmacy benefit services and the entity that contracts with the covered plan to provide those services would be the covered service provider. As in the TPA example, even if the entity contracting or arranging with the covered plan is not providing the services itself, it nonetheless would be responsible for making the disclosures to the responsible plan fiduciary required under the final rule, and therefore must be able to obtain information from the provider performing the pharmacy benefit management services necessary for those disclosures.

Questions may arise regarding which party is the covered service provider and which party is the responsible plan fiduciary in the context of a multiple employer welfare arrangement (MEWA).[138] For MEWAs that are considered single ERISA plans, the responsible plan fiduciary for the covered plan would receive the disclosures from the party that contracts with the covered plan to provide pharmacy benefit management services. In the case of a MEWA that is not considered a single ERISA plan but rather involves a number of covered plans each sponsored by an employer individually, the party operating the MEWA is likely to be the covered service provider that contracts with the individual covered plans to provide pharmacy benefit management services. In that case, the MEWA operator would have the responsibility to make the disclosures required by the final rule to the responsible plan fiduciaries (*i.e.*, the employers or other fiduciary responsible for entering into the contract or arrangement to provide such services),[139] and therefore must obtain the necessary information from the provider (*e.g.*, as a subcontractor) performing the pharmacy benefit management services.

Covered plans alternatively may access pharmacy benefit management services through employer consortiums or other types of employer groups. The analysis of who the covered service provider is in those arrangements would depend on the details of the arrangement and, specifically, which entity contracts with the covered plan to provide the pharmacy benefit management services. If the consortium or other group assists in negotiating with the provider of pharmacy benefit management services but the covered plan contracts directly with the provider—which the Department believes is the predominant approach—the provider of pharmacy benefit management services would be the covered service provider. However, if the consortium or other employer group were to contract to provide the services to the covered plan, the consortium or other group would be the covered service provider.

Finally, a covered plan may directly contract with more than one entity for pharmacy benefit management services as such services are defined in paragraph (d) of the rule. In such circumstances, the covered plan would thus have more than one PBM, each of which would be a covered service provider and responsible for making its own disclosures with respect to services under its contract or arrangement with the covered plan.

1.4.1. Definition of Pharmacy Benefit Management Services—Paragraph (d)

Paragraph (d) of the final rule[140] defines pharmacy benefit management services as services necessary for the management or administration of a covered plan's prescription drug benefits (including the covered plan's provision of prescription drugs through the plan's medical benefit), regardless of whether the person, business, or entity

[137] ERISA section 408(b)(2)(B)(ii)(I)(bb) (''The term 'covered service provider' means a service provider that enters into a contract or arrangement with the covered plan . . .''); Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure; Interim Final Rule, 75 FR 41600, 41606 (July 16, 2010) (''In the view of the Department, the service provider directly responsible to the plan for the provision of services is the appropriate party to ensure that the required disclosures under the regulation are made.'').

[138] For more information on MEWAs, see *MEWAs Multiple Employer Welfare Arrangements under the Employee Retirement Income Security Act (ERISA): A Guide to Federal and State Regulation*, available at *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/mewa-under-erisa-a-guide-to-federal-and-state-regulation.pdf*.

[139] *See* paragraph (m)(4) defining ''responsible plan fiduciary.''

[140] 29 CFR 2550.408b–22(d).

performing the service identifies itself as a ''pharmacy benefit manager.'' The definition includes a list of examples of such services, as follows:

- acting as a negotiator or aggregator of rebates, fees, discounts and other price concessions for prescription drugs;
- establishing or maintaining prescription drug formularies;
- establishing or maintaining pharmacy networks, through contract or otherwise, including a mail order pharmacy, a specialty pharmacy, a retail pharmacy, a nursing home pharmacy, a long-term care pharmacy, and an infusion or other outpatient pharmacy, to provide prescription drugs;
- performing utilization review and management, including the instituting and processing of prior authorization requests for drugs, step therapy protocols, patient compliance analyses, conducting therapeutic intervention, and administering generic and biosimilar substitution programs.

The definition also includes examples of other services that, in conjunction with any of the services described above, are considered pharmacy benefit management services. These services are:

- processing and payment of claims for prescription drugs;
- adjudicating appeals or grievances related to the covered plan's prescription drug benefits;
- recordkeeping related to the covered plan's prescription drug benefits; and
- performing regulatory compliance with respect to the covered plan's prescription drug benefits under the contract or arrangement.

As discussed above, pharmacy benefit management encompasses a number of services related to developing drug formularies, negotiating with drug manufacturers for rebates and other discounts, negotiating with pharmacies, and processing claims and other functions for covered plans. The examples provided in the definition are intended to describe the services expansively to ensure comprehensive disclosures are made. Consequently, the definition specifies that whether the person providing the services identifies itself as a PBM is not dispositive of the requirement to disclose. Additionally, a person will be a covered service provider by virtue of performing any of the services identified in the definition; covered service provider status does not depend on comprehensively providing all the services set forth in the definition.

The definition in the final rule was revised from the proposal based on comments stating that certain examples included in the proposed definition were too broad. Commenters identified the following examples as ones that in isolation may identify service providers that should not be considered to provide pharmacy benefit management services: ''processing and payment of claims for prescription drugs;'' ''adjudicating appeals or grievances related to the covered plan's prescription drug benefits;'' ''recordkeeping related to the covered plan's prescription drug benefits;'' and ''regulatory compliance with respect to the covered plan's prescription drug benefits under the contract or arrangement.'' One commenter, for example, said that health reimbursement account (HRA) service providers may process and pay claims for prescription drugs as part of their account administration, but the commenter did not believe the Department should cover HRA service providers as providers of pharmacy benefit management services.

The Department is persuaded by the examples provided by these commenters that the examples may be too broad in isolation, and has accordingly revised the definition of pharmacy benefit management services. Under the revised definition, certain services described in the examples will, standing alone, be considered pharmacy benefit management services. Those services are: acting as a negotiator or aggregator of rebates, fees, discounts, and other price concessions for prescription drugs; establishing or maintaining prescription drug formularies; establishing or maintaining pharmacy networks, through contract or otherwise, including a mail order pharmacy, a specialty pharmacy, a retail pharmacy, a nursing home pharmacy, a long-term care pharmacy, and an infusion or other outpatient pharmacy, to provide prescription drugs; and performing utilization review and management, including the instituting or processing of prior authorization requests for drugs, step therapy protocols, patient compliance analyses, conducting therapeutic intervention, and administering generic and biosimilar substitution programs. These services can be considered core pharmacy benefit management services.

The Department revised the example regarding utilization review and management based on comments suggesting that the example should be expanded to be comprehensive. In the final rule, the words ''instituting or'' were added before ''processing of prior authorization requests for drugs,'' so that the example extends to ''*instituting or* processing of prior authorization requests for drugs'' and the word ''biosimilar'' was added to the phrase regarding administering generic substitution programs, so that the example reads ''administering generic *and biosimilar* substitution programs.''

Other examples in the definition will be considered pharmacy benefit management services only if they are performed ''in conjunction with'' the core services. Those services are: processing and payment of claims for prescription drugs; adjudicating appeals or grievances related to the covered plan's prescription drug benefits; recordkeeping related to the covered plan's prescription drug benefits; and performing regulatory compliance with respect to the covered plan's prescription drug benefits under the contract or arrangement. Under this approach, entities who provide these services along with the core pharmacy benefit management services would consider the compensation from these services when determining if the $1,000 threshold is met for status as a covered service provider. Compensation received in connection with these services would be disclosed under the various disclosure provisions in the final rule.

Some commenters focused on the example regarding ''performing regulatory compliance'' and asked whether, under that example, providers of legal services would be considered covered service providers. The revised definition should make clear that attorneys and other providers of legal services would generally not be considered providers of pharmacy benefit management services under the final rule. The definition is intended to encompass entities that perform any of the core services described above and also provide regulatory compliance—for example, ensuring compliance with the rebate pass through requirements of ERISA section 408(b)(2)(C) when that section takes effect. Under the definition of pharmacy benefit management services in the final rule, it is not necessary for an entity to provide all the services described in the examples. One commenter said the word ''and'' connecting the examples might suggest that all such examples must be satisfied for the definition to apply. The Department has replaced ''and'' with ''or'' and, under the language of the definition as revised, the Department does not believe there is potential for confusion.

Commenters suggested that the Department make other changes to this definition in the final rule. One commenter said that the example ''acting as a negotiator or aggregator of rebates, fees, discounts and other price

concessions for prescription drugs'' is unnecessarily broad and could encompass negotiators of price concessions whose services are separate from the procurement and management of prescription drug coverage traditionally associated with pharmacy benefit management services. The commenter also said any definition should be clear that pharmacies themselves are not pharmacy benefit management service providers. In the Department's view, acting as a negotiator or aggregator of rebates, fees, discounts and other price concessions for prescription drugs is a core component of pharmacy benefit management services so it has retained that aspect of the definition as proposed. The Department understands that pharmacies do not perform the core services as described above and therefore agrees that they would not be considered providers of pharmacy benefit management services under the final rule.

Several commenters asked for specific items to be added to the definition. Suggestions included adding a reference to administration of a pharmacy benefit, in whole or in part, to the definition; adding a reference to establishing or maintaining prescription drug formularies that require beneficiaries to apply to manufacturer patient assistance-related programs and adding a reference to activity of a provider of pharmacy benefit management services or an affiliate that manages, co-manages, or private-labels pharmaceutical products. The Department has not adopted these changes because it believes the existing language in the definition is adequate to cover the activities suggested by commenters. For example, administration of a pharmacy benefit is specifically referenced in the general language in paragraph (d)(1), which states ''the term 'pharmacy benefit management services' means services necessary for the management or administration of a covered plan's prescription drug benefits (including the covered plan's provision of prescription drugs through the plan's medical benefit) . . .'' Paragraph (d)(2)(ii) provides that pharmacy benefit management services include ''[e]stablishing or maintaining prescription drug formularies'' which the Department believes is broad enough to cover establishing or maintaining prescription drug formularies that require beneficiaries to apply to manufacturer patient assistance-related programs as well as selecting PBM-affiliated pharmaceutical products for the formulary.

One commenter suggested the definition of pharmacy benefit management services should include a rebuttable presumption under which a health plan service provider providing what generally may be considered pharmacy benefit management services as illustrated by the examples would be presumed to be a covered service provider unless reasonably determined not to be by the applicable group health plan fiduciaries. Another commenter suggested a special rule under which pharmacy benefit management services would not include activities performed by ''an integrated health care delivery system that includes a nonprofit health insurance issuer in which enrollees primarily use pharmacies that are entirely owned and operated by the nonprofit health insurance issuer.'' The Department has not adopted the rebuttable presumption because it does not believe a responsible plan fiduciary should be in a position to excuse a particular entity from being considered a covered service provider. The Department also has not adopted the special rule for the nonprofit health insurance issuer described by the commenter because it was not persuaded that covered plans entering into that arrangement would not benefit from the disclosures under the final rule.

There were additional comments on how the definition of pharmacy benefit management services should be phrased. One commenter suggested that the definition should reference subsidiaries, parents, and affiliates of the entity providing pharmacy benefit management services. The Department does not believe that is necessary because the final rule has a definition of ''affiliate'' that includes these entities.

One commenter believed that the final rule should clarify that the definition of pharmacy benefit management services relates to prescription drugs reimbursed under the medical benefit, and specifically that the following compensation streams are covered: compensation received by PBMs, TPAs, carriers, specialty pharmacies, and affiliated entities in connection with medical-benefit drugs; rebates, administrative fees, and other payments tied to physician-administered or specialty drugs; provider-side revenue, including markups, reimbursement differentials, and site-of care-related compensation; and any other direct or indirect remuneration arising from the management, distribution, or reimbursement of such drugs.

The Department believes the definition in the final rule adequately includes that reference in the language. In paragraph (d)(1) of the final rule, the definition states: ''the term 'pharmacy benefit management services' means services necessary for the management or administration of a covered plan's prescription drug benefits (*including the covered plan's provision of prescription drugs through the plan's medical benefit*) . . . .'' (Emphasis added).

1.4.2. Affiliates, Agents and Subcontractors—Paragraph (m)

The final rule's defined terms ''affiliate,'' ''agent,'' and ''subcontractor'' identify parties other than the covered service provider that may perform pharmacy benefit management services and may receive compensation in connection with the contract or arrangement that the covered service provider has with a covered plan for pharmacy benefit management services. The services and compensation of these entities are required to be disclosed under the final rule. As noted above, the final rule places the obligation on the covered service provider to make the disclosures, including to seek any required information from these parties as needed for the disclosure. Paragraph (c)(2) clarifies that affiliates, agents, and subcontractors of covered service providers do not, themselves, become covered service providers as a result of providing services pursuant to the contract or arrangement.[141]

Under paragraph (m)(1) of the final rule, an affiliate is an entity that ''directly or indirectly (through one or more intermediaries) controls, is controlled by, or is under common control with such person or entity; or is an officer, director, or employee of, or partner in, such person or entity.'' The definition states that unless otherwise specified, an ''affiliate'' in the regulation refers to an affiliate of the covered service provider. In other contexts, the Department has said ''control'' refers to the power to exercise a controlling influence over the management or policies of a person other than an individual.[142]

Paragraph (m)(5) defines a subcontractor as a ''person or entity (or an affiliate of such person or entity) that is not an affiliate of the covered service provider and that, pursuant to a contract or arrangement with the covered service provider or an affiliate, reasonably expects to receive $1,000 or more in compensation for performing one or more services described pursuant to paragraph (d) of this section provided

[141] This clarifying provision is also in ERISA section 408(b)(2)(B)(ii)(III) and the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)(1)(iii)(D)).

[142] *See, e.g.*, 29 CFR 2550.404c–1(e)(3).

for by the contract or arrangement'' with the covered plan. Accordingly, under the definition, an affiliate of a subcontractor would also be considered a subcontractor for purposes of the regulation, including the disclosure requirements. This means that compensation to a subcontractor's affiliate must be disclosed if received in connection with the pharmacy benefit management services provided to the covered plan.

The definitions of the terms ''affiliate'' and ''subcontractor'' are generally consistent with the definitions of these terms in ERISA section 408(b)(2)(B) and the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)).[143] The Department believes they are well understood by stakeholders.

The final rule also includes, in addition to ''affiliates'' and ''subcontractors,'' the term ''agent,'' defined in paragraph (m)(2) as ''any person or entity authorized (whether that authorization is expressed or implied) to represent or act on behalf of another person or entity.'' Unless otherwise specified, an ''agent'' for purposes of the regulation refers to an agent of the covered service provider. Although parties performing services provided for under the contract or arrangement on behalf of the covered service provider should generally fall within the broad term ''subcontractor,'' the additional defined term ''agent'' is included based on the concern that, in the context of pharmacy benefit management services, entities that receive undisclosed compensation in connection with a covered service provider's contract or arrangement with a covered plan for pharmacy benefit management services may not technically fall within the definition of an ''affiliate'' or a ''subcontractor,'' or may take the position that they do not. As one example, the Department is aware that some providers of pharmacy benefit management services have formed rebate aggregators or GPOs outside of the laws of the United States.[144] The Department intends that any compensation received by these entities in connection with a covered service provider's contract or arrangement with a covered plan for pharmacy benefit management services would be disclosed under the final rule.

The Department requested comments on the proposed definitions of affiliate, agent, and subcontractor, including whether parties such as rebate aggregators or GPOs (or any other parties that fell within the proposed definition of agent) would be likely to be covered by either of the other proposed definitions (*i.e.*, affiliate or subcontractor).

Many commenters supported an approach in the regulation that would result in comprehensive disclosure of compensation associated with pharmacy benefit management services. Some commenters specifically referenced challenges to transparency associated with vertically integrated providers of pharmacy benefit management services.

Regarding the goal of comprehensive disclosures, some commenters said the phrasing of the definitions of ''affiliate,'' ''subcontractor,'' and ''agent'' might have loopholes, particularly with respect to rebate aggregators, GPOs, and similar entities. For example, some commenters said the definition of ''affiliate'' referenced common control but might not cover entities that have contractual relationships with a provider of pharmacy benefit management services. Some commenters suggested that the Department should specifically identify rebate aggregators, GPOs, and similar entities as entities for which compensation must be reported, regardless of their relationship with the covered service provider. Other commenters believed that the term ''agent'' in the final rule would be critical to ensuring disclosure of compensation received by rebate aggregators, GPOs, and similar entities, as that defined term does not require any ownership or control. One commenter said the Department should align with ERISA section 726 and use the ''applicable entity'' definition.

Other commenters said the Department should eliminate affiliates and agents from the disclosure obligations altogether or narrow them so that they are covered only if performing pharmacy benefit management services. These comments appeared to be based on the perception that, absent this change, the rule would require disclosure of compensation received by these entities unconnected to the performance of pharmacy benefit management services. One commenter said that if the Department did not narrow the definitions of these entities, it should provide a safe harbor for affiliates and subcontractors that receive compensation solely in the form of arm's length, market-rate fees for discrete services performed under separate commercial contracts, without discretion to influence formulary placement, plan design, or compensation structures applicable to the covered plan.

After considering comments on these definitions, the Department decided to retain the definitions as proposed, based on the view that they will ensure comprehensive disclosure of compensation received in connection with a covered service provider's contract or arrangement with a covered plan for pharmacy benefit management services, consistent with the goals of this rulemaking and the language of section 408(b)(2)(B), as amended. The Department did not eliminate the definitions of affiliates and subcontractors, or switch to the defined term ''applicable entity,'' because ERISA section 408(b)(2)(B) specifies that affiliates' and subcontractors' services and compensation must be disclosed. The Department additionally agrees with commenters who believed that the term ''agent'' is needed in the context of a rule requiring disclosure of compensation in connection with a covered service provider's contract or arrangement with a covered plan for pharmacy benefit management services. The term ''agent'' is needed to ensure that compensation received by rebate aggregators, GPOs, and similar entities would be disclosed, even if such parties may take the position that they are not ''affiliates'' or ''subcontractors.'' As one commenter described, these entities act on behalf of providers of pharmacy benefit management services in negotiating, aggregating, and receiving manufacturer remuneration.

With respect to commenters who believed that the final rule might require disclosure of compensation of affiliates who do not have any involvement in the pharmacy benefit management services, the Department points to the regulatory text that provides for disclosure of the various forms of compensation received by the covered service provider, an affiliate, an agent, or a subcontractor ''in connection with'' the service contract or arrangement. As discussed in greater detail below, the Department intends that ''in connection with'' will be interpreted broadly to cover compensation that is received based in whole or in part on the service contract or arrangement. If the standard is not satisfied with respect to compensation received by an affiliate, then disclosure is not required.

Some commenters addressed proposed paragraph (c)(2) which stated that ''no person or entity is a 'covered

[143] *See* ERISA section 408(b)(2)(B)(ii)(I)(cc) and (ff); 29 CFR 2550.408b–2(c)(1)(viii)(A) and (F).

[144] *See, e.g.*, Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

service provider' solely on the basis of providing services as an affiliate, an agent, or a subcontractor of the covered service provider.'' Some commenters supported this provision as providing clarity regarding which party has the obligation to provide the required disclosures. Another commenter asked the Department to delete this provision to ensure that all such parties will provide the required disclosures, noting that it was not clear what recourse covered plans would have if such parties did not provide the required information and data. A few other commenters also expressed concern about whether covered service providers would be able to obtain information from other parties in the pharmaceutical supply chain to supply the required disclosures to the covered plan.

The Department has retained paragraph (c)(2) in the final rule, as proposed, as a matter of consistency with ERISA section 408(b)(2)(B) which also places the responsibility for disclosure on the entity with the direct relationship with the covered plan. This structure does not, however, absolve affiliates, agents, and subcontractors from supplying the information required by ERISA section 408(b)(2)(B) or this regulation. For the covered service provider to participate in and receive compensation in connection with these contracts and arrangements, these parties must all be prepared to make the required disclosures so that contracts and arrangements with covered plans do not result in prohibited transactions. Responsible plan fiduciaries of covered plans that do not receive required disclosures under the final rule may take advantage of the administrative exemption that involves notifying the Department about covered service providers' failures to meet their disclosure obligations.[145]

The Department has considered comments about the potential burden on smaller covered service providers obtaining the information and providing the detailed disclosures under the final rule. In response, the Department notes that ERISA section 408(b)(2)(B) does not provide an exemption from the disclosure requirements for small service providers. Also, to the extent that these smaller covered service providers provide services to smaller employers or smaller self-insured group health plans, the Department believes these burdens are alleviated by the more limited scope of the final rule extending the regulatory disclosure requirements only to larger self-insured group health plans.

[145] *See* paragraph (n) of the final rule.

1.5. Affiliated Providers of Brokerage or Consulting Services—Paragraph (c)(1)(ii)

Paragraph (c)(1)(ii) of the final rule identifies as covered service providers parties described in paragraph (c)(1)(i) or their affiliates that enter a contract or arrangement with a covered plan to provide advice, recommendations, or referrals of pharmacy benefit management services. These covered service providers have the obligation under the final rule to disclose their services and compensation and to allow for an audit, as discussed below. This provision in the final rule is unchanged from the proposal.

The Department's stated purpose in the proposal for including these entities as covered service providers was to address concerns about brokers and consultants receiving payments from parties they are recommending, which may be undisclosed to their covered plan clients. The Department stated that these arrangements have high potential for conflicts of interest that warrant disclosure. The Department further stated that to the extent that PBMs as described in paragraph (c)(1)(i) of the proposal, or their affiliates, also provide ''brokerage services'' or ''consulting'' to self-insured group health plans regarding pharmacy benefit management services, the Department had determined that special provisions under the rule would be needed. The Department said that these entities should be included in the definition of covered service providers under the rule to ensure that conflicts associated with the affiliation are disclosed and, further, to allow affiliated brokers and consultants to determine the extent of their obligations under the statutory exemption in ERISA section 408(b)(2)(B).

Commenters who addressed inclusion of brokers and consultants as covered service providers suggested that a meaningful approach to disclosures for these parties would involve disclosure of the total net cost of the entire benefit for the upcoming year. Commenters expressed that this would provide a simple data point that would allow responsible plan fiduciaries to easily compare competing service provider bids even across different business models that may, or may not, incorporate rebate guarantees. The Department considered these comments but determined not to add a total net cost type of disclosure to the final rule. These comments and the Department's responses are discussed in section E.3.11.1 of this preamble.

2. Overview of Covered Service Provider Obligations Under This Final Rule

2.1. General

Under this final rule, covered service providers will be required to provide specified disclosures to responsible plan fiduciaries of covered plans and also permit the responsible plan fiduciaries to conduct an audit for accuracy of the disclosures. The disclosures will generally focus on the services provided, the compensation received, and the arrangements with other parties in the pharmaceutical supply chain.[146] The disclosures will be provided on an initial basis prior to the covered plan entering into the service contract or arrangement, or an extension or renewal, and then on a semiannual basis thereafter (or quarterly, at the plan's request).

With respect to brokers and consultants that are affiliated with providers of pharmacy benefit management services and recommend those services (covered service providers under paragraph (c)(1)(ii)), the required disclosures under the final rule will ensure that the responsible plan fiduciaries that may hire these brokers or consultants for their advice, recommendations, and referrals, are aware of the other sources of compensation that the brokers and consultants may be receiving, also so as to evaluate the potential impact on their services to the plan and the reasonableness of their compensation.

2.2. Breadth of Disclosure Obligation

Throughout the final rule, the disclosure obligation is phrased in terms of compensation ''in connection with'' the service contract or arrangement. This language largely mirrors the corresponding provisions in ERISA section 408(b)(2)(B) which require disclosure of direct compensation and indirect compensation reasonably expected to be received ''in connection with'' the services provided.[147]

The Department intends that the language ''in connection with'' will be construed broadly and consistently with how the Department construes the language in its service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)(1)). The Department stated in the preamble to that rule that: ''[t]o the extent a covered service provider reasonably expects that

[146] The term ''compensation'' is defined in paragraph (m)(3) of the proposed regulation as anything of monetary value but does not include any item or service valued at $250 or less, in the aggregate, during the term of the contract or arrangement.

[147] ERISA section 408(b)(2)(B)(iii)(III) and (IV)(aa).

compensation will be received, which is based in whole or in part on its service contract or arrangement with the covered plan, the compensation will be considered 'in connection with' such contract or arrangement.'' [148]

Some commenters on the Department's proposal said that a broad and comprehensive disclosure obligation was critical and suggested additional language that they thought would be needed to ensure the intended breadth, such as using ''as a result of'' instead of ''in connection with.'' Some commenters suggested a string of words such as ''in connection with, as a result of, or in any way connected with, services provided to the plan'' to ensure broad disclosure.

The Department has considered these comments but has determined to retain the proposed language ''in connection with'' to describe the breadth of the disclosure obligation. The Department believes there is value to using language like that of ERISA section 408(b)(2)(B) as well as the service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)(1)). The Department believes the interpretive position stated above, under which compensation will be required to be disclosed if it is (or will be) received, based in whole or in part on its service contract or arrangement with the covered plan, is appropriate to ensure comprehensive disclosure. The Department does not think that ''as a result of'' or other suggested wording is clearly broader.

Relatedly, in the preamble to the proposal, the Department requested comment on payments from drug manufacturers that may be based on a structure of incentives not solely related to the contract or arrangement with the self-insured group health plan.[149] The Department sought comment on whether the final rule should specify that such disclosures would be made on a pro-rata basis.

Several commenters said that it is common for providers of pharmacy benefit management services to negotiate rebates and other manufacturer payments on the basis of participants across multiple plan sponsors, so these commenters supported a pro-rata approach as a way for responsible plan fiduciaries to assess the compensation the provider is receiving in connection with a particular covered plan. One commenter said the Department should specify that pro-rata allocation based on an objective and consistently applied metric—such as enrollment share, utilization share, or claims volume—constitutes a compliant disclosure methodology. A few other commenters thought that a pro-rata disclosure might not relate to the actual rebate structure with respect to a particular covered plan and therefore may have limited value as a disclosure to responsible plan fiduciaries. In response, the Department has added text to the final rule in paragraph (e)(3) and paragraph (g)(2) clarifying that indirect compensation includes ''compensation based on a structure of incentives not solely related to the contract or arrangement with the covered plan[.]'' Thus the Department confirms that such compensation must be disclosed, but has not further specified that it must be disclosed on a pro-rata basis versus another reasonable method.

2.3. Disclosure of Monetary Amounts

Paragraph (k) of the final rule [150] provides information about the manner of disclosure, including a requirement that disclosures must be ''clear and concise, free of misrepresentation, and contain sufficient specificity to permit evaluation of the reasonableness of the service contract or arrangement.'' For required descriptions of compensation amounts, paragraph (k) provides that these descriptions must be expressed as a monetary amount and may be estimated to the extent that the actual amount is not reasonably ascertainable but shall contain sufficient information and specificity to permit evaluation of the reasonableness of the compensation received by the covered service provider, an affiliate, an agent or a subcontractor.

The Department intends that disclosures of a monetary amount (even if estimated) in this context, furnished with the specificity required under paragraph (k), will further the transparency goals of this rulemaking which are intended to facilitate a responsible plan fiduciary's assessment of reasonableness of compensation and potential for or existence of conflicts of interest in the provision of pharmacy benefit management services. This would also foster a fairer prescription drug market that lowers costs.

Several commenters strongly supported this aspect of the proposal with one commenter taking the position that the disclosure of a monetary amount is the most important provision in the rulemaking. Some commenters said that formulas and percentages can be used by providers of pharmacy benefit management services to obscure compensation received. One commenter said that the Department should specifically provide that compensation estimates should be ''grounded in good faith assumptions based on contractually defined methodologies, historical utilization and rebate experience or other information reasonably available at the time of disclosure.'' Other commenters supported flexibility to use alternative methodologies and said this is how compensation arrangements are structured. A commenter said there would be no greater need to finalize this more prescriptive standard for PBM disclosures than in other contexts.

The Department agrees with the commenters who said that disclosure of a monetary amount is preferable to a formula or other methodology and has finalized that provision in paragraph (k) as proposed. The Department believes that the responsible plan fiduciaries of the large self-insured group health plans that are covered plans under the final rule will have sufficient resources to analyze the more detailed disclosures of monetary amounts. The Department believes that the commenter's suggested language (that the estimates should be ''grounded in good faith assumptions based on contractually defined methodologies, historical utilization and rebate experience or other information reasonably available at the time of disclosure'') provides helpful guidance to covered service providers and has added it to paragraph (k) in the final rule.

2.4. Structure of the Final Rule

The specific elements of the disclosure and audit provisions are discussed in greater detail below. Paragraph (e) of the final rule establishes initial disclosure requirements. Paragraph (f) is reserved for initial disclosure requirements for fully insured group health plans. Paragraph (g) establishes semiannual disclosure obligations. Paragraph (h) is reserved for semiannual disclosure obligations for fully insured group health plans. Paragraph (i) establishes a requirement for the covered service provider to provide certain information upon request of the responsible plan fiduciary of the covered plan. Paragraph (j) establishes the audit rights that must be provided to the covered plan under the service contract or arrangement. Paragraph (k) addresses the manner of disclosure and paragraph (l) addresses

[148] Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure, 77 FR 5632, 5637 (Feb. 3, 2012).

[149] *See also* ERISA section 408(b)(2)(B)(iii)(IV)(aa) (requiring a description of all indirect compensation ''including compensation from a vendor to a brokerage firm based on a structure of incentives not solely related to the contract with the covered plan'').

[150] 29 CFR 2550.408b–22(k).

disclosure errors. Paragraph (m) provides definitions for certain terms used in the regulation.

Overall, the disclosures are intended to provide responsible plan fiduciaries of covered plans with a fuller picture of the terms under which the services will be provided, so they can assess both the reasonableness of the compensation in light of the services being (or to be) provided and the potential for or existence of conflicts of interest that may impact the quality of services provided. The Department believes that these disclosures will provide necessary information to responsible plan fiduciaries of these larger self-insured group health plans who are required to determine that the services contract or arrangement meets the standards for an exemption under ERISA section 408(b)(2).

3. Initial Disclosure Requirements—Paragraph (e)

Paragraph (e) of the final rule [151] sets forth the initial disclosure requirements. Covered service providers of pharmacy benefit management services are required under the final rule to produce these disclosures to the responsible plan fiduciary, in writing, no later than the date that is reasonably in advance of the date on which the contract or arrangement is entered, extended, or renewed. For extensions and renewals, 90 calendar days is deemed ''reasonably in advance,'' absent an agreement between the covered service provider and the plan to a longer timeframe.

The final rule, in some instances, requires disclosure of amounts reasonably expected to be paid to the covered service provider or an affiliate, an agent, or a subcontractor. As noted above, paragraph (k) requires descriptions of compensation to be expressed as a monetary amount—for example, $1,000. The amounts can be provided as an estimate, to the extent that the actual amount is not reasonably ascertainable; but in any event, the disclosures must contain sufficient information and specificity to permit evaluation of the reasonableness of the compensation to be received by the covered service provider, an affiliate, an agent, or a subcontractor. Estimates shall be grounded in good faith assumptions based on contractually defined methodologies, historical utilization and rebate experience, or other information reasonably available at the time of disclosure.

3.1. Time Period for Initial Disclosure, Extensions and Renewals

The Department proposed that a reasonable period of time for responsible plan fiduciaries to receive the initial disclosure in the context of extensions and renewals of the contract or arrangement would be 30 days. This timeframe was intended to align with to other disclosure requirements in the Title XXVII of the Public Health Service (PHS) Act, Chapter 100 of the Internal Revenue Code, and Part 7 of ERISA that require 30-day timelines for disclosures, including the summary of benefits and coverage (SBC) requirements under PHS Act section 2715, as added by the Affordable Care Act and incorporated into ERISA section 715 and Code section 9815, for renewals, reissuances and reenrollments.[152] Aligning the timing requirements with other disclosures that group health plans and issuers already provide was intended to minimize compliance burdens by streamlining the collection of similar data and disclosure for multiple purposes during the same cadence. The Department sought comment on the proposed timing requirements for the initial disclosure including whether additional specificity would be needed for the timing of the disclosure outside of the context of contract extensions and renewals.

While one commenter supported the proposed 30-day time frame, a few other commenters said that plan fiduciaries would need disclosure at an earlier date to inform initial contract negotiations. Commenters offered different suggested longer time frames, including 60 or 90 days in advance of the date of contract, extension or renewal; 60 days from request of the responsible plan fiduciary; or, for extensions and renewals, sufficiently in advance of the earliest contractual deadline by which the plan fiduciary must act to avoid automatic renewal. A few commenters suggested timeframes that would allow disclosures after execution of the contract, while others emphasized that the disclosures must be prospective to assist responsible plan fiduciaries in assessing the reasonableness of the contract or arrangement.

The final rule provides that 90 days in advance of the extension or renewal is reasonable, to ensure that plan fiduciaries have sufficient time to review the disclosures as part of the contracting process. The Department agrees with the commenters who said that initial disclosures should be provided in advance of the contract to be useful to responsible plan fiduciaries. The Department selected a specific number of days (*i.e.,* 90 days) prior to the extension or renewal because it has an advantage of simplicity over some of the other commenters' suggestions and would allow time for plan fiduciaries to solicit competing bids and evaluate information in the disclosures to prudently select a service provider. Under the final rule, parties remain free to negotiate for a longer period.

The Department did not propose any specific time frame for what would be deemed reasonable in the context of new contracts or arrangements. Although some commenters suggested some specific time frames, as noted above, the Department does not believe it is necessary to establish a default timeframe as that timing can be more easily managed by the responsible plan fiduciary who is considering entering into a contract or arrangement with a new covered service provider.

3.2. Description of Services

Under paragraph (e)(1), the initial disclosure must include a description of each pharmacy benefit management service, or of the advice, recommendations, or referrals regarding the provision of pharmacy benefit management services to be provided to the covered plan pursuant to the contract or arrangement. This provision mirrors the provision in ERISA section 408(b)(2)(B)(iii)(I).[153]

Full disclosure of the services is essential so that the responsible plan fiduciary can satisfy its duties under ERISA at the outset of the contract or arrangement and its ongoing duty to monitor. Full disclosure helps ensure that both parties have a common understanding of the services to be performed as part of the contract or arrangement. Absent full disclosure of services, questions may arise as to whether a responsible plan fiduciary has effectively approved otherwise discretionary behavior by the covered service provider.

Full disclosures are also important for covered service providers. Depending on the pharmacy benefit services being provided, if they are not performed in accordance with parameters established under the contract or arrangement with the covered plan, the provider may have assumed discretionary authority or control over the administration of the

[151] 29 CFR 2550.408b–22(e).

[152] *See* 29 CFR 2590.715–2715.

[153] ''A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary addressing time, manner, and content of such disclosures): (I) A description of the services to be provided to the covered plan pursuant to the contract or arrangement.''

covered plan. Providers who exercise such discretionary authority or control fall within the definition of a fiduciary under ERISA section 3(21)(A) and are subject to ERISA's fiduciary duties in section 403 and 404, and the prohibited transaction provisions in ERISA section 406. Therefore, it is crucial that disclosures be complete and accurate and carefully written in a manner that conforms with the plain language requirements in paragraph (k) of the final rule. When disclosures meet these standards, both parties to the contract or arrangement are more likely to have a common understanding of their roles and limitations under the contract or arrangement and the law.

Relatively few commenters addressed the general requirement in the proposal to provide a description of services to be provided to the covered plan pursuant to the contract or arrangement. One commenter asked the Department to add specificity regarding the level of detail required, after further stakeholder input. Another commenter suggested that the description should have increased granularity to specify which entity (*i.e.,* the covered service provider, an affiliate, an agent, or a subcontractor) will be providing the services and the compensation to be received by service. The Department believes that the requirement in the final rule is clear and straightforward, and it determined not to increase complexity by adding further requirements specifying the level of detail to be provided or requiring the disclosures to identify which entity will be providing the services. Therefore, the Department is finalizing the description of services disclosure as proposed.

Some commenters identified certain policies and practices that may be implemented and administered by providers of pharmacy benefit management services that the commenters believed should be disclosed under the final rule. Examples include utilization management; cost sharing policies; and use of copay accumulators, copay maximizers or alternative funding programs. The Department views these as examples of services that are offered by providers of pharmacy benefit managers and agrees that initial disclosure under the final rule of the services to be provided would include disclosure of these types of services that will be implemented and administered by covered service providers with respect to a covered plan.

3.3. Direct Compensation

Under paragraph (e)(2), the initial disclosure must include a description of direct compensation the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive in connection with the pharmacy benefit management services under the contract or arrangement. Specifically, the final rule requires a description of the amount of all direct compensation, both in the aggregate and by service, that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive on a semiannual (or quarterly, upon the covered plan's request) basis in connection with pharmacy benefit management services under the contract or arrangement. An example is an administrative fee calculated on a per-participant, per-month basis. ERISA section 408(b)(2)(B)(iii)(III) likewise provides for a description of direct compensation reasonably expected to be received by the covered service provider, an affiliate, or a subcontractor.[154]

For purposes of paragraph (e)(2) of the final rule, the term ''direct compensation'' means compensation received directly from the covered plan or from the plan sponsor on behalf of the covered plan regardless of whether such compensation is paid from plan assets. It is important to ensure that all direct compensation is disclosed, regardless of the source of the payment, to avoid frustrating the purposes of this final rule because service providers to covered plans sometimes are paid, in whole or in part, directly from the general assets of the employer sponsoring the covered plan as opposed to a plan asset trust. Consequently, responsible plan fiduciaries may find it challenging to assess the overall reasonableness of the covered service provider's compensation if this source of revenue is excluded from disclosure.

The Department revised paragraph (e)(2) of the final rule so that the reporting period is semiannual or, at the request of the covered plan, quarterly. This change was made in other paragraphs throughout the final rule to align with the reporting period in ERISA section 726.

3.3.1. Bundled Services Arrangements

In the proposal, the Department requested comments as to whether the requirements under the proposed rule for disclosure of direct compensation as defined in paragraph (e)(2) would ensure sufficient disclosure of information for bundled services, or whether the description of direct compensation under paragraph (e)(2) for a bundled services option should include additional information, such as the bundled discounted value along with a description of services provided in the bundle.

A number of commenters said the Department should require covered service providers to unbundle and disclose compensation attributable to each discrete service, rather than permitting a single aggregate figure. Some commenters provided examples of scenarios that they believed necessitated unbundling. For example, one commenter asserted that bundled service arrangements may be used to obscure the cost of the services and that unbundling is especially important to uncover potential preferential pricing to affiliates. Another commenter believed that it is important for plan fiduciaries to understand the portion of a bundled service fee attributable to administrative fees to ensure that the plan is not paying twice for the same administrative service.

Other commenters were less sure that unbundling would be helpful or appropriate. One commenter stated that pharmacy benefit services are commonly offered on a full-service basis and requiring unbundling would be hypothetical and could mislead plan fiduciaries. A different commenter supported permitting covered service providers to disclose an aggregate figure with respect to direct compensation on the basis that the commenter believed this is the approach permitted by ERISA section 408(b)(2)(B).

Upon consideration of these comments, the Department determined to add a provision in paragraph (e)(2) of the final rule stating that bundled services or aggregated compensation arrangements must include a reasonable and good faith allocation of the compensation associated with each service in the bundle. This is consistent with the overarching standard in paragraph (e)(2) which provides that the disclosure must include a description of the amount of all direct compensation ''both in the aggregate and by service'' that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive. This standard is more specific than the statutory provision in ERISA section 408(b)(2)(B) but in the Department's view it is appropriate for the large self-insured group health plans that are covered plans under the final rule to receive more detailed information. The

[154] ''A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary addressing time, manner, and content of such disclosures) . . . (III) A description of all direct compensation, either in the aggregate or by service, that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with the services described in subclause (I).''

Department also believes it is appropriate for covered service providers to make a reasonable and good faith allocation of the compensation associated with each of the services, despite the fact that these services may commonly be offered on a full-service basis. The Department does not share the commenter's concern about the potential for misleading plan fiduciaries; rather, unbundling may benefit group health plans by giving them the opportunity to consider a competitive bidding approach for each service, allowing them to design a plan that meets their unique needs to deliver costs savings and efficiencies. Allowing bundled services or aggregated compensation arrangements without specificity about the compensation associated with each service in the bundle, on the other hand, risks creating an unwarranted loophole for certain arrangements.

3.4. Indirect Compensation

The final rule includes a new paragraph (e)(3) entitled ''Indirect Compensation'' under which there are four subparagraphs listing disclosure obligations as follows: (i) payments from drug manufacturers, (ii) spread compensation, (iii) pharmacy recoupment, and (iv) price protection agreements. Subparagraphs (i)–(iv) correspond to proposed paragraphs (e)(3)–(6). These subparagraphs are discussed in the next sections of the preamble. Disclosure of indirect compensation is required under ERISA section 408(b)(2)(B)(iii)(IV), which provides that disclosures must include a description of indirect compensation reasonably expected to be received by the covered service provider, an affiliate, or a subcontractor in connection with the services disclosed under the statute, as well as a description of the arrangement pursuant to which the indirect compensation is paid, the services for which the indirect compensation will be received, and an identification of the payer of the indirect compensation.[155]

The Department introduced the paragraph heading ''Indirect Compensation'' in the final rule for consistency with ERISA section 408(b)(2)(B)—which distinguishes direct versus indirect compensation—and also in response to comments that asked for clarification of the distinction between the two.

Paragraph (e)(2) of the final rule includes a definition of ''direct compensation'' which is compensation received directly from a covered plan or from the plan sponsor on behalf of the plan (regardless of whether such compensation is paid from plan assets). The disclosures identified in paragraph (e)(3) of the final rule would be considered indirect compensation. Paragraph (e)(3) also makes clear that indirect compensation includes amounts based on a structure of incentives not solely related to the contract or arrangement with the covered plan.[156] As discussed above, this language is intended to ensure disclosure of rebates and other payments that may be based on a number of participants across multiple plan sponsors.

3.5. Payments From Drug Manufacturers

Under subparagraph (e)(3)(i), the initial disclosure must include a description of the monetary amount of any rebate, fee, alternative discount or other remuneration reasonably expected to be received from any drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates) by the covered service provider, an affiliate, an agent, or a subcontractor, in the aggregate and for each drug on the formulary, in connection with the contract or arrangement with the covered plan. The disclosure must cover each semiannual period (or quarter) under the contract or arrangement and must disclose both amounts reasonably expected for claims incurred during the period and amounts reasonably expected that are related to utilization of such drug spending. For example, this disclosure will include any amounts the covered service provider reasonably expects to receive based on achieving utilization thresholds like volume-based rebates. The disclosure must specify both the amount that is reasonably expected to be passed on to the covered plan and, if applicable, the plan sponsor, and the amount that will be retained by the covered service provider, affiliate(s), agent(s), or subcontractor(s).

Under subparagraph (e)(3)(iv), the initial disclosure also must also include a description of any inflation protection or price protection agreements that the covered service provider, an affiliate, an agent, or a subcontractor has entered with any drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), regarding prescription drugs dispensed under the service contract or arrangement with the covered plan. The disclosure must specify the amount reasonably expected to be retained by the covered service provider, an affiliate, an agent, or a subcontractor in connection with each prescription drug product and under each such contract or arrangement and the price protection amount that will be passed on to the covered plan and, if applicable, plan sponsor, for each semiannual period (or quarter). The disclosure must cover amounts reasonably expected to be received for claims reasonably expected to be incurred during the period and amounts reasonably expected to be received related to utilization of such drug or spending on such drug. The Department separated the disclosure required under subparagraph (e)(3)(iv) from the disclosure required under subparagraph (e)(3)(i) because of the contingent nature of inflation and price protection.

The disclosure required by these provisions would be intended to cover any and all payments reasonably expected to be received from drug manufacturers, distributors, wholesalers, or rebate aggregators (or other purchasing entities designed to aggregate rebates), by the covered service provider, an affiliate, an agent, or a subcontractor in connection with their services to the covered plan, regardless of how they are characterized. The term ''agent'' is intended to capture rebate aggregators and GPOs, to the extent they may take the position that they do not fall within the definition of affiliate or subcontractor, so that reasonably expected payments to those entities in connection with the services contract or

[155] ''A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary addressing time, manner, and content of such disclosures): . . . '(IV)(aa) A description of all indirect compensation that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with the services described in subclause (I)–(AA) including compensation from a vendor to a brokerage firm based on a structure of incentives not solely related to the contract with the covered plan; and (BB) not including compensation received by an employee from an employer on account of work performed by the employee. (bb) A description of the arrangement between the payer and the covered service provider, an affiliate, or a subcontractor, as applicable, pursuant to which such indirect compensation is paid. (cc) Identification of the services for which the indirect compensation will be received, if applicable. (dd) Identification of the payer of the indirect compensation.' ''

[156] *See* ERISA section 408(b)(2)(b)(iii) (''A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary addressing time, manner, and content of such disclosures): . . . (IV)(aa) A description of all indirect compensation that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with the services described in subclause (I)–(AA) including compensation from a vendor to a brokerage firm based on a structure of incentives not solely related to the contract with the covered plan . . .'').

arrangement would be part of the initial disclosures.

In the proposal, the disclosure obligation was phrased in terms of ''payments'' from drug manufacturers and aggregators. The Department sought comments on whether the provisions in proposed paragraph (e)(3) and proposed paragraph (e)(6) adequately described the type of payments that may be received in this respect. The Department also sought comment on whether the broad term ''payments'' would be sufficient to define the disclosure obligation or whether more specificity would be needed to ensure full disclosure.

Many commenters responded to the proposed requirement for disclosure of payments from drug manufacturers and aggregators to a covered service provider. Commenters expressed both support and concern as to the forms of compensation to be disclosed as a manufacturer payment, the granularity of information reported, and the interaction of the disclosures with other requirements introduced by the CAA, 2026.

Several commenters said the Department should adopt the proposed disclosure of manufacturer payments in both the aggregate and for each drug on the formulary, with some commenters suggesting that additional granularity in disclosures would be necessary. These commenters generally encouraged the Department to broadly construe the types of compensation to be disclosed under this provision to ensure the disclosure would cover all manner of compensation paid by drug manufacturers. While many commenters supported use of broad and general language to describe the disclosure obligation, some also suggested either exemplary or enumerated breakouts delineating information into categories of compensation such as the common types of payments (*e.g.,* administrative fees, data fees, and access fees), discounts, and other compensation structures, to avoid the possibility that the disclosure requirements could be evaded through reclassification of manufacturer payments as various types of fees or alternative forms of compensation not explicitly in connection with the service contract or arrangement. A few commenters emphasized the need to ensure that disclosure obligation included amounts retained by GPOs, which the Department confirmed in an earlier preamble paragraph describing the disclosure obligation.

Several commenters suggested that additional disclosure elements be added. A few commenters suggested that disclosure include information about the manufacturer's net price, which would assist fiduciaries in evaluating the components of drug costs including remuneration to providers of pharmacy benefit management services. One commenter recommended that the final rule should require disclosure of information related to the specific manufacturer rebate contract the covered service provider would apply to claims for drugs submitted to a plan and the amount of rebates, on a per-National Drug Code basis, applicable to such rebate contract. Another commenter said that the final rule should require disclosure of manufacturer payments to break out the amounts retained and passed through at the level of each entity in the supply chain; require disclosure of the ownership, governance, and compensation structure of all entities involved in negotiations for manufacturer rebates or price concessions; and break out manufacturer payments made to the covered service provider and its affiliated entities separately.

The Department has finalized the provisions regarding disclosure of payments from drug manufacturers in subparagraphs (e)(3)(i) and (e)(3)(iv) with modifications. In the final rule, the requirement to disclose manufacturer payments in subparagraph (e)(3)(i) is phrased in terms of rebates, fees, alternative discounts or other remuneration. Further, both subparagraph (e)(3)(i) and (e)(3)(iv) refer to payments from drug manufacturers, distributors, wholesalers, or rebate aggregators (or other purchasing entities designed to aggregate rebates). These changes provide additional specificity as to the type of payments and the types of payors that would result in the required disclosures. This terminology also aligns with terminology in ERISA sections 408(b)(2)(C) and 726.[157]

Additionally, the reporting period is a semiannual period or, at the request of the plan, a quarter, which aligns with the reporting period in ERISA section 726(b).[158]

The Department did not identify any additional specific payment types in the regulatory text as requested by some commenters (*e.g.,* administrative fees, data fees, and access fees) based on the view that ''other remuneration'' is a broad term that would encompass all such payments and that it was desirable to use the same terms as ERISA sections 408(b)(2)(C) and 726. The Department also did not add a requirement to disclose the specific rebate contract associated with the payments as one commenter suggested. Such contracts would be available as part of an audit, which the Department believes strikes the correct balance in terms of the burden of the disclosure requirements.[159]

Some commenters said that an initial disclosure of manufacturer payments reasonably expected on a per-drug basis, as had been proposed, would be speculative and thus of limited use to responsible plan fiduciaries assessing the reasonableness of compensation for a contract or arrangement under ERISA section 408(b)(2). The commenters also said this approach was burdensome and generally misaligned with the comparable provisions regarding payments from drug manufacturers introduced by the CAA, 2026, which were only on a retrospective basis, and risked exposing sensitive information to be used for anti-competitive purposes. Some commenters said the Department should permit the disclosure in the aggregate, or by therapeutic category or formulary tier, rather than at the per-drug level using the requirements set forth in that section. A few commenters said that the new subparagraph (C) of ERISA section 408(b)(2), as added by the CAA, 2026 amendments, will require full rebate pass-through to group health plans and thereby will address concerns about a potential misalignment of incentives between covered service providers and group health plans related to manufacturer payments. Commenters said this obviated the necessity for the granular disclosure of

[157] ERISA section 726(b)(2)(A)(i) provides for reports regarding drugs for which a claim was filed for the applicable period including: ''(X) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration; (XI) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—(aa) for claims incurred during the reporting period; and (bb) that is related to utilization of such drug or spending on such drug.'' ERISA section 726(e)(1) provides a definition of applicable entity as follows: ''The term 'applicable entity' means—(A) an applicable group purchasing organization, drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), or associated third party; (B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such a plan or issuer, or any entity described in subparagraph (A); or (C) such other entity as the Secretary may specify through rulemaking.''

[158] ERISA section 726(b)(1) provides for disclosures ''not less frequently than every 6 months . . . or, at the request of a group health plan, not less frequently than quarterly . . .''

[159] The Department believes that the disclosure of drug pricing methodology in paragraph (e)(7) is responsive the commenters who suggested disclosing manufacturer net price information.

such payments under the Department's rule.

The Department did not eliminate the initial disclosure of manufacturer payments altogether or revise the rule to permit an aggregate initial disclosure based on therapeutic category or formulary tier, as some commenters suggested. The fact that ERISA section 726 is limited to a retrospective disclosure does not indicate that the Department's final rule should have a similar scope. Rather, the Department believes that the prospective disclosures are consistent with ERISA section 408(b)(2)(B) because they serve a distinct purpose in assisting responsible plan fiduciaries in assessing the reasonableness of the contract or arrangement and the compensation of the covered service provider and its affiliates, agents, and subcontractors at the time of contracting and in monitoring these contracts or arrangements thereafter. This disclosure of manufacturer payments for each drug on the formulary is important to assess the compensation to providers of pharmacy benefit management services and their affiliates, agents and subcontractors for each such drug.[160] An aggregate disclosure, on the other hand, might permit a covered service provider to obscure the covered service provider's financial incentives to select a particular prescription drug for the formulary.

It is important to note that in the final rule, these detailed disclosures are required only for covered plans, which are generally the larger self-insured group health plans (*i.e.,* the plans of specified large employers and the specified large plans) but also do not include group health plans established by a plan sponsor that is, or that is affiliated with, a drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates). As discussed elsewhere, the Department has mirrored the approach Congress took in the CAA, 2026 amendments regarding which responsible plan fiduciaries should receive the detailed disclosures. The more limited scope of the final rule should mitigate some concerns regarding the administrative burden to covered service providers of providing information on manufacturer payments and to responsible plan fiduciaries of reviewing such information as well as concerns about anti-competitive behavior.

To assist covered service providers that will need to make the detailed initial disclosures under subparagraphs (e)(3)(i) and (iv), the Department also added a new sentence to paragraph (k)(2) providing guidance on the methodology of developing the estimate, as suggested by a commenter. That sentence provides that ''estimates shall be grounded in good faith assumptions based on contractually defined methodologies, historical utilization and rebate experience, or other information reasonably available at the time of disclosure.'' The final rule also includes confidentiality provisions that are designed to address concerns about redisclosure of rebate information and use of such information for purposes unrelated to the covered plan's contract or arrangement, as discussed in section E.8 and E.9 of this preamble.

A few commenters directly addressed disclosure of price-protection agreements, with one commenter in favor of the disclosure as a measure of informing fiduciaries about how these agreements may influence behavior of providers of pharmacy benefit management services regarding higher list prices even when net price is offset by rebates. A few other commenters said the CAA, 2026 amendments did not require disclosure of these agreements, indicating Congress' view that disclosure would not be necessary for responsible plan fiduciaries in their review and evaluation of pharmacy benefit manager services arrangements. The Department believes that disclosure of these agreements is likely to provide insight regarding drug pricing-related incentives to responsible plan fiduciaries of the larger self-insured group health plans and is necessary to assess the reasonableness of compensation under the contract or arrangement required under the statutory exemption contained in ERISA section 408(b)(2). Therefore, the Department has retained this requirement in the final rule. The Department is also of the view that the disclosure of these agreements will help responsible plan fiduciaries analyze the full impact on participant costs and promote the use of lower cost alternatives.

Finally, the Department acknowledges that when the rebate pass-through provision in ERISA section 408(b)(2)(C) becomes effective, there likely will be increased transparency into rebate arrangements and other payments from drug manufacturers, and possibly reduced reliance on them. The Department does not see that potential development as a reason to eliminate the disclosure altogether. The Department believes it is still important to require transparency regarding how the payments are being handled for responsible plan fiduciaries to satisfy their fiduciary duties and the reasonableness assessment required under the statutory exemption. In this regard, the Department notes that ERISA section 408(b)(2)(C) will require the rebates, fees, alternative discounts, and other remuneration not only to be passed through to the covered plans but also to be fully disclosed to such plans.[161] The Department anticipates that requiring those disclosures in this regulation will make the transition to that disclosure process smoother, once those provisions (under section 408(b)(2)(C)) become fully effective, and envisions that it will leverage such disclosures in any future rulemaking or guidance implementing section 408(b)(2)(C) to minimize duplicative regulatory requirements.

3.6. Spread Compensation

Subparagraph (e)(3)(ii) of the final rule includes several disclosure requirements related to spread compensation. Under this subparagraph, the initial disclosure must include a list of drugs on the formulary, and for each drug: the contracted compensation to be paid by the covered plan for the drug to the covered service provider or an affiliate, an agent, or a subcontractor; the contracted compensation to be paid to the pharmacy by the covered service provider, or an affiliate, an agent, or a subcontractor, on behalf of the group health plan; and the difference between the two. This difference is defined in the final rule as spread compensation. Subparagraph (e)(3)(ii) further requires a description of the amount of spread compensation reasonably expected to be received by the covered service provider, an affiliate, an agent and a subcontractor in connection with the service contract or arrangement, for claims filed during each semiannual period (or quarter), both in the aggregate and for each drug on the formulary, and for each pharmacy channel (*i.e.,* retail pharmacy, mail order pharmacy, and specialty pharmacy) available under the contract or arrangement. The subparagraph additionally requires the disclosure to include a description of arrangements, incentives, contractual provisions, and policies that will be implemented under the service contract or arrangement that direct patients to pharmacies that are affiliates of the covered service provider.

[160] In requiring disclosure of all direct compensation and all direct compensation that a covered service provider, an affiliate, and a subcontractor ''reasonably expect[ ]'' to receive, Congress in ERISA section 408(b)(2)(B) clearly contemplated a prospective disclosure. ERISA section 408(b)(2)(B)(iii)(III) and (IV).

[161] ERISA section 408(b)(2)(C)(ii)(1)(bb).

The Department sought comments on the requirements under the proposed rule for disclosure of spread compensation, including whether the provision required disclosure of information sufficient to assess reasonableness and what challenges would arise from a covered service provider providing, or a responsible plan fiduciary reviewing, this level of disclosure. The Department also sought comments on whether arrangements with retail, mail order, and specialty pharmacies are sufficiently similar to one another so that dividing disclosures into these three channels is efficient, and whether greater transparency would incentivize the use of a pass-through pricing or a flat-fee compensation model.

Many commenters said the spread pricing disclosure provisions should be adopted in the final rule as a means of improving transparency into this historically opaque PBM revenue stream. Commenters expressed the view that the availability of such information would allow plan fiduciaries to better assess compensation arrangements consistent with their obligations under ERISA. A few commenters believed that transparency into spread compensation would incentivize the adoption of pass-through pricing and flat fee models with one commenter suggesting the Department should consider exempting or requiring reduced disclosure for providers using those models. One commenter observed that incorporating drug-level spread disclosure in the final rule could be consistent with and complementary to the requirement in ERISA section 726, enabling fiduciaries to perform both prospective review and retrospective verification of such amounts. Another commenter observed that spread compensation may not be addressed by the rebate-pass through provision in ERISA section 408(b)(2)(C), so disclosure will be important to understand this revenue stream that will continue to exist after the rebate-pass through provision takes effect.

Several commenters agreed with the Department's designation of three pharmacy channels—retail, mail order and specialty—in the proposal for spread pricing disclosure. However, some commenters believed it would also be important to break out PBM-affiliated versus non-affiliated pharmacies within these channels. Commenters said this would allow responsible plan fiduciaries to identify incentives in these arrangements and assess their impact on plan costs. Several commenters said the Department should require disclosure of arrangements, incentives, and contractual provisions that may direct patients to affiliated pharmacies or higher-spread channels. Another commenter said that the Department should also break out disclosure of spread by drug category (generic, brand, and specialty).

Other commenters said that the Department's proposal to require disclosure with respect to spread compensation reasonably expected for all formulary drugs across each pharmacy channel would impose extreme administrative burden upon covered service providers. Commenters said responsible plan fiduciaries would be overwhelmed with the expanse of data, could not meaningfully process such information to evaluate the overall reasonableness of the arrangement, and could face increased litigation risk based on having received such detailed information. Several commenters said they would support disclosure of aggregate amounts of spread compensation by pharmacy channel. Commenters also suggested that the Department permit disclosure of spread compensation as a percentage of drug spend rather than a dollar amount.

Commenters also made recommendations that they said would better align the final rule with the CAA, 2026 amendments. A few said the Department should not require any initial disclosure of spread pricing on the basis that initial disclosures are not part of the CAA, 2026 statutory framework. One commenter said if the Department proceeded with this element of the initial disclosure, it should clarify methodologies for initial estimations and provide specific guidance to clarify ''reasonably expected.''

In the final rule, the Department has revised the disclosure of spread compensation to align with the structure and phrasing of the similar requirement in ERISA section 726(b)(2)(A)(i)(I)–(III).[162] Thus subparagraph (e)(3)(ii)(A) requires a list of drugs on the formulary; the contracted compensation to be paid by the covered plan to the covered service provider, an affiliate, an agent, or a subcontractor for each drug (identified by National Drug Code); the contracted compensation to be paid to the pharmacy by the covered service provider, an affiliate, an agent, or a subcontractor for each such drug (identified by National Drug Code); and the difference between the two. To align with ERISA section 726, the Department also revised the reporting period so that it is a semiannual period (or at the request of the plan, a quarter).

Although the final rule requires disclosure of spread by pharmacy channel (retail, mail order, and specialty), the Department did not differentiate PBM-affiliated pharmacies versus non-affiliated pharmacies for purposes of the spread compensation disclosure provisions in the final rule because the Department was not convinced that this additional disclosure regarding spread compensation would be the easiest way for responsible plan fiduciaries to evaluate the potential for steering or pricing variations involving affiliated pharmacies. Rather, the Department believes that a more direct, narrative disclosure as suggested by some commenters may assist responsible plan fiduciaries; so for that reason, subparagraph (e)(3)(ii)(C) was added to the final rule requiring disclosure of arrangements, incentives, contractual provisions and policies that will be implemented under the service contract or arrangement that direct patients to pharmacies that are affiliates of the covered service provider. Additionally, as discussed below in section E.3.9 of this preamble, compensation reasonably expected to be received by pharmacies that are affiliated with a covered service provider when a covered plan's participants fill prescriptions at that pharmacy would be disclosed to the covered plan's responsible plan fiduciary as part of the category of ''other'' compensation. The Department did not require the disclosure to be categorized by drug category (generic, brand, and specialty) because that did not appear to be necessary in light of the disclosure at the individual drug level.

To address anticipated burdens in preparing the disclosures, some commenters requested limiting the disclosure obligation in the final rule to aggregate amounts of spread compensation by pharmacy channel. Other commenters suggested allowing disclosure of spread compensation as a percentage of drug spend rather than a dollar amount. The Department did not make these revisions because the

[162] Requiring reports to group health plans offered by a specified large employer or that are specified large plans including ''(i) a list of drugs for which a claim was filed and, with respect to each such drug on such list—(I) the contracted compensation paid by the group health plan or health insurance issuer for each covered drug (identified by the National Drug Code) to the entity providing pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer; (II) the contracted compensation paid to the pharmacy, by any entity providing pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer, for each covered drug (identified by the National Drug Code); (III) for each such claim, the difference between the amount paid under subclause (I) and the amount paid under subclause (II)[.]''

Department believes that concerns about administrative burden and utility to responsible plan fiduciaries are alleviated by the more limited scope of the final rule to the larger self-insured group health plans.

The Department also did not eliminate the initial disclosure regarding spread pricing altogether. Even though ERISA section 726 does not include initial disclosures, the Department determined that an initial disclosure of this important compensation stream was consistent with ERISA section 408(b)(2)(B) and needed for responsible plan fiduciaries of covered plans evaluating the services contract or arrangement at the time of contracting. The Department included guidance on methodology in paragraph (k)(2) of the final rule which provides that ''estimates shall be grounded in good faith assumptions based on contractually defined methodologies, historical utilization and rebate experience or other information reasonably available at the time of disclosure.''

The Department did not expressly exempt covered service providers using pass-through pricing and flat fee models as suggested by one commenter, but notes that covered service providers who do not reasonably expect to receive spread compensation would have no disclosure under this subparagraph of the final rule. PBM compensation models can change over time and be referred to by different names. By not providing a categorical exemption for certain models, the Department ensures that covered service providers provide disclosure under paragraph (e)(3)(ii) if they reasonably expect to receive such compensation.

3.7. Pharmacy Recoupment

Under subparagraph (e)(3)(iii) of the final rule, the initial disclosure must include a description of amounts of copay claw-back compensation and other retroactive adjustment to pharmacy reimbursement reasonably expected to be recouped from a pharmacy by a covered service provider, an affiliate, an agent, or a subcontractor in connection with prescription drugs dispensed under the contract or arrangement, for each semiannual period (or quarter). The final rule defines a copay claw-back as the dollar amount of the difference between a copayment or coinsurance amount paid to the pharmacy by a plan participant or beneficiary and the reimbursement to the pharmacy. Under subparagraphs (e)(3)(iii) and (k)(2), the disclosure must be expressed as a monetary amount per semiannual period (or quarter) and must specify the anticipated total number of transactions.

Where a covered service provider, an affiliate, an agent, or a subcontractor claws back any portion of a payment to a pharmacy made at point-of-sale and does not pass along the full amount recouped to the covered plan, information as to the value of any such amount recouped may not be otherwise available to a responsible plan fiduciary assessing the reasonableness of compensation under the contract or arrangement. For example, where the pharmacy's reimbursement price for dispensing a drug is less than the copayment made to the dispensing pharmacy by a participant or beneficiary and the covered plan's cost share for the drug is zero dollars, the responsible plan fiduciary may be unaware of the difference between the cost of the drug and the copayment that results in compensation to the covered service provider, an affiliate, an agent, or a subcontractor recouping such difference. The Department believes that additional disclosure of the total number of transactions reasonably expected to occur in the reporting period would provide the responsible plan fiduciary key information needed to assess the pervasiveness of this practice and whether adjustments to the plan's cost sharing structure may be appropriate.

The Department sought comments on this disclosure element in the proposed rule, including whether the proposed provision's scope of required disclosure of information for copay claw-back payments would be sufficient to assess reasonableness and whether other types of recouped payments should be included. If commenters believed the final rule should require disclosure of information for recouped payments other than copay claw-backs, the Department asked the commenters to describe the type(s) of recouped payments recommended to be included and how disclosure of this information is necessary to assess the reasonableness of the compensation under the contract or arrangement.

A number of commenters said the initial disclosure of copay claw-backs would be an important compensation element for responsible plan fiduciaries to be aware of in connection with their assessment of a contract or arrangement. Several commenters asked the Department to take additional steps in the final rule related to recoupment of compensation from pharmacies—either to require disclosure of all types of retroactive payments imposed by pharmacy benefit management service providers on pharmacies or to outright prohibit such retroactive payments under ERISA. Commenters also asked the Department to expand the disclosure to cover additional types of recoupment mechanisms that generate compensation. Several commenters mentioned effective rate reconciliation, which they described as a practice whereby PBMs periodically adjust pharmacy reimbursement to match an ''aggregate effective rate,'' clawing back amounts previously paid. Commenters asking the Department to prohibit these payments pointed to the negative impact on plan participants and pharmacies. One commenter said the disclosure of copay claw-backs should be broken out by affiliated and non-affiliated pharmacies.

Other commenters said the proposed disclosure of copay claw-backs should not be adopted in the final rule because this type of compensation was not included in the disclosures outlined by Congress in the CAA, 2026 amendments. One such commenter said this was not a common feature of group health plan contracts or arrangements, so the Department should allow covered service providers to provide a simple negative response to that required disclosure category.

The Department believes that compensation recouped from pharmacies should be disclosed to responsible plan fiduciaries of covered plans for purposes of assessing the reasonableness of a contract or arrangement to provide pharmacy benefit management services. The Department was persuaded by commenters that, to ensure comprehensive disclosure, the requirement should be expanded to include any other retroactive adjustment to pharmacy reimbursement reasonably expected to be recouped from a pharmacy in connection with prescription drugs dispensed under the service contract or arrangement. In response to the commenter who believed this to be uncommon, the Department confirms that a covered service provider who does not reasonably expect to receive this type of compensation would not make a disclosure under this subparagraph of the final rule.

The Department did not revise the requirement in the final rule to require a breakdown of pharmacy recoupments from affiliated versus nonaffiliated pharmacies. The Department has determined to address the issues associated with PBM-affiliated pharmacies in subparagraph (e)(3)(ii)(C) which requires a description of arrangements, incentives, contractual provisions and policies that will be

implemented under the service contract or arrangement that direct patients to pharmacies that are affiliates of the covered service provider.

The Department did not eliminate this disclosure element of the rule even though the CAA, 2026 amendments do not include specific disclosures regarding recoupment of compensation from pharmacies. The Department believes that such disclosures are appropriate under ERISA section 408(b)(2) because they will assist responsible plan fiduciaries in assessing the reasonableness of the contract or arrangement and the compensation of the covered service provider and its affiliates, agents, and subcontractors at the time of contracting and in monitoring these contracts or arrangements thereafter. Moreover, comprehensive disclosure is consistent with ERISA section 408(b)(2)(B), which requires disclosure of ''all direct compensation'' and ''all indirect compensation'' reasonably expected to be received by covered service providers, affiliates, and subcontractors.

3.8. Compensation for Termination of Contract or Arrangement

Under paragraph (e)(4) of the final rule, the initial disclosure must include a description of any compensation that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive in connection with termination of the contract or arrangement, and how any prepaid amounts will be calculated and refunded upon such termination. The provision on termination of compensation mirrors ERISA section 408(b)(2)(B)(iii)(VI).[163]

In the Department's view, a determination of reasonableness necessitates that a responsible plan fiduciary be aware upfront of any termination costs or potential costs to a covered plan. Without this information, a responsible plan fiduciary cannot sufficiently evaluate the economic consequences of such termination to the covered plan. Paragraph (e)(4) will, for example, enable the responsible plan fiduciary to understand and ensure proper treatment of any rebates owed at the time of the termination. While covered service providers may recoup reasonable amounts for actual losses upon early termination of the contract or arrangement, no contract or arrangement is reasonable if it does not permit termination by the covered plan without penalty on reasonably short notice under the circumstances to prevent the covered plan from becoming locked into a contract or arrangement that has become disadvantageous.[164]

Commenters on the Department's proposal generally did not address termination fees in any detail but several expressed the view that the comprehensive approach to disclosure in the proposal—including the termination fees—would assist responsible plan fiduciaries in fulfilling their statutory obligations. One commenter said visibility into costs of termination are needed for fiduciaries to understand the financial implications of ending the arrangement. Another commenter asked the Department to expand the disclosure to specify certain elements would be covered such as different impacts for different types of terminations, whether the compensation is direct or indirect, and the details of what entity is paying the compensation, what entity is receiving it, and how the compensation relates to the covered plan's arrangement. A few commenters on the other hand said the Department should not include this disclosure in the final rule because it is not a compensation element specified for disclosure in ERISA section 726, with one commenter expressing concern that this provision would invite regulatory scrutiny of lawful contractual provisions negotiated at arm's-length.

The Department agrees with commenters who said that disclosure of compensation reasonably expected in connection with termination of the contract or arrangement is a necessary component of comprehensive disclosure for responsible plan fiduciaries of covered plans determining the reasonableness of the contract or arrangement. Further, this disclosure element is consistent with ERISA section 408(b)(2)(B), so the Department believes that including it in the final rule will not materially increase the likelihood regulatory scrutiny of these contractual provisions. As stated elsewhere, the Department believes that ERISA section 408(b)(2) assists responsible plan fiduciaries in assessing the reasonableness of the contract or arrangement and the compensation of the covered service provider and its affiliates, agents, and subcontractors at the time of contracting and in monitoring these contracts or arrangements thereafter. On the other hand, the Department is not persuaded that there is value commensurate to the burden associated with adding additional specific elements to the disclosure of termination compensation, such as whether the compensation is direct or indirect, and the details of what entity is paying the compensation, what entity is receiving it, and how the compensation relates to the covered plan's arrangement, as suggested by one commenter. For these reasons, the Department has adopted this disclosure in the final rule as proposed.

3.9. Other Compensation

Paragraph (e)(5) provides a catch-all provision for any compensation not disclosed under paragraphs (e)(1)–(4). The disclosure must include a description of any such compensation that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive in connection with the contract or arrangement for the semiannual period (or quarter), regardless of whether such compensation is paid regularly or irregularly or from plan assets or is subject to any contingency or other condition. The disclosure must also include an identification of the payer of such compensation, an identification of the services for which such compensation will be received, and a description of the arrangement between the payer and the covered service provider, an affiliate, an agent, or a subcontractor, as applicable, pursuant to which such compensation is paid.

Several commenters who supported comprehensive disclosure under the Department's rule expressed uncertainty that this aspect of the proposal would achieve the desired result. In particular, some thought the Department intended an aggregate disclosure that would not require specification of the particular amount of compensation and the source. A few other commenters did not think ''other'' was an appropriate category of compensation to be included in the final rule based on the fact that ERISA section 726 does not include that category of compensation, and the commenters were concerned that the category could be overbroad and interpreted to require disclosure of compensation from services other than pharmacy benefit management services.

In response to comments, the Department revised the wording of the ''other compensation'' category to make clear it is not an aggregate disclosure; the requirement is now to disclose ''any'' compensation not already disclosed under paragraphs (e)(1)–(4), along with the payer of the

[163] ''A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary addressing time, manner, and content of such disclosures) . . . . (VI) A description of any compensation that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with termination of the contract or arrangement, and how any prepaid amounts will be calculated and refunded upon such termination.''

[164] 29 CFR 2550.408b–2(c)(3).

compensation, the services for which it will be received, and a description of the arrangement pursuant to which it will be received. This specific disclosure is what the Department had intended. The Department also added the language ''regardless of whether such compensation is paid regularly or irregularly or from plan assets or is subject to any contingency or other condition'' to underscore the breadth of the disclosure obligation.

The Department did not eliminate the category of ''other'' compensation altogether in response to comments regarding alignment with the CAA, 2026 amendments. The Department believes that ERISA section 408(b)(2) serves a distinct purpose in assisting responsible plan fiduciaries in assessing the reasonableness of the contract or arrangement and the compensation of the covered service provider and its affiliates, agents, and subcontractors at the time of contracting and in monitoring these contracts or arrangements thereafter. Further, comprehensive disclosure is consistent with ERISA section 408(b)(2)(B), which requires disclosure of ''all direct compensation'' and ''all indirect compensation'' reasonably expected to be received by covered service providers, affiliates, and subcontractors. Under ERISA section 408(b)(2)(B) as amended by the CAA 2026, the Department has authority to address time, manner, and content of the disclosures.

In connection with this category of ''other'' compensation, the Department sought comments on whether it should specify any other type of compensation that may be received by covered service providers instead of having those items disclosed in the catch all ''other'' category. The Department specifically asked about disclosure requirements related to compensation received by entities providing pharmacy benefit management services in connection with copay maximizer, copay accumulator, or alternative funding programs. Many commenters said that the final rule should include a specific disclosure regarding these programs, as the commenters said copay maximizer, copay accumulator, and alternative funding programs generate an increasing amount of compensation to providers of pharmacy benefit management services, including in the form of per-claim or per-enrollee fees; administration or technology fees; spreads or retained margins; and gain-share or savings-based payments for the design, implementation, or administration of these programs. Commenters suggested that use of such programs should be disclosed to permit the responsible plan fiduciaries to make decisions regarding their use. A few other commenters suggested the programs should be prohibited.

Commenters also suggested that the final rule should identify other examples of compensation streams that should be disclosed, including compensation from float (*i.e.,* interest on funds held or transferred on behalf of the plan); compensation from PBM-affiliated pharmacies; compensation received from pharmacy benefit manager-affiliated prescription drugs that are dispensed to the covered plan under the service contract or arrangement; compensation from rebate claw-backs (for seeking a lower cost or clinically superior drug); compensation associated with prescription drugs covered by the plan but reimbursed under the medical benefit, such as rebates, administrative fees and other payments tied to physician-administered or specialty drugs; and others.

The Department carefully considered commenters' suggestions regarding additional disclosure categories but determined that a robust list of additional disclosure items would overly complicate the regulatory text. The Department determined that the broad category of ''other'' compensation would be preferable to avoid creating any definitional loopholes or other unforeseen consequences associated with adding additional disclosure categories. However, based on the list of additional compensation streams commenters identified, the Department is persuaded that the other compensation category is critical to ensuring full disclosure and therefore did not eliminate it as requested by some commenters.

3.10. Formulary Placement Incentives

Paragraph (e)(6) requires the initial disclosures to include specified information regarding formulary placement incentives. The purpose of paragraph (e)(6) is to assist responsible plan fiduciaries in evaluating the covered service provider's formulary selections and how the selections might be influenced by incentives, arrangements, and payments. While paragraph (e)(3)(i) requires covered service providers to provide a description of the *amounts of payments* reasonably expected to be paid by drug manufacturers or rebate aggregators in connection with the contract or arrangement, paragraph (e)(6) requires a *description of the arrangements* so that the responsible plan fiduciary can gain additional insight as to their impact. The disclosures are set forth in three subparagraphs, each of which address different aspects of formulary design and maintenance.

3.10.1. Subparagraph (e)(6)(i)

Under subparagraph (e)(6)(i), the initial disclosure must include a description of any formulary placement incentives and arrangements that the covered service provider, an affiliate, an agent, or a subcontractor has entered with any drug manufacturer in connection with the contract or arrangement with the covered plan. The disclosure must also include an explanation of how the incentives and arrangements affect services to and are aligned with the interests of the covered plan and/or its participants and beneficiaries, such as by controlling prescription drug costs, providing clinically superior drugs, or both.

Formulary incentives or arrangements widely reported on in industry literature include concessions made by a drug manufacturer for including its drugs in a formulary, for tiering of drugs within a formulary, for excluding or tiering of other manufacturers' drugs within a formulary, and for treating a drug differently than therapeutically equivalent drugs (including biosimilar biological products) under a utilization management protocol. In addition, adding to a formulary a drug that is manufactured or co-manufactured by the PBM or an affiliate, in the view of the Department, would be a formulary placement incentive that triggers the disclosure required under subparagraph (e)(6)(i).

Under subparagraph (e)(6)(i), the covered service provider is required to provide an explanation of how the formulary placement incentives and arrangements affect services to and align with the interests of the covered plan and/or its participants and beneficiaries. The concept of alignment is inherently dependent on the specific facts and circumstances of the incentive or arrangement in question. However, examples of incentives or arrangements that are aligned with the interests of the covered plan and/or its participants and beneficiaries are those that aim to control prescription drug costs, provide clinically superior drugs, or both. In this regard, the Department notes that any given formulary placement incentive or arrangement can be aligned with the interests of the covered plan and/or its participants and beneficiaries based on a combination of the clinical value and cost-effectiveness of the associated drug, even though the drug is not necessarily clinically superior to all alternatives.

The Department anticipates that, in connection with developing these disclosures, covered service providers will carefully review the incentives and arrangements to determine how the incentives and arrangements would impact services to the covered plan. Likewise, covered service providers are required to determine that they could accurately disclose how the incentives and arrangements are aligned with the interests of the covered plan and/or its participants and beneficiaries, whether by contributing to controlling prescription drug costs, by providing clinically superior drugs, or both.

In the proposal, the Department requested comments on the proposed requirement to explain how formulary incentives and arrangements affect services to and are aligned with the interests of the covered plan and/or its participants and beneficiaries, and in particular whether commenters believed this requirement would contribute to the elimination of incentives and arrangements that are not aligned with the interests of the covered plan and/or its participants and beneficiaries. Further, to ensure that the final rule appropriately protects the interests of the participants in covered plans, the Department sought comment on whether any assertions of clinical superiority provided in the disclosure should be required to be accompanied by evidence. The Department also asked whether there are other examples of incentives or arrangements that align with the interests of the covered plan and/or its participants and beneficiaries (other than by controlling prescription drug costs, providing clinically superior drugs, or both) that should be specified in the regulatory text.

The Department received comments supporting the proposed requirement to disclose formulary incentives as a means of allowing responsible plan fiduciaries to understand incentives of pharmacy benefit management service providers associated with formulary decisions that may affect access to, and costs of, prescription drugs under the service contract or arrangement. Several commenters suggested that the final rule should specify that the required disclosure extends to how drug manufacturer payments impact tier placement, prior authorization, or step therapy, and may require drugs to be excluded from the formulary.

With respect to the proposed requirement to provide an explanation of how the incentives and arrangements affect services to and are aligned with the interests of the plan and/or its participants and beneficiaries, for example by controlling drug prices, providing clinically superior drugs, or both, some commenters agreed with the concept but believed that covered service providers may provide conclusory responses that might be of limited use. One commenter said that assertions of clinical superiority should be accompanied by peer-reviewed evidence or FDA recognized clinical data, and another commenter believed that evidence to support the assertion should be available upon request. However, several other commenters believed such claims could be supported by other methods such as a short evidentiary basis or a detailed analysis.

Other commenters expressed concerns about the burdens to the covered service provider and the potential market impact of the proposed disclosures. These commenters said that the disclosures may impact pharmacy benefit management service providers' ability to maintain competitive rebate leverage. Some commenters asked the Department to permit a narrative qualitative type of disclosure regarding formulary design principles rather than the disclosure of the incentive arrangements. Commenters also asked the Department to align with the approach taken by Congress in ERISA section 726, which focuses on a retrospective disclosure regarding the plan's highest spend drugs and involves standardized formulary placement rationales developed by the Secretary (along with the Secretary of Treasury and Health and Human Services).[165]

After considering these comments, the Department determined to finalize this paragraph as proposed, and has redesignated it as subparagraph (e)(6)(i) in the final rule. The Department believes there is value in covered service providers carefully reviewing the incentives and arrangements in light of the requirement to provide an explanation of how the incentives and arrangements affect services to and are aligned with the interests of the covered plan and/or its participants and beneficiaries. The Department did not require assertions of clinical superiority to be accompanied by any specific type of justification, to avoid additional costs and burden to covered service providers. The type of justification provided will be evaluated for persuasiveness by the responsible plan fiduciaries, who may seek additional information as they determine appropriate. The Department did not revise subparagraph (e)(6)(i) specifically to require the disclosure to address how incentives may address tier placement, prior authorization, and step therapy, and may result in drugs being excluded from the formulary and other related matters because the Department believes that the language of the required disclosures in subparagraph (e)(6)(i) and (ii) (discussed below) is broad enough to capture such information.

One commenter said that the final rule also should specify that formulary placement driven by lowest net cost to the plan and participant combined, after all compensation to the pharmacy benefit management service provider, would be most aligned with plan and participant interests. The Department did not add this additional language to the regulatory text because cost was already addressed in the language of subparagraph (e)(6)(i) regarding controlling prescription drug costs.

The Department decided to retain the disclosure of the incentive arrangement rather than a narrative qualitative type of disclosure regarding formulary design principles, as suggested by some commenters, because the Department was not convinced that a narrative would allow the responsible plan fiduciary to assess the incentives associated with formulary decisions that may affect access to, and costs of, prescription drugs under the service contract or arrangement.

The Department did not eliminate this disclosure altogether to align with ERISA section 726, as some commenters suggested. The Department believes this disclosure has value as a component of the initial disclosure so that plan fiduciaries will have the information at the time of contracting, which is key to making the reasonableness determination required under ERISA section 408(b)(2)(B). The Department believes that the burden described by commenters will be alleviated by the more limited scope of the final rule to the larger self-insured group health plans and that concerns about potential market impact are addressed by the confidentiality provision in paragraph (k)(4).[166]

[165] ERISA section 726(b)(2)(A)(iii) (Requiring disclosure of, ''with respect to any drug for which gross spending under the group health plan or health insurance coverage exceeded $10,000 during the reporting period or, in the case that gross spending under the group health plan or coverage exceeded $10,000 during the reporting period with respect to fewer than 50 drugs, with respect to the 50 prescription drugs with the highest spending during the reporting period—(I) a list of all other drugs in the same therapeutic class as such drug; (II) if applicable, the rationale for the formulary placement of such drug in that therapeutic category or class, selected from a list of standard rationales established by the Secretary, in consultation with stakeholders; and (III) any change in formulary placement compared to the prior plan year'').

[166] One commenter said, in connection with the proposed paragraph on formulary incentives, that

One commenter said the formulary incentive disclosures and other disclosures in paragraph (e)(6) would not be necessary in the future because of the newly added ERISA section 408(b)(2)(C) that will require pass-through of rebates, fees, alternative discounts and other remuneration to covered plans; at that time, the commenter said the covered plans will receive the full benefit of such payments. The Department has considered this comment but determined that a disclosure of formulary placement incentives will nevertheless have value in revealing to plan fiduciaries whether these arrangements may affect covered plan participants' access to, and costs to them of, prescription drugs under the service contract or arrangement. Adding this to the initial disclosures now also will provide plan fiduciaries a better sense of the accuracy of those future pass-through amounts and how they are calculated.

3.10.2. Subparagraph (e)(6)(ii)

Under subparagraph (e)(6)(ii), the initial disclosure also must include an identification of reasonably available therapeutically equivalent alternatives (including biosimilar biological products) for any drug on the formulary with respect to which the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive any payment by the manufacturer or rebate aggregator that is not passed through to the covered plan. This provision also requires the covered service provider to explain the reason for omitting such alternatives from the covered plan's formulary.

The purpose of this provision is to provide the responsible plan fiduciary with information on the constitution of the formulary and the extent to which its overall composition was influenced by lower cost and/or clinical efficacy, as discussed above, as opposed to financial incentives. For instance, when the formulary contains a drug for which the covered service provider will receive a payment from the drug manufacturer (and not pass the payment through to the covered plan), subparagraph (e)(6)(ii) requires the subject disclosure to identify reasonably available therapeutically equivalent alternatives or biosimilar biologic products that do not similarly compensate the covered service provider. This disclosure thus will enable responsible plan fiduciaries to evaluate the way the covered service provider has designed the formulary and the extent to which its composition might be overly influenced by conflicts of interests that impact the quality or performance of services and that require mitigation. The mere fact that alternatives without manufacturers' payments may exist in the marketplace is not dispositive of an unreasonable contract or arrangement; therefore, subparagraph (e)(6)(ii) requires the disclosure to explain the reason for their omission from the formulary, such as the alternatives having lower clinical efficacy, higher pricing, or inadequate supply.

In the final rule, the Department has required identification of reasonably available therapeutically equivalent alternatives modifying the proposal to include ''*biosimilar biological products,*'' based on several comments that said that as used by the Food and Drug Administration, the term ''therapeutically equivalent alternatives'' applies to small molecule drugs, and not biological products.

Subparagraph (e)(6)(ii) of the final rule does not define ''identification'' with respect to reasonably available alternatives. At a minimum, however, this identification must include enough information about the alternatives that the responsible plan fiduciary is able to consult a publicly available directory to complete a prudent analysis.[167] Typically, this will include the manufacturer's name, the generic or trade name of the drug, and dosage form. The disclosure is required to include only a reasonable number of alternatives, not every alternative on the market.

The Department requested comments on whether the final rule should contain an explicit standard with respect to the number of alternatives versus allowing the contracting parties the leeway to establish parameters on their own. One commenter said the rule should have a minimum standard such as requiring identification of at least three therapeutically equivalent alternatives with the lowest net cost available on the market, rather than leaving this to negotiation. Another commenter supported leaving this to the contracting parties but said the final rule should provide that defining therapeutic equivalents by reference to the Orange Book maintained by the Food and Drug Administration would be considered a reasonable approach. Based on limited commenter feedback, the Department determined that requiring a specific number of alternatives to be identified may prove too prescriptive, so it determined to allow the contracting parties to determine parameters. The Department agrees with the commenter who suggested that reference to the Orange Book maintained by the Food and Drug Administration would be considered a reasonable approach.

Other commenters on the proposal also said the Department should align its approach with that of ERISA section 726(b)(2)(A)(iii), which will require notification of changes in the formulary placement compared to the prior year, or should withdraw its proposed disclosure altogether in light of that statutory provision. The Department did not adopt a provision in which the disclosure focused on formulary placement compared to the prior plan year because a change in a formulary placement is not the focus of subparagraph (e)(6)(ii) and that type of disclosure would not yield any information in the case of a new contract or arrangement. The Department did not eliminate this disclosure altogether as a means of aligning with ERISA section 726 because the Department believes this disclosure has value as a component of the initial disclosure so that plan fiduciaries will have the information at the time of contracting in order to conduct a reasonableness assessment under ERISA section 408(b)(2)(B).

3.10.3. Subparagraph (e)(6)(iii)

Under subparagraph (e)(6)(iii), if the covered service provider, an affiliate, an agent, or a subcontractor retains authority to modify the formulary during the term of the contract or arrangement 4—such as by adding or removing drugs or changing their tiering—the initial disclosure must include an explanation of the reasons for retaining such authority and the expected frequency of such changes. Further, the disclosure must state that the responsible plan fiduciary will be notified reasonably in advance of any modifications that, individually or in the aggregate, are reasonably expected to have a material impact on the reasonableness of compensation under the contract or arrangement. The disclosure also must notify the responsible plan fiduciary of the covered plan's right to terminate the

the final rule must require disclosure of compensation received by a provider of pharmacy benefit management services when a PBM-affiliated product is preferred on a formulary or dispensed under the service contract or arrangement. This comment is discussed in the section on ''other'' compensation under paragraph (e)(5).

[167] *See, e.g.,* U.S. Food and Drug Administration's National Drug Code Directory, available at *https://dps.fda.gov/ndc* (last accessed July 31, 2025); U.S. Food and Drug Administration's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations,* available at *https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm* (last accessed July 31, 2025).

contract or arrangement on reasonably short notice under the circumstances.

The purpose of the advance disclosure requirement is to notify the responsible plan fiduciary sufficiently in advance of the upcoming formulary modification so that the responsible plan fiduciary can either consent or raise an objection. Modifying the formulary is an act of plan administration, with important consequences to the covered plan and its participants. The responsible plan fiduciary could not properly carry out its responsibilities under ERISA without this advance notice, and likewise the covered service provider might be exercising discretionary authority or responsibility in the administration of the covered plan if it unilaterally effected the modifications without the responsible plan fiduciary's consent.

With respect to this advance notice requirement, the proposed regulation did not specify a number of days ''in advance'' for the notice to be provided. The Department stated that ideally, the notice would be given sufficiently in advance so that responsible plan fiduciary has a reasonable period to consider the modification and consent or raise an objection. The Department requested comments on whether the final rule should provide more specificity regarding the timing of this advance notice, and stated that it was considering whether to require the notice to be furnished at least 75 days in advance of the change, to allow the covered plan to provide notice to plan participants at least 60 days prior to the date the upcoming material modification becomes effective, if required.[168]

While several commenters supported the 75-day advance notice timeframe as providing responsible plan fiduciaries with sufficient time to evaluate the change before it takes effect, another commenter opposed the advance notice requirement stating that it could delay patient access to newly approved drugs. The commenters opposed to 75-day advance notice timeframe did not propose alternative timeframes. The Department determined, in light of concerns about prompt patient access to newly approved drugs, that it would not specify a timeframe for the advance notice provision in the final rule. Instead, it would leave the decision up to the responsible plan fiduciary and the covered service provider.

The advance notice requirement is triggered only with respect to formulary modifications that, individually or in the aggregate, are reasonably expected to have a material impact on the reasonableness of compensation under the contract or arrangement. In this way, the trigger is carefully tied to matters of compensation—the chief topic of ERISA section 408(b)(2).

For this purpose, subparagraph (e)(6)(iii) provides that the term ''material'' means an amount that is 5 percent or more, or such lower percentage or dollar amount that may be agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement, of the aggregate compensation (on a semiannual basis, or at the request of the covered plan, quarterly basis) disclosed pursuant to subparagraph (e)(3)(i) of the final rule, adjusted for any increases previously disclosed under paragraph (e)(6). Thus, the base amount on which the materiality of the modification is judged would initially be the amount disclosed pursuant to subparagraph (e)(3)(i), but it would increase by the amount of any modifications disclosed under subparagraph (e)(6)(iii).

The following example illustrates how the base amount subparagraph (e)(6)(iii) adjusts as material modifications are made to the formulary. Assume that in advance of entering a contract with a covered plan, a covered service provider discloses pursuant to subparagraph (e)(3)(i) reasonably expected payments on a semiannual basis of 100 dollars. After entering the contract, a contemplated modification in the first semiannual period would result in an increase in compensation above the initially-disclosed amount (100 dollars) by two percent. Advance disclosure of this modification would not be required by subparagraph (e)(6)(iii), unless the parties had agreed to a two percent threshold. A contemplated modification in the second semiannual period would result in an increase in compensation above the initially-disclosed amount (100 dollars) by four percent. Because the aggregate of the second semiannual period modification (four percent increase to initially-disclosed amount) and the first semiannual period modification (two percent increase to initially-disclosed amount) collectively are expected to exceed five percent, advance notice of the second semiannual modification would be required under subparagraph (e)(6)(iii). The disclosure would need to describe the aggregate (six percent) increase to the initially-disclosed amount. Going forward, the five percent threshold in subparagraph (e)(6)(iii) would apply to the initially disclosed amount (100 dollars) plus the amount disclosed under paragraph (e)(6) (six dollars, or six percent of 100 dollars).

The Department proposed a materiality standard as a trigger to balance the amount of disclosure provided to responsible plan fiduciaries of covered plans. Without a materiality standard, the Department was concerned that responsible plan fiduciaries might be inundated with advance notices of formulary modifications. This concern was based on the understanding that PBMs make frequent changes to formularies.

The materiality standard has two components: it includes a ceiling of a five percent impact over the base amount, and it also allows for the covered service provider and responsible plan fiduciary to negotiate a lower threshold (dollar or percentage).[169] The Department understands that in other contexts, materiality is determined based on the significance to the impacted parties.[170] However, the Department also believes that covered service providers and responsible plan fiduciaries may appreciate a bright line rule as an alternative.

In the proposal, the Department sought comments on the proposed definition of materiality and whether commenters believed the approach taken in the proposal is workable and identifies an appropriate test for materiality. The Department asked whether the test for materiality in the proposal, which was based on a 5 percent increase over the estimated amount of expected rebates from manufacturers or aggregators, should be broadened to include other compensation, such as spread. The Department also asked about alternative tests for materiality, including whether it would be better to trigger advance disclosure on ''any non-trivial changes in the formulary that could affect the covered service provider's own compensation.''

Several commenters suggested changes to the proposed approach to the materiality standard. A few commenters said the provision should be broadened to apply to material increases in other compensation such as spread. Other commenters said that the provision should also apply to material increases

[168] *See* 29 CFR 2590.715–2715(b).

[169] The parties may agree to other changes to the formulary that would trigger advance notification to the responsible plan fiduciary. It is a best practice but also on the part of the fiduciary a matter of prudent dealing on behalf of the plan to memorialize in writing any such negotiated advance notice thresholds or triggers.

[170] *See, e.g., Basic Inc.* v. *Levinson,* 485 U.S. 224, 240 (1988).

in plan costs, cost-sharing, or utilization management structure.

A few commenters said the Department should eliminate the general materiality standard (*i.e.,* ''the responsible plan fiduciary must be notified in advance of any modifications that, individually and in the aggregate, *are reasonably expected to have a material impact on* the reasonableness of compensation under the service contract or arrangement'') and instead use only a percentage threshold.

After considering comments on this paragraph, the Department decided to finalize it as proposed with a focus on formulary changes that materially impact rebates, fees, alternative discounts and other remuneration from drug manufacturers, distributors, wholesalers, and rebate aggregators (or other purchasing entities designed to aggregate rebates) that will be received by the covered service provider, an affiliate, an agent, or a subcontractor. The Department did not expand the provision to apply to material increases in other compensation such as spread because it was not convinced that spread compensation is necessarily a driver of formulary changes such that changes should be brought to the attention of the responsible plan fiduciary in advance; rather, it is appropriate for material increases in spread compensation to be subject to the overage explanation in paragraph (g)(4). The Department did not require a disclosure based on material increase in plan costs or other factors such as cost-sharing because it determined that changes that will increase compensation for covered service providers (and affiliates, agents, or subcontractors) should be the focus of this disclosure under ERISA section 408(b)(2). The Department also did not replace the general standard that ''the responsible plan fiduciary must be notified in advance of any modifications that, individually and in the aggregate, *are reasonably expected to have a material impact on* the reasonableness of compensation under the service contract or arrangement'' with a percentage threshold, because it preferred to leave responsible plan fiduciaries the opportunity to negotiate a lower materiality threshold.

A few commenters opposed the disclosure in subparagraph (e)(6)(iii) as they said it was inconsistent with the statutorily mandated framework in the CAA, 2026. The Department disagrees that this provision exceeds its authority. As set forth above, modifying the formulary is an act of plan administration. To rely on the exemption when contracting with a plan to provide pharmacy benefit management services, ERISA section 408(b)(2)(B) as amended by the CAA, 2026 in fact requires that PBMs as covered service providers make disclosures sufficient to permit the responsible plan fiduciary to assess the reasonableness of the compensation that is to be received. Without notice to the responsible plan fiduciary so that the fiduciary can monitor the service contract or arrangement and the covered service provider can avoid exercising discretionary authority or responsibility in the administration of the covered plan, the exemption cannot function, and a fiduciary cannot meet its duties under ERISA section 404.

3.11. Drug Pricing Methodology

Under paragraph (e)(7), the initial disclosure must include a description of the net price per course of treatment or single fill, such as a 30-day or 90-day supply, to the covered plan of each drug on the formulary, as defined by National Drug Code, after rebates, fees, alternative discounts, or other remuneration received from applicable entities, for each pharmacy channel, expressed as a monetary amount. If a monetary amount is not ascertainable, the covered service provider must disclose the methodology used by the covered service provider, an affiliate, an agent, or a subcontractor, under the contract or arrangement, to determine the net price the covered plan will pay for each drug on the formulary, for each pharmacy channel, along with an objective means to verify the accuracy.

The final rule therefore requires the covered service provider to disclose the net price to the covered plan of each drug on the formulary by pharmacy channel, including mail order pharmacy, retail pharmacy, and specialty pharmacy. The net price refers to the total cost to the covered plan after rebates, fees, alternative discounts, or other remuneration received by applicable entities would be applied to the price paid by the plan. The covered service provider would disclose to the responsible plan fiduciary the net price of each drug as a monetary amount when such figures can be ascertained by available information.

In instances where a monetary amount cannot be ascertained by the covered service provider, the paragraph (e)(7) disclosure requirement may be satisfied if the covered service provider instead discloses the methodology that will be used to determine the cost to the covered plan and an objective means to verify the accuracy of that methodology. An example of this methodology would be a price determined by reference to AWP, and a direction to the plan as to where the AWP that will be used may be located. Depending on the specific pricing methodology being used, other examples of information that may be provided by the covered service provider, enabling the responsible plan fiduciary to verify the accuracy of the disclosed drug pricing methodology, could include pricing indices, rate schedules, benchmark formulas, or similar objective data sources.

The Department has no single specific list or benchmark in mind to satisfy this verification requirement. The covered plan and covered service provider are best situated, on a case-by-case basis, to establish solutions that meet their individual needs. The intent of this provision is to address the reported opacity in the pharmaceutical supply chain and to remedy the imbalance in bargaining power between covered plans and large providers of pharmacy benefit management services.

The paragraph (e)(7) disclosure requirements serve to establish price transparency to ensure a responsible plan fiduciary can effectively evaluate whether the contract or arrangement with the covered service provider is reasonable. The responsible plan fiduciary gains clear and upfront awareness of drug costs and can assess the fairness and predictability of such prices, preventing arbitrarily inflated net costs and enabling the selection of pricing models most aligned with the interests of the covered plan. Additionally, the (e)(7) provision limits opportunities for covered service providers to use non-transparent discretionary pricing formulas that could obscure the true costs of drugs on the formulary.

Commenters who supported this provision in the proposal said it would assist fiduciaries in evaluating drug pricing arrangements and formulary policies, and it would also ensure that pharmacy benefit managers do not implement discretionary pricing methodologies. One commenter particularly supported the ability of fiduciaries to verify the pricing information.

The Department had proposed disclosure of ''net cost'' to the covered plan of each drug on the formulary, for each pharmacy channel. The Department revised the language in the final rule to use the phrasing ''the net price per course of treatment or single fill, such as a 30-day or 90-day supply to the plan . . . after rebates, fees, alternative discounts, or other remuneration'' received from drug manufacturers, distributors, wholesalers, or rebate aggregators (or

other purchasing entities designed to aggregate rebates). The Department believes this is clearer than the phrasing ''net cost'' and the terminology aligns with ERISA section 726(b)(2)(A)(i)(VII).

One commenter who supported the disclosures recommended aligning pricing disclosure requirements under the rule with pricing disclosures required under ERISA section 726 and requested the Department clarify that the net cost of each drug be disclosed as the ''average net unit cost.'' The commenter did not describe how the average net unit cost related to the net cost language in ERISA section 726, so the Department declined to adopt that additional language.

In the proposal, the Department requested comments on whether the language in the proposed price disclosure provision provided sufficient clarity to covered service providers regarding their disclosure obligations or whether adjustments should be made. The Department asked whether, for example, the provision should specify how the term ''drug'' will be defined, and if so, the Department asked commenters to please provide suggested language. Several commenters suggested that the term drug be identified by reference to the National Drug Code. Some commenters specified that it should be at the 11-digit level (as opposed to the 5-digit or 9-digit level), which a commenter said is the standard identifier throughout the pharmaceutical supply chain and is necessary to prevent PBMs from aggregating disclosures and obscuring individual drug pricing. The Department has added a reference to the National Drug Code to paragraph (e)(7) in the final rule. The Department expects the disclosure to include the 11-digit code, as the industry standard, but has not included that specification in the final rule to avoid the potential that such specification could become outdated. Additionally, ERISA section 726 includes National Drug Code reporting without specifying the 11-digit code.

Commenters suggested additional changes that the Department did not accept. Several commenters suggested aggregate reporting of drug pricing information, including specific information by therapeutic category or pharmacy channel; and one commenter supported it as an addition to individual drug pricing, while another commenter suggested it as an alternative. The commenter who suggested it as an alternative to individual drug pricing said aggregate price disclosure would have the benefit of advancing transparency in a more targeted way while avoiding transmittal of commercially sensitive individual drug pricing information. A few commenters also said that this rule should require disclosure of net cost to include breakouts identifying whether a prescription was filled at a pharmacy owned by or affiliated with the covered service provider. The Department believes the disclosure of pricing information at the individual drug level in the final rule is appropriate as an initial disclosure to responsible plan fiduciaries contracting for pharmacy benefit management services. Additional disclosures such as aggregate disclosure by therapeutic category, pharmacy channel, or pharmacy affiliation would increase the burden to covered service providers.

Some commenters said that drug level disclosure would not be necessary for effective fiduciary oversight; would possibly overwhelm responsible plan fiduciaries; and would exceed the framework established by Congress in ERISA section 726, which requires pricing disclosure only for drugs for which a claim was filed. As discussed above, the Department believes that the paragraph (e)(7) disclosure requirements will assist responsible plan fiduciaries in their assessments of contracts or arrangements with providers of pharmacy benefit management services, including by allowing them to select drug pricing models most aligned with the interests of the self-insured group health plan, and limiting opportunities for covered service providers to use non-transparent discretionary pricing formulas that could obscure the true costs of drugs on the formulary. The Department believes disclosures under ERISA section 408(b)(2) assist responsible plan fiduciaries in assessing the reasonableness of the contract or arrangement and the compensation of the covered service provider and its affiliates, agents, and subcontractors at the time of contracting and in monitoring these contracts or arrangements thereafter.

Finally, commenters expressed concern about confidentiality of disclosures related to drug prices and drug pricing methodologies. The Department has adopted paragraph (k)(4) in the final rule that permits covered service providers to require responsible plan fiduciaries to require third parties and their subcontractors to execute reasonable confidentiality provisions preventing redisclosure by such parties and limiting use of such information to purposes related to the covered plan's contract or arrangement.

3.11.1. Net Effective Cost Disclosure

Several commenters recommended that the Department add a new provision to the final rule requiring covered service providers defined in paragraph (c)(1)(ii) (*i.e.,* brokers and consultants) to disclose information using a net effective cost model for bids to provide pharmacy benefit management services furnished as part of a request for proposal. These commenters said that bids submitted as part of a request for proposal for pharmacy benefit management services which focus on the value of rebates or other price concessions from drug manufacturers can obscure the total net cost incurred by a plan for providing its pharmacy benefit, as bids structured on securing sizable rebates for high-list-price drugs may still result in a higher cost to the plan than an option structured on using lower-list-price drugs, generics, or biosimilars. These commenters also said that requiring disclosure of bids using a net effective cost model would align the incentives of all parties in the supply chain and present competing models in a simple and comparable manner while preserving the various mechanisms used by covered service providers for negotiating price concessions and other factors to reduce the ultimate cost to the plan for providing a pharmacy benefit. The commenters proposed a definition of ''net effective cost'' for use in the regulatory text.

The Department considered these comments and concluded that a disclosure that is simple and would allow responsible plan fiduciaries to compare competing bids could be a helpful tool for responsible plan fiduciaries. However, the suggestion centered around a detailed and technical definition of net effective cost, and the Department was reluctant to adopt this disclosure as a requirement in the final rule based on limited comments.

3.12. Statement of Fiduciary Status

Under paragraph (e)(8), the initial disclosure must include, if applicable, a statement that the covered service provider, an affiliate, an agent, or a subcontractor will provide, or reasonably expects to provide, services pursuant to the contract or arrangement directly to the covered plan as an ERISA fiduciary.

As relevant to this final rule, ERISA provides that a person is generally a fiduciary with respect to a covered plan to the extent he exercises any discretionary authority or discretionary control respecting management of such

plan or exercises any authority or control respecting management or disposition of its assets, or do so, or has any discretionary authority or discretionary responsibility in the administration of such plan.[171] In complying with paragraph (e)(8), therefore, the covered service provider should carefully consider whether it, or an affiliate, an agent, or a subcontractor, will meet this definition in its services to the covered plan.

The Department has previously explained in this respect that a person who performs ''purely ministerial functions . . . within a framework of policies, interpretations, rules, practices and procedures made by other persons'' is not a fiduciary under this test.[172] To avoid fiduciary status, a covered service provider should ensure that its services to the covered plan, and the services of its affiliates, agents, and subcontractors, are not discretionary, but instead operate within policies and procedures disclosed to and approved by the responsible plan fiduciary.[173]

Multiple commenters expressed support for the proposal's broad disclosure requirement, indicating that transparency regarding fiduciary roles is essential to helping plan sponsors and fiduciaries clearly understand whether covered service providers or their affiliates have legal obligations to act in the best interest of the plan as required under ERISA. In their view, without knowing when fiduciary duties apply, plan sponsors cannot properly evaluate whether covered service provider's decisions are loyal fiduciary judgments or if financial incentives are influencing decision-making that may not be in the best interest of the plan.

Multiple other commenters generally opposed the statement of fiduciary status required under the proposal. A commenter noted that a statement of fiduciary status is not required under the disclosure provisions of the CAA, 2026, and that the statement seems to exceed the statutory purpose of ERISA section 408(b)(2). According to the commenter, it is immaterial to the framework under section 408(b)(2) whether or not the covered service provider believes it is a fiduciary. Some commenters suggested that the fiduciary status disclosure may cause confusion about ERISA's definition of fiduciary, which is well-understood to be a functional test. The commenters noted that disclosing a statement as to fiduciary status does not, by itself, create such status if the person does not meet the functional test, and that meeting the function test confers fiduciary status even without a statement. According to commenters, the initial disclosure could therefore mislead a responsible plan fiduciary into believing that a covered service provider is a fiduciary even if the purported fiduciary does not actually meet the functional test described in ERISA section 3(21).

A commenter suggested that the fiduciary statement should instead focus on those duties that the plan and covered service provider have separately and expressly agreed are fiduciary in nature. The commenter explained that any arrangement under which a plan fiduciary intends to confer on another entity the role of fiduciary would be the subject of a separate, explicit, and specific written undertaking agreed to by all parties. Another commenter similarly suggested that the statement should identify whether the covered service provider will provide services to the plan in a fiduciary capacity, or has entered into any agreement that could be construed as conferring discretionary authority or control over plan management or plan assets, which result in fiduciary status under ERISA section 3(21)(A). Another commenter suggested that the proposal should be modified to additionally require a negative disclosure when a covered service provider does not believe it is a fiduciary.

Commenters also requested several other clarifications and changes to the proposed requirement. A commenter requested clarification that a plan fiduciary, other than the PBM, is not liable for any failure of the PBM to provide the statement required by the regulation. Another commenter requested confirmation that the functional fiduciary test under ERISA section 3(21)(A) would still generally apply to pharmacy benefit service arrangements. A commenter also requested confirmation that ERISA makes clear that when a fiduciary is acting in a non-fiduciary capacity, such as when a PBM sells services to a plan, such activities are not a conflict of interest so long as they do not relate to the party's fiduciary role.

A commenter suggested that a covered service provider should be required to update their statements whenever there is a material change to the provider's fiduciary status or conflicts of interest or compensation, with materiality defined explicitly in relation to the affected plan sponsor. The commenter also recommended the fiduciary status statement requirement be changed to require semiannual and material event restatements, explaining that annual or even semiannual updates would be insufficient given the dynamic nature of PBM operations, vertical integration, and the frequency with which formulary and network changes can alter fiduciary analysis. The commenter also recommended that the regulation should be revised to indicate that the failure to acknowledge that the PBM is acting as a fiduciary is, itself, a breach of its fiduciary duty.

After reviewing the public comments, the Department has decided to include the disclosure of fiduciary status in the final regulation, and to not limit it to instances where fiduciary status is expressly agreed upon contractually. The Department agrees with commenters that argued the importance of responsible plan fiduciaries knowing whether a party will be providing or reasonably expects to provide services to the plan as an ERISA fiduciary, given the provider's heightened level of responsibility under ERISA. In the Department's view, this importance does not change based on whether a person is a functional fiduciary or expressly agrees by contract to perform fiduciary functions. The Department is not persuaded that disclosure of fiduciary status is inconsistent with section 408(b)(2) of ERISA. As indicated in both the proposal and elsewhere in this final rule, the statutory basis for this regulation includes section 408(b)(2)(B) of ERISA, which also contains a requirement to disclose if a covered service provider will provide, or reasonably expects to provide, services as a fiduciary within the meaning of section 3(21) of ERISA.

The Department does not share the concern of some commenters that an initial disclosure may mislead responsible plan fiduciaries into believing a covered service provider is a fiduciary even if the service provider does not actually meet the functional test described in section 3(21). As some commenters noted, the functional test for fiduciary status under section 3(21) is well understood. The Department's guidance and numerous court decisions make clear that a person is a fiduciary only to the extent it meets the functional

[171] ERISA section 3(21)(A)(i) and (iii) (29 U.S.C. 1002(3)(21)(A)(i) and (iii)). ERISA section 3(21)(a)(ii) (29 U.S.C. 1002(3)(21)(A)(ii)) is not described in the text as it pertains to the provision of investment advice for a fee.

[172] Interpretive Bulletin 75–8, 29 CFR 2509.75–8 (Q&A D–2).

[173] The test for fiduciary status under section 3(21) of ERISA is a functional test. While effective policies and procedures enable service providers to act ministerially and thereby avoid discretionary acts described in section 3(21) of ERISA, express disclaimers of fiduciary status, standing by themselves, have no such effect.

definition in the statute.[174] The disclosure requirement in the final regulation does not change the functional test for identifying fiduciaries. We also note that if a covered service provider fails to provide the statement of fiduciary status, the exemption at paragraph (n) of the final regulation is available for the responsible plan fiduciary.

The Department agrees with the commenter who said the statement of fiduciary status should be updated and has added a requirement to update this statement in the semiannual disclosure, in paragraph (g)(5) of the final rule. With respect to other suggestions to require additional disclosure of information, and updates to the information disclosures, the Department did not receive sufficient information from commenters for consideration. The Department has not made any changes in response to these comments.

3.12.1. Examples

A number of commenters supporting the proposal's statement of fiduciary status also suggested that the final rule include examples illustrating fiduciary status that may be taken on by PBMs. According to some, the proposal effectively allows PBMs, rather than responsible plan fiduciaries, to determine when they are acting as fiduciaries for purposes of the disclosure requirement. They indicated that the fiduciary status of a PBM performing PBM services is not always clear-cut in practice, and, as a result, similarly situated PBMs and responsible plan fiduciaries may reasonably reach different conclusions about whether specific conduct gives rise to fiduciary status that must be disclosed. Commenters cautioned that PBMs may adopt unduly narrow interpretations of fiduciary status, allowing activities that involve discretion or meaningful influence over plan assets, plan administration, or plan management to be characterized as non-fiduciary by default. Some also opined that PBMs often have evaded ERISA fiduciary duties by asserting they perform only ''ministerial'' functions, with one commenter suggesting that the Department provide further guidance on ''ministerial'' functions.

Some commenters said that the regulation could be strengthened if it includes examples of how PBMs function as fiduciaries. In their view, this would promote consistent application of the disclosure requirement and help responsible plan fiduciaries identify PBM fiduciary functions that are inconsistent with PBM pricing arrangements and increase the cost of medicines. Some commenters identified as possible examples for the regulation activities related to designing utilization management plans, designing pharmacy benefit networks, and developing other formulary changes that they believe can cause PBMs to operate as fiduciaries under ERISA.

With respect to fiduciary status, the proposal explained that ERISA provides that a person is generally a fiduciary with respect to a self-insured group health plan to the extent he exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets, or has any discretionary authority or discretionary responsibility in the administration of such plan.[175] However, a person who performs ''purely ministerial functions . . . within a framework of policies, interpretations, rules, practices and procedures made by other persons'' is not a fiduciary under this test.[176] Whether a person is a fiduciary under the function test depends on the surrounding facts and circumstances. Because the test is based on function, a person may be a fiduciary with respect to some activities, but not others. For example, as noted in the proposal, a covered service provider that unilaterally modifies a self-insured group health plan's formulary may be exercising discretionary authority or responsibility in the administration of the plan.[177] The Department believes providing more comprehensive guidance on fiduciary status, as requested by commenters, is beyond the scope of this regulatory project.

3.12.2. Conflicts Disclosure

In the proposal, the statement of fiduciary status also included a conflict-of-interest disclosure. Specifically, the proposal included a requirement to ''disclose any activity or policy that may create a conflict of interest, including, for example, if such entity will benefit financially from drug substitution, from incentivizing use of affiliated pharmacies when other network pharmacies offer lower costs, or from step therapy or 'fail first' protocols that require participants and beneficiaries to use drugs that generate greater manufacturer rebates than other therapeutically equivalent drugs on the formulary.''

A commenter questioned the need for the separate conflicts disclosure and the proposal's examples of potential conflicts in light of the CAA, 2026. The commenter explained that while the proposal suggested that such a conflict could include the use of a step therapy protocol requiring beneficiaries to use specific drugs to ''generate higher manufacturer rebates than other therapeutically equivalent drugs,'' manufacturer rebates are a means to lower plan costs. The commenter asserted that it is difficult to see how that scenario could be a ''conflict of interest'' because under the CAA, 2026's 100% rebate pass-through requirements, manufacturer payments associated with the plan's drug utilization flow entirely to the plan. The commenter observed that if a step therapy protocol results in greater manufacturer rebates, the plan receives 100% of that value. The commenter requested that the Department clarify that the conflict-of-interest disclosures relate to those areas in which the covered service provider serves as a fiduciary. In the commenter's view, that clarification would help avoid potential confusion around the types of examples provided in the proposal. Another commenter suggested that the conflicts disclosure should apply only to activities ancillary to the covered service provider's role as an expressly agreed upon fiduciary. Another commenter suggested that the conflicts of interest disclosure should be strengthened to require a description of the processes to identify and mitigate conflicts of interest, such as objective third-party evaluation of identified conflicts and management of recusals.

The Department decided not to include the conflict disclosure in the final rule. The Department had intended that the conflict disclosure would be applicable to activities and policies related to the covered service provider's services as a fiduciary. However, after consideration of comments on the proposed statement of fiduciary status and the conflict disclosure, the Department concluded that the totality of the other disclosures in the final

[174] *See, e.g.,* Advisory Opinion 2001–02A (Feb. 15, 2001), available at *https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/advisory-opinions/2001-02a; Pegram* v. *Herdrich*, 530 U.S. 211 (2000).

[175] ERISA section 3(21)(A)(i) and (iii).

[176] Interpretive Bulletin 75–8, 29 CFR 2509.75–8 (Q&A D–2).

[177] 91 FR at 4367 (''Modifying the formulary is an act of plan administration, with important consequences to the self-insured group health plan and its participants. The responsible plan fiduciary could not properly carry out its administrative responsibilities under ERISA without [the proposed] advance notice, and likewise the covered service provider might be exercising discretionary authority or responsibility in the administration of the self-insured group health plan if it unilaterally effected the modifications without the responsible plan fiduciary's consent.'').

rule—particularly disclosures regarding the indirect compensation to be received by the covered service provider and its affiliates, agents, and subcontractors—will provide responsible plan fiduciaries with meaningful information to assess the potential conflicts of interest. Additional conflict disclosure associated with the statement of fiduciary status could prove duplicative and may therefore be confusing to responsible plan fiduciaries.

3.13. Statement of Audit Right

Under paragraph (e)(9), the initial disclosure must provide a statement of the covered plan's right to the audit described in paragraph (j) of the final rule and the procedures for requesting such an audit. Among other things, paragraph (j) ensures that the contract or arrangement does not contain terms that would impede the covered plan's ability to conduct an audit. As discussed in preamble section E.8., the right to audit the completeness and accuracy of the required disclosures is an essential part of the final rule's framework for establishing transparency in the marketplace for pharmacy benefit management services. Paragraph (e)(9) ensures that the responsible plan fiduciary is aware of the audit rights that are preserved in the regulation.

Several commenters said the audit provision exceeded the Department's statutory authority, and they submitted related comments saying that the initial disclosure should not include this statement of audit right. The Department has discussed the comments on its statutory authority below and has determined to adopt the audit provision in the final rule with modifications clarifying the scope of limitations for confidentiality agreements related to such an audit and the timing requirements for a service provider to provide the information required for the audit. Accordingly, the final rule also includes the required statement of audit right in the initial disclosure.

4. Initial Disclosure Requirements for Fully Insured Group Health Plans Reserved—Paragraph (f)

As discussed above, the regulatory initial disclosure requirements for fully insured group health plans are reserved. ERISA section 408(b)(2)(B) continues to obligate all covered service providers, including group health plan issuers and related vendors who meet that definition, to comply with the statutory disclosure requirements to rely on the exemption.

5. Semiannual Disclosure Requirements—Paragraph (g)

Paragraph (g) of the final rule [178] requires semiannual (or at the request of the covered plan, quarterly) disclosures of the actual compensation received or reasonably expected to be received for the semiannual (or quarterly) period by the covered service provider and its affiliates, agents, and subcontractors in connection with the services provided under the contract or arrangement with the covered plan. This disclosure will serve an important purpose for the responsible plan fiduciary's monitoring obligations with respect to the services contract or arrangement with the covered plan.

Under the final rule, the semiannual (or quarterly) disclosure must cover amounts actually received during the period plus any amounts that are reasonably expected to be received in connection with services during the period. Language was added in the final rule to ensure full disclosure of amounts earned during the disclosure period, even if payment has not yet been received. This approach has the advantage of providing fiduciaries with a fuller picture of the compensation arrangements as compared to an approach based strictly on when compensation is received, which may be impacted by lagging payments. This also aligns with the approach in ERISA section 726, which bases certain disclosures on claims filed during the reporting period and requires disclosure of amounts received or expected to be received.[179]

While selection of these covered service providers will be made based on the initial disclosures, which require disclosure of compensation ''reasonably expected'' to be received, the responsible plan fiduciary's ability to evaluate compensation actually received (or earned during the period but not yet received) is intended to facilitate ongoing oversight of the service arrangement.[180] The semiannual (or quarterly) disclosures would be required to be provided no later than 30 calendar days after the end of each six-month period (or, quarter) beginning on the date the contract or arrangement is entered, with respect to the preceding reporting period.

The content of semiannual disclosures generally tracks the specific categories of compensation that were included in the initial disclosures. Thus, these disclosures would address direct compensation (paragraph (g)(1)) as well as indirect compensation (paragraph (g)(2)), including but not limited to manufacturer payments, spread compensation, copay claw-backs and other pharmacy recoupment, and price protection agreements. Like the initial disclosures, the semiannual disclosures also contain a catch-all category for any ''other compensation'' not covered by the specific compensation categories (paragraph (g)(3)). The disclosure also must include an updated statement of fiduciary status, if applicable, to the extent not previously disclosed as part of the initial disclosures (paragraph (g)(5)), and would include a disclosure of the audit rights under the final rule (paragraph (g)(6)).

Unlike the initial disclosures, the semiannual disclosures would contain amounts of compensation actually received plus any amounts reasonably expected to be received for the semiannual (or quarterly) period for each of these categories. Compensation amounts should not be re-disclosed for a later period in which it is actually received. This clarification is so that covered service providers are not double reporting compensation under this final rule.

Semiannual disclosures must include an overage explanation, if applicable. Consistent with the purpose of these disclosures to assist responsible plan fiduciaries in their ongoing monitoring of the contract or arrangement, paragraph (g)(4) requires a disclosure if any category of compensation to the covered service provider, an affiliate, an agent, or a subcontractor described in paragraph (g), in the aggregate, materially exceeds the corresponding estimate described in paragraph (e). Thus, for example, if the actual amount of spread compensation disclosed in the semiannual disclosure materially exceeded the amount identified in the initial disclosure, this overage explanation requirement would be triggered.

The overage explanation provision requires an identification of the amount of the overage (in the aggregate) and the reason for the overage. For this purpose, the term ''materially'' means 5 percent

[178] 29 CFR 2550.408b–22(g).

[179] ERISA section 726(b)(2)(A)(i) required information to be provided regarding drugs for which a claim was filed for the applicable period including: ''(X) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration; (XI) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—(aa) for claims incurred during the reporting period; and (bb) that is related to utilization of such drug or spending on such drug.''

[180] As discussed above, the semiannual disclosure requirements for fully insured group health plans are reserved.

or more, or such lower percentage or dollar amount as may be agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement. This definition of materiality generally parallels the approach taken in paragraph (e)(6)(iii) (relating to the advance notification requirement for modifications to a formulary).

The overage explanation will help responsible plan fiduciaries by emphasizing areas where categories of compensation materially exceeded the parties' expectations at the outset of the contract or arrangement. A responsible plan fiduciary will be able to take the explanation into account when deciding on the continuing reasonableness of the contract and whether to continue the service relationship with the covered service provider.

The Department notes that the semiannual disclosure obligation is not directly stated in ERISA section 408(b)(2)(B); however, the statute does require disclosure of changes to the information provided in the initial disclosures,[181] and the Department has the authority to regulate the timing of these disclosures. With respect to the compensation disclosures, changes to this information must be disclosed as soon as practicable, but generally no later than 60 calendar days from the date on which the covered service provider is informed of such change.[182] The Department believes that in the pharmacy benefit management context, it is more efficient to have a semiannual (or quarterly) disclosure that would provide all the compensation received in the prior 6 month period (or quarter), rather than a requirement to disclose changes on an ongoing basis.

As indicated above, the primary purpose of paragraph (g) is to ensure that responsible plan fiduciaries have more than just the estimates provided in the initial disclosure (before the contract or arrangement was even entered) under paragraph (e) of the final rule when conducting their statutory duty to monitor the ongoing reasonableness of the covered plan's service relationship with the covered serve provider. In this way, the final rule responds to those instances of reported opacity in the pharmacy benefits management industry.

5.1. Timing of the Disclosures

In the proposal, the Department asked for comments on ways to simplify or streamline the semiannual disclosure without compromising its stated purpose. The Department said it had considered and rejected the idea of proposing annual disclosures of compensation actually received, rather than semiannual disclosures, based on the understanding that pharmacy benefits management service contracts often are only one year in duration. Consequently, in such cases, a disclosure of actual compensation received after the expiration of the contract would seem to be of significantly less value to the responsible plan fiduciary than if it had been received during the term of contract, while the fiduciary's duty to monitor the reasonableness of the relationship is ongoing and, if needed, changes still can be made in response to these disclosures during the contract period.

A number of commenters supported the Department's proposal on the basis that it would facilitate monitoring by responsible plan fiduciaries and accountability of covered service providers at an appropriate interval before the parties would begin renegotiating their contract or arrangement. One commenter said the semiannual period was appropriate given that many service arrangements operate on annual contract cycles, and the semiannual disclosure would provide responsible plan fiduciaries with information that would be timely and actionable, whereas annual disclosures would occur too late to allow meaningful corrective action. Some commenters specifically supported the semiannual time frame as being consistent with the ERISA section 726 reporting period.

A few other commenters suggested semiannual disclosures would be too frequent, with one commenter suggesting that there should be an initial disclosure and thereafter annual disclosures prior to exercising any renewal or extension option. One commenter said that the proposed requirement to provide the disclosure 30 days after the end of the semiannual period would not allow the covered service provider to account for all payments since manufacturer payments may lag due to quarterly billing practices. One commenter asked the Department to make clear that payments received in a subsequent reporting period should be reported in that period if not previously reported.

In the final rule, the Department has retained the semiannual reporting period but also provides for a quarterly reporting period upon the request of the covered plan, in alignment with the reporting periods in ERISA section 726. The Department did not receive a significant number of comments objecting to the 30-day time frame for the disclosure and believes that prompt disclosure following the end of the reporting period is important, so it did not extend the time period for the semiannual (or quarterly) disclosure to be made. The covered service provider can report any amounts in a future semiannual (or quarterly) disclosure from a prior reporting period that were not previously reported. The Department notes, however, that the requirements in paragraphs (g)(2)(i) and (iv) as well as (g)(3) are phrased in terms of compensation received or *reasonably expected to be received.*

5.2. Changes From the Proposal

Regarding the substance of the semiannual (or quarterly) disclosures, several commenters said that the Department should make changes that correspond to changes suggested for the initial disclosures, particularly regarding alignment with ERISA section 726. The final rule does generally incorporate corresponding changes to the initial disclosures, including those designed to align with ERISA section 726, all of which were discussed previously in this preamble section E.3.

One commenter suggested that covered service providers should provide an updated statement of fiduciary status whenever there is a change to the fiduciary status or related conflicts of interest. The Department agrees that disclosure of fiduciary status should be updated, but decided to include a requirement to update them in the semiannual (or quarterly) disclosure, not whenever a change happens. This disclosure appears in a new paragraph (g)(5) and is based on the wording of paragraph (e)(8) which is the corresponding initial disclosure.

5.3. Overage Explanation

Some commenters on the Department's proposal said the proposed overage explanation was appropriate and would assist responsible plan fiduciaries in monitoring the reasonableness of the compensation and the contract or arrangement. A few supportive commenters said additional consequences and enforcement options,

[181] ERISA section 408(b)(2)(B)(v)(II) (''A covered service provider shall disclose any change to the information required under clause (iii) and (iv) as soon as practicable, but not later than 60 days from the date on which the covered service provider is informed of such change, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, in which case the information shall be disclosed as soon as practicable.'')

[182] *See id.,* noting that if a disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, the information shall be disclosed as soon as practicable.

such as civil penalties, would be needed to ensure the overage explanations would not be incomplete or delayed.

A few commenters addressed the proposed materiality threshold of 5 percent. Some said it was appropriate, but others opined that it was either too high or too low. The commenter who said the 5 percent threshold was too high said that with six categories of compensation specified in the rule, covered service provider compensation could increase by up to 30 percent across the board with no overage explanation. A commenter who thought the 5 percent threshold was too low said that variations between projected and actual compensation are the natural result of changes in utilization and other factors over the course of the plan year. The commenter believed that ERISA section 408(b)(2) requires the contract or arrangement to be reasonable at the time it is entered into and does not require the fiduciary to precisely track prospective estimates. The commenter said the threshold should be significantly increased to at least 20 percent and be triggered by aggregate compensation increases not variations in individual categories. Further the commenter said the overage explanation should not be applied to manufacturer payments that are subject to the rebate pass-through to the covered plan.

In the final rule, the Department revised the language in the overage explanation to make clear the focus is compensation to the covered service provider, an affiliate, an agent, or a subcontractor. The Department agrees with the commenter that the overage explanation should not be applied to payments that are passed through to the covered plan. The Department further determined that the approach in the proposal in which the materiality threshold applied to each category of compensation and required the covered service provider to explain the reason for the overage was a straightforward way to assist the responsible plan fiduciary in its monitoring of the service contract or arrangement. Providing for a disclosure based on aggregate overage across categories may result in an explanation that involves multiple reasons and is less clear.

With respect to potential enforcement or civil penalties, section E.13 of this preamble discusses consequences of noncompliance.

6. Semiannual Disclosure Requirements for Fully Insured Group Health Plans Reserved—Paragraph (h)

As discussed above, the regulatory semiannual disclosure requirements for fully insured group health plans are reserved. ERISA section 408(b)(2)(B) continues to obligate all covered service providers, including group health plan issuers and related vendors who meet that definition, to comply with the statutory disclosure requirements to rely on the exemption.

7. Reporting and Disclosure Information Upon Request—Paragraph (i)

Under paragraph (i) of the final rule,[183] certain information must be provided upon written request of the covered plan's responsible plan fiduciary. The required information is any other information relating to the contract or arrangement that is required for the covered plan to comply with the reporting and disclosure requirements of Title I of ERISA and the regulations, forms, and schedules issued thereunder. The information must be provided reasonably in advance of the date upon which such responsible plan fiduciary states that it must comply with the applicable reporting or disclosure requirement, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, in which case the information must be disclosed as soon as practicable. This paragraph is finalized as proposed.

The information that might be requested by a responsible plan fiduciary may include information needed to complete the covered plan's Form 5500 filing.[184] In 2010, the Department issued supplemental FAQs stating that certain fees received by PBMs for services to an ERISA plan that are paid with plan assets are reportable direct compensation on Schedule C of the Form 5500.[185] Further, the Department stated that discount and rebate revenue would be reportable indirect compensation to the extent the plan and the PBM agree that these payments will be used to compensate the PBM for services to the plan.[186] While information to support these Schedule C items would likely be provided as part of the semiannual disclosure in paragraph (g), paragraph (i) would underscore the covered service provider's obligation to provide any information that is needed to complete the Form 5500 report.

The CAA, 2021 also added annual reporting requirements (Prescription Drug Data Collection) about prescription drug and health care expenditures under Code section 9825(a), ERISA section 725(a), and PHS Act section 2799A–10(a).[187] To comply with the reporting requirement, a responsible plan fiduciary may also request information needed to comply with reporting obligations under ERISA section 725, which was added by the CAA, 2021. The information required under ERISA section 725, and parallel provisions under the Code and PHS Act, includes the 50 most frequently dispensed brand prescription drugs, the 50 most costly prescription drugs by total annual spending, and the 50 prescription drugs with the greatest increase in plan expenditures over the preceding plan year. Further, the group health plan is required to report information on rebates, fees, and any other remuneration paid by drug manufacturers to the covered plan or its administrators or service providers overall, with respect to each therapeutic class of drugs, and for each of the 25 drugs that yielded the highest amount of rebates and other remuneration from drug manufacturers during the plan year. As part of these requirements, group health plans are also required to report spread amounts retained by its PBM(s).

One commenter said that requiring the covered service provider to provide ''any other information relating to the contract or arrangement'' is overbroad and said the final rule should clarify that the scope of information required upon request is limited to information reasonably within the covered service provider's possession or control and reasonably related to the underlying disclosure obligations of this rule. The commenter also said the standard for delayed disclosure should be revised from ''extraordinary circumstances beyond the covered service provider's control'' to a ''commercially reasonable efforts'' standard. The Department has not adopted these changes as it believes that other information relating to the contract or arrangement is sufficiently limited by the purpose of the section which is for the covered plan to obtain information needed to comply with the reporting and disclosure requirements of Title I of the Act, the regulations in this chapter, and forms and schedules issued under Title I. If a covered plan requires information to comply with its reporting obligations, the covered service provider must provide it

[183] 29 CFR 2550.408b–22(i).

[184] 29 CFR 2520.103–1.

[185] Supplemental Frequently Asked Questions about the 2009 Schedule C, Q26, available at *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/reporting-schedule-c-faq.pdf.*

[186] *Id.*, at Q27.

[187] *See* Centers for Medicare & Medicaid Services, *Prescription Drug Data Collection (RxDC)* (Sept. 10, 2024), available at *https://www.cms.gov/marketplace/about/oversight/other-insurance-protections/prescription-drug-data-collection-rxdc.*

reasonably in advance of the date upon which such responsible plan fiduciary states that it must comply with the applicable reporting or disclosure requirement under Title I of ERISA. The Department believes a ''commercially reasonable'' standard for supplying the information may result in covered plans not receiving required information in time to satisfy their reporting or disclosure requirements.

8. Right to Audit—Paragraph (j)

Paragraph (j) [188] establishes a right for covered plans to audit their covered service providers at least once per year. The purpose of the audit provision in the final rule is to enable responsible plan fiduciaries to verify the accuracy of the disclosures made under the final rule. In describing the scope of the audit provision, paragraph (j)(1) narrowly reflects this purpose. The Department chose not to limit a covered plan's ability to audit their covered service providers only with respect to each plan year to avoid foreclosing a covered plan's ability to cross-reference actual service delivery against compensation disclosures regardless of plan year to identify issues or concerns related to the accuracy of the disclosure, such as hidden costs, billing inconsistencies, or complete disclosure failures.

The final rule provides that the parties would share the audit costs as follows. The covered plan will be responsible for compensating the auditor. The covered service provider will bear the costs of providing the auditor with the information, data, and other materials needed to perform the audit. The Department believes this shared cost approach is fair, balanced, adequately protective of covered plans, and not unduly financially burdensome to covered service providers.

Under the final rule, the covered plans have the sole authority to select the auditor, and the covered service providers are prohibited from imposing limitations on the selection process. Likewise, the final rule broadly prohibits covered service providers from imposing restrictive conditions on the auditor, such as the location of the audit or the number of records to be provided, including contracts with retail pharmacies and drug manufacturers. The final rule, however, provides that the scope of the audit is limited to the disclosures made under the final rule.

The Department considers the audit provision to be necessary to ensure a proper and meaningful audit so that the accuracy of the disclosures can be verified. A right to audit the veracity of any and all disclosures made by the covered service provider to a responsible plan fiduciary as required by this regulation, including the responsibility of the covered service provider to deliver all necessary information to conduct such an audit, is an essential part of the rule's framework for establishing transparency in the marketplace for pharmacy benefit management services. As a general matter, the Department believes that covered service providers will be mindful of the regulation's audit rights when developing their disclosures, and the audit rights therefore are deliberately intended to result in disclosures that are more carefully constructed, robust, and transparent. Further, to the extent that an audit reveals information that was not previously disclosed or flaws in the disclosure, the responsible plan fiduciary can evaluate the additional information in assessing the reasonableness of the compensation and determining whether additional payments should have been passed through to the covered plan or whether to exercise other rights.

In this regard, responsible plan fiduciaries must periodically monitor compliance by covered service providers with the terms of their agreements and the reasonableness of their compensation under the agreements to ensure continuation of the agreement meets the requirements of ERISA section 408(b)(2) as well as the general fiduciary obligations under ERISA section 404. In satisfying its monitoring obligations, however, the responsible plan fiduciary retains discretion as to when, if at all, to request an audit of disclosures issued by the covered service provider. The right to conduct an audit does not need to be exercised. A responsible plan fiduciary may reasonably determine that the expense incurred by the plan to audit the covered service provider under this section outweighs the likely benefit to the plan resulting from such audit where additional circumstances suggesting the covered service provider is noncompliant with the terms of the contract or arrangement or the requirements of the regulation are absent.

8.1. General Comments

After considering comments on the proposal, the Department determined to finalize the audit provision with minor changes, as discussed below. Several commenters said that audits are essential for plan fiduciaries to assess the accuracy of the required disclosures. Commenters said that audits are already often standard practice, and the final rule will set expectations and requirements for auditing across service providers and responsible plan fiduciaries. Commenters also identified issues that have arisen in the absence of a clear audit right: PBMs sometimes limit responsible plan fiduciaries' discretion in choosing auditors or do not provide material information necessary for a complete audit. The Department finds these comments persuasive because of the role audits play already, the value commenters saw in the audit rights, and the opportunity to create a baseline standard for audits to help ensure that the disclosures required by the rule are accurate.

In the proposal, the Department sought comments on the scope of the audit considering the purpose of the rulemaking. Some commenters suggested that the Department expand the audit requirement so that plan fiduciaries would be able to use an audit to assess the extent to which service providers complied with the terms of their contract rather than limiting the audit to the accuracy of their disclosures. Other commenters said maintaining the proposed scope of the audit provision would be preferable and expanding beyond verification of required disclosures would be inconsistent with the objectives of the rule. The Department is not persuaded that the audit rights should extend beyond requiring needed information to validate the disclosures required in the rule. Such a requirement would be beyond the scope of the rule, which is designed to ensure plan fiduciaries have the information they need to assess whether the contract or arrangement is reasonable.

Some commenters said the proposed audit provision exceeded the Department's regulatory authority and therefore should not be included in the final rule. They said the Department's regulatory authority under ERISA section 408(b)(2)(B) is limited to ''time, manner, and content'' of the disclosures. Further, the commenters said that new ERISA section 408(b)(2)(C) contains audit rights that are limited to the rebate-pass through provision, which they believed suggested that Congress did not intend broader audit rights.

The Department does not agree that the final rule's provision preserving covered plans' audit rights exceeds its regulatory authority. Congress specified the Department's authority in ERISA section 408(b)(2)(B) with respect to the time, manner, and content of disclosures. In the Department's view, shared by many commenters, the audit provisions are necessary for responsible

[188] 29 CFR 2550.408b–22(j).

plan fiduciaries to verify accuracy of the disclosures and thus fulfill their ERISA section 404 duties. The audit provisions also make the reasonableness determination meaningful to fulfill the purpose of the statutory exemption. The Department believes that in the context of pharmacy benefit management services, where, historically, indirect compensation streams have not been transparent, ensuring that covered plans can audit the detailed disclosures in the final rule furthers the goal of this rulemaking. Further, the Department retains authority under ERISA section 505 to issue regulations necessary or appropriate to carry out the provisions of Title I of ERISA.

8.2. Auditor Selection and Audit Costs

Some commenters asked the Department to permit covered service providers to place reasonable limits on auditor selection, including limitations related to conflicts of interest or other anticompetitive behaviors. One commenter said auditors should be prohibited from receiving contingency fees, such as compensation based on a percentage of rebate payments not remitted to the group health plan. Other commenters stressed the need for the responsible plan fiduciary to retain the right to engage the auditor of its choosing and not be subject to limitations placed by the covered service provider.

The Department agrees with commenters who said the auditor selection should be the sole responsibility of the responsible plan fiduciary. Such responsible plan fiduciaries are required under ERISA to make a prudent and loyal selection of an auditor as a plan service provider. The Department is concerned that if the final rule permitted covered service providers to impose additional limitations, such limitations could potentially be used to limit auditor selection in ways that are inconsistent with the covered plans' interests.

Some commenters also addressed the cost sharing provision in the proposal, under which the covered plan would pay for the selection and retention of the auditor and the covered service provider would pay for providing the requested information. Some commenters opposed this provision based on their interpretation that it would establish a 50–50 cost splitting requirement which they believed could involve the plan subsidizing the covered service provider's costs. Some commenters also believed that the approach in the proposal was inconsistent with the approach in new ERISA section 408(b)(2)(C) which provides that payment for the auditor shall not be made by the provider of pharmacy benefit management services. One commenter said the covered plan should bear all the costs of the audit including the cost of providing the requested information.

The Department believes these comments were based on misinterpretation of the proposed cost sharing provision. The Department did not intend to establish a strict 50–50 cost splitting requirement; rather, as stated above, the proposal provided that the covered plan would pay for the selection and retention of the auditor and the covered service provider would pay for the costs of providing the required information. The Department does not believe this approach is inconsistent with ERISA section 408(b)(2)(C) which also provides that the payment from the auditor shall not be made by the provider of pharmacy benefit management services. Therefore, the Department decided to adopt the cost sharing provision as proposed. The Department did not adopt the commenter's suggestion for the covered plan to bear the entire cost of the audit because we are concerned that approach would create a barrier to covered plans exercising audit rights.

In the proposal, the Department asked for comments on whether there are any circumstances in which the covered service provider should bear the entire cost of the audit, such as if the audit reveals a certain level of inaccurate disclosures. If commenters agreed, the Department asked how the final rule should identify a level of disclosure inaccuracy that would trigger the obligation for the covered service provider to bear the entire audit cost.

A few commenters expressed agreement with this approach but did not suggest a materiality threshold. One commenter suggested a threshold of a 5-percent deviation between disclosed and actual compensation in any of the categories, as an incentive for accurate disclosure. In considering these comments, the Department will not adopt a materiality standard without an objective threshold, based on the view that the lack of an objective threshold would lead to disputes related to whether a covered service provider would have the obligation to bear all the audit costs in any particular case. Moreover, the Department was not persuaded that the 5 percent threshold as suggested by one commenter represented a significant enough disparity to be used in the final rule as a threshold for the covered service provider to bear all the audit costs. Although the Department has used a 5 percent threshold for materiality elsewhere in the final rule, in those cases, the 5 percent threshold triggered an additional disclosure requirement. In the Department's view, a requirement that the covered service provider bear all the audit costs should not be based on the same threshold as provided for additional disclosures. Lacking more specific suggestions and considering the burden this would create, the Department declined to adopt a provision under which covered service providers would bear all audit costs.

8.3. Provision of Data and Confidentiality

Some commenters argued that the audit right as proposed was problematic as it could require service providers to provide sensitive or proprietary information to auditors and responsible plan fiduciaries. Several commenters suggested that the final rule explicitly provide that covered services providers may limit use of data to the group health plan's purposes, noting that the new ERISA section 408(b)(2)(C) has similar language allowing reasonable restrictions (as determined by the Secretary) on confidentiality related to rebate contracts to prevent re-disclosure of such contracts *or use of such information in audits for purposes unrelated to the section*. The Department notes that the audit provision in the proposal addressed confidentiality concerns by allowing ''reasonable confidentiality agreements to prevent redisclosure of such information.'' However, the Department believes adding additional language may help alleviate these concerns, so it has revised the language in paragraph (j)(3) of the final rule to allow ''reasonable confidentiality agreements to prevent redisclosure of such information and to limit use of such information for purposes related to the covered plan's contract or arrangement.'' [189]

Some commenters expressed concern about the volume of information that may be requested as part of the audit and asked the Department to confirm that statistically valid sampling methodologies would be permitted. Other commenters said that sampling could be used to obscure potentially improper transactions. For the reason cited by this commenter, the Department determined not to expressly permit sampling under the final rule;

[189] As discussed below, paragraph (k)(4) of the final rule makes clear that information provided in the audit may be shared with State or Federal Government regulators or with legal counsel even if unrelated to the purpose of the covered plan's contract or arrangement.

but it notes that the audit provision is limited to ''all records, claims and transaction-level data, and other information *reasonably necessary* to confirm the accuracy of any disclosure made to comply with this section . . . .'' (Emphasis added).

Several commenters addressed access to claims and payment data. Some asked the Department to ensure that auditors would not be limited from accessing claims and payment data as needed for verifying the accuracy of the disclosures. Others suggested a more affirmative obligation to provide this information. As proposed, the audit provision required the covered service provider to make available to the auditor ''all records, data, and other information reasonably necessary to confirm the accuracy of any disclosure made to comply with this section, including contracts with retail pharmacies and drug manufacturers . . . .'' Although the Department believes that this language preserves access to data needed to confirm accuracy of disclosure, and that the rule is sufficiently tailored to require an audit of only that information used to produce the required disclosures, a reference to claims and transaction-level data was added to the final rule for avoidance of doubt. Paragraph (j)(3) of the final rule therefore provides that the covered service provider shall make available to the auditor ''all records, claims and transaction-level data, and other information . . .'' In sum, plan fiduciaries' auditors need access to material information to assess the quality and accuracy of the disclosures, as required in the rule, and the comments illustrate the need for an audit right. The Department believes that the audit provision in the rule is properly scoped to meet the needs of plan fiduciaries.

8.4. Timeframes

As in the proposed rule, the audit provision in the final rule preserves the right to an audit ''[n]ot less than once per year.'' This approach leaves it to the parties to define ''year'' for this purpose, *e.g.*, contract year, calendar year, or plan year. The Department invited comments on whether the final rule should be more prescriptive on this point. Some commenters said it would be helpful to specify whether the reference to year meant contract year, plan year, or calendar year to avoid unnecessary disputes. One commenter noted that the audit provision in new ERISA section 408(b)(2)(C) is based on a ''plan year'' and recommended that the Department align with that approach. Other commenters suggested that the parties should retain flexibility to define the relevant ''year.'' The Department determined after consideration of these comments to finalize the provision as proposed. The Department believes that allowing the parties flexibility to define the relevant year is preferable to specifying an approach that may not work for all covered plans.

Another commenter asked the Department to confirm that the language in proposed paragraph (j)(6), which provided that ''the scope of the audit may be limited to the period covered by the disclosures under this section,'' was intended to mean that the scope of the audit could be limited to the period after the effective date of the final rule as applied to the particular covered service provider arrangement. The Department agrees that is the intent of this language and has changed ''may be'' to ''is'' for additional certainty.

One commenter asked the Department to define the period within which audit materials must be produced. Under proposed paragraph (j)(5), covered service providers would be required to provide information reasonably necessary to confirm the accuracy of disclosures within a ''commercially reasonable period.'' The commenter said the phrase ''commercially reasonable period'' could lead to disputes about compliance. The commenter suggested that the final rule should specify that requested audit materials must be provided within a defined outside period, such as no more than 60 calendar days after receipt of the request, absent extraordinary circumstances. The Department agrees with this commenter that it is preferable to state a specific period for compliance, coupled with an exception for extraordinary circumstances, and therefore has adopted the suggested 60-day timeframe absent extraordinary circumstances beyond the covered service provider's control.

8.5. Compliance With the Audit Requirement

Several commenters raised issues related to compliance with the audit requirement. One commenter asked for confirmation that failure to provide information in compliance with the audit provision would result in a prohibited transaction. Another commenter asked the Department to include a safe harbor protecting covered service providers from liability when information held by affiliates, agents, or subcontractors is not produced due to circumstances outside the covered service provider's control, provided the covered service provider exercises reasonable diligence to obtain and provide such information. In response, the Department confirms that a covered service provider's failure to provide information in compliance with the audit provision would result in a prohibited transaction, absent availability of another prohibited transaction exemption. In that event, the administrative prohibited transaction exemption granted in paragraph (n) of the final rule would be available to the responsible plan fiduciary to avoid liability. The covered service provider could be subject to a civil penalty under ERISA section 502(i), which authorizes the Secretary to assess a civil penalty on a party in interest in the case of a transaction prohibited by ERISA section 406. The Department declines to offer a safe harbor for such covered service providers but notes that its authority under ERISA section 502(i) is discretionary.

9. Manner of Disclosure—Paragraph (k)

Paragraph (k) [190] includes four separate provisions regarding the manner of disclosures under the regulation. Each is discussed below.

9.1. Plain Language

Paragraph (k)(1) specifies that all disclosures must be clear and concise, free of misrepresentations, and contain sufficient specificity to permit evaluation of the reasonableness of the contract or arrangement. The paragraph further specifies that, for example, the Department will consider the use of generic industry terms, jargon, or legalese, without definition, to lack the sufficient specificity required under the preceding sentence unless the language in question specifically refers to objectively determinable definitions, standards, or other similar guidelines that are publicly available or will be provided by the covered service provider to the responsible plan fiduciary free of charge and within a reasonable period of time following the request.

Commenters said disclosures should be clear, concise, and presented in plain language so that plan fiduciaries could understand and use them. Another commenter recommended requiring PBMs and related entities to define proprietary, specialized, or industry-specific terminology in plain language or link such terms to objective definitions. The Department agrees and therefore finalized as proposed.

9.2. Description of Compensation

With respect to descriptions of compensation required under the final

[190] 29 CFR 2550.408b–22(k).

rule, paragraph (k)(2) requires that they must be expressed as a monetary amount (for example, $1,000) and may be estimated to the extent that the actual amount is not reasonably ascertainable. However, the disclosure must contain sufficient information and specificity to permit evaluation of the reasonableness of the compensation received by the covered service provider, an affiliate, an agent, or a subcontractor. Several commenters supported the requirement that compensation be expressed as a monetary amount, describing it as the single most important provision of this rulemaking. These commenters argued that formulas, percentages, and benchmark-based descriptions could obscure actual dollar flows and hinder meaningful transparency. Some commenters noted that their individual company experience demonstrates that monetary transparency is both feasible and commercially viable.

A few commenters supported the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)(1)) and the statutory provision at ERISA section 408(b)(2)(B) framework in lieu of a monetary amount. However, many other commenters disagreed, stressing that formulas and percentages obscure actual dollars flowing to and from a covered plan. Several commenters suggested that, if the actual amount of compensation is not reasonably ascertainable, the estimated compensation should be grounded in a good faith assumption based on contractually defined methodologies, historical utilization, and rebate experience, or other reasonable information available at the time of disclosure. The Department agrees. Comments on the proposed paragraph (k)(2) and the Department's responses are discussed in section E.2.3 of this preamble.

9.3. Machine-Readability Format

Paragraph (k)(3) of the final rule provides that upon request of a responsible plan fiduciary, descriptions of compensation must be provided in a machine-readable file within a reasonable time after such request. The rule defines ''machine-readable file'' as a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost. This requirement is designed to ensure that a responsible plan fiduciary can obtain information in this format if the responsible plan fiduciary determines that this will aid in its evaluation of the reasonableness of the contract or arrangement. Therefore, the contract or arrangement may not foreclose responsible plan fiduciaries from selecting the machine-readable format.

The Department received comments supporting this provision in the proposal. One commenter said the ''upon request'' approach strikes the correct balance because not every responsible plan fiduciary will have the capacity to process machine-readable data so requiring that format for all disclosures would be too burdensome.

Several commenters supported the use of machine-readable files to help facilitate actuarial analysis, benchmarking, comparison, oversight, and access to claims detail. A few commenters, however, argued that machine-readable files impose significant technical infrastructure costs on covered service providers. Others supported alternative formats to machine-readable files such as PDF, excel (.xlsx) and .csv files. Commenters explained that plain language disclosures can improve usability and comprehension for plan fiduciaries. Some commenters suggested that covered service providers should be required to provide information in formats negotiated and agreed upon by the covered plan. Several commenters requested the Department to establish a uniform, machine-readable schema to improve comparability, reduce ambiguity, and enhance usability.

In addition, several commenters said the Department should provide technical specifications with respect to the machine-readable format, with one commenter asking the Department to clarify that the Department's Transparency in Covered (TiC) prescription drug machine-readable file requirements, once implemented, will be deemed sufficient. The Department agrees that machine-readable files can be useful to a responsible plan fiduciary but is finalizing the ''upon request'' structure to balance the need for transparency against the administrative burden of requiring machine-readable files as a default for every disclosure. For those responsible plan fiduciaries who request machine-readable files, the Department is considering future guidance to adopt a standardized disclosure framework under this rulemaking.

Some commenters requested that the Departments define what is a ''reasonable time'' under Paragraph (k)(3). Some suggested 30 days from the close of the most recent applicable semiannual period, or thirty days from the date of request, or whichever is sooner. The Department agrees that 30 days seems commercially reasonable but is declining to adopt a definition of ''reasonable time'' under this rulemaking given the limited number of comments it received.

9.4. Confidentiality Agreements

Paragraph (k)(4) addresses confidentiality agreements. The paragraph states that, except as provided in paragraph (j)(3), the covered service provider and its affiliates, agents, and subcontractors may not impose restrictions on the covered plan's use of disclosures required under this section, or the contract or arrangement described in paragraph (c)(1) of this section, with specific exceptions. Namely, the covered contract or arrangement may require the responsible plan fiduciary to require third parties with whom it shares the disclosures (and any subcontractors of the third parties) to execute reasonable confidentiality agreements that prevent redisclosure and also limit use of the disclosures to purposes related to the covered plan's contract or arrangement. Further, paragraph (k)(4)(ii) of the final rule adds language clarifying that neither paragraph (k)(4) nor paragraph (j)(3) would restrict a covered plan, auditor, or a third party hired by the plan, or their subcontractors, from sharing information with State or Federal Government regulators or with legal counsel, even if the activities of those entities are unrelated to the purpose of a covered plan's contract or arrangement.

The primary purpose of paragraph (k)(4) is to ensure that covered service providers are not able to undermine responsible plan fiduciaries' efforts to evaluate their compensation by limiting the covered plan's ability to meaningfully use information in the disclosures, for example, by restricting responsible plan fiduciaries from sharing the information with other plan service providers, such as third-party auditors, consultants, attorneys, or advisors, and such service providers' subcontractors, for quality control, evaluation, comparing, benchmarking, renegotiating, and other purposes. At the same time, paragraph (k)(4) would protect covered service providers by ensuring covered plans take steps to prevent redisclosure of the information by third parties with whom covered plans share the disclosures (and the third parties' subcontractors), and use of the disclosed information for purposes unrelated to the covered plan's contract or arrangement.

Comments on confidentiality agreements addressed both the use of the disclosures by responsible plan

fiduciaries and by third parties. Some commenters believed it was very important to ensure that covered service providers did not prevent responsible plan fiduciaries from using the disclosures to compare service provider offerings, for example, and from sharing the disclosures with third party service providers, such as consultants and legal counsel, or third-party subcontractors, such as data analytics service providers. Other commenters expressed concern about how third parties may use the information in the disclosures in other contexts and asked the Department to permit covered service providers to require reasonable confidentiality agreements governing the plan's use of the disclosed information, including limiting the use for fiduciary purposes only. Commenters also referenced confidentiality provisions in ERISA section 726 and suggested a similar approach in the final rule.

The Department believes that the approach taken in the proposal generally strikes the correct balance in ensuring that responsible plan fiduciaries may share information with third party service providers (and their subcontractors) but also preventing further redisclosure. In response to commenters' concerns about how the information might be used by third parties, the Department has added language to the final rule permitting confidentiality agreements to limit use of disclosure information ''to purposes related to the covered plans contract or arrangement.'' This is similar to language added in ERISA section 408(b)(2)(C) which permits, in the context of the audit provision, reasonable restrictions (as determined by the Secretary) on confidentiality to prevent redisclosure of disclosed rebate contracts or use of such information in audits ''for purposes unrelated to this section.'' Under this language, service providers would not be able to use the disclosures in contexts other than services to the covered plan (with the exception for State and Federal Government regulators). In combination with the confidentiality provisions in the final rule's audit provision (paragraph (j)(3)), the Department believes this should, in large part, address commenters' concerns about confidentiality. The Department is concerned that commenters' suggestions to limit covered plans' and responsible plan fiduciaries' use of disclosure information to fiduciary oversight purposes might allow covered service providers to unnecessarily intrude on responsible plan fiduciaries' contracting processes, or could have other unintended consequences, and therefore did not incorporate any such limits.

10. Disclosure Errors—Paragraph (l)

Paragraph (l)[191] provides a rule for disclosure errors. Under the final rule, no contract or arrangement will fail to be reasonable under the regulation solely because the covered service provider, acting in good faith and with reasonable diligence, makes an error or omission in disclosing the information required pursuant to paragraphs (e), (g), or (j), so long as the covered service provider discloses the correct information to the responsible plan fiduciary as soon as practicable, but not later than 30 calendar days from the date on which the covered service provider knows of such error or omission. Several commenters supported the approach taken in the proposal, and it was finalized as proposed.

11. Additional Suggestions

11.1. Additional Disclosures or Other Provisions

A number of commenters suggested that the final rule should identify additional specific categories of compensation that would be required to be disclosed under the final rule. As discussed in section E.3.9 of this preamble, the final rule does not identify any additional specific compensation streams for disclosure because the requirement to disclose ''other compensation'' received in connection with the contract or arrangement would cover all such compensation.

The Department also received other suggestions for additional disclosures. These suggestions included disclosure of biosimilar adoption rates to evaluate whether the formulary is cost-effective, disclosure of the covered plans' regulatory status and applicable patient protections, disclosure of any circumstances when the compensation received by the PBM does not reflect fair market value, and others. The Department did not expand the final rule to include these commenters' suggestions because of limited information about impact of the additional disclosures and the Department determined that the focus of the final rule should remain on the disclosures that had been proposed, as the Department believes they will be the most useful to the responsible plan fiduciaries of the larger self-insured group health plans in assessing the reasonableness of the contract or arrangement with the covered plan.

Other commenters asked for substantive provisions to be added to the final rule. For example, one commenter asked the Department to put in place an exception process for step therapy requirements in ERISA plans. Another commenter asked the Department to require PBMs serving ERISA plans to preference generic drugs when available. The Department determined that substantive provisions of this type are outside the scope of the rulemaking.

One commenter offered an alternative to the approach taken in the proposed rule that would involve disclosures the commenter referred to as core disclosures. These core disclosures related to categories already in the Department's proposal, including a description of services, a statement of fiduciary status, and a disclosure of direct and indirect compensation, although some of the disclosures would be at an aggregate level. The commenter suggested additional disclosure elements that would allow responsible plan fiduciaries to compare PBM services, including a rebate collection rate, a disclosure of the percentage of rebates shared with the plan, a calculation of gross rebates expressed on a per member per month basis, the number of pharmacies in the PBM's standard retail network, formulary exceptions: number and claims impact, number of covered drugs, and utilization management turnaround times, with additional disclosure for PBMs that operate or have a financial interest in an affiliated pharmacy. The Department has discussed above that it believes that the detailed disclosures under the final rule will assist responsible plan fiduciaries of the larger self-insured group health plans in assessing the reasonableness of contracts or arrangements, so it has not adopted this commenter's suggestions for more aggregate disclosures. However, the Department found the commenter's suggestions for additional disclosures to enable comparison of PBM services potentially useful, and it will consider whether to incorporate the suggestions into future subregulatory guidance.

11.2. Bona Fide Services Fees

A few commenters suggested that the Department should specify as part of the final rule that providers of pharmacy benefit management services and their affiliates, agents, and subcontractors should only be compensated by ''bona fide service fees'' which the commenters said describes fees limited to fair market

[191] 29 CFR 2550.408b–22(l).

value of services and that are not tied to drug prices, rebates or other financial incentives. One commenter said the Department should opine that a fee would not be reasonable unless it meets this definition. The commenter noted that this concept is included in new subparagraph (C) of ERISA section 408(b)(2), which was part of the CAA, 2026 amendments to ERISA effective for plan years after August 3, 2028.[192] Another commenter said the Department should define acceptable compensation standards that separate PBM revenue from list prices.

The Department recognizes that the rebate pass-through provision in ERISA section 408(b)(2)(C) preserves covered service providers' ability to receive ''bona fide services fees,'' indicating that Congress intended for parties to adjust their compensation arrangements accordingly. However, the Department believes that it is premature and beyond the scope of this final rule to establish herein that compensation arrangements involving rebates are per se unreasonable. The Department is considering future rulemaking or subregulatory guidance addressing what is a ''bona fide service fee'' under ERISA section 408(b)(2)(C).

11.3. Claims and Transaction-Level Data

Many commenters asked the Department to require claims data and other transaction-level data be provided to responsible plan fiduciaries. Commenters argued that claims and transactions-level data originate from the group health plan and its participants and beneficiaries and therefore should be treated as a plan asset. Some of these comments asked the Department to confirm that such information would be available under the audit provision, which the Department has addressed in section E.8. of this preamble. The Department confirms that such information must be made available under the audit provision to the extent required to verify any, or all, of the disclosures required under this rule and has added that language to the regulatory text. However, the Department declines to mandate the affirmative disclosure of such data in this final rule outside of the context of an audit to verify disclosures, to keep the final rule focused on covered service provider, affiliate, agent, and subcontractor services, compensation and compensation arrangements.

11.4. Provide the Disclosures to the Department

Several commenters suggested that the final rule should require submission of the disclosures to the Department for oversight and enforcement purposes, and that the Department consider publishing information for other stakeholders to view and use. A few commenters suggested that reporting could be accomplished through the Form 5500 *Annual Return/Report of Employee Benefit Plan.* The Department believes that this rulemaking under ERISA section 408(b)(2) is properly focused on disclosures to responsible plan fiduciaries of covered plans, and it is not prepared as part of this rulemaking project to create a reporting structure under which information would be provided to the Department, outside of the reporting provision in the administrative exemption in paragraph (n), which is discussed in section E.13 of this preamble. Likewise, expanding the Form 5500 is outside the scope of this rulemaking.

11.5. Standardized Template

Commenters also asked the Department to create a standardized data template to assist covered service providers as well as responsible plan fiduciaries. Commenters said this approach would support responsible plan fiduciaries in comparing arrangements. Some of these commenters suggested a standardized summary of the disclosures. The Department agrees and is considering developing a standardized template of the final rule's disclosure requirements to be made available following publication of the final rule.

11.6. Guidance and Interpretive Questions

Commenters asked the Department to provide guidance for responsible plan fiduciaries regarding how to evaluate the disclosures provided under the final rule. For example, several commenters asked the Department to establish a process-based safe harbor under ERISA section 404(a) for fiduciaries who follow a structured analytics process when selecting a covered service provider to a group health plan. One commenter outlined numerous benefits with a process-based safe harbor, including upfront due diligence in contract negotiation and vendor selection, reduced compliance burdens, enhanced participant protection, and statutory alignment that would create a unified compliance framework for the responsible plan fiduciary. The Department strongly agrees and is considering separate rulemaking under ERISA section 404(a) for group health plans.

Several commenters also asked the Department to establish safe harbors for fiduciaries who act in good faith to comply with their oversight obligations. Commenters also raised some interpretive questions that they asked the Department to respond to in the final rule. These questions included the status of plan data as a plan asset, the distinction between settlor and fiduciary functions in the context of pharmacy benefits, and whether disclosures under the rule are considered plan documents under ERISA section 104(b). The Department has not responded to these interpretive questions in the final rule's preamble but will consider requests for subregulatory guidance following publication of the final rule.

Commenters also asked the Department to state that the final rule would not preempt state licensing and regulation of pharmacy benefit management provisions. The Department is of the view that the preemption of state laws would be an interpretive matter that would not be addressed by a provision in the final rule, and therefore, the Department has not added a provision or statement in the final rule regarding preemption.

12. Privacy Issues

In addition to the confidentiality provisions contained in paragraph (k)(4) addressing the ability of self-insured group health plans to disclose information to third parties (and the third parties' subcontractors) received from covered service providers, the Department has considered the level of personally identifiable information that may be contained in those disclosures. Under ERISA section 726, Congress included privacy requirements applicable to the entities providing pharmacy benefit management services.[193] Under the privacy requirements, information disclosed to group health plans from entities providing pharmacy benefit management services pursuant to ERISA section 726 must comply with the privacy regulations promulgated under section 13402(a) of the Health Information Technology for Economic

[192] ERISA section 408(b)(2)(C)(vi) (''Nothing in this subparagraph shall be construed to—. . . (I) prohibit reasonable payments to entities offering pharmacy benefit management services for bona fide services using a fee structure not described in this subparagraph, provided such fees are transparent and quantifiable to group health plans and health insurance issuers; [or] (II) require a third-party administrator of a group health plan or covered service provider for pharmacy benefit management services under such health plan or health insurance coverage to remit bona fide service fees to the group health plan[.]'').

[193] ERISA section 726(b)(4).

and Clinical Health Act at 42 U.S.C. 17932(a) and the Health Insurance Portability and Accountability Act of 1996 in part 160 and subparts A and E of part 164 of title 45, Code of Federal Regulations (collectively, the HIPAA privacy regulations). Under these privacy regulations, the information provided to group health plans must contain only summary health information as defined in 45 CFR 164.504(a). The privacy regulations also restrict the group health plan's further sharing of the information disclosed under ERISA section 726 only to the entity that provided the information to the group health plan (*i.e.,* the entity providing pharmacy benefit management services), that entity's business associates as defined in 45 CFR 160.103, or as permitted by the HIPAA privacy regulations.

Many commenters requested that the Department consider addressing privacy protections in the final rule and specifically requested that use and disclosure of the information contemplated in this rule be consistent with HIPAA. Commenters suggested the Department look to the privacy protections contained in ERISA section 726 as a framework for addressing privacy in this rule. Commenters raised that group health plans should be able to share information they receive from covered service providers with HIPAA compliant business associates they contract with such as consultants, auditors, and actuaries, to assist group health plans with analysis of the information. Some commenters requested that the Department clarify that covered service providers cannot restrict group health plans' access to protected health information under HIPAA.

As part of the Department's effort to align this rule with the CAA, 2026 amendments, the Department is applying the privacy protections contained in ERISA section 726 to the disclosures required under this final rule. Under ERISA section 726, Congress has set forth privacy protections when entities providing pharmacy benefit management services on behalf of group health plans are required to disclose information with respect to the compensation those entities receive for those services and for the costs of drugs they place on the group health plan's formulary. As discussed in section D. of this preamble, there are similarities between ERISA section 726 and this final rule in the information required to be disclosed and in the parties disclosing and receiving the information, and thus the same privacy concerns that arise under ERISA section 726 apply to the disclosures in this final rule under ERISA section 408(b)(2) as well. Therefore, the Department is of the view that the HIPAA privacy protections contained in ERISA section 726, including the limitation to summary health information, only applies to the disclosures under this final rule. Nothing in ERISA section 726 should be construed to limit or otherwise affect a group health plan's access to claims or transaction level-data, including in respect of the audit provisions of this final rule, otherwise permitted or required under ERISA, HIPAA, or other appliable law.

13. Consequences of Non-Compliance and Proposed Administrative Class Exemption for Responsible Plan Fiduciary—Paragraph (n)

13.1. Statutory Framework

As directed by President Trump's Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First,* this final rule aims to promote transparent pricing and create a fairer and more competitive prescription drug market that lowers costs and ensures accountability across the healthcare system. Responsible plan fiduciaries of covered plans will be able to use the disclosures in their process of selecting a provider of pharmacy benefit management services, engaging an affiliated broker or consultant, monitoring these service providers' operations and compliance with contractual obligations, and in analyzing the drivers of prescription drug costs.

In this regard, responsible plan fiduciaries must determine that service provider relationships involving the covered plan meet certain conditions in an exemption to avoid constituting a prohibited transaction under ERISA. Specifically, unless an exemption applies, the furnishing of goods, services, or facilities between a self-insured group health plan and a party in interest to the plan is a prohibited transaction under ERISA section 406(a)(1)(C). A person providing services to the self-insured group health plan is defined by ERISA to be a ''party in interest'' to the self-insured group health plan.

ERISA section 408(b)(2) exempts certain arrangements between ERISA-covered plans (including larger self-insured group health plans) and service providers that otherwise would be prohibited transactions under ERISA section 406. Section 408(b)(2) provides relief from ERISA's prohibited transaction rules for service contracts or arrangements between a plan and a party in interest if the contract or arrangement is reasonable, the services are necessary for the establishment or operation of the plan, and no more than reasonable compensation is paid for the services.

If the terms of an exemption are not satisfied, responsible plan fiduciaries entering into service arrangements with parties in interest to self-insured group health plans, and the parties in interest themselves, may be subject to enforcement action by the Department and imposition of a civil penalty.[194] The Department's enforcement will be aided by the requirement in the administrative class exemption in paragraph (n) (discussed in the next section) that plan fiduciaries report to the Department a covered service provider's non-compliance with the disclosure or audit provisions.

A number of commenters on the Department's proposed rule raised concerns that the prohibited transaction framework under which the rule was proposed would result in insufficient incentives for compliance by providers of pharmacy benefit management services and, relatedly, that the final rule placed too much responsibility on responsible plan fiduciaries to identify noncompliance. Some commenters referenced the need for civil penalties. In the Department's view, the approach in the final rule will allow the Department to be alerted to instances of noncompliance, but that is not the only means by which noncompliance could be discovered; and, the Department retains its investigative authority under ERISA. In addition, as set forth above, the Department has authority under ERISA section 502(i) to assess a civil penalty against a party in interest in the event of a prohibited transaction.

13.2. Administrative Class Exemption

The Department recognizes that there may be circumstances when a responsible plan fiduciary enters into (or extends or renews) a contract or arrangement that appears to meet the requirements of this final rule under ERISA section 408(b)(2), but the covered service provider fails to comply with its obligations, including by not disclosing the required information or failing to comply with an audit request. Without

[194] ERISA section 502(a)(5) provides that ''the Secretary may bring a civil action to enjoin any act or practice which violates any provision of ERISA . . . or to obtain other appropriate equitable relief (i) to redress such violation or (ii) to enforce any provisions of this title or the terms of the plan.'' ERISA section 502(i) authorizes the Secretary to assess a civil penalty on a party in interest in the case of a transaction prohibited by ERISA section 406.

an exemption, the covered service provider's failure would result in a prohibited transaction by both the service provider and the responsible plan fiduciary.

The Department proposed an administrative class exemption in paragraph (n) to provide relief for responsible plan fiduciaries in the event covered service providers fail to comply with the regulation, consistent with the approach in ERISA section 408(b)(2)(B)(viii) and the Department's service provider regulation for pension plans (29 CFR 2550.408b–2(c)(1)(ix)), both of which provide exemptions for responsible plan fiduciaries who do not receive necessary disclosures from covered service providers to their ERISA-covered plans or are impeded in their right to access information related to the contract or arrangement as required under the regulation.

After consideration of comments, as discussed below, the Department has determined to adopt paragraph (n) in the final rule,[195] with minor modifications. The exemption provides responsible plan fiduciaries with relief from the restrictions of ERISA section 406(a)(1)(C) and (D) if, among other things, the responsible plan fiduciary did not know that the covered service provider failed to comply with the final rule and ''reasonably believed'' that the regulatory requirements were satisfied.[196] Upon discovery of a failure to comply, the responsible plan fiduciary must take certain specified steps within designated timeframes, as described in paragraphs (n)(1) and (2), including notifying the Department of any failures that are not corrected within the designated timeframes. In this way, the administrative class exemption will facilitate oversight by the Department of those covered service providers that fail to comply with the regulation. Paragraphs (n)(3) and (4) set forth the timing, content and other requirements applicable to the notice required to be filed with the Department by the responsible plan fiduciary. The Department notes that parties seeking to avail themselves of the relief provided by the exemption would need to be able to demonstrate compliance with the conditions of the exemption.

In the proposal, the Department requested comments on the administrative class exemption. The Department received several comments in support of the administrative class exemption and its protection for fiduciaries acting in good faith. While some commenters suggested that the full burden of a covered service provider's failure to provide complete and accurate disclosures should fall on the covered service provider, many appreciated the balance between ensuring transparency and avoiding unfair liability for circumstances outside of the responsible plan fiduciary's control.

Some commenters requested that the notifications received by the Department from responsible plan fiduciaries should be used to bring enforcement actions against providers of pharmacy benefit management services that engage in noncompliance, evasion, or unreasonable compensation practices. According to a commenter, this proactive approach is necessary to deter such providers from improper disclosure. While the Department is not making any changes to the text of paragraph (n) to address this comment, the Department reiterates its position from the proposal that ''[t]he Department's enforcement will be aided by the requirement . . . that plan fiduciaries report to the Department a service provider's non-compliance with the disclosure or audit provisions.'' [197]

One commenter supported the proposed administrative exemption but asked that it be expanded to cover third party administrators (TPAs), in addition to responsible plan fiduciaries. According to this commenter, a plan may contract with a TPA under an administrative services-only contract, and the TPA subcontracts with a PBM to administer the pharmacy benefit to the plan. If the PBM does not comply with the requirements of the regulation, the responsible plan fiduciary would be required to name the TPA under the administrative exemption. The commenter expressed concern that this exposes the TPA to liability for failures outside their control and could chill TPA–PBM subcontracting arrangements. To address this, the commenter requested an administrative exemption for TPAs that exercise due diligence and rely on a PBM for preparation of required disclosures.

The Department declines to expand the exemption in this way. As described in the proposal, the exemption is necessary for the responsible plan fiduciary to avoid engaging in a prohibited transaction when the covered service provider fails to meet its obligations.[198] In requesting additional relief, the commenter did not provide an explanation for the types of prohibited transactions in which a TPA would engage. Additionally, the commenter did not explain how additional exemptive relief for TPAs would protect plans, their participants and beneficiaries. If TPAs need relief from the prohibited transaction provisions, they can apply for an administrative exemption under the Department's Procedures Governing the Filing and Processing of Prohibited Transaction Exemption Applications.[199]

13.3. Terminating the Contract

Paragraph (n)(5) of the administrative exemption addresses the potential that the responsible plan fiduciary would terminate the contract or arrangement in connection with the covered service provider's failure to comply with its obligations under the final rule. It provides that if the covered service provider fails to comply with the written request to correct the failure within 90 calendar days of such request, the responsible plan fiduciary shall determine whether to terminate or continue the contract or arrangement consistent with its duty of prudence under ERISA section 404 and shall document the basis for that determination.

This provision is based on a similar provision in ERISA section 408(b)(2)(B)(viii)(IV), and the Department's service provider regulation for pension plans, but it does not include language from these sources that suggests that a responsible plan fiduciary must always terminate a contract or arrangement with a noncompliant covered service provider if the failure to disclose relates to future services. Although the provisions in ERISA section 408(b)(2)(B)(viii)(IV) and the Department's service provider regulation for pension plans provide that the contract or arrangement must be terminated as ''expeditiously as possible, consistent with the duty of prudence,'' the Department is wary of imposing an absolute requirement to terminate a contract as a condition of obtaining the prohibited transaction relief under paragraph (n) because it could cause concerns about the

[195] 29 CFR 2550.408b–22(n).

[196] The Department notes that the fact that the service transaction, for the responsible plan fiduciary, is the subject of an exemption will not relieve the covered service provider, as the other party in interest to the transaction, from ERISA's prohibited transaction provisions. Thus, regardless of the relief available to the responsible plan fiduciary pursuant to paragraph (n) of the final rule, a disclosure failure or other failure to comply with the final rule will nonetheless result in a prohibited transaction and potential civil penalty or liability on the part of the covered service provider.

[197] Improving Transparency into Pharmacy Benefit Manager Fee Disclosure, 91 FR 4348, 4372 (Jan. 30, 2026).

[198] ''Without an exemption, the covered service provider's failure would result in a prohibited transaction by both the service provider and the responsible plan fiduciary.'' 91 FR at 4372.

[199] 29 CFR 2570.30–2570.52.

responsible plan fiduciary's ability to prudently provide for plan benefits. Such a requirement to terminate could be read as precluding a responsible plan fiduciary from continuing a contract or arrangement for some period even if, taking into account surrounding facts and circumstances, it reasonably determines that it would be prudent and in the best interest of participants and beneficiaries to do so.

The Department solicited comments on this approach in the proposal and received several comments supporting the proposed administrative exemption's flexible approach. Commenters emphasized that requiring termination of a service provider contract could harm plan participants, including by denying their continuity in access to benefits and health care services. One commenter requested the Department add a condition that, absent extraordinary circumstances, a contract or arrangement with a noncompliant service provider should not extend beyond the end of the current plan year without corrective action. Another commenter suggested that the provisions in paragraph (n)(5) describing the termination of a services contract or arrangement should apply only when the fiduciary believes the noncompliance is material and requested that the Department confirm that a plan fiduciary is not required to terminate a service arrangement based solely on a material disclosure deficiency. The Department does not agree that there should be a specific ''extraordinary circumstances'' or ''materiality'' requirement governing whether the contract or arrangement should continue beyond the plan year, but instead thinks it is appropriate to retain the overarching requirement that a fiduciary would make this determination consistent with its duties of prudence and loyalty.

Some commenters supported the Department's flexible approach, but suggested that, in order to ensure such flexibility is not abused, the Department should add a requirement that the responsible plan fiduciary document its analysis of whether it is prudent to continue a service or arrangement with a PBM that has failed to comply with the applicable conditions. Documentation would allow the Department to monitor whether responsible plan fiduciaries do terminate contracts and thus determine whether the flexibility is being abused by fiduciaries who fail to act on disclosed non-compliance.

The Department is revising paragraph (n) to add this documentation requirement. As granted, paragraph (n)(5) reads, ''If the covered service provider fails to comply with the written request under paragraph (n)(1)(ii) of this section within 90 calendar days of such request, the responsible plan fiduciary shall determine whether to terminate or continue the service contract or arrangement consistent with its duty of prudence under section 404 of the Act, and shall document the basis for that determination.'' This documentation should not be a mere check the box exercise, but reflect the responsible plan fiduciary's considerations, alternatives, and how the responsible plan fiduciary will ensure no further compliance failures. Responsible plan fiduciaries should also retain the documentation in case a need arises to demonstrate to the Department compliance with the administrative class exemption.

Some commenters expressed concern about the timing requirements in the proposed administrative exemption, particularly that responsible plan fiduciaries notify the Secretary within 90 calendar days of a covered service provider's failure to comply. One commenter asked about interim protections for plans and beneficiaries during the 90-day period. Another commenter said that 90 days is an insufficient remediation period because a responsible plan fiduciary may not be able to find a replacement service provider within 90 days and would risk losing exemption protection.

The Department notes that nothing in the exemption requires plan fiduciaries to terminate or even decide whether to terminate a services contract or arrangement within 90 days. Responsible plan fiduciaries are required to request in writing that the covered service provider correct the failure ''upon discovering that the covered service provider failed to meet any requirement.'' If the covered service provider fails to comply with that requirement within 90 calendar days of the request, then the responsible plan fiduciary must notify the Secretary of the failure and determine whether to terminate the contract. At all times, the responsible plan fiduciary must continue to act in the interests of the plan, its participants and beneficiaries.

13.4. Findings

The Department is granting the administrative class exemption in paragraph (n) pursuant to its authority under ERISA section 408(a) and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (89 FR 4662 (Jan. 24, 2024)). The attention of interested persons is directed to the following: (1) the fact that a transaction is the subject of an exemption under ERISA section 408(a) does not relieve a fiduciary, or other party in interest with respect to a self-insured group health plan, from certain other provisions of ERISA, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of ERISA section 404 which require, among other things, that a fiduciary act prudently and discharge his or her duties respecting the plan solely in the interests of the participants and beneficiaries of the plan; (2) the Department finds that the administrative class exemption is administratively feasible, in the interests of self-insured group health plans and their participants and beneficiaries and protective of the rights of participants and beneficiaries of the self-insured group health plans; (3) the administrative class exemption is applicable only to transactions that satisfy the conditions specified in the exemption; and (4) the administrative class exemption is supplemental to, and not in derogation of, any other provisions of ERISA, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

14. Statutory Authority for and Placement of the Final Rule

14.1. Statutory Authority

Section 408(b)(2)(A) of ERISA exempts from the prohibitions of ERISA section 406(a) ''reasonable'' contracts or arrangements with a party in interest, including a fiduciary, for office space, or legal, accounting, or other services necessary for the establishment or operation of the plan, if no more than reasonable compensation is paid. Section 408(b)(2)(B) of ERISA clarifies that, in the case of a covered service provider who provides services to group health plans no such contract or arrangement is ''reasonable'' unless the disclosure requirements in subparagraph (iii) of section 408(b)(2)(B) of ERISA are satisfied.

As originally enacted, ERISA section 408(b)(2)(B) described two categories of covered service providers to group health plans, namely providers of ''brokerage services'' and ''consulting services'' with respect to certain sub-services, although these terms were undefined. CAA, 2026 amended ERISA section 408(b)(2)(B) and broadened its scope to make clear that it encapsulated

a much wider array of covered service providers who provide services to group health plans, including providers of pharmacy benefit management services.[200] It also provided specific regulatory authority to the Secretary of Labor to address time, manner, and content of disclosures under that subsection.[201] Therefore, the Department is relying on its authority to regulate entities providing pharmacy benefit management services and entities providing advice, recommendations, or referrals regarding the provision of pharmacy benefit management services, and who are affiliated with providers of pharmacy benefit management services, pursuant to sections 505 and 408(b)(2)(B) of ERISA.

Several commenters argue the Department exceeded the statutory authority granted to it in ERISA section 408(b)(2) by extending beyond direct compensation paid by the plan for services. The Department disagrees.

As discussed in section C of this preamble, section 408(b)(2) provides relief from ERISA's prohibited transaction rules for service contracts or arrangements between a plan and a party in interest if the contract or arrangement is reasonable, the services are necessary for the establishment or operation of the plan, and no more than reasonable compensation is paid for the services. Section 408(b)(2)(B)(iii) closely tracks the Department's regulation for pension plan services arrangements. It requires covered service providers to group health plans to disclose the following to take advantage of the exemption: the services to be provided; the status of the covered service provider, an affiliate, or subcontractor as a fiduciary, if applicable; the direct and indirect compensation reasonably expected to be received by the covered service provider, their affiliates and their subcontractors; as well as allocations of compensation reasonably expected to be made among the covered service providers and its affiliates and subcontractors.

Several commenters noted that Congress acted in the CAA, 2026 amendments specifically to clarify the meaning and scope of ''services'' under ERISA section 408(b)(2)(B). According to a comment submitted by the U.S. House Committee on Education and the Workforce in response to this rulemaking, Congress replaced the narrow ''brokerage'' and ''consulting'' terminology with a detailed and expansive list of services to confirm that ERISA section 408(b)(2)(B) reaches the full range of services that affect plan participants' access to and cost of health benefits. To put it another way, Congress made these changes to section 408(b)(2)(B) so that covered service providers performing *any* of the services enumerated in the statute must disclose both direct and indirect compensation to a group health plan.[202]

The Department is of the view that the CAA, 2026 did not alter these substantive disclosure obligations. Furthermore, in specifying that the disclosure obligation under the exemption extends to ''indirect compensation,'' Congress clearly intended that payments from third parties and the related arrangements under which such payments are made are appropriate and necessary subjects of disclosure. The Department is well within its authority to require disclosure of payments from, and arrangements with, drug manufacturers, third party administrators, and others. For these reasons, the Department disagrees that it exceeded the statutory authority granted to it in ERISA section 408(b)(2) by extending beyond direct compensation paid by the plan for services.

Several commenters also argue that ERISA section 726, as enacted by the CAA, 2026, preempts or limits the Department's ability to engage in this rulemaking. The Department disagrees.

As discussed in section D of this preamble, Congress added ERISA section 726, as part of the CAA, 2026. ERISA section 726 establishes new disclosure and reporting obligations for entities that provide pharmacy benefit management services to group health plans and health insurance issuers in Part VII of ERISA, outside of the prohibited transaction framework in Part IV of ERISA.

As one stakeholder commented, section 726 of the CAA, 2026 contains no preemptive language; it does not prohibit the Department from rulemaking under ERISA section 408(b)(2), nor does it state that its provisions are exclusive or that other disclosure regimes are barred. Congress was aware of the E.O. 14273 (Apr. 2025) directing the Department to improve employer health plan fiduciary transparency through rulemaking. Prior to enacting the CAA, 2026, Congress could have prohibited the Department from rulemaking under ERISA section 408(b)(2)(B) or it could have included preemptive language—it intentionally did not. Instead, Congress *doubled down* and strengthened the Secretary's authority to issue regulations governing the time, manner, and content of the required disclosures by covered services providers to group health plans required under ERISA section 408(b)(2)(B)(iii).

Even so, in addition to its authority under ERISA section 408(b)(2), the Department has the express authority under ERISA section 505 to ''prescribe such regulation as [it] finds necessary and appropriate'' and to ''define accounting, technical and trade terms.'' This authority is undisturbed by the new provisions of the CAA, 2026.

For these reasons, the Department disagrees that Congress preempted this rule or limited the Department's rulemaking authority by passing ERISA section 726, as enacted by the CAA, 2026.

A few commenters argued that the Department failed to provide adequate notice of its legal theory after the passage of the CAA, 2026. The Department disagrees. Contrary to commenters' assertions, the proposed rule clearly identified ERISA section 408(b)(2) and section 505 as the source of the Department's authority to prescribe these regulations.

A few commenters also asserted that the Department somehow changed its legal theory when it extended the comment period for this rule by 15 days, following the enactment of the CAA, 2026. This mischaracterizes the Department's actions. After Congress enacted the CAA, 2026, the Department extended the comment period for 15 days for the express purpose of allowing stakeholders to evaluate and comment on whether the rule should be adjusted due to the new statutory provisions. The Department chose to draw the public's attention to the CAA, 2026 and specifically seek comments on the interaction with the proposal to ensure robust public input on that matter. Commenters had notice and a full opportunity to submit comments on the interaction with the CAA, 2026, including the statutory authority, as evidenced by the substantial volume of

[200] *See* ERISA section 408(b)(2)(B)(ii)(I)(bb) (AA) and (BB).

[201] *See* ERISA section 408(b)(2)(B)(iii) (''A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary, addressing time, manner, and content of such disclosures) . . .'').

[202] As discussed in section D of this preamble, entities that do not provide pharmacy benefit management services and who are not affiliates of such entities that provide advice, recommendations, or referrals regarding the provision of pharmacy benefit management services, but who otherwise provide *any* of the services enumerated under ERISA section 408(b)(2)(B) to group health plans and meet the compensation threshold are obligated to make disclosures in accordance with the statute to rely on the exemption. In this regard, EBSA is providing a temporary enforcement policy for those providers as discussed in section D.

comments addressing precisely these issues.

14.2. Placement

This final rule, establishing disclosure requirements for covered service providers to covered plans, will appear at 29 CFR 2550.408b–22. In connection with this final rule, the Department is also revising its existing service provider regulation (29 CFR 2550.408b–2(c)(2)) in the Code of Federal Regulations to cross-reference the final rule.

15. Severability

The Department proposed under paragraph (o) that if any provision of the rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof. The Department did not receive any comments on this provision. The final rules adopt this provision in paragraph (o) [203] without change.

16. Effective and Applicability Dates—Paragraph (p)

Paragraph (p) [204] provides both an effective date and an applicability date for the final rule. Under paragraph (p)(1), the final rule is effective 60 calendar days after the date of the publication in the **Federal Register**. Once effective, however, paragraph (p)(2) provides that the rule is applicable to plan years beginning on or after July 1, 2027. This approach is intended to balance the need for prompt action to increase transparency into contracts and arrangements with PBMs and affiliated brokers and consultants with due concern for the cost and burden associated with revising current and future contracts or arrangements to satisfy the requirements of the final rule.

In the proposal, the Department stated that the rule would be effective 60 days after publication and applicable for plan years beginning on or after July 1, 2026. Commenters said that operational changes would be needed and that proposed timeframe would be infeasible given the likely timing of issuance of the final rule. Some commenters suggested that one year would be needed from finalization of a final rule. Other commenters urged the Department not to delay finalizing so that responsible plan fiduciaries could receive the benefits of the disclosures under the final rule as soon as possible.

The provisions in this final rule implement those statutory disclosure requirements in section 408(b)(2)(B), dictating against delaying applicability longer than necessary to allow parties to develop compliance structures. Accordingly, the Department has made the final rule effective January 4, 2027, and applicable to plan years beginning on or after July 1, 2027.

F. Regulatory Impact Analysis

Summary

The Department has examined the impacts of this final rule as required by Executive Order 12866,[205] Executive Order 13563,[206] Executive Order 14192,[207] the Paperwork Reduction Act of 1995,[208] the Regulatory Flexibility Act,[209] section 202 of the Unfunded Mandates Reform Act of 1995,[210] Executive Order 13132,[211] and the Congressional Review Act.[212]

1. Executive Orders 12866, 13563 and 14192

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Under Executive Order 12866, ''significant'' regulatory actions are subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as ''economically significant'');

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

This final rule seeks to build upon the existing provisions of ERISA section 408(b)(2), as amended, including the 2012 final regulation and relevant provisions of the CAA, 2021 and CAA, 2026. Based on the Department's estimates, OMB's OIRA has determined this rulemaking is economically significant per Executive Order 12866 section 3(f)(1) as it is likely to have an impact of $100 million or more in any one year. The Department has provided an assessment of the potential costs, benefits, and transfers, associated with this final rule, and OMB has reviewed this final rule.

Executive Order 14192, titled ''Unleashing Prosperity Through Deregulation,'' was issued on January 31, 2025. Section 3(a) of Executive Order 14192 requires an agency, unless prohibited by law, to identify at least ten existing regulations to be repealed when the agency issues a new regulation. In furtherance of this requirement, section 3(c) of Executive Order 14192 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with prior regulations. A significant regulatory action (as defined in section 3(f) of Executive Order 12866) that would impose total costs greater than zero is considered an Executive Order 14192 regulatory action. The final rule would require covered service providers, including PBMs, to provide fee and compensation structure disclosures to responsible plan fiduciaries of large self-insured group health plans. As such, this final rule is considered regulatory and is expected to contribute to the Department's regulatory burden under Executive Order 14192.

2. Introduction and Need for Regulation

The rising cost of pharmaceutical drugs has been an increasing concern for the U.S. healthcare system in recent years. Between January 2022 and January 2023, nearly 5,900 prescription drug products in the National Drug Code Directory reported a price change,

[203] 29 CFR 2550.408b–22(o).

[204] 29 CFR 2550.408b–22(p).

[205] Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

[206] Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011).

[207] Unleashing Prosperity Through Deregulation, 90 FR 9065 (Feb. 6, 2025).

[208] 44 U.S.C. 3506(c)(2)(A). (1995).

[209] 5 U.S.C. 601–612 (1980).

[210] 2 U.S.C. 1501–1504 (1995).

[211] Federalism, 64 FR 43255 (Aug. 10, 1999).

[212] 5 U.S.C. 801–808 (1996).

with more than 70 percent (4,300) of these products experienced an increase in their manufacturer list price, and 46 percent (2,000) of those price increases exceeded the rate of inflation.[213] While the annual average rate of prescription price increase has fallen in recent years, prescription drug spending in the U.S. still increased by 7.9 percent in 2024 to $467.0 billion, driven by increased utilization and the entry of new drugs.[214] Despite this growth, the share of total health spending on prescription drugs has remained relatively stable over time (increasing from 7.4 percent in 1970 to 8.8 percent in 2024).[215]

However, an increasing share of these costs appears to have shifted from individuals directly to insurance. According to the National Health Expenditure Accounts (NHEA) data, public and private health insurance accounted for only 16 percent of national prescription drug spending in 1970, increasing to 87 percent in 2024, with out-of-pocket and other third-party payers and programs making up the balance.[216] Moreover, a survey of large employers reported that pharmacy costs are consuming an increasing share of their healthcare budgets, with a median of 24 percent of employer healthcare spending in 2024 and employers expecting an 11 to 12 percent annual increase in pharmacy costs in 2025 and 2026.[217]

Due to the complexity of the pharmaceutical supply chain and the multitude of players involved in the sourcing, manufacturing, distribution, and delivery of pharmaceutical products to end-users, responsible plan fiduciaries of self-insured group health plans often outsource pharmacy benefit management services to intermediaries, such as PBMs. PBMs manage and administer prescription drug benefits between the self-insured group health plans, pharmacies, pharmaceutical companies, and other intermediaries. In this capacity, PBMs develop prescription drug formularies and benefit designs for self-insured group health plans, negotiate rebates with drug manufacturers for placement on those formularies, establish preferred pharmacy networks, and process prescription drug claims. As a result, PBMs influence multiple aspects of self-insured group health plans' prescription drug benefit design, affecting costs and fees, while responsible plan fiduciaries are charged with monitoring the PBMs' actions to ensure the service contract or arrangement is reasonable.

2.1. Fiduciary Challenges of Monitoring PBMs

Under ERISA, the persons responsible for hiring the self-insured group health plan's service providers are plan fiduciaries. In the PBM context, these ''responsible plan fiduciaries'' may be the self-insured group health plans' sponsor or another fiduciary such as a committee made up of plan sponsor employees. Responsible plan fiduciaries are required to act solely in the interests of plan participants and their beneficiaries when administering plan benefits and to ensure that plan assets are used exclusively to provide benefits and pay plan expenses. While they may engage service providers to provide benefits for the plan, plan fiduciaries are responsible for prudently negotiating terms when entering a contract, so that only reasonable and necessary costs are paid, and conflicts of interest are disclosed and mitigated. They are also required to monitor service providers' performance. Moreover, for these responsible plan fiduciaries to avoid a prohibited transaction by relying on ERISA section 408(b)(2), they must determine, among other things, that the contract or arrangement is reasonable.

In the prescription drug space, these responsibilities can be particularly challenging, as plan fiduciaries often contract with a PBM to administer the self-insured group health prescription drug coverage, create the self-insured group health plan's formulary with varying cost-sharing amounts, and manage participant claims and appeals. In doing so, PBMs may separately enter into agreements with multiple entities, including with pharmacies to dispense drugs and with manufacturers for rebates to guarantee preferred placement on the self-insured group health plan's formulary. As a result of those independent relationships, PBMs may have numerous conflicts of interest related to providing prescription drug services as well as several different payment streams that responsible plan fiduciaries are required to monitor in accordance with their fiduciary duties to ensure that the compensation related to these services is reasonable.

Failure to adequately fulfill their responsibility risks legal action for responsible plan fiduciaries. In recent years, multiple cases have been brought by plan participants claiming that their plan fiduciaries did not fulfill their fiduciary responsibilities regarding PBM services by incurring excessive fees, failing to negotiate better pricing terms for prescription drugs, and not behaving prudently when selecting the plan's PBM.[218] These cases highlight the plaintiffs' expectation that responsible plan fiduciaries scrutinize the agreements they enter into with PBMs, including by analyzing compensation disclosures, rooting out conflicts of interest, and auditing PBM's performance to ensure that prescription drug benefits are managed transparently, in accordance with the health plan documents and ERISA, and in the best interest of plan participants.

Often, though, the underlying agreements that PBMs negotiate on behalf of self-insured group health plans with drug manufacturers and pharmacies for these services are not shared with the self-insured group health plans themselves, nor are the relationships between PBMs and their affiliates. Contracts between PBMs and self-insured group health plans often include savings guarantees based on list prices rather than net prices, the latter of which are not disclosed. These contracts may fail to disclose the size of rebates or rebate terms, and limit the self-insured group health plan's right to audit.[219] Such an arrangement, which prevents self-insured group health plans' responsible plan fiduciaries from evaluating drug utilization and spending, the cost effectiveness of the formulary, and the gross profit of the PBM, ''deprives employers of the ability to completely understand the drug benefit design, evaluate the efficiency of

[213] Arielle Bosworth, Steven Sheingold, Kenneth Finegold, Bisma A. Sayed, Nancy De Lew, Benjamin D. Sommers, Changes in the List Prices of Prescription Drugs, 2017–2023, ASPE Office of Health Policy, October 6, 2023.

[214] Centers for Medicare & Medicaid Services, *National Health Expenditure Data, NHE Fact Sheet,* available at *https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.*

[215] Centers for Medicare & Medicaid Services, *National Health Expenditure Accounts, National Health Expenditures Data, National Health Expenditures by Type of Service and Source of Funds, CY 1960–2024,* available at *https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical.*

[216] Centers for Medicare & Medicaid Services, *National Health Expenditure Accounts,* National Health Expenditures *Data, Table 16. Retail Prescription Drugs Expenditures 1970–2024,* available at *https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical.*

[217] Business Group on Health, *Executive Summary: 2026 Employer Health Care Strategy Survey,* (Aug. 19, 2025), available at *https://www.businessgrouphealth.org/resources/2026-employer-health-care-strategy-survey-executive-summary.*

[218] See *Knudsen* v. *MetLife Grp., Inc.,* 117 F.4th 570 (3d Cir. 2024); *Navarro* v. *Wells Fargo & Co.,* No. 24–CV–3043 (LMP/DTS), 2025 WL 897717 (D. Minn. Mar. 24, 2025); *Lewandowski* v. *Johnson & Johnson,* No. CV 24–671 (ZNQ) (RLS), 2025 WL 288230 (D.N.J. Jan. 24, 2025).

[219] Robin Feldman, *Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers Testimony* (Mar. 30, 2023), at the U.S. Senate, Finance Committee, available at *https://www.finance.senate.gov/imo/media/doc/Feldman%20Written%20Testimony%20.pdf.*

their drug utilization, and assess the PBM's performance.'' [220] According to the 2024 KFF Employer Health Benefits Survey, of employers with 500 or more workers that offer health benefits, 37 percent did not know how much was received in rebates negotiated by their PBM or health plan,[221] suggesting that many plans and their sponsors have little insight into PBM rebate practices.[222]

Even when pharmacy benefit consultants are used to select PBMs and assess their contract proposals, responsible plan fiduciaries can struggle to evaluate the arrangements, as drug classifications are inconsistent across PBMs, making it difficult to compare competing PBM bids or secure favorable contract terms.[223] Exacerbating matters further, many pharmacy benefit consultants receive undisclosed compensation from the same PBMs that they are tasked with evaluating, including bonuses, shares of rebates, and per-prescription fees. For example, it has been reported that consultants can receive anywhere from $1 to $5 per prescription from the largest PBMs.[224]

This creates conflicts of interest, where consultants may be incentivized to recommend PBMs offering the highest payouts to them, rather than PBMs that deliver the best value for self-insured group health plans and their participants, which makes the fiduciary task of selecting and monitoring PBMs to protect the interests of the self-insured group health plan and its participants even more challenging. The transparency created by this final rule would help plan fiduciaries to be aware of this conflict and to consider its impact on decisions being made.

[220] Ge Bai, Mariana P. Socal, & Gerard F. Anderson, *Policy Options to Help Self-Insured Employers Improve PBM Contracting Efficiency,* Health Affairs Blog (May 29, 2019), available at *https://www.healthaffairs.org/content/forefront/policy-options-help-self-insured-employers-improve-pbm-contracting-efficiency.*

[221] KFF, *2024 Employer Health Benefits Survey* (Oct. 9, 2024), available at *https://www.kff.org/report-section/ehbs-2024-section-13-employer-practices-provider-networks-coverage-for-glp-1s-abortion-and-family-building-benefits/.*

[222] Arthur Allen, *Employers Haven't a Clue How Their Drug Benefits Are Managed,* KFF Health News (Oct. 9, 2024), available at *https://kffhealthnews.org/news/article/employer-drug-benefits-pbms-survey-kff/.*

[223] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive? International Journal of the Economics of Business* (June 26, 2015), available at *https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.*

[224] United States District Court for the District of New Jersey, *Lewandowski* v. *Johnson & Johnson, No. 1:24–cv–00671* (D.N.J. Feb. 5, 2024), available at *https://litigationtracker.law.georgetown.edu/wp-content/uploads/2024/02/lewandowski-v-johnson-and-johnson_2.5.24_Complaint.pdf.*

2.2. PBM Revenue-Generating Practices and the Impact on Self-Insured Group Health Plan Costs

PBMs utilize several practices to generate revenue when providing services to self-insured group health plans, including but not limited to rebates, price protection, spread pricing, copay claw-backs, specialty drugs administration, steering patients toward PBM-owned mail-order and specialty pharmacies, and high markups on generic drugs. Responsible plan fiduciaries, to fulfill their obligations regarding the selection and monitoring of service providers, need to know and understand the financial interests of PBMs and their relationships with other actors when providing these services. Additionally, when relying on ERISA section 408(b)(2) to avoid a prohibited transaction, they need to determine that the contract or arrangement is reasonable. The following sections discuss common PBM practices in greater detail, the lack of transparency surrounding these practices, and how they can impact the costs and services provided to self-insured group health plans.

2.2.1. Rebates

PBMs generate a significant portion of their revenues through their negotiated share of rebates, which are payments made by the drug manufacturers to issuers or PBMs to receive preferential placement on the formulary, the list of drugs covered by the self-insured group health plan.[225] Many contracts do not require PBMs to disclose the rebates that they receive—therefore self-insured group health plans often are unaware if monies are being refunded; [226] however, a frequently cited industry estimate is that ''PBMs achieve rebates of 30 percent off list price, accounting for all discounts and fees.'' [227] While Part D plan sponsors and their PBMs are required to disclose rebates retained by PBMs to the Centers for Medicare & Medicaid Services (CMS),[228] PBM contracts with issuers and self-insured group health plans often do not directly disclose the magnitude of rebates.[229] This in turn allows PBMs to retain rebates received from manufacturers, unless their service contracts explicitly require sharing of any rebates.[230] Smaller self-insured group health plans, in particular, are less likely to receive any share of rebates due to weaker negotiating power compared to large self-insured group health plans.[231]

Further obscuring the actual rebate amount, the three largest PBMs, which account for roughly 80 percent of the prescription drug market, have created affiliated entities known as rebate aggregators, which serve as intermediaries between PBMs and drug manufacturers to negotiate and collect rebates. While PBMs argue that these entities provide greater bargaining power and savings, because rebate aggregators retain a share of the rebate themselves, depending on the terms of the contract between the self-insured group health plan and the PBM, they effectively reduce any rebate the PBM might be required to share with an issuer or self-insured group health plan, while, as an affiliated entity, still maximizing the PBM's profits. Additionally, according to a 2024 Federal Trade Commission (FTC) report, two of the three largest PBMs' rebate aggregators were found to be offshore entities, further limiting oversight and transparency.[232]

The lack of transparency surrounding net prices has harmful effects on costs. For self-insured group health plans that rely on benefit consultants in their selection process, PBM proposals are

[225] Nicole Rapfogel, *5 Things to Know About Pharmacy Benefit Managers,* Center for American Progress (Mar. 13, 2024), available at *https://www.americanprogress.org/article/5-things-to-know-about-pharmacy-benefit-managers/#:~:text=Rebate:%20A%20price%20concession%20paid,in%20part%20or%20in%20full.*

[226] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive*? International Journal of the Economics of Business (June 26, 2015), available at *https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.*

[227] Health Affairs, *Health Policy Brief: Pharmacy Benefit Managers* (Sept. 2017), available at *https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/healthpolicybrief_178.pdf.*

[228] Social Security Act section 1150A.

[229] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive*? International Journal of the Economics of Business (June 26, 2015), available at *https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.*

[230] Frier Levitt, *Pharmacy Benefit Manager Expose: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, and Employers, and Taxpayers, The Community Oncology Alliance* (Feb. 2022), available at *https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf.*

[231] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive?* International Journal of the Economics of Business (June 26, 2015), available at *https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741 https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.*

[232] Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

often presented comparing the rebate guarantees, which encourages selection of the PBM with the highest rebate revenue. These guarantees are presented in aggregate across all impacted prescriptions regardless of which drugs are dispensed. As argued by the National Formulary Council, this ''obscures'' group health plan sponsors' visibility into the actual net prices of drugs on their formularies as well as the size of the rebates and other revenue (*e.g.,* administrative fees, formulary placement fees, inflation penalties) that PBMs receive from manufacturers.'' [233] This can incentivize PBMs to prioritize drugs with higher rebates, such as brand-name prescription drugs, over lower-cost but equally effective alternatives, increasing overall pharmacy costs. Moreover, while responsible plan fiduciaries generally receive notice of formulary changes, the disclosures typically do not include data to inform a responsible plan fiduciary of the financial impact of such changes or their effect on the self-insured group health plan participants.[234] This lack of transparency limits self-insured group health plans' ability to assess the reasonableness of the changes, which can result in unintended consequences for plan participants.

Rebates received by self-insured group health plans can offset premiums and other healthcare costs. Without transparent disclosures providing detailed descriptions of rebates, responsible plan fiduciaries are unable to assess whether the underlying fees for PBM services are reasonable, particularly given the potential harm to self-insured group health plan participants and beneficiaries.

2.2.2. Price Protection

PBMs can further negotiate with drug manufacturers to receive additional rebates to protect them from price increases, known as price or inflation protection. In such instances, the manufacturer agrees to a maximum price paid for the drug so that if the wholesale acquisition cost (WAC) exceeds the agreed upon threshold, the PBM receives an additional rebate from the manufacturer, beyond the existing rebates and discounts.[235] This practice is similar to the inflationary rebate provisions included in the Inflation Reduction Act (IRA) of 2022, which require manufacturers to pay rebates to Medicare if they increase prices beyond the rate of inflation.[236]

Rather than discouraging price hikes, price protections can incentivize manufacturers to raise list prices more strategically. The Senate Finance Committee found that manufacturers timed their WAC price increases to avoid paying additional rebates under the price protection terms in the PBM contracts.[237] As such, while both PBMs and self-insured group health plans could potentially benefit from price protection rebates, rebate practices also add an additional layer of complexity to contracts which can make it hard to determine if the arrangements are reasonable.

2.2.3. Spread Pricing

Under a spread pricing model, payments for individual prescription claims received by the PBM from self-insured group health plans or issuers often exceeds the reimbursement amount it pays to the pharmacy, allowing the PBM to retain the difference, or ''spread'' without disclosing this additional revenue to self-insured group health plans.[238] One source found that spread pricing accounted for an estimated 10 to 15 percent of a PBM's revenue.[239] Separately, the FTC observed combined spread pricing income for the three largest PBMs totaling $1.4 billion between 2017 and 2022 on just 51 drugs.[240] Spread pricing may provide benefits such as price predictability. However, its lack of transparency can make it difficult for plan sponsors to determine whether such arrangements provide better value than available alternatives.

PBMs' failure to disclose the actual spread makes it difficult, if not impossible, for self-insured group health plans to know whether they are unwittingly paying unreasonable costs for medications and treatment. Consequently, this practice has led to an increased number of State lawsuits that stem from allegations of deceptive practices resulting in financial losses.[241] For example, in 2018, the Ohio Office of Attorney General reported that Centene Corporation, which oversaw Ohio's Department of Medicaid prescription drug program, had engaged in spread pricing which cost the State program nearly $225 million in excess payments.[242] Ohio brought a lawsuit against Centene, who ultimately agreed to pay $88.3 million to the State [243] [244] and also switched to a pass-through pricing contract, which increased payments to pharmacists by 5.7 percent, though this was significantly less than the ''spread'' of 31.4 percent on generic drug claims from April 2017 to March 2019.[245] These findings suggest that a lack of transparency in PBM pricing can make it difficult for group health plans to determine the true cost of pharmacy benefit services.

[233] Rochelle Henderson, Julie Patterson, and John Michael O'Brien, *Prescription Rebate Guarantees: Employer Insights,* 30 American Journal of Managed Care 574–80 (July 19, 2024), available at *https://www.ajmc.com/view/prescription-rebate-guarantees-employer-insights.*

[234] Linda Nilsen, *Written Testimony for the ERISA Advisory Council Hearing on PBM Compensation and Fee Disclosure,* (Aug. 20, 2014), available at *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure-nilsen-08-20.pdf.*

[235] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 14, 2021), available at *https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.*

[236] Center for Medicare and Medicaid Services, *Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Policies in the Calendar Year 2025 Physician Fee Schedule Final Rule* (Nov. 2024), available at *https://www.cms.gov/files/document/medicare-prescription-drug-inflation-rebate-program-final-fact-sheet.pdf.*

[237] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 14, 2021), available at *https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.*

[238] KFF, *Medicaid Pharmacy Benefits State Fact Sheets* (Aug. 6, 2020), available at *https://www.kff.org/statedata/medicaid-pharmacy-benefits-state-fact-sheets/.*

[239] Colorado Health Institute, *Pharmacy Benefit Managers: As Drug Prices Soar, Policymakers Take Aim* (Aug. 2018), available at *https://www.coloradohealthinstitute.org/research/understanding-pharmacy-benefit-managers.https://www.coloradohealthinstitute.org/sites/default/files/file_attachments/Pharmacy%20Benefit%20Managers.pdf.*

[240] Federal Trade Commission, *Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers,* (Jan. 2025), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf.*

[241] None of the discussed lawsuits have occurred in states that have banned spread pricing.

[242] Ohio Auditor of State, *Ohio's Medicaid Managed Care Pharmacy Services* (Aug. 16, 2018), available at *https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.*

[243] Ohio's Office of Attorney General, *Centene Agrees to Pay a Record $88.3 Million to Settle Ohio PBM Case Brought by AG Yost* (June 14, 2021), available at *https://www.ohioattorneygeneral.gov/Media/News-Releases/June-2021/Centene-Agrees-to-Pay-a-Record-$88-3-Million-to-Se#:~:text=(COLUMBUS%2C%20Ohio)%20%E2%80%94%20Centene,for%20pharmacy%20services%20it%20provided.*

[244] Centene has made settlements with 18 states worth $964.8 million. James Drew, Centene PBM Settlement with South Carolina Raises Total Payout to $964.8M, St. Louis Business Journal (Jan. 4, 2024), available at *https://www.bizjournals.com/stlouis/news/2024/01/04/centene-pbm-settlement-south-carolina-raises-total.html.*

[245] Health Data Plan Solutions, *Ohio Department of Medicaid (ODM) Analysis of Pass-Through Pricing Implementation* (Sept. 10, 2019), *https://medicaid.ohio.gov/wps/wcm/connect/gov/8c7214d2-2215-4b30-a03f-9df486ff1fe5/ODM-HDS-Qtr1-Analysis.pdf?MOD=AJPERES.*

2.2.4. Copay Claw-Backs

PBMs also generate profits through copay claw-backs, which can occur when the copayment an insured individual pays at a pharmacy exceeds the total cost of the drugs purchased. This practice results in patients paying more for prescriptions by using their insurance rather than purchasing them directly from the pharmacy, with the excess amount going to the PBMs. Self-insured group health plans' responsible plan fiduciaries are generally unaware of this practice and the resulting revenue, however, since the net drug prices that PBMs negotiate with pharmacies are often not disclosed to self-insured group health plan responsible plan fiduciaries.

A 2018 study using pharmacy claims data and National Average Retail Price (NARP) data, which contained drug prices paid by issuers as reported by pharmacists, found that commercially insured patients' copayments for generic prescriptions exceeded the total cost of the medicine 23 percent of the time.[246] This means that nearly a quarter of the time, patients would find it cheaper to pay the out-of-pocket cost rather than to rely on their insurance. In one particularly egregious example, a patient paid a $285 copay in 2016 for a prescription whose cash cost was only $40, resulting in the PBM retaining a profit of $245.[247]

The practice had been exacerbated by prohibitions on pharmacies from disclosing lower cash prices to patients due to ''gag clauses'' in their contracts with issuers and PBMs.[248] Congress outlawed such gag clauses through the *Patient Right to Know Drug Prices Act* in 2018, though the Federal law did not resolve all transparency issues in drug pricing.[249] While the legislative changes may have curtailed the practice, NARP data collection was discontinued after six months, which has made it difficult to continue monitoring the issue to assess whether it is still pervasive.

2.2.5. Specialty Drugs

PBMs have also utilized their management and distribution of specialty drugs to increase their profits. Specialty drugs are typically defined by (1) their complex handling, administration, or formulation requirements; (2) the severity or rarity of the condition being treated; and (3) their high cost.[250] However, there is no standard definition of a specialty drug. These drugs are often used to manage complex, chronic conditions, such as HIV, cancer, hepatitis, and cystic fibrosis. Not surprisingly, specialty drugs are among the most expensive. Although fewer than two percent of the population uses specialty drugs, those prescriptions account for 51 percent of total pharmacy spending.[251]

The high prices associated with specialty drugs can translate into larger manufacturer rebates, which may incentivize PBMs to design formularies that classify more prescription drugs as specialty drugs. A 2016 study found that, between 2003 and 2014, the share of specialty prescription products filled by commercially insured patients increased from 3.0 to 11.8 percent.[252] Moreover, once a drug is added to a PBM's specialty drug list, it can trigger exclusivity provisions in contracts that require the use of the PBM's affiliated specialty pharmacy.[253] While some of this increase may reflect the evolving characteristics of innovative drugs, the lack of a uniform definition and transparency regarding specialty drug classifications may create incentives for PBMs to classify drugs based on financial considerations.

Since PBMs often benefit financially from the placement of specialty drugs on formularies, this may create a conflict of interest in formulary design. Such a conflict could lead to the exclusion of lower-cost, equally effective alternatives, which would further limit access to prescription drugs.[254]

2.2.6. High Markups on Generic Drugs

Compared to branded or specialty drugs, generic manufacturers rarely negotiate rebates with PBMs. Instead, PBMs can generate profits by basing reimbursement amounts to pharmacies on their own proprietary price lists for generic drugs, in a process known as maximum allowable costs (MAC) pricing. While pharmacies purchase prescription drug products from various wholesalers directly, they are reimbursed by PBMs at the MAC price, which may be below the average wholesale price. Moreover, MAC prices are updated frequently—often on a weekly basis—and so pharmacies do not know the reimbursement amount until they submit a claim.[255]

Pharmacy reimbursement rates are often compared to the National Average Drug Acquisition Cost (NADAC), which is a commonly used benchmark for pharmacy acquisition costs based on data reported by pharmacies to CMS.[256] While PBMs offer lower cost-sharing on generics, PBMs can still steer patients toward affiliated pharmacies and give those pharmacies preferential reimbursement rates. This practice allows PBM-affiliated pharmacies to earn revenues for generics that significantly exceed their estimated drug acquisition costs. A 2024 FTC report examining reimbursement rates for two generic cancer drugs found that PBMs reimbursed affiliated pharmacies at rates 20 to 40 times higher than the NADAC. For example, in 2022, commercial health plans reimbursed affiliated pharmacies for one generic prostate cancer drug over $5,800 per month, approximately 25 times the $229 NADAC. This pattern was observed across both commercial and Medicare Part D payer groups, leading to nearly

[246] This data includes self-insured group health plans. *See* Karen Van Nuys, Geoffrey Joyce, Rocio Ribero, & Dana P. Goldman, *Overpaying for Prescription Drugs: The Copay Clawback* (Mar. 13, 2018), available at *https://schaeffer.usc.edu/research/overpaying-for-prescription-drugs/.*

[247] Megan Thompson, W*hy a Patient Paid a $285 Copay for a $40 Drug,* (Aug. 19, 2018), available at *https://www.pbs.org/newshour/health/why-a-patient-paid-a-285-copay-for-a-40-drug.*

[248] Karen Van Nuys, Geoffrey Joyce, Rocio Ribero, & Dana P. Goldman, *Overpaying for Prescription Drugs: The Copay Clawback* (Mar. 13, 2018), available at *https://schaeffer.usc.edu/research/overpaying-for-prescription-drugs/.*

[249] 132 Stat. 3672—Public Law 115–263.

[250] Huseyin Naci & Aaron S. Kesselheim, *Specialty Drugs—A Distinctly American Phenomenon,* The New England Journal of Medicine (June 4, 2020), available at *https://eprints.lse.ac.uk/105102/4/nejmp1909513.pdf.*

[251] NAIC, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation,* (2023), available at *https://content.naic.org/sites/default/files/inline-files/PBM%20White%20Paper%20Draft%20Adopted%20B%20Committee%2011-2-23_0.pdf.*

[252] Stacie B. Dusetzina, *Share of Specialty Drugs in Commercial Plans Nearly Quadrupled, 2003–2014,* Health Affairs (July 2016), available at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1657?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.*

[253] Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf* (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

[254] Trevor J. Royce, Caroline Schenkel, Kelsey Kirkwood, Laura Levit, Kathryn Levit, & Sheetal Kircher, *Impact of Pharmacy Benefit Managers on Oncology Practices and Patients, JCO Oncology Practice* (Apr. 20, 2020), available at *https://pmc.ncbi.nlm.nih.gov/articles/PMC7351331/.*

[255] Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

[256] Casey B. Mulligan, *Restrict the Middleman? Quantitative Models of PBM Regulations and Their Consequences,* National Bureau of Economic Research (March. 2023), available at *https://www.nber.org/system/files/working_papers/w30998/w30998.pdf.*

$1.6 billion in excess dispensing revenue for affiliated pharmacies.[257]

2.3. Summary

The previous sections illustrate the various practices that PBMs use to generate revenue and how these practices can impact access and costs of prescription drugs for self-insured group health plans, participants and beneficiaries. Moreover, these practices are often designed to mask how revenue is generated, making it difficult for responsible plan fiduciaries of self-insured group health plans to make informed decisions when selecting a PBM, as well as to monitor its activities once they have entered into an agreement. These practices underscore the importance of greater transparency and accountability in the operations of PBMs. Transparent disclosures to responsible plan fiduciaries of self-insured group health plans regarding payments, compensation, arrangements between the PBM and affiliates, agents, and subcontractors, and the right to audit and access information are needed to enable responsible plan fiduciaries to make prudent decisions when selecting and monitoring PBMs and to ensure that the contract or arrangement, and the fees charged to self-insured group health plans, are reasonable. These decisions are crucial in ensuring patients have access to timely and affordable prescription drugs.[258]

3. Regulatory State

3.1. History of 408(b)(2) Regulations

In December 2007, the Department issued a proposed regulation requiring service providers to disclose specified information before a contract was entered into that would allow responsible plan fiduciaries to assess whether a contract or arrangement was ''reasonable'' under Section 408(b)(2) of ERISA. The required disclosures included information on all compensation to be received and any conflicts of interest that may adversely affect the service provider's performance of the contract or arrangement. The Department proposed that this information was necessary for responsible plan fiduciaries to make informed assessments and decisions about the services, costs, and the providers, in accordance with their responsible plan fiduciary obligations.[259]

Under that proposed regulation, all employee benefit plans subject to Title I of ERISA were subject to the regulation's disclosure requirements, including both pension and welfare plans. However, the Department received a number of comments arguing against the inclusion of welfare plans, asserting that the disclosures contemplated were already made available to responsible plan fiduciaries through State regulatory processes. Additionally, the Department received comments suggesting that the inclusion of PBMs under the rule was contrary to the rationale for the rule itself. In particular, commenters argued that PBMs should be excluded from the rule because the FTC, at the time, had determined that market forces provide sufficient information to responsible plan fiduciaries, that excessive mandatory disclosure could weaken competition, and that this would negatively affect the delivery of prescription drugs to group health plan participants and beneficiaries.[260]

While the view of the Department was that fiduciaries and service providers to welfare benefit plans would similarly benefit from regulatory guidance in this area, it acknowledged that there are significant differences between service and compensation arrangements of welfare plans and those involving pension plans. As such, the Department expressed its intention to develop separate, and more specifically tailored, disclosure requirements for welfare benefit plans, and excluded them from the final rule.[261]

The 408(b)(2) disclosures required by the 2012 final regulation provided responsible plan fiduciaries of retirement plans with necessary information about the compensation arrangements of their service providers, enabling them to better assess whether those compensation arrangements were reasonable.[262] As a result, these disclosures helped responsible plan fiduciaries make more cost-effective investment choices, such as opting for cheaper share classes. Flows into the cheapest share classes of open-end mutual funds that indicated they distributed to retirement channels more than doubled from 2011 to 2013, indicating a substantial increase after the final rule took effect.[263] However, the fees charged to plan participants had been declining both before and after the final rule took effect, making it difficult to isolate the specific benefits that resulted from this regulation.[264]

Building on this regulatory framework, Congress expanded similar requirements to a portion of the group health plan market. In the CAA, 2021, Congress amended the ERISA section 408(b)(2) statutory exemption to add a new paragraph (B) applicable to certain services arrangements with group health plans, effective December 27, 2021.[265] As part of the amendment, Congress designated the pre-existing text as ERISA section 408(b)(2)(A).[266] The requirements in ERISA section 408(b)(2)(B) as originally enacted in CAA, 2021 applied to a group of covered service providers, defined as persons or entities who provide ''brokerage services'' or ''consulting'' to group health plans with respect to a list of sub-services including pharmacy benefit management services.[267]

ERISA section 408(b)(2)(B) closely tracks the Department's regulation for pension plan arrangements. It requires disclosure of: the services to be

[257] Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

[258] U.S. House Committee on Oversight and Accountability, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* (2024), available at *https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf.*

[259] 72 FR 70988 (Dec. 13, 2007).

[260] 75 FR 41600 (July 16, 2010).

[261] *Id.*

[262] 77 FR 5632 (Feb. 3, 2012).

[263] Based on internal analysis performed by EBSA.

[264] Investment Company Institute, *The Economics of Providing 401(k) Plans: Services, Fees, and Expenses, 2023* (July 2024) at 11, available at *https://www.ici.org/system/files/2024-07/per30-06.pdf.*

[265] Section 202 of Title II of Division BB of the Consolidated Appropriations Act, 2021.

[266] ERISA section 408(b)(2)(A) now provides an exemption for ''[c]ontracting or making reasonable arrangements with a party in interest for office space, or legal, accounting, or other services necessary for the establishment or operation of the plan, if no more than reasonable compensation is paid therefor.''

[267] Specifically, as originally enacted ERISA section 408(b)(2)(B)(ii)(I)(bb)(AA) defined a covered service provider as one who provides *brokerage services* ''provided to a covered plan with respect to selection of insurance products (including vision and dental), recordkeeping services, medical management vendor, benefits administration (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness services, transparency tools and vendors, group purchasing organization preferred vendor panels, disease management vendors and products, compliance services, employee assistance programs, or third party administration services.'' ERISA section 408(b)(2)(B)(ii)(I)(bb)(BB) as originally enacted defined a covered service provider as one who provides *consulting services* ''related to the development or implementation of plan design, insurance or insurance product selection (including vision and dental), recordkeeping, medical management, benefits administration selection (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness design and management services, transparency tools, group purchasing organization agreements and services, participation in and services from preferred vendor panels, disease management, compliance services, employee assistance programs, or third party administration services.''

provided; the status of the covered service provider, an affiliate, or subcontractor as a fiduciary, if applicable; the direct and indirect compensation reasonably expected to be received by the covered service provider, their affiliates and their subcontractors; as well as allocations of compensation reasonably expected to be made among the covered service providers and its affiliates and subcontractors. It also establishes ongoing disclosure obligations in the event of a change in the information required to be provided in the initial disclosures, and disclosures to be provided upon the written request of the responsible plan fiduciary as needed for the plan to comply with the reporting and disclosure requirements of title I of ERISA.

Congress continued to expand the transparency and fiduciary oversight of PBM services under the CAA, 2026. Specifically, CAA, 2026 amended ERISA section 408(b)(2) in several ways relevant to providers of pharmacy benefit management services, including by revising the definition of covered service provider to remove the words ''brokerage services'' and ''consulting,'' clarifying that providers of pharmacy benefit management services (as well as a broad range of other service providers to group health plans, including third party administrators) are covered service providers and are required to make the disclosures under the statute to rely on the prohibited transaction exemption, and by adding disclosure requirements, requirements to pass through to the plan rebates received from certain parties in the pharmaceutical supply chain, and related audit requirements.[268] It requires providers of PBM services to disclose direct and indirect compensation, including administrative fees, network fees, spread pricing and rebates, to plan fiduciaries. It further requires that PBMs pass 100 percent of all rebates, fees, alternative discounts, and other manufacturer remuneration directly back to the group health plans. Plan sponsors are also granted the statutory right to conduct annual compliance audits using an independent auditor of their choosing, legally stripping PBMs of their ability to veto the auditor.

CAA, 2026 also amended ERISA to add section 726, *Oversight of Entities that Provide Pharmacy Benefit Management Services.*[269] Section 726 requires that entities that provide pharmacy benefit management services to certain group health plans (including through health insurance issuers) provide not less frequently than every 6 months reports to the large group health plans that include specified information with respect to drugs covered by the group health plan. These reports must break down gross and net drug spending, manufacturer rebates, spread pricing, and pharmacy compensation. A summary of the required information is to go to all plans. To further ensure transparency, ERISA-covered plans must issue an annual notice to participants regarding these PBM reporting requirements and provide detailed, claim-level pricing data upon request.

Finally, Executive Order 14273 directed the Department to propose regulations to improve employer health plan fiduciary transparency into the direct and indirect compensation received by PBMs.[270]

3.2. Current Regulatory Action

Like the Department's 2012 final pension disclosure regulation, the final rule is intended to ensure transparency by requiring covered service providers to make adequate disclosures to the responsible plan fiduciaries so that they can perform their duties under ERISA in assessing the reasonableness of the arrangement with the service provider. The specific disclosure requirements are explained in detail in the preamble.

Overall, the disclosures are intended to provide responsible plan fiduciaries with a fuller picture of the terms under which the services will be provided, so they can assess both the reasonableness of the compensation in light of the services being provided, and the potential for or existence of conflicts of interest that may impact the quality of services provided. The Department believes that these disclosures will provide necessary information to responsible plan fiduciaries who are required to determine that the services contract or arrangement meets the standards for an exemption under ERISA section 408(b)(2).

4. Baseline

The baseline for this analysis reflects the current legal and regulatory framework, including the existing provisions of ERISA section 408(b)(2), as amended, and applicable provisions of the CAA, 2021. The CAA, 2021 effectively extends the disclosure requirements from the 2012 final regulation to include ''brokerage services'' or ''consulting'' to group health plans with respect to a list of sub-services including pharmacy benefit management services. The CAA, 2021 amendments require disclosure of certain information including services to be provided and a description of the direct and indirect compensation to be received by specified parties in connection with the services. These disclosures are to be made not later than the date that is reasonably in advance of the date on which the contract or arrangement is entered into, extended or renewed. As a result, the baseline includes burden for disclosure requirements for covered service providers that provide pharmacy benefits management services to group health plans sent before a contract is entered into, extended or renewed, but does not include burden for additional content for the initial disclosure and burden for other new disclosures.

As discussed in the section of the preamble titled ''Consolidated Appropriations Act, 2026'' most of the requirements for the CAA, 2026 are new and therefore are not included in the baseline. Additionally, many of the requirements of the CAA, 2026 are not codified by the final rule, so their burden is not included in this analysis. The CAA, 2026 provisions amend ERISA section 408(b)(2) subparagraph (B) to explicitly apply to all pharmacy benefit management services. This analysis interprets the changes to who is a covered service provider under 408(b)(2) as a clarification of prior congressional intent under the CAA, 2021. Therefore, this analysis does not attribute additional burden to who is a covered service provider beyond what was estimated in the proposed rule's analysis, as the burden estimates in the proposed rule already included these entities.

The final rule may overlap with some requirements from the CAA, 2026, including some requirements for disclosure under Section 726. To the extent those requirements align, their burden is accounted for in this RIA. If they do not align, the burden for the requirements from the CAA, 2026 is not included. Burden for non-aligning requirements of the CAA, 2026, while not included in the burden estimates here, could be included in future rulemaking related to Section 726. So, to the extent the requirements of CAA, 2026 differ from the requirements of 408(b)(2) as amended by CAA 2021 or the final rule, those requirements are not included in this analysis.

These requirements are expected to impose costs for PBMs and may potentially impose new costs on other

[268] Consolidated Appropriations Act, 2026, Division J, Title VII, section 6702.

[269] Consolidated Appropriations Act, 2026, Division J, Title VII, section 6701.

[270] Lowering Drug Prices by Once Again Putting Americans First, 90 FR 16441 (Apr. 15, 2025).

service providers that assist plans in their compliance. The final rule provides meaningful benefits to self-insured group health plans, participants, and beneficiaries. Benefits, costs, and transfers associated with the final rule are measured as changes relative to the baseline.

5. Summary of Impacts

The final rule is expected to increase transparency in PBM compensation arrangements, helping self-insured group health plans' responsible plan fiduciaries and other stakeholders to better understand PBM practices and make more cost-effective choices. This transparency would increase competition in the market for PBM services, enable responsible plan fiduciaries to compare offerings across PBMs, empower responsible plan fiduciaries to negotiate more favorable contract terms, reduce impacts on the self-insured group health plan and participants resulting from PBMs' conflicts of interest, and encourage PBMs to accurately classify prescription drugs, resulting in lower costs to both self-insured group health plans and participants.

Self-insured group health plans, third-party administrators (TPAs), and PBMs will incur costs to review this rule and comply with the additional disclosure requirements in the final rule. However, the Department has determined that the benefits of the final rule justify the costs. In accordance with OMB Circular A–4, Table 1 depicts an accounting statement summarizing the Department's assessment of the benefits, costs, and transfers associated with these regulatory actions. The Department is unable to quantify all benefits, costs, and transfers of the final rule, but has sought, where possible, to describe these non-quantified impacts. The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs resulting from the provisions of the final rule.

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TABLE 1. Accounting Statement

Benefits:	Estimate (Primary)	Estimate (Low)	Estimate (High)	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($million/year)	$293.0	$146.5	$586.0	2026	7 percent	2026–2035
	$293.0	$146.5	$586.0	2026	3 percent	2026–2035
Quantified Benefits using Willingness to Pay: • Improved welfare due to lower cost prescription drugs will result in an average undiscounted benefit of $293.0 million annually.						
Non-Quantified Benefits and/or Mechanisms Yielding Quantified Benefits: • Improved understanding of PBMs by self-insured group health responsible plan fiduciaries. • Reduced administrative burden on self-insured group health plans due to lower search and preparation costs for PBM selection and contract negotiations. • Greater ability for self-insured group health responsible plan fiduciaries to compare offerings across PBMs, fostering competition, and improving drug pricing. • More favorably negotiated contracts for self-insured group health responsible plan fiduciaries with PBMs, resulting in lower costs and more appropriate coverage. • Reduced conflicts of interest that currently influence PBMs' key decisions regarding rebates, formulary design, and prescription drug pricing. • Reduced costs to self-insured group health plans and employers, allowing them to shift resources to other benefits or priorities. • Improved health outcomes for participants and beneficiaries arising from increased adherence to medication as a result of lower cost prescription drugs.						
Costs:	Estimate	Year Dollar	Discount	Period Covered		
Annualized Monetized ($million/year)	$60.95	2026	7 percent	2026–2035		
	$59.43	2026	3 percent	2026–2035		
Quantified Costs: • For familiarization with the final rule, ERISA covered self-insured group health plans, TPAs, and PBMs will incur approximately $20.8 million in the first year. • For developing and maintaining the IT infrastructure systems, PBMs will incur $80.3 million in the first year and $21.9 million in subsequent years. • For preparing the required disclosures, PBMs and ERISA covered self-insured group health plans will annually incur approximately $12.5 million. • For ERISA-covered self-insured group health plans preparing audit requests, and PBMs providing requested information to plans, will annually incur approximately $16.0 million.						
Transfers:	Estimate (Primary)	Estimate (Low)	Estimate (High)	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($million/year)	$818.4	$409.2	$1,636.9	2026	7 percent	2026–2035
	$818.4	$409.2	$1,636.9	2026	3 percent	2026–2035
Quantified Transfers: • Transfers from PBMs to self-insured group health plans and health plan participants of $818.4 million annually due to reduced prescription prices.						
Non-Quantified Transfers: • Potential transfers from traditional PBMs to transparent PBMs like fully pass-through PBMs as self-insured group health responsible plan fiduciaries are better able to evaluate compensation structures. • Potential transfers from affiliated to unaffiliated pharmacies, as PBMs remove preferential treatment of						
Perpetual Time Horizon Costs: • Annualized Cost (in 2024 dollars) (E.O. 14192 accounting): $53.9 million.						

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6. Affected Entities

Table 2 summarizes the number of self-insured group health plans, TPAs, pharmacies, manufacturers, wholesalers, and PBMs that would be affected by the final rule. These estimates and their sources are discussed in greater detail later in Section 6 of the RIA.

TABLE 2. Affected Entities

	Total
Large, self-insured Group Health Plans with 100 to 999 participants and beneficiaries	113,226
Large, self-insured Group Health Plans with 1,000 or more participants and beneficiaries	17,876
PBMs	73
Issuers	373
Issuers/State combinations in group market	809
TPAs	205
Pharmaceutical Manufacturers	1,436
Pharmaceutical Wholesalers	1,427

6.1. Self-Insured Group Health Plans

The final rule applies only to a subset of ERISA-covered group health plans, which are self-insured group health plans. Fully insured ERISA plans are not subject to the final rule and are therefore excluded from the estimates. As discussed in the preamble, the final rule applies only to self-insured plans of specified large employers and self-insured group health plans that are specified large plans. A specified large employer generally means an employer that employed an average of at least 100 employees on business days during the preceding calendar year or plan year, as applicable, and that employs at least one employee on the first day of the calendar year or plan year. A specified large plan generally means a group health plan that had an average of at least 100 participants on business days during the preceding calendar year or plan year, as applicable. Self-insured plans with 100 or more participants are used as a proxy for identifying an affected plan.

Additionally, the final rule also excludes group health plans whose sponsors are in the drug supply chain. The Department does not have a sense of how many plans would be directly impacted by this exclusion, but anticipates that it would not constitute a significant number as they would be limited to large, self-insured plans whose sponsors are in drug supply chain. As a result, the Department assumes that the impact of this exclusion is negligible.

The Department estimates that there are 113,226 self-insured group health plans with 100 to 999 participants and beneficiaries, and 17,876 self-insured group health plans with 1,000 or more participants and beneficiaries.[271] While all 131,102 of these plans are considered self-insured group health plans, the Department uses this distinction to categorize self-insured group health plans by size and other unique features. The 2025 KFF Employer Health Benefits Survey also found that nearly all covered workers (99 percent) are at firms that provide prescription drug benefits to enrollees in their group health plans.[272] [273] As such, the Department assumes that all large, self-insured group health plans will be affected by the final rule.

6.2. TPAs and Issuers

The Department also estimates that the final rule will affect 205 TPAs and 373 issuers (*i.e.,* health insurance companies) in the group market with 809 issuers/State combinations [274] that provide services such as plan management to self-insured group health plans. The Department assumes that these TPAs and issuers will provide their services to self-insured group health plans with fewer than 1,000 participants and beneficiaries. TPAs and issuers are typically hired by self-insured group health plans to perform key administrative and compliance functions, including claims processing, formulary design, and oversight of pharmacy benefits. These service providers will offer economies of scale in regulatory compliance by leveraging their expertise and infrastructure to implement the final rule's requirements on behalf of multiple self-insured group health plans. While responsible plan fiduciaries remain ultimately responsible for ensuring compliance, they rely on TPAs and issuers to manage the day-to-day operations of the self-insured group health plan and fulfill the requirements of the final rule. Plans may contract with the TPAs or issuers, who in turn sub-contract with PBMs. In that case, the TPAs or issuers would be covered service providers. The TPAs or issuers would be responsible for making the disclosures to the self-insured group health plan as required under the final rule and therefore must be able to obtain information from the provider performing the pharmacy benefit management services necessary for those disclosures.

[271] The Department estimated that there are 113,226 self-insured ERISA-covered group health plans with 100 to 999 participants and 17,876 self-insured ERISA-covered group health plans with 1,000 or more participants using the 2024 Medical Expenditure Panel Survey Insurance Component (MEPS–IC) and the 2022 County Business Patterns from the Census Bureau.

[272] KFF reported this estimate for large firms only, as small firm respondents had a high percentage of ''don't know'' responses to these questions.

[273] KFF, *2025 Employer Health Benefits Survey* (Oct. 22, 2025), *https://www.kff.org/report-section/ehbs-2024-section-9-prescription-drug-benefits/.*

[274] An ''issuer/state combination'' refers to a health insurance issuer and the state in which it offers coverage, such that the same issuer operating in multiple states is treated as separate issuer/state combinations. Data source: Centers for Medicare and Medicaid Services, *2023 Medical Loss Ratio Data, https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources.*

6.3. Participants and Beneficiaries

There are approximately 72.4 million participants and beneficiaries enrolled in ERISA-covered, large, self-insured group health plans. Of these, approximately 69.7 million are under the age of 65.[275] According to the 2024 Center for Disease Control's (CDC) National Center for Health Statistics, United States, 67.8 percent of individuals under the age of 65 with private health insurance used a prescription medication in the past year[276] or 47.2 million covered participants and beneficiaries.[277]

6.4. PBMs

According to the Pharmaceutical Care Management Association (PCMA),[278] there were 70 full-service PBMs in 2021. Between 2021 and 2023, six new full-service PBMs entered the marketplace. During this same time, eight PBMs were acquired by other PBMs, primarily through mergers between small or mid-size companies. Furthermore, five PBMs that were previously not classified as ''full-service'' have expanded their services. As a result, the net number of full-service PBMs in the marketplace was 73 in 2023.[279]

6.5. Brokers and Consultants

To the extent PBMs or their affiliates also act as brokers or consultants for large, self-insured group health plans with respect to pharmacy benefit management services, they are covered service providers under the final regulation. The Department requested comments on the number of brokers and consultants that are PBMs or affiliates of PBMs, as well as on their arrangements with large, self-insured group health plans and PBMs, and on costs, if any, that they will incur in complying with the requirements of the regulation.

The Department received several comments regarding the definition of the pharmacy benefit management services and the entities that would be covered under the regulation. Some commentators raised concerns that because Congress had not defined pharmacy benefit management services in CAA, 2026, the Department's proposed definition was too broad and would include unintended services. Other commenters, however, raised concerns about the potential exclusion of PBM-owned or PBM-affiliated rebate aggregators and related entities under a narrower definition. These entities may participate in rebate flow arrangements and other compensation structures associated with PBM operations that would fall under the final rule's disclosure and audit provisions. However, they could potentially evade reporting requirements by using offshore rebate aggregators and group purchasing organizations (GPOs) unless the Department includes them as related parties. Although the Department did not receive sufficient information or data to estimate the number of rebate aggregators or related entities that may be affected, the Department acknowledges that such entities may incur costs to comply with the disclosure and audit requirements under the final rule.

6.6. Drug Manufacturers, Wholesalers and Pharmacies

According to the U.S. Census Bureau, there were 1,436 drug manufacturers in 2023[280] and 1,427 pharmaceutical drug wholesaler distributors in 2021.[281] Additionally, the U.S. Census Bureau reported there were 41,792 pharmacies and prescription drug stores in 2023, though a number had closed in the preceding years which makes estimating the current number challenging.[282] Other studies report a different number of pharmacies and different trends in industry growth depending on the methodology used.[283] [284] One of these studies finds more turnover for independent pharmacies relative to chain pharmacies. Independent pharmacies were more than twice as likely to close as chain stores, though the overall decline was driven largely by chain pharmacy closures due to their market share. These trends correspond with reported increases in planned closures, mergers, and acquisitions, and the integration of PBMs with large pharmacy chains. The study noted that the closures might have been driven by lower reimbursement rates for unaffiliated pharmacies rather than PBM affiliated counterparts and by the increased exclusion of independent pharmacies from pharmacy networks.[285]

Pharmacies can be subject to the final rule if they perform PBM-type functions or are affiliated with the covered service provider in a way that makes their compensation relevant and disclosable. The Department does not know how many pharmacies fall into this category.

7. Research Examining the Impact of PBMs on Prescription Drug Costs

Research shows mixed impact of PBMs on prescription drug costs. Some studies suggest that PBMs can lower costs by negotiating rebates and managing drug utilization, and that the absence of PBMs leads to greater inefficiencies and higher prescription drug prices. In contrast, other studies find that PBMs can inflate costs through spread pricing, formulary design, and requiring the use of mail-order or specialty pharmacies. These studies are discussed in greater detail below.

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[275] Estimate is based on the Department's tabulations *of the March* 2025 *Current Population Surveyhttps://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2023.pdf* (CPS) Auxiliary Data.

[276] Centers for Disease Control and Prevention, National Center for Health Statistics, *Prescription Medication Use Among Adults* (2025), available at *https://nchsdata.cdc.gov/DQS/?topic=prescription-medication-use-among-adults&subtopic=&group=health-insurance-coverage-younger-than-65-years&subgroup=private&range=2019-to-2024.*

[277] *https://nchsdata.cdc.gov/DQS/?topic=prescription-medication-use-among-adults&subtopic=&group=health-insurance-coverage-younger-than-65-years&subgroup=private&range=2019-to-2023* This estimate was calculated in the following manner: 69.7 million participants and beneficiaries in ERISA-covered, large, self-insured group health plans × 67.8 percent = 47.2 million individuals.

[278] The PCMA is a national trade association representing the PBM industry. *See* Pharmaceutical Care Management Association, *About PCMA* (2026), *https://www.pcmanet.org/about/.*

[279] *https://www.pcmanet.org/rx-research-corner/the-pbm-marketplace-is-more-competitive-not-less/05/08/2023/* Pharmaceutical Care Management Association, *The PBM Marketplace Continues to Evolve* (Apr. 11, 2023).

[280] U.S. Census Bureau, *2023 Economic Surveys Business Patterns, 325412: Pharmaceutical Preparation Manufacturing* (2023), available at *https://data.census.gov/profile/325412_-_Pharmaceutical_Preparation_Manufacturing?n=325412&g=010XX00US.*

[281] National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers, 87 FR 6708 (Feb. 4, 2022)*https://www.federalregister.gov/documents/2022/02/04/2022–01929/national-standards-for-the-licensure-of-wholesale-drug-distributors-and-third-party-logistics.*

[282] U.S. Census Bureau, *All Sectors: County Business Patterns, including ZIP Code Business Patterns, by Legal Form of Organization and Employment Size Class for the U.S., States, and Selected Geographies: 2023, Economic Surveys, ECNSVY Business Patterns County Business Patterns, Table CB2300CBP* (2025), available at

[283] Mattingly, T. Joseph, Maitreyi Sahu, & Kelly E. Anderson., Community *Pharmacy Turnover and Context of Openings and Closings by Ownership Type,* 6(8) In *JAMA Health Forum,* (2025) American Medical Association.*https://jamanetwork.com/journals/jama-health-forum/fullarticle/2836775.*

[284] Jenny S. Guadamuz, G. Caleb Alexander, Genevieve P. Kanter, & Dima Mazen Qato, *More US Pharmacies Closed Than Opened In 2018–21; Independent Pharmacies, Those in Black, Latinx Communities Most at Risk: Study Examines US Pharmacy Closures at the County Level, 2018–21,* Health Affairs (2024), available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2024.00192.*

[285] Jenny S. Guadamuz, G. Caleb Alexander, Genevieve P. Kanter, & Dima Mazen Qato, *More US Pharmacies Closed Than Opened In 2018–21; Independent Pharmacies, Those in Black, Latinx Communities Most at Risk: Study Examines US Pharmacy Closures at the County Level, 2018–21,* Health Affairs (2024), available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2024.00192.*

7.1. Research Finding That PBMs Generate Cost Savings and Their Absence Increases Prescription Drug Costs

PBMs argue that they generate cost savings for employers, health plans, participants, beneficiaries, and taxpayers. For example, a 2025 study funded by the three largest PBMs—Caremark, Express Scripts, and OptumRx— found that PBMs reduce prescription drug costs for plan sponsors and their members. The authors estimate that PBM operating margins account for less than five percent of overall prescription drug costs and that approximately 98 percent of manufacturer rebates in recent years have been passed through to plan sponsors.[286]

It is important to note that low profit margins in the PBM industry may be an artifact of discretionary accounting practices which allow PBMs to choose whether to count pass-through payments, such as rebates, as revenue. This, coupled with vertical integration which obfuscates where profits are generated, can make profit margins appear artificially low.[287] Moreover, the 2025 study does not account for significant variability across plan types and PBM contracts. For example, another 2025 paper suggests that larger employers were more likely to receive manufacturer rebates than small employers, with only 15 percent of small employers [288] reporting capturing rebates, compared to 49 percent of large employers in 2024.[289] Evidence from a 2015 paper finds that the average retail spread retained by PBMs is below two percent, though the Department notes that even a two percent spread represents a substantial amount when applied to prescription drug spending in billions of dollars. The study further shows that net prices for branded drugs with rebates have grown more slowly than those without rebates. According to the authors, plan sponsors rely on PBMs because they can negotiate larger discounts with manufacturers and pharmacies, develop formularies that encourage the use of lower-cost drugs, and manage pharmacy networks more efficiently than plan sponsors could on their own. The study concludes that PBMs create significant value by managing prescription drug spending, which can help reduce premiums and out-of-pocket costs for patients.[290]

Furthermore, a 2016 study, commissioned by a PBM trade association highlights the methods PBMs use to generate savings including negotiating rebates and discounts, encouraging the use of generics and alternatives, managing high-cost specialty medications, and expanding access via mail-service and specialty pharmacy channels. The study estimated that PBMs could generate $350 billion in savings for commercial plans and their members from 2016 to 2025 while promoting proper utilization and adherence to treatment. However, this analysis assumes that PBMs fully utilize their cost-saving tools: selective formularies with four or more tiers, pre-approval for step-therapy, strong incentives to use mail service, preferred pharmacy options with high performance networks, and high usage of specialty pharmacies.[291] It is also important to note that the study bases its estimates on several assumptions about prescription drug trends, including price inflation and specialty drug growth. The authors also do not control for any inflationary pressure that PBMs themselves may have on the list price of prescription drugs. Additionally, this study does not account for the varying efficacy of utilization management and adherence programs across heterogeneous patient populations, which poses limitations in accurately estimating cost savings. Finally, it is worth noting that the study does not discuss the impact of transparency on the ability of PBMs to continue to provide these services and generate savings.

A 2022 study, also funded by the same PBM trade association, estimates the societal value of PBM services using a quantitative model that reflects the structure of the U.S. prescription drug market. The paper compares current PBM operations with three hypothetical scenarios: the absence of PBM services, the use of government-enforced price controls, and in-house management of PBM functions by individual health plans.[292]

In the first scenario, PBM services are estimated to annually contribute an additional $145 billion more in societal value than would be experienced without PBM services, though more than one-third of the calculated value is attributed to manufacturer rebates. This estimate is based on $168 billion in quantified benefits, which include negotiated rebates, increased use of generic drugs, improved adherence, and reduced tax distortion, minus $22 billion in resource costs associated with providing PBM services.[293]

In the second scenario, PBM services are estimated to provide an additional $192 billion in societal value each year, compared to a healthcare system operating under government-enforced price controls. This estimate reflects the model's assumption that government-enforced price controls could lower drug utilization, weaken market-based price mechanisms, and significantly diminish incentives for pharmaceutical innovation.

Finally, in the third scenario, PBM services are estimated to provide between $64 to $81 billion more in societal value compared to a system in which self-insured group health plans perform all PBM functions internally, without relying on specialized PBM companies. This estimate reflects the model's assumption that self-insured group health plans would retain only a portion of PBM functions under this model, leading to decreased efficiency and increased operational costs.[294]

While these studies suggest the potential positive impact that PBMs may have in controlling costs, some studies have found that the absence of PBMs can result in higher costs for self-insured group health plans as well as State and federal government programs. For example, the Department of Labor's Inspector General conducted an audit of its Office of Workers' Compensation Programs (OWCP) in 2023 and concluded that the program lacked a ''pharmacy benefit manager to help contain costs'' between 2015 and 2020.

[286] Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* (Apr. 2025), available at *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.*

[287] Karen Mulligan and Darius Lakdawalla, *Hidden Profits? How Accounting Conventions and Vertical Consolidation can Obscure PBM Profitability,* Schaeffer Center White Paper Series (Jan. 22, 2026), available at *https://schaeffer.usc.edu/research/pbm-profitability/.*

[288] The paper defines a small employer as an employer with fewer than with than 5,000 employees.

[289] Pharmaceutical Group Companies, *2025 Trends in Specialty Drug Benefits Report* (2025), *https://www.psgconsults.com/blog/untapped-potential-medical-drug-rebate-strategies-for-payers/.*

[290] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive?* International Journal of the Economics of Business (June 26, 2015), available at *https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.*

[291] Visante, *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers,* Prepared for Pharmaceutical Care Management Association (PCMA) (Feb. 2016), available at *https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf.*

[292] Casey B. Mulligan, *The Value of Pharmacy Benefit Management,* NBER Working Paper Series (July 2022), available at *https://www.nber.org/system/files/working_papers/w30231/w30231.pdf.*

[293] *Id.*

[294] *https://www.nber.org/system/files/working_papers/w30231/w30231.pdf Id.*

Due to the absence of a PBM, OWCP could not capitalize on strategies typically facilitated by a PBM. For instance, OWCP did not have a process to identify other available pricing models or ensure its pricing was competitive with others in the industry. Specifically, OWCP did not compare its pricing to publicly available benchmarks, such as the MAC, NADAC, and the ACA Federal Upper Limit. Additionally, OWCP did not have a mechanism, or a contract, to incorporate rebates for pharmacy expenditures in its Federal Employees' Compensation Act (FECA) pharmaceutical program. The report noted that these rebates could have resulted in substantial savings for brand-name prescription drugs. As a result, the failure to incorporate these measures reportedly led up to $321.3 million in excess spending during the audit period.[295]

A 2021 study compared the experience of two State Medicaid programs managing their specialty pharmacy benefits with respect to Hepatitis C therapies: Michigan, which centralized purchasing Hepatitis C drugs from manufacturers, and Illinois which relied on PBMs to manage purchasing and utilization of the drugs. Using CMS drug purchasing data from 2015 to 2019, the study found that Illinois's PBMs purchased cheaper generic alternatives when they became available in 2019. In contrast, Michigan continued to purchase more expensive brand-name prescription drugs. These findings suggest that Illinois, through their PBM, was able to quickly pivot to cheaper generic alternatives as soon as they were available, while Michigan continued to rely on more expensive brand drugs, resulting in a 55 percent gap in unit prices between the two States. This translated into additional costs for Michigan of $36 million in the latter part of 2019 alone.[296]

Following West Virginia's decision to carve prescription drugs out of their Medicaid managed care program in 2017, its Department of Health and Human Resources, Bureau for Medical Services commissioned a report to assess the potential savings they achieved from moving from a PBM-related managed care organization (MCO) to a fee-for-service approach. The report projected West Virginia would save $50 million in administrative costs under the change.[297]

However, later that year, America's Health Insurance Plans (AHIP) commissioned a review of that West Virginia study, which argued the projection was overstated, as the actual savings accounted for less than five percent of MCO administrative expenses, totaling approximately $9 million. The AHIP report found that, between April 2016 and June 2017, the use of generics declined by 0.6 percentage points (from 86.5 percent to 85.9 percent) resulting in a 12.5 percent increase in the cost per prescription. It also argued that while some administrative costs would be eliminated under a pharmacy carve-out, such as the need for a Medicaid pharmacy director and fewer provider calls related to the prescription drug benefit, these savings were minimal, amounting to only two to three percent of overall administrative costs. The carve-out model also introduced new costs for West Virginia as the health plan would still need to obtain and manage prescription drug data for patient care coordination. Additionally, under the carve-out model, MCOs no longer receive this data in the format they use, but instead according to the State's required transmission format. Adapting to this format may require modifying the data system, which would add to the administrative costs. As a result, the AHIP report argued that cost increases associated with the carve-out model outweighed the savings, leading to an additional $18 million in annual Medicaid spending.[298]

7.2. Research Finding That PBM Business Practices Lead to Higher Prescription Drug Costs

Other sources suggest that PBM business practices may lead to higher prescription drug costs for employers, health plans, participants, and pharmacies. For instance, a 2024 investigation by the New York Times found that PBMs pushed patients toward higher out-of-pocket cost drugs, marked up low-cost prescription drugs excessively, and drove local pharmacies out of business. The investigation also found that PBMs restricted access to prescriptions by requiring patients to use their own mail-order or specialty pharmacies, even when a local pharmacy could have filled the prescription more quickly, resulting in a delay in treatment. The investigation provided an example of one PBM that overcharged the State employee health plan in Oklahoma by more than $120,000 annually for a cancer drug, charging the plan $138,000 annually for a prescription drug that the patient could purchase online for $14,000.[299]

The 2024 investigation discussed several PBM practices which ultimately contribute to higher prescription drug costs. First, PBM's demand for increasing discounts or rebates from drug manufacturers for a drug's formulary placement may raise prescription drug list prices as drug manufacturers attempt to maintain their profit margins. This can result in higher out-of-pocket costs for patients, particularly if their cost sharing is a percentage of the list price. Additionally, this can lead to PBMs diverting patients toward brand-name prescription drugs, whose higher list prices result in greater rebates, rather than generic alternatives. However, higher list prices can also lead to increased out-of-pocket costs for patients. Furthermore, PBMs influence the prescription cost options available to employers, who often select plans based on perceived cost savings. The cost controls that PBMs market to employers to reduce premiums or plan expenditures, however, can result in higher out-of-pockets costs for employees due to less favorable copayments or coinsurance.[300]

The U.S. Senate Committee on Finance considered the role of PBM rebates in its 2021 investigation on the cost of insulin and the role of PBMs and manufacturers in influencing prices.[301] The Committee found insulin prices rose between 33 and 70 percent between 2014 and 2019, driven by both manufacturer pricing strategies and PBM practices. Manufacturers raised

[295] U.S. Department of Labor, Office of Inspector General-Office of Audit, *Report to the Office of Workers' Compensation Programs, OWCP Did Not Ensure Best Prices and Allowed Inappropriate Potentially Lethal Prescriptions in The FECA Program* (Mar. 31, 2023), available at *https://www.oig.dol.gov/public/reports/oa/2023/03-23-001-04-431.pdf.*

[296] Ike Brannon & Anthony L. Sasso, *The Myth That the State Can Do It Better: Hepatitis C Drug Centralized Pharmaceutical Purchasing Versus Pharmacy Benefit Managers* (May 25, 2021), available at *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3852446.*

[297] Navigant, *Pharmacy Savings Report: West Virginia Medicaid, Actuarial Assessment of the SFY18 Impact of Carving out Prescription Drugs from Managed Care for West Virginia's Medicaid Program* (Feb. 25, 2019), available at *https://www.ncpa.co/pdf/state-advoc/west-virginia-report.pdf.*

[298] Alex Cohn, Joel Menges, Amira Mouna, & Leigh Schreiber, *Assessment of Report on Impacts of West Virginia Medicaid Prescription Drug Carve-Out, Prepared for America's Health Insurance Plans,* The Menges Group (Apr. 2019), available at *https://themengesgroup.com/wp-content/uploads/2022/06/assessment_of_study_of_wv_rx_carve-out_impacts_april_2019.pdf.*

[299] Rebecca Robbins & Reed Abelson, *The Opaque Industry Secretly Inflating Prices for Prescription Drugs,* The New York Times (June 21, 2024), available at *https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html.*

[300] *Id.*

[301] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 14, 2021), available at *https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.*

their WAC or list prices, repeatedly, often in tandem with competitors, without improvement in drug efficacy. Meanwhile, the three largest PBMs accepted generous rebates that were tied to these higher list prices, leveraging formulary exclusions to pressure manufacturers into offering large rebates in exchange for formulary placement.

Manufacturers maintained or raised list prices to ensure PBM rebates and protect their products' formulary placement, resulting in dramatic increases in rebates for insulin prescriptions during that period. Examining the growth by specific manufacturers, the Committee reported that Sanofi's rebates increased by approximately 50 percent between 2013 and 2018, and Novo Nordisk's rebates increased by approximately 20 percent between 2014 and 2017. The Committee concluded that PBM contracting did little to control insulin pricing, and in many cases, made the problem worse.[302]

These findings were corroborated by a 2021 cross-sectional study which found that while average list prices for 32 insulin products increased by over 40 percent between 2014 and 2018, the average net prices received by manufacturers fell 31 percent. Moreover, while the share of insulin expenditures accruing to manufacturers and health plans fell respectively by one-third and one-quarter in that time period, the share of insulin expenditures retained by pharmacies increased by 229 percent, the share retained by PBMs increased 155 percent, and the share retained by wholesalers increased by 75 percent.[303]

Furthermore, a Delaware State auditor report examined the PBM Express Scripts' management of State employee prescription drug plans between 2018 and 2020 and found that administrative fees, spread pricing, and direct pharmacy fees led to $24.5 million in excess costs. During this period, the average cost per prescription under the State plan increased by 14.3 percent, which was nearly triple the national drug inflation rate of 4.7 percent. Despite using a pass-through pricing model, Express Scripts charged the State over $104 million in administrative fees, averaging $21.05 per claim or nearly 13 percent of total claim costs. The report also highlighted that, in a sample from one independent pharmacy, Express Scripts paid nothing to the pharmacy for the 9,255 claims (39 percent of the sample), while still billing the State plan a total of $109,504 for those claims. In many of these instances, the employees' copayments appeared to cover the cost of the drug, raising concerns that the PBM retained 100 percent of the amount billed as profit.[304]

8. Research on How PBM Disclosures Impact Prescription Drug Costs

Prior to 2023, the FTC issued several advocacy letters and studies that opposed greater PBM transparency and disclosure requirements, arguing that such disclosures could undermine competitive processes. However, the FTC reversed this position in 2023, following compelling evidence and congressional pressure from Senator Grassley[305] and others, and withdrew those letters and studies, cautioning that horizontal and vertical integration in the industry along with other practices meant that their prior materials may not reflect current market dynamics.[306] This withdrawal underscores the need to assess how PBM disclosures affect the pharmaceutical market. Some studies suggest that PBM disclosures can lower prescription drug costs by improving the negotiation leverage of responsible plan fiduciaries, whereas other studies find that they may inadvertently increase costs by reducing competition among PBMs, pharmacies, and manufacturers. In contrast, other studies find that the effects of PBM disclosures vary depending on market conditions. These studies are discussed in greater detail below.

8.1. Research Finding That PBM Disclosures Lowers Prescription Drug Cost

Some studies have found that PBM disclosures may help reduce prescription drug costs. For example, in October 2024, CBO analyzed various approaches to reducing prescription drug prices, including price transparency. CBO estimated that requiring PBMs to share their prescription drug price information with health issuers would reduce prescription drug prices by 0.1 percent to 1.0 percent. CBO noted that increased transparency would help some PBM clients, particularly smaller plans, negotiate better contract terms. These plan sponsors often have limited access to pricing information, and such disclosure requirements would improve their bargaining position. CBO predicted that the overall impact of these disclosures would be limited, as many existing contracts between PBMs and plan sponsors in the private health insurance market already include provisions for information sharing, suggesting a significant portion of the insured market would remain unaffected.[307] However, the self-insured plans covered in this final rule is not subject to state disclosure laws, thus the final rule could have a bigger impact than CBO's estimates.

Similarly, in December 2024, CBO estimated the budgetary effects of a bill, the *Pharmacy Benefit Manager Reform Act,* which would require PBMs to annually report detailed information to plan sponsors about their services, though disclosures to plans sponsors for businesses with fewer than 50 employees would be more limited.[308] The bill would also ban spread pricing and require PBMs and their affiliates to pass 100 percent of the rebates, fees, discounts, or other remuneration received from pharmaceutical manufacturers, distributors, or other third parties related to use of prescription drugs by plan enrollees to plan sponsors.

CBO estimated that this bill could reduce net retail prescription drug costs by more than 0.5 percent in the first full year of implementation, which could lower average premiums for employment-based health insurance by less than 0.1 percent in the first year, compared to what they would be under current law. CBO estimated that the effect on premiums would diminish over time, reaching less than 0.01 percent by 2034 as PBMs employ new ways to generate revenue outside of the disclosure requirements. However, this does not imply that premiums would decline; rather, premiums are still

[302] *Id.*

[303] Karen Van Nuys, Rocio Ribero, Martha Ryan, & Neeraj Sood, Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018, *JAMA Health Forum* (Nov. 5, 2021), available at *https://pubmed.ncbi.nlm.nih.gov/35977268/.*

[304] State of Delaware, Office of Auditor of Accounts, *Lack of Transparency & Accountability in Drug Pricing Could be Costing Taxpayers Millions* (June 17, 2021), available at *https://auditor.delaware.gov/wp-content/uploads/sites/40/2021/06/RPT_PBM_061721_FINAL.pdf.*

[305] Press release, Senators Push FTC to Review Pharmacy Benefit Managers' Role in Insulin Prices (May 19, 2022), available at *https://www.grassley.senate.gov/news/news-releases/senators-push-ftc-to-review-pharmacy-benefit-managers-role-in-insulin-prices.*

[306] Federal Trade Commission, *Federal Trade Commission Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports That No Longer Reflect Current Market Realities* (July 18, 2023), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf.*

[307] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices* (Oct. 2024), available at *https://www.cbo.gov/system/files/2024-10/58793-rx-drug-prices.pdf.*

[308] *S.1339—Pharmacy Benefit Manager Reform Act,* 118th Congress (2023–2024), *https://www.congress.gov/bill/118th-congress/senate-bill/1339.*

expected to increase, but at a slower rate than they would have otherwise.[309] As the final rule does not prohibit spread pricing or require that PBMs pass on 100 percent of rebates, fees, or discounts that they receive from manufacturers, the Department believes that PBMs may not need to offset these revenue sources and that the impacts of the final rule would not diminish to the extent that CBO had estimated for the *Pharmacy Benefit Manager Reform Act.* The Department discusses the possibility of the final rule's impact diminishing over time in the Uncertainty Section of this regulatory analysis.

8.2. Research Finding That PBM Disclosures Increases Prescription Drug Cost

Other studies have found that PBM disclosures may increase prescription drug costs. For instance, a 2023 industry paper commissioned by a PBM trade association analyzed the impact of disclosure requirements, such as the *PBM Transparency Act of 2023,*[310] on competition among PBMs, manufacturers, and pharmacies. Although the proposed bill would have prohibited PBM pricing practices, including spread pricing, the paper specifically examined the effects of its disclosure requirements. The paper argues that disclosure requirements could increase prescription drug prices by reducing competition across these groups. By requiring manufacturers to disclose pricing details, the author contends that manufacturers may hesitate to offer significant discounts, fearing competitors will mimic their pricing strategies. This can lead to implicit price coordination, where manufacturers keep prices higher to avoid undercutting each other, resulting in a potential cost of up to $26.9 billion.[311]

This phenomenon is documented in the 2021 Senate Finance Committee Report, which found that PBMs' negotiations with insulin manufacturers, including the use of formulary exclusions, encouraged manufacturers to rapidly increase their list price in parallel with competitors. This practice, known as ''shadow pricing,'' occurs when one manufacturer closely follows another's price increase to remain competitive for preferred formulary placement. This approach enables manufacturers to provide large rebates and maintain market access.[312] The 2023 industry paper further argues that disclosures could increase costs of pharmacies by $8.0 billion and by PBMs by as much as $48.0 billion if tax distortion from rebates or discounts applied at the point of sale are included.[313]

However, as mentioned above, while the FTC issued 11 advocacy letters and reports prior to 2015 which argued that certain State and Federal proposals to increase PBM transparency could undermine competitive processes, the FTC issued a statement withdrawing this stance in 2023. In the statement, the FTC cautioned against reliance on those letters as they may no longer reflect current market realities, raising ''its concerns about how PBMs may be using market power to undermine competition from independent pharmacies, and its concerns about the role of PBMs in determining the prices consumers pay for prescription drugs, including the impact of PBM rebates.'' [314]

8.3. Research Finding That PBM Disclosures Have Mixed Impact on Prescription Drug Costs

In contrast, some research finds mixed results regarding PBM disclosures on prescription drug costs and other aspects of the market. For example, a 2025 study examining Medicare Part D data from 2016 to 2022 found that state laws requiring PBMs to disclose rebate information did not reduce prescription drug costs, including premiums, deductibles, or out-of-pocket spending. The study also found no meaningful differences in responses between PBM-affiliated and unaffiliated plans. However, the authors identified a spillover effect in multi-state plans, where states without transparency laws experienced roughly a seven percent increase in drug costs compared to states with transparency requirements. These findings suggest that while disclosure mandates may improve transparency, their direct effects on consumer drug spending remain uncertain.[315]

Additionally, Scanlon (2024) used outpatient prescription drug claims data for chronic conditions of employer-sponsored health plans from 2014 to 2022 to examine two types of State-level PBM disclosures: inter-firm disclosures [316] and disclosures to regulators.[317] Focusing on disclosures related to rebate/pricing information, the paper found that the impact of inter-firm disclosures, those most like the ones contemplated in this rulemaking increased prescription drug costs for plans (the plan's share of the gross price for the prescription as negotiated between the health plan and PBM, after factoring in fee schedules and discounts) by 3.5 percent, but reduced out-of-pocket costs for participants (the sum of the copayment and coinsurance) by 1 percent.[318]

However, the impact of inter-firm disclosures varied by the competitiveness of the drug market. In competitive markets, the disclosures increased costs to plans while the impact on participants was insignificant. Alternatively, in monopoly drug markets, there was no significant impact on plans while patient costs significantly declined. The author argues this was because in competitive markets, disclosing price information reduces competition between drug manufacturers which increased gross prices and the plans' total costs; in a monopoly market, disclosures reduced information asymmetry and strengthened health plans' bargaining power, resulting in a 9.4 percent decrease in out-of-pocket costs for these drugs. Additionally, States that required PBMs to disclose to pharmacies the sources used to determine MAC prices and update the information regularly, had 8.6 percent

[309] Congressional Budget Office, *Cost Estimate of S. 1339 Pharmacy Benefits Manager Reform Act* (Dec. 5, 2024), available at *https://www.cbo.gov/system/files/2024-12/s1339.pdf.*

[310] *S.127—Pharmacy Benefit Manager Transparency Act of* 2023, 118th Congress (2023–2024), *https://www.congress.gov/bill/118th-congress/senate-bill/127.*

[311] Casey B. Mulligan, *Restrict the Middleman? Quantitative Models of PBM Regulations and Their Consequences,* National Bureau of Economic Research (Mar. 2023), available at *https://www.nber.org/system/files/working_papers/w30998/w30998.pdf.*

[312] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 14, 2021), available at *https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.*

[313] Casey B. Mulligan, *Restrict the Middleman? Quantitative Models of PBM Regulations and Their Consequences,* National Bureau of Economic Research (Mar. 2023), available at *https://www.nber.org/system/files/working_papers/w30998/w30998.pdf.*

[314] Federal Trade Commission, Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports that No Longer Reflect Current Market Realities, (July 20, 2023), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf.*

[315] Nicola Maria Fiore, *Can Transparency Reduce Drug Costs* (as revised, Apr. 17, 2026), available at *https://ssrn.com/abstract=5710162; http://dx.doi.org/10.2139/ssrn.5710162.*

[316] ''Inter-firm disclosures'' are defined as disclosures where PBMs share pricing information with health plans, pharmacies, and drug manufacturers. As referred to in this paper, ''health plans'' include health insurance issuers.

[317] ''Disclosures to regulators'' are defined as disclosures where PBMs report pricing details to government authorities. These included state regulations related to auditing, pharmacy networks and fiduciary duties.

[318] Ginger Scanlon, *Prescription for Savings? Disclosure in the Drug Market* (Dec. 20, 2024), available at *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5021179.*

more pharmacies per capita and 10 percent more independent pharmacies overall than States that did not require those disclosures, improving patient access.[319]

The author concluded that inter-firm disclosures increase costs for plans but lower them for participants. This effect depended on the competitiveness of the drug market. For monopoly drugs, inter-firm disclosures resulted in more efficient contracting, which led to lower drug costs. When applied to more competitive markets, however, the disclosures discouraged competition among drug manufacturers. As a result, the author advocated for utilizing PBM disclosures in monopoly drug markets. The Department notes that the study was limited to actual amounts paid by plans and participants per prescription and did not account for rebates and other incentive payments to health plans that may have been applied later. As a result, the negative impact on plan costs of inter-firm disclosures may be overstated.[320]

9. Benefits and Transfers

The Department expects that the final rule would improve transparency in PBM operations, as directed by Executive Order 14273.[321] The final rule is expected to assist responsible plan fiduciaries in their selection and monitoring of service providers providing prescription drugs, and to foster a more efficient and competitive prescription drug market. These improvements are anticipated to generate the following economic and societal effects experienced by participants, beneficiaries, enrollees, and the broader healthcare system:

- improved understanding of PBMs by self-insured group health plans' responsible plan fiduciaries,
- greater ability for responsible plan fiduciaries to compare offerings across PBMs, fostering competition and improving pricing,
- stronger negotiating positions for responsible plan fiduciaries, enabling better contractual terms with PBMs,
- reduced conflicts of interest that currently influence PBMs' key decisions regarding rebates, formulary design, and prescription drug pricing,
- reduced prescription costs for self-insured group health plans and participants,
- improved patient health outcomes due to increased treatment adherence from better access to more affordable prescription drugs,
- reduced costs to self-insured group plans and employers, allowing them to shift resources to other benefits or priorities.

This analysis provides both a qualitative discussion of the benefits and transfer impacts of the final rule as well as a quantitative analysis of the benefits. The Department's qualitative discussion focuses on how the final rule would enable self-insured group health plans, participants, and other stakeholders to better utilize the information provided by PBM disclosures.[322] The Department received multiple comments stating that increased transparency would reduce hidden fees, strengthen fiduciary oversight and negotiations, lower prescription drug costs, improve patient access to medications, and promote competition based on price and value rather than opaque financial arrangements. The Department agrees with the commenters regarding these anticipated benefits.

The Department also included in the proposed rule a quantitative analysis on the impact of lowered negotiating costs to self-insured group health plans and plan sponsors and reduced prescription drug costs for self-insured group health plans and participants. In the proposal, the Department utilized two alternative approaches, direct Willingness-to-Pay (WTP) and Quality Adjusted Life Years (QALY), to quantify the benefits from price decreases and requested comments on the appropriateness of each approach. Upon reviewing comments and further analysis, the Department has determined the WTP approach is more appropriate for this analysis. The Department has also included a QALY analysis in the uncertainty section.

WTP is defined as the maximum amount of money an individual would voluntarily exchange to obtain a benefit, given their budget constraints.[323] [324] [325] Because WTP is expressed in monetary terms, it is directly comparable to costs. In the context of reduced prescription drug prices, ideally WTP would measure, through consumer preferences, the total value patients place on improved medication adherence and the health improvements that follow—which would encompass reduced healthcare expenditures, extended life expectancy, and improved quality of life (possibly *net* quality changes including long-term improvements but also more immediate side effects). In this sense, a WTP-based consumer surplus measure would measure the direct welfare gained from the price reduction.

In contrast, QALYs indirectly measure welfare gains from improved health outcomes. Utilizing observed and reported patient health outcomes, QALYs quantify health gains in standardized units which allows them to be monetized using an indirect WTP value, such as the value of a statistical life (VSL), to compare health benefits to regulatory costs. QALYs are also a widely utilized measure in the health economics literature.[326] While they remain a comprehensive and accepted indirect measure of health outcome benefits, QALYs suffer from restrictive assumptions about how to value different health states, such as QALY gains being measured proportionally regardless of health state or age.[327]

Having weighed the attributes and limitations of both approaches, the Department has decided to pursue the WTP approach for the final rule. This decision is supported by other commenters, who advocated the use of WTP over QALY.[328] They argued that current regulatory guidance indicates direct WTP is the preferred measurement and that WTP more accurately captures the welfare impacts of all affected participants.[329]

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[319] *Id.*

[320] The author utilizes the MarketScan prescription claim database for her analysis, which reports actual payment amounts paid by health plans and patients per prescription. The database does not include information on net costs to plans, meaning that rebates or other forms of incentive payments that may later offset costs to plans were not captured.

[321] *Lowering Drug Prices by Once Again Putting Americans First,* 90 FR 16441 (Apr. 15, 2025), available at .*https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf.*

[322] If the various mechanisms and outcomes discussed above could be quantified and were then summed simplistically, the result would almost certainly include double counting.

[323] Office of Management and Budget, *Circular A–4* (Oct. 9, 2003), available at *https://www.federalregister.gov/documents/2003/10/09/03-25606/circular-a-4-regulatory-analysis.*

[324] Department of Health and Human Services, *Guidelines for Regulatory Impact Analysis* (2016), available at *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//171981/HHS_RIAGuidance.pdf.*

[325] Environmental Protection Agency, *Guidelines for Preparing Economic Analyses* (Dec. 2024), available at *https://www.epa.gov/system/files/documents/2024-12/guidelines-for-preparing-economic-analyses_final_508-compliant_compressed.pdf.*

[326] James Hammitt, *QALYs Versus WTP,* Risk Analysis, Vol. 22, No. 5, (2002).

[327] Matthew Adler, *QALYs and Policy Evaluation: A New Perspective,* Yale Journal of Health Policy, Law, and Ethics (2006).

[328] Comment ID: EBSA–2026–0001–0056.

[329] The most direct consumer impact of this final rule is reducing prescription drug prices, so analytically, it is feasible to use a direct-WTP approach to valuing morbidity effects, per HHS's Guidelines for Regulatory Impact Analysis: ''Analysts should first . . . determine whether suitable WTP estimates of reasonable quality are

Continued

Upon reviewing the comments, the Department has revised some of its underlying assumptions and application of the methodologies discussed to assess benefits of this final rule. These changes will be discussed in greater detail in the affected sections.

9.1. Benefits and Transfers to Self-Insured Group Health Plans

9.1.1. Improved Understanding of PBMs by Plans

PBM disclosures would provide self-insured group health plans with greater insight into previously hidden fees, rebates, and discounts, as well as potential conflicts, which would lead to a better understanding of PBM costs and practices. For example, these disclosures would reveal to self-insured group health plans how much of the negotiated rebates are retained by PBMs and their agents, versus being passed through to self-insured group health plans, participants, and beneficiaries, enabling them to accurately assess the true costs of pharmacy benefits and if they are reasonable. Self-insured group health plans would be able to compare the prices they were charged for pharmacy claims to the reimbursement rates pharmacies received from PBMs through ''spread pricing,'' and how much participants and beneficiaries paid at the point of sale through copays and coinsurance. This would allow self-insured group health plans to calculate how much the PBMs collected from each transaction. As a result, self-insured group health plans would more easily be able to monitor PBMs and the indirect fees they charge.

9.1.2. Increased PBM Market Place Competition and Self-Insured Group Health Plans Negotiating Better Contractual Terms

Increased transparency into compensation arrangements would help self-insured group health plans better assess costs across different PBM providers, leading to more informed decision-making when selecting a PBM, increasing competition, and allowing self-insured group health plans to negotiate better contract terms.[330] Requiring PBMs to disclose pricing structures, discounts, and rebates reasonably in advance of entering into a contract or arrangement with a self-insured group health plan will help responsible plan fiduciaries determine the reasonableness of the proposed fees, including all direct and indirect compensation. Moreover, these disclosures could limit PBMs' ability to engage in spread pricing or accept undisclosed rebates, helping to ensure that formulary and reimbursement decisions better reflect clinical value and affordability.[331]

When evaluating the potential impact of a bill requiring additional transparency by PBMs related to utilization and direct and indirect compensation (as well as banning spread pricing and requiring pass-through rebates), CBO estimated only minimal cost savings, with premiums reduced by 0.1 percent in the first year of the rule with those savings eroding over time.[332] In their analysis, CBO stated that they also expected a portion of PBM clients, particularly sponsors of small- and medium-sized health plans, who had limited access to this information under current law, to obtain better terms in contract negotiations following these disclosures. The additional pressure from responsible plan fiduciaries coupled with more transparent pricing could lead to new entries in the PBM market, including pass-through and fee-based models, and could result in market-wide changes in pricing behavior. CBO did not, however, estimate these second-order effects.

While commenters couldn't provide market-share data on pass-through PBMs, they indicated it was growing as ''employers become more aware of the pricing distortions in traditional PBM models.'' A 2024 survey aimed to gauge U.S. employers' perspectives on various factors, including PBM transparency and premiums, among private and public employers suggests these new entries were viewed favorably. The findings indicated that employers who used transparent PBMs were 1.6 times more likely to report lower premiums (42 percent compared to 27 percent) and 30 percent less likely to report higher premiums (29 percent compared to 41 percent) than those utilizing the three largest PBMs.[333]

Additionally, by requiring disclosures that clearly define contract terms, responsible plan fiduciaries can better assess potential cost levers when evaluating proposals. Currently, PBMs may provide their own definitions for brand, generic and specialty drugs. In doing so, PBMs can change a drug's classification to meet contracted guarantees or maximize their own fees. This can allow PBMs to classify certain prescription drugs as ''specialty'' drugs to justify higher markups or cost-sharing requirements.[334] By requiring PBMs to disclose spread pricing at the individual drug and pharmacy channel level, how formulary placement incentives and arrangements affect services, and reasons why reasonably available therapeutic equivalent alternative drugs (including biosimilar biological products) were omitted from the formulary, responsible plan fiduciaries can attain more appropriate formulary placement, more equitable patient cost-sharing, and broader access to prescription drugs that have been previously miscategorized, which could result in reduced prescription drug spending for large, self-insured group health plans and lower out-of-pocket costs for participants.

Similarly, definitions of rebates and discounts can be manipulated by PBMs to exclude ''other'' indirect payments to avoid contractual pass-through payments. This can be particularly problematic when PBMs contract with an affiliated service provider that can in turn influence how acquisition costs or rebates are defined, allowing gaming of contracts.[335] By clarifying these terms prior to entering agreements, responsible plan fiduciaries can negotiate better contract terms. A 2024 survey found that 33 percent of employers had lower than average premiums following the adoption of more comprehensive definitions of the term ''rebate'' to include other revenue streams, such as access fees and credits in their contracts.[336]

available. If not, they should use monetized QALYs'' (p. 18).

[330] Matthew Fiedler, Loren Adler, & Richard G. Frank, *A Brief Look at Current Debates About Pharmacy Benefit Managers,* The Brookings Institution (2023), *https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/.*

[331] National Alliance of Healthcare Purchaser Coalitions, *A Playbook for Employers: Addressing Pharmacy Benefit Management Misalignment* (2023), available at *https://www.nationalalliancehealth.org/wp-content/uploads/NationalAlliance_PBM_PB_2023_A.pdf.*

[332] Congressional Budget Office, *S. 1339, Pharmacy Benefit Manager Reform Act* (2024), *https://www.cbo.gov/system/files/2024-12/s1339.pdf.*

[333] National Alliance of Healthcare Purchaser Coalitions, *Pulse of the Purchaser 2025 Survey Results* (Sept. 8, 2025), *https://www.nationalalliancehealth.org/resources/pulse-of-the-purchaser-2025-survey-results/.*

[334] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (2024), *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

[335] National Alliance of Healthcare Purchaser Coalitions, *A Playbook for Employers: Addressing Pharmacy Benefit Management Misalignment* (2023), *https://www.nationalalliancehealth.org/wp-content/uploads/NationalAlliance_PBM_PB_2023_A.pdf.*

[336] National Alliance of Healthcare Purchaser Coalitions, *Pulse of the Purchasers: 2024 Survey Reports,* (2024), *https://www.nationalalliancehealth.org/wp-content/uploads/Pulse-of-the-Purchaser-Fall-2024.pdf.* It is important to note that 9 percent of respondents

The additional transparency and clarified terms can also reduce the complexity and scope of comparing proposals and contract negotiations, further reducing costs for self-insured group health plans. By removing the need for self-insured group health plans to independently verify price models, rebates, and fee structures, the required disclosures would limit search costs and reduce the resources needed to select a PBM and prepare for contract negotiations. Even a modest reduction in preparation costs, such as a one-hour reduction in the time for a legal professional to prepare for negotiations, could result in estimated cost savings of approximately $7.1 million across the 39,331 impacted self-insured group health plans that are expected to initiate new contracts, extend existing contracts, or renew contracts each year.[337]

By obtaining disclosures in advance of finalizing the contract, responsible plan fiduciaries can identify problematic provisions and negotiate modifications with the PBMs. For example, this allows responsible plan fiduciaries to negotiate the removal of certain contractual terms that may limit the fiduciary from obtaining data related to prescription drugs, and negotiate for stronger audit rights in order to verify claim accuracy, monitor the PBMs' performance, and ensure contract compliance.[338] As a result, increased transparency could foster greater competition within the market, leading to more competition, lower prices and improved contract terms, as well as better value and lower health-care costs for self-insured group health plans and their participants and beneficiaries. The resulting savings could in turn allow self-insured group health plans, employers, and plan sponsors to invest those resources elsewhere.[339]

9.1.3. Reduced Conflicts of Interest in PBM Practices

Greater transparency in PBM operations could help reduce the conflicts of interest that influence PBMs' key decisions regarding rebates, formulary design, and reimbursement rates. Currently, PBMs often have significant existing relationships with consultants, manufacturers, rebate aggregators, and pharmacies which can circumvent claims of transparency in pricing. Even consultants advising plans on the selection of PBMs and the structure of their contracts may receive payments from PBMs based on the number of prescriptions or the number of covered employees, which may well influence their recommendations to plans.[340] Employers that receive confirmation that advisors do not receive direct or indirect compensation from PBMs or related third parties reported reduced annual premiums.[341]

Even with pass-through pricing enshrined in PBM contracts, without disclosures detailing existing relationships, these agreements can be compromised if PBMs subcontract with affiliated service providers. PBMs may structure preferred pharmacy networks so that patients are directed or are required to fill prescriptions at PBM-affiliated pharmacies, which are then reimbursed at a greater rate than independent pharmacies.[342] In contrast, requiring full disclosures of all revenue streams with affiliated pharmacy-related entities can result in reduced premiums.[343] PBMs may also utilize rebate aggregators to negotiate and collect rebates from drug manufacturers, whose extracted fees have been estimated to have doubled between 2018 and 2022. PBMs that use affiliated rebate aggregators can reduce the rebate that would be passed through to plans while retaining the rebate portion collected by the rebate aggregators if that relationship is not disclosed and addressed in the contract, resulting in higher plan costs.[344]

By requiring PBMs to disclose these relationships prior to entering into a formal agreement, the rule enables responsible plan fiduciaries to better evaluate whether there are sufficient mechanisms in place to ensure that those relationships do not adversely impact the self-insured group health plan and its participants and beneficiaries. Moreover, receiving updated information over the course of the contract will allow responsible plan fiduciaries to continue to monitor these relationships so that PBMs continue to perform their function without subordinating plan interests. As such, the final rule will help to reduce conflicts and mitigate the risks that arise from them, resulting in more efficient and cost-effective pharmacy benefits for self-insured group health plans, including the replacement of more expensive drugs with cheaper, yet equally effective alternatives on the formularies.

9.2. Transfers and Benefits to Participants and Beneficiaries

9.2.1. Improved Health Benefits From Greater Drug Adherence

The disclosures required of PBMs in the final rule will help to reduce information asymmetry and aid self-insured group health plans' responsible plan fiduciaries in their selection of and negotiations with PBMs, helping to reduce costs for the self-insured group health plans and lower prescription drug prices.[345] By reducing prescription costs, the final rule could improve adherence to prescribed drugs, as patients are less likely to skip or reduce doses, delay refills, or forgo treatment due to financial concerns. Improved treatment adherence supports disease management and is associated with better overall health outcomes. Research corroborates that poor treatment adherence is associated with poorer health outcomes and significantly higher mortality rates.[346] [347] In the

reported high premiums following adoption of enhanced definitions of rebates.

[337] This estimate is calculated as: 131,102 self-insured group health plans × ⅓ of plans contracts with PBMs expiring annually = 39,331 self-insured group health plans negotiating contracts annually × $181.06 hourly wage of legal professional × 1 hour = $7,121,198.

[338] Remy Samuels, *PLANSPONSOR Roadmap: A PBM Process* (Apr. 21, 2025) *https://www.plansponsor.com/plansponsor-roadmap-a-pbm-process/.*

[339] See discussion of the exclusive purpose rule in ERISA section 403(c), supra note 75.

[340] Advisory Council of Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure,* (Nov. 2014), available at *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure.pdf.*

[341] National Alliance of Healthcare Purchaser Coalitions, *Pulse of the Purchasers: 2024 Survey Reports* (2024), available at *https://www.nationalalliancehealth.org/wp-content/uploads/Pulse-of-the-Purchaser-Fall-2024.pdf.*

[342] U.S. House Committee on Oversight and Accountability, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* (2024), available at *https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf.*

[343] National Alliance of Healthcare Purchaser Coalitions, *Pulse of the Purchasers: 2024 Survey Reports* (2024), available at *https://www.nationalalliancehealth.org/wp-content/uploads/Pulse-of-the-Purchaser-Fall-2024.pdf.*

[344] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

[345] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices* (Oct. 2024), *www.cbo.gov/publication/58793.*

[346] Teresa B. Gibson, Xue Song, Berhanu Alemayehu, Sara S. Wang, Jessica L. Waddell, Jonathan R. Bouchard, & Felicia Forma, *Cost Sharing, Adherence, and Health Outcomes in Patients with Diabetes,* American Journal of Managed Care 16(7) (2010), *https://pubmed.ncbi.nlm.nih.gov/20712392/;* Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality, British Medical Journal,* (2006), available at *https://pmc.ncbi.nlm.nih.gov/articles/PMC1488752/pdf/bmj33300015.pdf;* Donald Pittman, William Chen, Steven Bowlin, and JoAnne Foody, *Adherence to Statins, Subsequent Healthcare Costs, and*

Continued

context of the final rule, the required disclosures could enable plan sponsors to design benefits and formularies that help reduce out-of-pocket costs and improve prescription adherence, particularly for patients at high risk of hospitalization which could ultimately improve patient health outcomes over the long term. These outcomes are embedded in the value quantified in Section 9.2.3.

9.2.2. Reduced Prescription Payments for Participants and Beneficiaries

The Department believes that increased transparency from PBM disclosures will reduce prescription prices, resulting in a transfer, by correcting pricing distortions that currently inflate the prices that participants and beneficiaries face for prescription drugs. By highlighting preferential pricing for certain drugs and distribution channels, disclosures may result in self-insured group health plans retaining greater rebate shares, increasing the use of generics and biosimilars, and promoting less expensive pharmacy networks. This can result in cost savings for self-insured group health plans, which may share these cost savings with plan participants through reduced premium payments, as well as lower out-of-pocket costs that participants and beneficiaries face when filling their prescriptions.

Manufacturers factor rebates into their bottom line, which incentivizes them to increase list prices of covered drugs to protect their net prices. As a result, patients may pay cost-sharing based on the drug's list price, even though the net price after rebates is substantially lower.[348]

A 2023 U.S. Senate Finance Committee hearing further discussed that rebate-driven models reward manufacturers with greater volume and market share, making it difficult for lower-cost or new competitors to gain formulary access. Existing manufacturers can offer large rebates by leveraging their sales volume or by bundling multiple drugs into a single rebate agreement. These arrangements can effectively exclude competitors that cannot match the financial value of rebates, even if they offer lower-price alternatives. The Committee characterized this dynamic as the ''rebate trap,'' in which rebates contribute to higher list prices, particularly for brand-name and specialty drugs. This dynamic reinforces market concentration and limits price competition, ultimately contributing to higher costs for self-insured group health plans and patients.[349]

As the prescription drug market becomes more transparent through the proposed disclosures, it may discourage PBM practices that favor high-rebate drugs over lower-cost drug alternatives. This shift could support more cost-effective and clinically driven formulary design. Moreover, PBMs may also pass through a greater share of the rebates to self-insured group health plans, ultimately helping to reduce prescription costs, particularly for specialty and brand-name drugs where rebate amounts tend to be the highest.[350] This, coupled with cost reductions stemming from improved contract negotiations related to spread pricing, copay claw-backs, and pharmacy reimbursement, may result in lower costs to participants and beneficiaries at the point of sale. Such reductions resulting from these disclosures would be particularly meaningful for individuals who heavily rely on prescription medication or who manage chronic health conditions, where even modest price differences can lead to substantial savings over time, and result in improved adherence to treatment plans.

Research from CBO on disclosures from PBMs to health plans estimated that requiring PBMs to share their drug price information with health issuers would lower the average net retail price of prescription drugs, approximately 0.1 percent to 1.0 percent.[351] Data from MEPS–HC indicates that average annual total prescription expenditures for individuals with private insurance aged 18 to 64 were approximately $1,548 for combined issuer and patient costs.[352] This translates into estimated, total prescription expenditures for self-insured participants and issuers of $81.8 billion annually.[353] Utilizing the CBO estimate of a one percent price reduction arising from PBM disclosures, the Department estimates that expenditures from patients and issuers will decline, producing an estimated $818.4 million transfer for the 52.9 million participants and beneficiaries [354] age 18 to 64 of large, self-insured group health plans covered by the final rule.[355] This estimate does not include the reduction in prescription costs for children in these plans, and therefore underestimates the full transfer effect. Because the policy estimated by CBO, however, is limited to only price disclosures and does not include information on conflicts of interest, audit rights and other additional elements of the final rule, this estimate may understate the impact of the final rule on prices.

The Department utilized the 1.0 percent price reduction estimated by CBO for the final rule in response to comments received. One commenter suggested that the CBO estimate likely underestimated the price reduction that would result from the rule, as the CBO estimate ''was based on a narrower set of transparency requirements than [the proposed rule].'' [356] The Department agrees that the rulemaking is more robust than the transparency requirements analyzed by CBO. Given the mixed results in the literature reviewed above, however, the quantitative range may also overstate the impact (and may even inappropriately omit any quantification of transfers potentially flowing the opposite direction). In response to this uncertainty, the Department also considered alternative rates of price reductions stemming from the increased transparency, ranging from a 0.5 percent to a 2 percent reduction in price. This analysis can be found in the Uncertainty section.

Cardiovascular Hospitalizations, American Journal of Cardiology 107(11) (2011), *https://pubmed.ncbi.nlm.nih.gov/21439533/.*

[347] Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality, British Medical Journal* (2006), available at *https://pmc.ncbi.nlm.nih.gov/articles/PMC1488752/pdf/bmj33300015.pdf.*

[348] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (2021), available at *https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.*

[349] United States Senate Committee on Finance, *Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayer* (Mar. 30, 2023), available at *https://www.finance.senate.gov/imo/media/doc/pharmacy_benefit_managers_and_the_prescription_drug_supply_chain_impact_on_patients_and_taxpayers.pdf.*

[350] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (2021), available at *https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.*

[351] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices* (2024), available at *https://www.cbo.gov/system/files/2024-10/58793-rx-drug-prices.pdf.*

[352] Based on data reporting insurer and patient expenditures for privately insured patients aged 18–64. *See* Department of Health and Human Services, Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey* (2025).

[353] This estimate is calculated as: $1,547.67 × 52,882,418 participants age 18 to 64 in large, self-insured plans = $81,844,531,866.

[354] Estimate is based on the Department's tabulations of the March 2025 Current Population Survey (CPS) Auxiliary Data.

[355] These estimates are calculated as: $81,844,531,866 × 1.00 percent = $818,445,319.

[356] Comment ID: EBSA–2026–0001–0056.

9.2.3. Quantified Benefits

While the Department utilized two different approaches to quantify benefits in the proposal, WTP and QALY, as discussed above, in response to comments and additional data the Department is using only the WTP method for its final rule analysis. Estimates using the QALY approach can be found in the Uncertainty section. Similarly, while an estimated price reduction of one percent is utilized for the primary analysis in this section, a sensitivity analysis utilizing estimates of 0.5 percent and 2.0 percent is included in the Uncertainty section.

9.2.3.1 Benefits Measured by Direct Willingness-to-Pay

The high rates of non-adherence for reasons of cost indicate a price level for many drugs that exceeds participant willingness-to-pay. This suggests that lowering prices will provide additional consumer surplus to participants and other purchasers of prescription drugs as many will improve their welfare from increasing consumption of their prescribed medications at lower prices. As insurers also contribute toward the cost of the drug through cost-sharing for the net retail price, the Department anticipates that insurers will also benefit from the additional consumer surplus gained from the final rule.

Utilizing data from MEPS–HC on average annual out-of-pocket expenditures for prescription drugs of participants in private group health plans in 2023 ($146), as well as the average annual expenditures from insurers for such participants in private group health plans ($1,402), the Department finds that the average annual expenditures for prescription drugs total $1,548.[357] This data also reports an annual average of 7 prescription fills for all such participants, suggesting an average prescription cost of $218 for combined insurer and participant expenditures.[358] Given an estimate of 52.9 million participants and beneficiaries, age 18 to 64 in large, self-insured group health plans [359] and assuming a similar utilization and cost of prescription drugs, the Department estimates total prescription drug expenditures for this population at approximately $81.8 billion arising from an estimated 375.5 million prescription fills annually.[360]

Research on demand for prescription drugs among those with commercial insurance indicates a price elasticity of approximately −0.358 across all prescriptions.[361] Utilizing the stated price elasticity, estimated price decrease, and prescription demand, the Department estimates that approximately 1.34 million additional prescription drugs will be purchased as a result of lower prices.[362] Given an average WTP of $218 per prescription, the Department estimates that the value of the gross willingness to pay would result in up to $293.0 million of benefits annually.[363] The $218 WTP includes not just consumers' but also insurers' portion of drug spending, reflecting an assumption that insurance markets capture pharmaceutical value, with such value taking various forms, including health improvements for consumers/patients and reduced non-adherence-related medical costs (with associated savings accruing to a combination of newly-adherent patients, premium-payers generally, and insurance companies).[364]

It is worth noting that this approach does not account for the marginal cost associated with the newly-filled prescriptions and therefore may overstate societal benefits of the final rule. The Department requested comments on refining the WTP approach and more generally on the preceding assumptions and calculations. The Department did receive several comments about the WTP approach.[365] Several comments provided general support for the WTP analysis, stating that it was more appropriate than QALY and would be the preferred approach as WTP more broadly captures the impact of the rule on all participants. One of the comments referenced OMB Circular A–4, suggesting that it indicates a clear preference for WTP over QALY-like measures. None of the comments offered data that might improve the WTP analysis from the proposal.

9.2.4. Transfers From Standard Traditional PBMs to Transparent PBMs

In response to the disclosure requirements, responsible plan fiduciaries may be increasingly inclined to utilize transparent PBMs like fully pass-through PBMs rather than PBMs using the standard business model. Under a fully pass-through pricing strategy, PBMs rely much more on administrative fees instead of other income streams, which can reduce hidden costs and conflicts of interest. This may be more attractive for responsible plan fiduciaries as it could potentially simplify auditing PBMs, lessening oversight and monitoring costs. One fully pass-through PBM testified before Congress that their first-year clients reported an average reduction in costs of 11 percent compared to other PBMs [366] while other fully pass-through PBMs have reported savings of as much as 30 percent.[367] As a result, in response to the final rule, responsible plan fiduciaries may engage fully pass-through PBMs in lieu of standard PBMs for their prescription drug services, resulting in a transfer of business across PBM type.[368]

One commenter stated that fully pass-through PBMs generally disclose more pricing information because their business model relies less on retained spread and manufacturer-side compensation. The commenter further indicated that the reported cost savings associated with fully pass-through PBMs are consistent with their experience in the market and emphasized that the price impact of

[357] Department of Health and Human Services, Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey* (2025).

[358] These estimates are calculated as $1,548 annual prescription expenditures ÷ 7.1 average annual prescriptions = $218 average cost of prescription for insurer and patient out-of-pocket expenses. Unrounded estimates are used in intermediate calculations, here and in subsequent analytic steps, and this practice explains any possible appearance of arithmetic discrepancies.

[359] Estimate is based on the Department's tabulations of the March 2025 Current Population Survey (CPS) Auxiliary Data.

[360] These estimates are calculated as: 52,882,418 participants in self-insured plans × 7.1 average prescription fills annually = 375,465,168 annual prescription fills for self-insured plan participants; $217.98 average cost × 375,465,168 prescriptions = $81.84 billion annual expenses for prescription drugs in large, self-insured plans.

[361] Abe Dunn, *Health Insurance and the Demand for Medical Care: Instrumental Variable Estimates Using Health Insurer Claims Data,* Journal of Health Economics, Vol. 48 (2016).

[362] This estimate is calculated as: −1 percent price reduction × −0.358 price elasticity × 375,465,168 prescriptions = 1,344,165 prescriptions.

[363] This estimate is calculated as: $217.98 average prescription WTP × 1,344,165 prescriptions = $293,001,152.

[364] Insurance markets are likely to be characterized by distortions, so an alternative approach to quantifying benefits might take the form of adding the consumer portion of pharmaceutical WTP to separately estimated changes in medical spending (see Table 11, later in this regulatory impact analysis). However, this approach may yield underestimates.

[365] Comment ID: EBSA–2026–0001–0056; EBSA–2026–0001–0258; EBSA–2026–0001–0458; EBSA–2026–0001–0484.

[366] Sharon Faust, *Prepared Testimony Before the United States Judiciary Committee* (May 11, 2025), available at *https://www.judiciary.senate.gov/imo/media/doc/2025-05-13_testimony_faust.pdf.*

[367] Alliance of Community Health Plans, *A Unique Approach: Transparent PBMs* (Apr. 2019), available at *https://achp.org/wp-content/uploads/PBM-Infographic_4.5.19.pdf.*

[368] Pharmaceutical Strategies Group, *2025 Trends in Drug Benefit Design Report* (June 2025), available at *https://link.psgconsults.com/2025-trends-in-drug-benefit-design-report.*

opacity in traditional PBM pricing structures can be substantial. Additionally, the commenter noted that the fully pass-through PBM market remains small relative to the larger vertically integrated PBMs, estimating that approximately ten percent or less of the market is currently served by fully pass-through PBMs. The Department appreciates the commenter's insights regarding pricing transparency, market structure, and the potential cost impacts associated with fully pass-through PBM models.

9.2.5. Transfers From PBM Affiliated Pharmacies to Unaffiliated Pharmacies

The final rule includes disclosures related to spread pricing, requiring information on the cost reimbursements for each drug on the self-insured group health plans' formulary for each pharmacy channel. Because PBMs often favor affiliated pharmacies, these disclosures may highlight price discrimination which has traditionally resulted in lower reimbursements and utilization rates for non-affiliated pharmacies. With the greater transparency required by the final rule, PBMs may choose to equalize treatment across all distribution channels which in turn may shift business from affiliated to non-affiliated pharmacies.

10. Costs

This final rule aims to enhance the responsible plan fiduciaries' ability to monitor costs and the administration of prescription drug benefits by PBMs, their agents, and affiliates, by requiring PBMs to provide disclosures regarding fees, pricing structures and potential conflicts of interest both prior to entering a service provider agreement, and semiannually during the agreement. In addition, PBMs must make available to responsible plan fiduciaries all information required to conduct audits to confirm the accuracy of any disclosure made to comply with the regulations.

Prior to this rulemaking, service providers that engage in consulting or provide brokerage services to self-insured group health plans for certain identified sub-services were already required under the CAA, 2021 to disclose to responsible plan fiduciaries a description of the service provided, direct and indirect compensation received, and the provider's fiduciary status with respect to the self-insured group health plan.[369] These disclosures are to be made not later than the date that is reasonably in advance of the date on which the contract or arrangement is entered into, extended or renewed. Moreover, while the Department did not issue specific rules governing these disclosures at the time, it provided guidance stating that the statute made unambiguous that covered service providers, as defined in the statute, must now disclose both direct and indirect fee compensation.[370]

When questioned by Congress in 2023 regarding PBMs' compliance with Section 408(b)(2), one PBM trade association responded that they believed their companies were in compliance and provided the appropriate disclosures related to direct and indirect compensation.[371] Additionally, several States have adopted disclosure requirements for PBMs regarding elements included in this final rule, including rebate payments, spread compensation and drug prices.[372]

This final rule provides a more detailed requirement of what information must be disclosed. It also requires initial disclosures and disclosures on a semiannual basis (or quarterly, at the plan's request) instead of just when the contract or arrangement is entered into, extended or renewed. As such, the Department assumes that PBMs already provide to various parties information like what is required under this final rule, though not necessarily at the same level of detail or frequency.

The Department acknowledges that PBMs, in revising their approach to documenting and disclosing their business practices to self-insured group health plans to be consistent with this final rulemaking, will incur additional costs. Moreover, by providing disclosures at a more granular level prior to entering into a formal agreement, the Department expects the self-insured group health plans may demand additional concessions, resulting in lower revenues for PBMs. This collection of costs would appropriately be included in any comparison with the benefits described, and in some cases illustratively quantified, elsewhere in this RIA.

10.1. Rule Familiarization and Compliance Costs

The Department anticipates that the costs related to this final rule will consist of both initial and annual costs. Initial costs include review of the regulation and identifying new requirements, developing templates for the new disclosures, and developing processes for capturing the necessary data (including automating systems). Ongoing costs will include the cost of producing the disclosures, transmitting them to responsible plan fiduciaries, and responding to audit requests.

Self-insured group health plans, issuers/State combinations, and TPAs are expected to review the final rule in order to familiarize themselves with the new requirements and how they will impact them. Self-insured group health plans with 1,000 or more participants and beneficiaries are expected to review the rule themselves. In contrast, self-insured group health plans with less than 1,000 participants and beneficiaries, are expected to utilize a TPA, issuer, or other service provider to review the final rule on the self-insured group health plan's behalf.

The Department assumes that it will take, on average, 5 hours for a legal professional for a large, self-insured group health plan to review the final rule, and 20 hours for a TPA or issuer to review the rule on behalf of each self-insured group health plan.[373] The Department further assumes a wage rate of $187.58 per hour for the legal review [374] and that this burden would only be incurred in the first year.

PBMs would also need to review the final rule and evaluate whether their current disclosure practices comply with the requirements. Because the majority of the rule is focused on PBM policies and actions, the Department assumes that similar to TPAs or issuers, this initial review will take four times as long for PBMs to review and identify current practices that are not consistent with the final rule's requirements than responsible plan fiduciaries. As such,

[369] 134 Stat. 1182—Public Law 116–260.

[370] Field Assistance Bulletin No. 2021–03, available at *https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03.*

[371] Committee on Education and the Workforce Subcommittee on Health, Employment, Labor and Pensions, *Competition and Transparency: The Pathway Forward for a Stronger Health Care Market,* (June 21, 2023).

[372] Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* (Mar. 2024), available at *https://www.gao.gov/assets/d24106898.pdf.*

[373] On average, the reading rate is 250 words per minute (WPM), which also corresponds to the typical length of a page. Therefore, a regulation document that is approximately 300 pages long would take about 300 minutes to read, translating to 5 hours (300 pages × 250 words per page ÷ 250 words per minute ÷ 60 minutes = 5 hours). The Department notes that this estimate applies to the plans. In contrast, TPAs, issuers, and PBMs are anticipated to require more time for their review, as discussed in the following paragraph.

[374] Internal DOL calculation based on 2026 labor cost data. For a description of DOL's methodology for calculating wage rates, see *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.*

the Department assumes that it will take, on average, 20 hours for a legal professional to review the final rule on behalf of PBMs at a wage rate of $187.58 per hour. The Department assumes this burden would only be incurred in the first year. Please see Table 2 for calculations and burden totals.

The Department requested comments on these assumptions. One commenter stated that the 20-hour review burden is underestimated. The commenter asserted that reviewing the rule would require multiple days of review, consultation with outside counsel, and coordination with technical experts to evaluate operational and implementation measures. However, the Department continues to believe that the estimate is appropriate because it reflects the average expected burden across entities. The Department acknowledges that individual entities may require more or less time depending on their size, structure, and existing compliance systems.

TABLE 2. Rule Familiarization Costs

Entities	Number of Entities	Number of Hours per Entity	Total Hour Burden	Hourly Wage	Cost
	(A)	(B)	(C) = (A x B)	(D)	(E) = (C x D)
Self-insured group health plans with 1,000 or more participants and beneficiaries	17,876	5	89,380	$187.58	$16,765,900
TPAs on behalf of client self-insured group health plans with less than 1,000 participants and beneficiaries	205	20	4,100	$187.58	$769,078
Issuers on behalf of client self-insured group health plans with less than 1,000 participants and beneficiaries	809	20	16,180	$187.58	$3,035,044
PBMs	73	20	1,460	$187.58	$273,867
First-year Total	**18,963**	**-**	**111,120**	**-**	**$20,843,890**

As stated above, the Department believes that most PBMs already have the required information needed to fulfill the disclosure requirements, as they manage complex healthcare operations and track the flow of pharmaceuticals and payments within the healthcare system as part of their regular business practices. Moreover, PBMs already provide this information, or elements of it, to self-insured group health plans and other entities, as required under the CAA, 2021 and State laws.[375] Therefore, the Department does not expect that PBMs will need to devote significant resources to obtain or share information on the services provided under the agreement, direct and indirect compensation, rebates, drug prices and the pricing methodology, reimbursement rates, formulary placement incentives, and agreements with agents, affiliates and subcontractors.

Nonetheless, greater transparency could identify practices such as rebates and spread pricing that are often regarded as hidden revenue mechanisms. As a result, PBMs may explore alternative revenue strategies, including fee-based models, and renegotiate contracts with self-insured group health plans, manufacturers, and wholesalers. Moreover, the Department anticipates that PBMs will need to revise current disclosure documents to include: revised definitions of contract terms that are objectively determinable; a description of all arrangements and compensation received by the PBM and any agents, affiliates or subcontractors related to providing these benefits; pricing and reimbursement information for all drugs on the formulary by distribution channel; more detailed descriptions of the services provided including the development and ongoing management of the formulary; as well as projecting potential costs and extracting actual payments to the level stipulated in this final rule. The Department acknowledges that these updates and revisions may require substantial effort and coordination by PBMs and their agents, affiliates and subcontractors.

In Table 3, the Department estimates the costs associated with PBMs developing and maintaining the IT infrastructure system necessary to collect and report the required data. To develop these estimates, the Department reviewed IT infrastructure costs associated with reporting complex, sensitive, or high-frequency data for similar disclosure regulations, including Prescription Drug Data Collection,[376] ACA Medical Loss Ratio (MLR) Reporting,[377] Medicare Part D Reporting

[375] National Academy for State Health Policy, *State Pharmacy Benefit Manger Legislation* (last updated Mar. 10, 2026), available at *https://nashp.org/state-tracker/state-pharmacy-benefit-manager-legislation/*.

[376] *Prescription Drug and Health Care Spending,* 86 FR 66662 (Nov. 23, 2021), available at *https://www.federalregister.gov/documents/2021/11/23/2021-25183/prescription-drug-and-health-care-spending.*

[377] *Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care* Act, 77 FR 28790 (May 16, 2012), available at *https://www.federalregister.gov/documents/2012/05/16/*

Continued

Requirements,[378] and the Hospital Price Transparency Requirements.[379] Of these rules, the IT costs associated with Prescription Drug Data Collection rule seemed most analogous to this final rule, as it specifically identified costs for PBMs to develop, implement, and maintain IT system changes to come into compliance with rulemaking related to prescription drug disclosures.

The Department used the Prescription Drug Data Collection rule as a benchmark but made a few notable adjustments. First, because the Department of Health and Human Services utilizes a different source for labor categories and wage rates than the Department, that information was mapped to the Department's source. Additionally, the hour burdens from the Prescription Drug Data Collection rule were adjusted downward by 50 percent to account for both the Prescription Drug Data Collection rule requiring additional information and calculations not found in this final rule, and the fact that the final rule relies on contract and pricing data that PBMs already track for commercial and compliance purposes, which should mitigate the associated costs. Finally, while data submission began in the second year for Prescription Drug Data Collection disclosures, the final rule requires reporting in the first year, and so the Department reallocated hour burdens from Prescription Drug Data Collection's second year into first and subsequent year categories for the final rule. Based on these considerations, the Department estimates the average, first-year per-PBM cost for designing, developing, and implementing the IT system to be $1,100,000.[380] In subsequent years, the estimated per-PBM average cost for maintaining and updating the IT system is $300,000.[381] This includes providing quality assurance, conducting maintenance and making updates, and updating any needed security measures.

The Department acknowledges that these costs likely vary by the size of PBMs as well as their business model (*i.e.,* fully pass-through PBMs and traditional PBMs may face very different costs to bring systems into compliance). Additionally, while the Department discounted the Prescription Drug Data Collection costs to reflect its impact on more of the overall market and requiring additional calculations and standardized submissions, the chosen discount rate may not have been appropriate.

The Department received several comments regarding its base-year cost assumptions. One commenter stated that the hour burden was underestimated, arguing that updating systems, generating required client reports, and maintaining the reporting infrastructure could require thousands of hours. Another commenter stated that rule review and compliance activities could exceed $1 million in annual expenditures. The Department acknowledges concerns regarding the cost and complexity of implementing the IT system changes. In response to these comments, the Department has revised its burden estimates to include an additional 160 hours of outside legal counsel support in the first year and 100 hours in subsequent years for reviewing, advising on, and facilitating compliance with IT system changes.

TABLE 3. Implementation of IT Infrastructure Costs

Task	Number of PBMs	Average Costs	Total Cost
	(A)	(B)	(C)
PBMs design, develop, and implement needed IT systems changes (first year)	73	$1,100,000	$80,300,000
PBMs maintain and update the IT system (subsequent years)	73	$300,000	$21,900,000
Three-year Average Costs	**73**	**$566,667**	**$41,366,667**

10.2. Disclosure Costs

The following sections discuss the number of notices that PBMs would provide to self-insured group health plans and the associated costs. These notices apply to self-insured plans with 100 or more participants and beneficiaries.

2012-11753/medical-loss-ratio-requirements-under-the-patient-protection-and-affordable-care-act.

[378] CMS, *Part D Reporting Requirements, https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/part-d-reporting-requirements.*

[379] *Price Transparency Requirements for Hospitals to Make Standard Charges Public,* 84 FR 65524 (Nov. 27, 2019), available at *https://www.federalregister.gov/documents/2019/11/27/2019-24931/medicare-and-medicaid-programs-cy-2020-hospital-outpatient-pps-policy-changes-and-payment-rates-and#p-40.*

[380] The Department estimates that each PBM will incur a one-time first-year cost and burden to design, develop, and implement any necessary IT system changes to collect and report the required data. The Department estimates that for each PBM, on average, it will take outside legal counsel (at $659.15 per hour) 160 hours, project management specialists 2,250 hours (at $131.29 per hour), business operations specialists 750 hours (at $124.74 per hour), as well as software and web developers, programmers, and testers 3,500 hours (at $178.08 per hour) to complete this task. The Department estimates the total burden per PBM will be approximately 6,660 hours, with an equivalent cost of approximately $1,117,702, rounded to $1,100,000. For all 73 PBMs, the total one-time first-year implementation and reporting burden is estimated to be 486,180 hours with an equivalent total cost of approximately $81,592,210.

[381] In addition to the one-time first-year costs and burdens previously estimated, PBMs will incur ongoing annual costs related to maintaining and updating IT systems, providing ongoing quality assurance, and submitting the required data to the Department. The Department estimates that for each PBM it will take outside legal counsel (at $659.15 per hour) 100 hours, project management specialists 500 hours (at $131.29 per hour), business operations specialists 50 hours (at $124.74 per hour), as well as software and web developers, programmers, and testers 750 hours (at $178.08 per hour) to perform these tasks. The Department estimates the total annual burden for each PBM will be 1,400 hours, with an equivalent cost of approximately $271,3579, rounded to $300,000. For all 73 PBMs, the total annual maintenance and submission burden is estimated to be 102,200 hours with an equivalent total cost of approximately $19,809,061.

10.2.1. Number of Notices From PBMs

10.2.1.1 Number of Initial Notices From PBMs

The final rule would require PBMs or other covered service providers to provide initial disclosures to responsible plan fiduciaries of self-insured group health plans, reasonably in advance of the date on which the contracts or arrangements are entered into, extended or renewed. Standard industry contracts appear to be for three-year periods, though it is unclear if the agreements themselves are extended or renewed during that time.[382] The Department anticipates that approximately one-third of the self-insured group health plans will annually initiate new contracts, extend existing contracts, or renew contracts.

The Department requested comments on this assumption and received responses that generally supported this assumption. One commenter stated that PBM contracts are usually set up as one-to-three-year agreements, with three years being the typical standard. They further noted that these contracts often renew automatically at the end of the term unless one party gives advance notice to end the agreement. Please see Table 4 for the estimated number of disclosures.

10.2.1.2 Number of Follow-Up Notices From PBMs

The final rule also requires that PBMs or other covered service providers furnish disclosures on a semiannual basis (or at the request of the covered plan, quarterly) within 30 calendar days following the conclusion of each six-month period starting from the contract or arrangement initiation date. The Department estimates that PBMs or other covered service providers would submit these disclosures to each self-insured group health plan twice each year. The required semiannual disclosures cover two quarters each year, leaving two quarters in which no semiannual disclosure is provided. During those remaining quarters, the Department assumes that ten percent of plans will request quarterly disclosures. Please see Table 11 for the estimated number of disclosures.

10.2.2. Number of Notices Upon Requests From PBMs

The final rule also requires PBMs or other covered service providers to provide any other information related to the contract or arrangement that is required for the self-insured group health plan to comply with the reporting and disclosure requirements of Title I of ERISA and the regulations, forms, and schedules issued, upon request of the responsible plan fiduciary. Without a strong data source for determining the number of expected requests, the Department assumes that approximately ten percent of responsible plan fiduciaries will request covered information annually. The Department requested, but did not receive comments on this assumption. Please see Table 4 for the estimated number of disclosures.

10.2.3. Number of Notices From Self-Insured Group Health Plans

10.2.3.1 Exemption for Responsible Plan Fiduciaries

The final rule also includes an administrative class exemption that would provide relief from ERISA section 406(a)(1)(C) and (D) for responsible plan fiduciaries who enter into a contract or arrangement, where the PBM or covered service provider fails to comply with its obligations under the regulation. To rely on the exemption, the responsible plan fiduciary must not have been aware that the PBM or covered service provider failed or would fail to meet these requirements and, upon discovering this omission, requests in writing that the PBM or other covered service provider furnish the required information or comply with the audit requirement. The Department does not have data on how often responsible plan fiduciaries do not receive all of the required disclosures from a covered service provider. In this analysis, the Department assumes that 0.3 percent of arrangements may experience an omission or error that will require the responsible plan fiduciary to send the request to the PBM.[383] This assumption is based on the Department's experience that it is rare for pension plans to submit a notice under the requirement in 29 CFR 2550.408b–2.

If the PBM or other covered service provider does not respond within 90 calendar days, the responsible plan fiduciary must notify the Department of the failure and further must assess whether to terminate or continue the service contract or arrangement consistent with the duty of prudence under section 404 of ERISA, including documenting the basis for that determination. The Department assumes that approximately 10 notices will be submitted, based on the experience that pension plans rarely submit these notices under the requirement in 29 CFR 2550.408b–2. The Department requested, but did not receive, comments on this assumption. Please see Table 4 for the estimated number of disclosures.

10.2.3.2 Number of Notices From Self-Insured Group Health Plans Requesting Audits Information

As part of their oversight responsibilities, responsible plan fiduciaries must assess the quality of the PBM or other covered service provider's performance under the contract or arrangement (*e.g.,* review and analyze claims data, network discounts, rebates, administrative fees), ensure that PBMs are meeting their contractual obligations, and ensure that self-insured group health plans are only paying reasonable and necessary costs. The final rule contains audit rights which are needed for fiduciaries to carry out these functions. While the cost of performing an audit of PBMs and other service providers is borne by the self-insured group health plan itself, service providers are required to provide the necessary information to the self-insured group health plan or its auditor. This final rule provides a self-insured group health plan's right to audit the PBM or other covered service provider not less than once per year. The PBM or other covered service provider must confirm receipt of the audit request within 10 business days and must provide the information within a commercially reasonable period.

The Department estimates that one-third of self-insured group health plans will annually submit a request to their PBM or other covered service provider for all information necessary to perform an audit. The Department does not anticipate smaller, self-insured group health plans to submit a request themselves, but expects all issuers or TPAs that market to those self-insured group health plans to request audit materials. Please see Table 4 for calculations on the number of notices.

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[382] Scott McEachern and Patrick Cambel, PBM Contracts: Understand then Optimize, Milliman White Paper (Aug. 2, 2020), available at *https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize.*

[383] Based on a review of the 2023 Form 5500 Schedule C filings, approximately 0.3 percent of ERISA-covered group health plans that filed Schedule C reported service providers who failed or refused to provide some of the information required to complete Part I. This estimate is used as a proxy for the percentage of self-insured group health plans that may need to request missing information from PBMs.

TABLE 4. Number of Notices

Notice	Number of Plans	Percent of Plans that will Initiate New Contracts, Extend Existing Contracts, or Renew Contracts	Percent of Plans Receiving or Sending Notices	Number of Notices Sent Each Year	Number of Notices
	(A)	(B)	(C)	(D)	(E) = (A x C x D) or (A x B x C x D)
Disclosures from PBMs to Self-insured Group Health Plans with 100 or more participants and beneficiaries					
PBMs provide initial disclosures to plans whose contract is entered, extended, or renewed for plans	131,102	33%	100%	1	43,701
PBMs provide missing/additional information requested by	131,102	33%	10%	1	4,370
PBM provides semiannual disclosures	131,102	100%	100%	2	262,204
PBM provides quarterly disclosures to plans upon request	131,102	100%	10%	2	26,220
Disclosures from Self-insured Group Health Plans with 100 or more participants and beneficiaries					
Plans send request to PBMs to disclose other/missing information	131,102	33%	0.3%	1	131
Plans document the basis for determination on whether to terminate or continue the service contract or arrangement, after PBMs has not responded in 90 days	10	-	100%	1	10
Plans send notice to DOL after PBMs has not responded in 90 days, and document basis for determination	10	-	100%	1	10
Self-insured Group Health Plans with 100 or more participants and beneficiaries send audit requests to PBM					
Plans send request for audits to PBMs	131,102	33%	100%	1	43,701
Total	**131,102**	**-**	**-**		**380,347**

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10.2.4. Costs of Disclosures

10.2.4.1 Initial Disclosures

The Department acknowledges that the final rule will impose costs associated with producing initial disclosures before a service contract or arrangement is entered into, extended or renewed. While the Department expects that much of this information will have already been provided to the self-insured group health plan under the solicitation process and in response to a Request for Proposal, it acknowledges that the rule requires additional elements to be included or expanded upon in the required disclosures. Moreover, while it is expected that PBMs have the necessary underlying information readily available, PBMs will need to prepare plan-specific disclosures such as detailed descriptions of projected compensation, payments, formulary placement incentives, and drug pricing.

The Department assumes that disclosures for large, self-insured group health plans with 100 or more participants and beneficiaries will need to be customized. Therefore, the Department estimates that it will take 30 minutes, due to the customization and review required. Please see Table 5 for calculations and burden.

Finally, paragraph (e)(9) of the proposal requires that the initial disclosure must provide that the responsible plan fiduciary will be notified in advance of any modifications to the formulary that, individually or in the aggregate, are reasonably expected to have a material impact on the reasonableness of compensation under the contract or arrangement. The Department considers that this is a regular business activity and PBMs are providing this information prior to the proposed regulation. Therefore, PBMs will not incur any additional cost burden.

The Department requested comments on these assumptions. One commenter stated that much of the information required for the initial disclosures is already collected and analyzed by PBMs as part of their normal business operations, including activities related to negotiating with manufacturers, setting reimbursement rates, designing formularies, and reporting to regulators. The commenter further stated that the incremental costs associated with compiling the required disclosures should be considered in light of PBMs' existing business operations and revenues, suggesting that the burden associated with the required disclosures is small relative to the PBMs' revenues. The Department appreciates this insight and has considered this comment in estimating the burden associated with preparing the initial disclosure. Specifically, the Department's burden estimates already reflect the assumption that PBMs collect and maintain the required information as part of their normal business operations.

10.2.4.2 Follow-Up Disclosures From PBMs

The final rule requires that PBMs or covered service providers furnish disclosures on a semiannual basis (or at the request of the covered plan, quarterly) within 30 calendar days following the conclusion of each six-month period starting from the contract or arrangement initiation date, disclosing the actual compensation that the PBM or other covered service provider received or reasonably expected to receive, under the specific categories that were estimated in the initial disclosures, as discussed earlier. This includes all direct compensation, rebate payments, spread pricing, copay claw-backs recouped from a pharmacy by the PBM or other covered service provider, price protection payments, and other compensation. If any category of compensation, in the aggregate, materially exceeds the corresponding estimate described in the initial disclosure, the PBM or other covered service provider must provide an identification of the amount and a reason for the overage. For this purpose, ''materially'' means five percent or more, or a lower dollar amount or percentage agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement.

It is anticipated that the PBM or other covered service provider will already possess the necessary information to fulfil this requirement, as these breakouts are already required in the initial disclosure and standard practice in PBM contracts is to regularly provide self-insured group health plans with invoices or statements that include claims payments, rebates, and administrative fees. The Department assumes these semiannual disclosures will require less time, as they often involve system-generated data, draw on similar information from initial disclosures, and rely on standardized templates. The Department assumes PBMs will rely on standardized templates and batch processing to prepare the notice. Therefore, the Department estimates that requiring PBMs to compile and disclose this information will require 15 minutes of work from a benefits specialist for compilation and distribution of the information semiannually, resulting in 30 minutes of benefit specialist time each year.

The required semiannual disclosures cover two quarters each year, leaving two quarters in which no semiannual disclosure is provided. During those remaining quarters, the Department also estimates that it will take 15 minutes of a benefit specialist's time to prepare and distribute the requested information. Please see Table 5 for calculations and burden.

The Department requested and received comments on these assumptions. One commenter stated that because the three largest PBMs process nearly 80 percent of all U.S. prescriptions they would assume most reporting obligations. As these PBMs and their subsidiaries generate more than $800 billion in annual revenue, the semiannual disclosure requirements would represent only minimal compliance costs relative to the scale of compensation they handle. The Department notes that it has assigned a minimal hour burden for the follow-up disclosures, which aligns with the commenter's assumptions.

10.2.4.3 Information Upon Request

Paragraph (i) of the final rule provides that, upon the written request of the responsible plan fiduciary, the covered service provider must furnish any other information relating to the contract or arrangement that is required for the self-insured group health plan to comply with the reporting and disclosure requirements of Title I of the Act and the regulations, forms and schedules issued thereunder. Paragraph (i)(1) requires the covered service provider to disclose the information requested reasonably in advance of the date upon which such responsible plan fiduciary states that it must comply with the applicable reporting or disclosure requirement, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, in which case the information must be disclosed as soon as practicable. The Department assumes that PBMs will rely on automated IT systems to prepare the information. Therefore, the Department estimates that it would only require 15 minutes of a benefit specialist's time to prepare and distribute the covered information for each plan annually. Please see Table 5 for the estimated costs of disclosures.

10.2.4.4 Notice to PBMs and DOL

The exemption contained in paragraph (n) of the final rule provides relief from the restrictions of ERISA section 406(a)(1)(C) and (D) for plan

fiduciaries who enter into a contract or arrangement where the PBM or other covered service provider fails to comply with its obligations under the regulation. Upon discovering that a PBM or other covered service provider failed to comply, the responsible plan fiduciary must request in writing that the PBM or other covered service provider furnish the information or comply with the audit requirement. As discussed earlier, the Department assumes that 0.3 percent of arrangements may experience an omission or error that will require the responsible plan fiduciary to send the request to the PBM or other covered service provider.[384] This assumption is based on the Department's experience that it is rare for pension plans to submit a notice under the requirement in 29 CFR 2550.408b-2. The Department also assumes that PBMs will rely on standardized templates and batch processing to prepare the notice. Therefore, the Department estimates that it will take 15 minutes of a benefit specialist's time to prepare and send the notice.

If the PBM or other covered service provider does not respond within 90 calendar days, the responsible plan fiduciary must notify the Department and further must assess whether to terminate or continue the service contract or arrangement consistent with the duty of prudence under section 404 of ERISA, including documenting the basis for that determination. As discussed earlier, the Department assumes that approximately 10 notices will be submitted. Similar to other notices, the Department assumes that PBMs will rely on standardized templates and batch processing to prepare the notice. Therefore, the Department estimates that it will take 15 minutes of a benefit specialist's time to document the basis for the determination, and 15 minutes of a benefit specialist's time to prepare and send the notice. Please see Table 5 for the estimated costs of disclosures.

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[384] Based on a review of the 2023 Form 5500 Schedule C filings, approximately 0.3 percent of ERISA-covered group health plans that filed Schedule C reported service providers who failed or refused to provide some of the information required to complete Part I. This estimate is used as a proxy for the percentage of self-insured group health plans that may need to request missing information from PBMs.

TABLE 5. Annual Disclosure Costs

	Number of Notices	Number of Hours Per Notice	Total Hour Burden	Hourly Wage Rate	Cost Equivalent of Hour Burden
	(A)	(B)	(C) = (A x B)	(D)	(E) = (C x D)
PBMs send disclosures to self-insured group health plans with 100 or more participants and beneficiaries					
PBMs provide initial disclosures to self-insured group health plans					
Legal professionals and benefit specialists prepare disclosures for self-insured group health plans	43,701	0.50	21,851	$156.16	$3,412,174
PBMs provide missing/other information requested by self-insured group health plans					
Benefit specialists prepare and send information to plans	4,370	0.25	1,093	$124.74	$136,278
PBMs provide semiannual disclosures to self-insured group health plans					
Benefit specialists prepare and send disclosures to plans	262,204	0.25	65,551	$124.74	$8,176,832
PBM provides quarterly disclosures to plans					
Benefit specialists prepare and send disclosures to plans	26,220	0.25	6,555	$124.74	$817,671
Self-insured group health plans with 100 or more participants and beneficiaries send notice to PBMs and DOL					
Self-insured group health plans send request to PBMs to disclose missing/other information					
Benefits specialists prepare and send request	131	0.25	33	$124.74	$4,085
Self-insured group health plans document the basis for determination on whether to terminate or continue the service contract or arrangement, after PBMs has not responded in 90 days					
Benefit specialists document determination	10	0.25	3	$124.74	$312
Self-insured group health plans send notice to DOL after the PBM has not responded within 90 days					
Benefits specialists prepare and send notice, and document basis for determination	10	0.25	3	$124.74	$312
Total	**336,636**	-	**95,087**	-	**$12,547,664**

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10.3. Audit Right Costs

A right to audit the veracity of any and all disclosures made by the PBM or other covered service provider to a responsible plan fiduciary under the terms of the contract or arrangement as required by this regulation is an essential part of the final rule's framework for establishing transparency in the marketplace for pharmacy benefit management services. This includes the responsibility of the PBM or other covered service provider to deliver all necessary information to conduct such an audit, subject to reasonable confidentiality agreements that prevent redisclosure of such information and limit its use to purposes related to compliance of the regulation. Though the final rule does not impose an obligation for responsible plan fiduciaries to conduct an audit, it does require that the PBM or other covered service provider allow, not less than once per year, for the self-insured group health plan to conduct an audit for accuracy of any disclosures made to comply with the regulation.

The Department received comments expressing concerns regarding the audit provisions, including the adequacy of confidentiality protections, potential disclosure of sensitive commercial information, auditor conflicts of interest, and appropriate limitations on the scope of audits. The Department appreciates these comments and discusses its consideration of these issues in the preamble. However, several commenters support the audit provisions and stated that an audit right would improve transparency and address limitations on data access to information held by PBMs. One commenter evaluates audit rights as a means of ensuring transparency to verify disclosures, noting that without meaningful audit authority, fiduciaries would be forced to rely solely on representations from covered service providers, thereby limiting the ability to conduct an independent audit. The Department appreciates their support for the audit provisions and agrees that enhanced transparency is essential for effective fiduciary oversight.

Under the final rule, the cost of selecting an auditor and performing an audit of PBMs and other service providers is borne by the plan itself, while service providers are required to provide the necessary information to the self-insured group health plan or its auditor without conditions that would restrict the self-insured group health plan's right to conduct the audit. The PBM or other covered service provider must confirm receipt of the audit request within 10 business days and must provide the information within a commercially reasonable period.

The Department received comments concerning whether there were circumstances where the covered service provider should bear the entire cost of the audit. One specifically raised concerns that requiring PBMs to financially contribute to the audit could compromise audit findings. Other commenters suggested the PBM should bear the full costs if the audit reveals material inaccuracies in the disclosures. The Department understands these concerns, and has determined that, consistent with the proposal, under the final rule plans that choose to conduct an audit bear the costs; PBMs and other service providers are only responsible for the cost of providing the underlying data to the auditor.

The Department estimates that only one-third of self-insured group health plans will annually submit a request to their PBM or other covered service provider for all information necessary to perform an audit. This assumption is based on PBM contracts being structured around a three-year master agreement and audits typically taking six to nine months to complete, making it challenging to conduct more than one audit in a given contract period.[385] As one commenter stated, PBM contracts are usually set up as one-to-three-year agreements, with three years being the typical standard. These contracts often renew automatically unless one party provides an advance notice to end the agreement.

To estimate the burden associated with responding to an audit request, the Department assumes that PBMs already have access to all information and data available, but may require time to compile the records, data and other necessary information, including contracts with retail pharmacies and drug manufacturers, for each self-insured group health plan. As one commenter stated, PBMs already collect and analyze the data underlying these disclosures as part of their normal business operations to negotiate with manufacturers, establish pharmacy reimbursement rates, design formularies, and report to State regulators and CMS (for Medicare Part D). Additionally, because this disclosure will also include contracts with agents, affiliates and service providers such as retail pharmacies and drug manufacturers, the Department also assumes that PBM may require additional legal assistance to put in place confidentiality agreements to prevent sharing of the disclosed information.

One commenter expressed concerns that these provisions could increase administrative burden and costs associated with responding to audit requests, particularly where proprietary information may be involved. However, as discussed above, the Department assumes that most PBMs maintain the underlying data needed for invoices, rebate reconciliation, and contractual compliance. Audit responses are often generated through standardized templates or automated reports, though custom data pulls may be required in some cases.

Therefore, the Department assumes that PBMs will rely on standardized templates and batch processing to prepare the audit request. The Department estimates it will take 30 minutes for a benefit specialist at a TPA or issuer to prepare and send the audit request on behalf of self-insured group health plans with 100 or more participants and beneficiaries. The Department also assumes it will take two hours of a PBM's benefit specialist and IT staff's time to prepare and disclose information needed for each requested audit, at a composite wage rate of $151.41.[386] This includes the time to retrieve documents, gather data and put in place any necessary confidentiality agreements. The Department requested, but did not receive, comments on these assumptions.

Please see Table 6 for calculations and burden.

[385] Janus Desquitado & Francis Ayson, PBM Best Practice Series: Pharmacy Benefit Claims Auditing, Milliman White Paper (Sept. 21, 2023), available at *https://www.milliman.com/en/insight/pbm-best-practices-pharmacy-benefits-claims-auditing.*

[386] The wage rate is calculated in the following manner: [($124.74 for a benefits specialist × (½)) + ($178.08 for an IT Professional) × (½))] = $151.41.

TABLE 6. Annual Audit Cost

	Number of Requests	Number of Hours Per Requests	Total Hour Burden	Hourly Wage	Cost Equivalent of Hour Burden
	(A)	(B)	(C) = (A x B)	(D)	(E) = (C x D)
Self-*insured group health plans with* 100 or more participants and beneficiaries send audit request					
Benefit specialists prepare and send audit request	43,701	0.5	21,851	$124.74	$2,725,631
PBMs prepare and disclose the needed info for the audit					
Benefit specialists and IT staff prepare for requested audit	43,701	2	87,402	$151.41	$13,233,537
Total	**43,701**		**109,253**	**-**	**$15,959,168**

10.4. Disclosure Mailing Costs

The proposed regulation does not preclude distribution through the use of electronic technology. Consequently, the Department has assumed that interactions between parties will be carried out electronically. As a result, all costs associated with distributing the disclosures have already been included in Section 11.2.3. The Department requested, but did not receive, comments on this assumption.

10.5. Summary of Total Costs

The total costs associated with the final rule have been provided below in Table 7. In comparison, according to the SEC 10-k filings, CVS Caremark, Express Scripts, and Optum Rx respectively 180.9 billion,[387] $216.7 billion,[388] and $154.7 billion [389] in revenue in 2025, resulting in a total of $552.3 billion. Therefore, the total three-year estimated average cost for this final rule represents 0.01 percent of total revenue of the three largest PBMs.

One commenter stated that the Department's comparison of implementation costs to PBM gross revenues does not fully reflect the financial structure of the PBM industry because a substantial portion of PBM revenue is paid out in pharmacy claims to pharmaceutical manufacturers. The commenter notes that, of the $481.1 billion in revenue cited by the Department for the three largest PBMs, approximately $469.9 billion was paid out in pharmacy claims. The commenter therefore suggests that comparing implementation costs to gross revenues understates the relative financial impact of the proposed requirements and states that the costs would represent a larger share of PBM gross profits.

The Department acknowledges the commenter's concern regarding the use of gross revenue to contextualize the estimated implementation costs. However, the commenter's concern appears to relate primarily to how the comparison is framed, rather than to the accuracy of the underlying revenue figures. The Department also notes that the commenter did not provide a source or methodology for the assertion that approximately $469.9 billion of the cited revenue was paid out in pharmacy claims. The Department continues to believe that revenue is an appropriate measure for assessing the relative scale of compliance costs across affected entities because compliance costs are generally borne by the enterprise as a whole. Although a portion of PBM revenue may be associated with claims payments and other pass-through transactions, those amounts remain part of the overall business activity and scale of the entity. Accordingly, the Department believes the revenue-based comparison remains appropriate for purposes of the analysis.

[387] The Form 10–K does not directly report the revenue for CVS Caremark. However, it provides revenue for the pharmacy services within the Health Services segment, which includes the pharmacy network, mail order pharmacies, and specialty pharmacies, and these services are generally managed by the PBM. (*Source:* SEC, *Form 10–K, CVS Health Corporation,* Annual Report (2025), available at *https://www.sec.gov/Archives/edgar/data/64803/000006480325000007/cvs-20241231.htm.*

[388] The Form 10–K does not directly report the revenue for Express Scripts. However, it provides revenue for the pharmacy services, and these services are generally managed by the PBM. Securities and Exchange Commission, *Form 10–K, Cigna. Annual Report* (2025), available at *https://d18rn0p25nwr6d.cloudfront.net/CIK-0001739940/64c4c39f-1b4e-4979-8b4a-bfc403377665.pdf.*

[389] The Form 10–K directly reports revenue for Optum Rx. Securities and Exchange Commission, *Form 10–K, Cigna. Annual Report* (2025), available at *https://www.unitedhealthgroup.com/content/dam/UHG/PDF/investors/2024/UNH-Q4-2024-Form-10-K.pdf.*

TABLE 7. Summary of Total Costs

	First Year Cost	Subsequent Year Cost	Ten-Year Average Cost
Rule Familiarization	$20,843,890	$0	$2,084,389
IT Infrastructure	$80,300,000	$21,900,000	$27,740,000
Disclosure	$12,547,664	$12,547,664	$12,547,664
Audit	$15,959,168	$15,959,168	$15,959,168
Total Costs	**$129,650,722**	**$50,406,832**	**$58,331,221**

10.6. Sensitivity Analyses of Costs

Given the uncertainty surrounding these cost estimates, particularly due to variation in plan complexity and PBM system capabilities, the Department conducted a sensitivity analysis to examine how the estimated costs would change if there was a decrease or increase in the hour burden from the primary assumptions. Please see Table 8 for the results of this sensitivity analysis.

TABLE 8. Sensitivity Analysis

	Ten-Year Average Annual Cost
25 Percent of Primary Scenario	$14,582,805
50 Percent of Primary Scenario	$29,165,611
Primary Scenario	**$58,331,221**
150 Percent of Primary Scenario	$87,496,832
200 Percent of Primary Scenario	**$**116,662,442

11. Uncertainty

11.1. Uncertainty Over Rebates' Impact on Costs

The Department expects that the final rule will have a significant impact on rebates, as PBMs will be required to disclose not only how much of the rebate the self-insured group health plan will receive, but also how much will be retained by the PBM and other service providers. The Department expects that highlighting these payments will result in responsible plan fiduciaries negotiating a greater share of rebates, potentially leading PBMs to fully pass through all rebates to the self-insured group health plan, which could lower plan costs or cause changes in other forms of payment. Furthermore, increased transparency could enable responsible plan fiduciaries to compare offerings across PBMs, fostering competition and improving drug pricing.

However, their effects on the patients' out-of-pocket costs remain uncertain, as discussed in Sections 8.1 and 8.2. This is primarily because rebates are typically paid to issuers or plan administrators rather than directly to group health plan participants, and the portion of those rebates passed through to participants can vary depending on plan design.[390]

11.2. Uncertainty Over Other PBM Practices on Costs

The final rule may also impact other PBM pricing strategies, including reducing the use of copay claw-backs, exclusionary formularies, and pharmacy network restrictions. However, their effects on employer costs and patients' out-of-pocket costs remain uncertain. These mechanisms are opaque,[391] and the variability in how they are implemented across self-insured group health plans contributes to significant uncertainty about their financial impact on patients. For example, copay claw-backs are difficult to identify in the claims data, and patients are often unaware that they have paid more than the actual cost of the drug. This lack of visibility makes it challenging to measure how frequently claw-backs occur or to evaluate their overall impact on patient spending. Since there is limited publicly available data on how these practices affect patient costs, it is difficult to assess whether any particular PBM arrangement is delivering cost-savings for patients or merely shifting costs in ways that are not easily understood or tracked.

11.3. Uncertainty Over the Impact of the Audit Rights on the Number of Audits Requested

The final rule intends to facilitate self-insured group health plan oversight of PBMs by enabling plans to request an audit so that they may have access to all information needed to assess the completeness and accuracy of the required disclosures. As discussed in the preamble of this regulation, PBMs often limit self-insured group health plans' audit rights by providing only a sample of records relating to contractual

[390] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive?, International Journal of the Economics of Business* (June 26, 2015), available at *https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.*

[391] Rebecca Robbins & Reed Abelson, *The Opaque Industry Secretly Inflating Prices for Prescription Drugs,* The New York Times (2024), *https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html.*

performance, requiring that the auditor be approved by the PBM, or requiring that the audit be conducted on-site at a facility chosen by the PBM. By removing these barriers, the audit requirement ensures that PBMs provide accurate and complete information to plans and their auditors, permitting plans to better determine if PBMs are complying with contract terms and to take corrective action as needed.

Currently, plans conduct audits, though often with less information and control over the audit process than the final rule ensures. Industry best practices suggest that ''plan sponsors should have their pharmacy claims audited. If the plan sponsor suspects the PBM is not adhering to the contract, or if the plan frequently changes benefits, then it is best to audit every year.'' [392] Because these audits can take up to nine months to perform, the Department has assumed that plans only conduct these audits once in a given three-year contract period.

By clarifying and standardizing audit rights, the final rule would provide plan fiduciaries with additional information relevant to oversight. However, it is uncertain whether the final rule would result in changes to the number of audits requested. In some cases, improved disclosures may reduce the need for additional audits by increasing transparency into PBM practices. In other cases, greater clarity regarding audit rights and available information may lead some plans to elect to make greater use of audits. To the extent that plans choose to increase their use of audits, any associated costs would be borne by the plan.

11.4. Uncertainty Over the Impact of the Rule on the PBM Market

The PBM market has been facing significant market consolidation in recent years, with the three largest PBMs controlling roughly 80 percent of the market.[393] Since the final rule would require PBMs to provide disclosures at a more granular level, the Department expects that self-insured group health plans may demand additional concessions during the contract negotiation process, putting downward pressure on prices. CBO suggested in their 2019 analysis of S.1895, *Lower Health Care Costs Act,* that ''smaller PBMs compete with larger PBMs by offering more transparent contracts. Removing that point of leverage may reduce the competitiveness of those smaller PBMs, which could reduce competition if larger PBMs garner greater market share as a result.'' [394]

The Department notes, however, that those PBMs that already leverage transparency in their contracts may not have their revenues significantly impacted by the final rule. While all PBMs would bear the costs of additional disclosures, more transparent PBMs would be less prone to contract revisions following those disclosures given that the required information has already been shared with the plan sponsor or issuer, and presumably priced into the contract. Less transparent PBMs, however, may need to make additional concessions and revisions in response to the disclosures, which would likely reduce their revenues. As such, the Department is unclear whether the final rule would impact market consolidation in the PBM space and if so, in what direction.

One commenter expressed concern that increased transparency is only an initial step toward addressing challenges in the PBM market, noting that future outcomes will determine whether the PBM market becomes more balanced or continues toward greater consolidation and fewer operating pharmacies. Another commenter similarly observed that transparency alone does not change the underlying incentives that influence stakeholder behavior within the system.

The Department acknowledges commenters' views that transparency, by itself, may not fully address the structural incentives affecting market participants. The purpose of this final rule is to provide plan sponsors with more complete and consistent information regarding prescription drug pricing and PBM practices. The information generated through the required disclosures may help group health plans identify inefficiencies, assess market dynamics, and evaluate options to protect participants and beneficiaries. Overall, the Department believes that the final rule can strengthen accountability, support more informed decision-making, and facilitate oversight of PBM market practices.

11.5. Uncertainty Over the Longevity of the Impact of Final Rule

The Department, when considering the impact of this final rule, relied heavily on analyses conducted by CBO for several prescription drug reform bills. In particular, CBO reviewed S. 1339 the *Pharmacy Benefit Manager Reform Act* which banned spread pricing, required PBMs to pass-through all rebates and required disclosures related to enrollees' use of prescription drugs, costs, rebates, fees, and cost-sharing amounts to plan sponsors.[395] CBO estimated that the reduction in plan premiums resulting from this bill would diminish significantly over time as ''contract terms between parties are redefined and PBMs find more ways to generate revenue outside of the disclosure requirements.'' [396] While the Department's proposal includes similar disclosure requirements as that of the CBO bill described above, it does not include all the elements CBO analyzed. As a result, the Department is unclear on whether its impacts of the final rule would abate over time. The Department requested, but did not receive, comments on this assumption.

11.6. Uncertainty Over the Benefit Estimates

The Department estimated in the proposed rule the benefits from improvements to health outcomes and reduced healthcare expenditures that will result from increased adherence due to lower prescription drug costs. Some commenters objected to this QALY approach and endorsed a WTP analysis, which was also calculated as part of the proposed rule. The Department ultimately agreed and used WTP to quantify benefits for the final rule. However, the Department included alternative QALY estimates in the Uncertainty section.

In the proposed rule, the Department used QALYs to look at the impact of improved prescription drug adherence on health following a price decline due to the expanded disclosures. However, due to data limitations, the Department was only able to produce QALY estimates for three common health conditions—diabetes, high blood pressure and heart disease. The Department received several comments suggesting that due to the limited nature of the QALY analysis, the Department should instead utilize WTP, arguing that it would more fully capture the welfare

[392] Janus Desquitado & Francis Ayson, PBM Best Practice Series: Pharmacy Benefit Claims Auditing, Milliman White Paper (Sept. 21, 2023), available at *https://www.milliman.com/en/insight/pbm-best-practices-pharmacy-benefits-claims-auditing.*

[393] Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

[394] Congressional Budget Office, *Cost Estimate: S. 1895, Lower Health Care Cost Act* (July 16, 2019), available at *https://www.cbo.gov/publication/55457.*

[395] Congressional Budget Office, *Cost Estimate: S. 1339, Pharmacy Benefit Manager Reform Act* (Dec. 5, 2024), available at *https://www.cbo.gov/publication/61050.*

[396] *Id.*

effects on all participants, not just those with chronic diseases.[397] While one such commenter generally favored WTP, they claimed it would not accurately reflect health gains for improved adherence, and so proposed that the Department carve out those conditions impacted by improved adherence, to avoid double counting, and use QALY measures for them. That commenter additionally recommended adding mortality improvements to the benefits calculation, though the Department, upon review, is concerned that including both mortality and morbidity benefits would overstate the benefits and so is limiting its QALY-focused analysis to just health improvements. The Department was subsequently able to acquire additional information and data that allow it to conduct a QALY analysis over the entire population, rather than limiting it to three health conditions. For the final rule the Department has utilized the QALY analysis to provide an alternative estimate to reflect some of the uncertainty of the benefits.[398] The Department has also provided a sensitivity analysis of both methods to reflect the uncertainty of the estimated range of price reductions that utilizes a low estimate of a 0.5 percent price reduction and a high estimate of a 2.0 percent price reduction in the sections that follow.

11.6.1.1 Improved Health Outcomes Among Patients Utilizing Quality Adjusted Life Years

As noted above in the Benefits sections, disclosures required of PBMs in the final rule will help to reduce information asymmetry and aid self-insured group health plans' responsible plan fiduciaries in their selection of and negotiations with PBMs, helping to reduce costs for the self-insured group health plans and lower prescription drug prices.[399] By reducing prescription costs, the final rule could improve adherence to prescribed drugs, as patients are less likely to skip or reduce doses, delay refills, or forgo treatment due to financial concerns. This will in turn improve disease management resulting in better overall health outcomes.

Price sensitivity towards drug adherence has been an increasing issue. A 2026 KFF health tracking poll reveals that concerns about drug affordability have grown over the past several years, from 44 percent in 2018 to 59 percent in early 2026.[400] The scale of this issue is reflected in the 2024 National Health Interview Survey, which found that approximately 8.0 percent of respondents aged 18 to 64 with private insurance reported not taking their medication as prescribed in order to save money.[401] Results from a meta-analysis of treatment adherence studies further indicated that nearly one-fourth (24.8 percent) of patients were non-adherent to medication for various reasons.[402] Research on prescription drug price elasticity find increases in direct consumer costs reduce prescription fills, suggesting a price elasticity of demand between −0.1 and −0.4.[403] Moreover, consumers' sensitivity to prescription drug prices, as evidenced by claims data showing that more than half of high-cost prescriptions go unfilled, suggests that even small price decreases could increase access to prescription drugs for participants and beneficiaries.[404] Additionally, research corroborates that poor treatment adherence is associated with poorer health outcomes and significantly higher mortality rates.[405] [406]

To estimate the potential benefit to participants and beneficiaries of the final rule, the Department has provided an analysis that estimates the averted healthcare costs arising from increased prescription drug adherence. The final rule is expected to have a small but meaningful effect on the net retail price of prescription drugs, which the Department estimates will decrease by one percent. This estimate is consistent with the 2024 CBO analysis [407] and other research on the effect of disclosures to group health plans and other service providers on prescription drugs.[408] While these studies offer a comparable assessment of the potential impact of required rebate disclosures from PBMs to self-insured group health plans, the final rule is distinct as it contains more significant requirements that mandate the disclosure of all forms of direct and indirect compensation, including spread pricing, affiliate payments, as well as rebates. The final rule also includes enforceable rights, such as audit provisions and notification to the Department of incomplete disclosure, that will enhance compliance. These requirements may yield more substantial benefits, particularly to mid-sized self-insured group health plans, which are typically less informed and have fewer resources to monitor contracted services. As such, the

[398] The QALY analysis illustrates how an analytic approach with many inputs drawn from outside directly-regulated market(s) has more opportunities for uncertainty to be introduced than an approach (such as the direct-WTP analysis) with inputs that are relatively few in number and minimally extrapolated across markets.

[399] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices* (Oct. 2024), *www.cbo.gov/publication/58793.*

[400] Kearney, Audrey, Julian Montalvo III, Ashley Kirzinger, & Liz Hamel, KFF (2026), *https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/#caa040a6-6e54-4977-9b45-f0d168f535eb.*

[401] National Center for Health Statistics, *Percentage of Adults aged 18–64 who did not Take Medication as Prescribed to Save Money in the Past 12 months, United States, 2019–2024,* National Health Interview Survey. Generated interactively: Jun 03 2026 from *https://www.cdc.gov/nchs/data/databriefs/db470.pdf.*

[402] Robin DiMatteo, *Variations in Patients Adherence to Medical Recommendations: A Quantitative Review of 50 Years of Research, Medical Care* (2004), *https://pubmed.ncbi.nlm.nih.gov/15076819/.*

[403] Michael Chernew, Mayur Shah, Arnold Wegh, Stephen Rosenberg, Iver Juster, Allison Rosen, Michael Sokol, Kristina Yu-Isenberg, & A Mark Fendrick, *Impact of Decreasing Copayments on Medication Adherence within a Disease Management Environment,* Health Affairs (2008), *https://pubmed.ncbi.nlm.nih.gov/18180484/;*

Dana Goldman, Geoffrey Joyce, Jose Escarce, Jennifer Pace, Matthew Solomon, Marianne Laouri, Pamela Landsman, & Steven Teutsch, *Pharmacy Benefits and the Use of Drugs by the Chronically Ill,* Journal of the American Medical Association (2004), *https://pubmed.ncbi.nlm.nih.gov/15150206/;*

Abe Dunn, *Health Insurance and the Demand for Medical Care: Instrumental Variable Estimates Using Health Insurer Claims Data,* Journal of Health Economics (2016), *https://pubmed.ncbi.nlm.nih.gov/27107371/.*

[404] IQVIA Institute, *Medicine Spending and Affordability in the United States: Understanding Patients' Costs for Medicines,* (Aug. 2020), *https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/medicine-spending-and-affordability-in-the-us.*

[405] Teresa B. Gibson, Xue Song, Berhanu Alemayehu, Sara S. Wang, Jessica L. Waddell, Jonathan R. Bouchard, & Felicia Forma, *Cost Sharing, Adherence, and Health Outcomes in Patients with Diabetes,* American Journal of Managed Care 16(7) (2010), *https://pubmed.ncbi.nlm.nih.gov/20712392/;*

Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality, British Medical Journal,* (2006), available at *https://pmc.ncbi.nlm.nih.gov/articles/PMC1488752/pdf/bmj33300015.pdf;*

Donald Pittman, William Chen, Steven Bowlin, and JoAnne Foody, *Adherence to Statins, Subsequent Healthcare Costs, and Cardiovascular Hospitalizations,* American Journal of Cardiology 107(11) (2011), *https://pubmed.ncbi.nlm.nih.gov/21439533/.*

[406] Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality, British Medical Journal* (2006), available at *https://pmc.ncbi.nlm.nih.gov/articles/PMC1488752/pdf/bmj33300015.pdf.*

[407] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices* (Oct. 2024), *www.cbo.gov/publication/58793.* As noted earlier in this regulatory impact analysis, the price-reduction range suggested by this report is between 0.1 percent and 1.0 percent.

[408] Ginger Scanlon, *Prescription for Savings? Disclosure in the Drug Market* (2024), available at *https://ssrn.com/abstract=5021179.*

Department believes that the final rule could reduce prices for prescription drugs more significantly, consistent with the effect of similar disclosures in other markets.[409]

The Department analyzes the impact arising from reduced prescription drug prices for the 52.9 million participants and beneficiaries aged 18 to 64 in large, self-insured plans.[410] Utilizing the National Health Interview Survey estimate of 8 percent cost-related non-adherence for prescription drugs among adults 18–64 with private health insurance, the Department estimates that approximately 2.9 million individuals in large, self-insured plans are non-adherent due to the cost of their medication.[411]

Data from MEPS–HC indicates that, for persons with a prescription medication reporting cost-related non-adherence, the average number of prescriptions each year (including refills) is approximately 21, resulting in an estimated 60.4 million prescriptions for individuals aged 18–64 in large, self-insured plans that are non-adherent to their medication due to cost.[412] Applying a one percent price reduction and an estimate price elasticity of demand of −0.358 for prescription drugs,[413] the Department estimates that an additional 216,131 prescriptions will be purchased by this group resulting in approximately 10,269 such participants improving their adherence to medication.[414] The Department believes that this calculation likely underestimates the number of participants that will improve their adherence to medication as a result of the rule.[415]

TABLE 9. Estimated Adherence Improvements

Price Reduction	Price Elasticity of Demand	Non-Adherent Population	Prescriptions for Non-Adherent Participants	Additional Prescriptions Arising from Rule	Estimated Population Experiencing Adherence Improvement
-1.0%	-0.358	2,868,342	60,371,715	216,131	10,269

Note: Some values in the table are rounded and may not result in precise calculations.

* Estimated population based on the self-insured participants aged 18 to 64 is 52,882,418.

Increased prescription adherence can reduce disease related medical costs due to improved health status and reduced utilization of medical care including hospitalizations, emergency room visits, and doctor appointments that would otherwise arise when medication for chronic diseases is not taken as prescribed.[416] Using data on medical events from the 2023 MEPS–HC, the Department estimates healthcare utilization for privately insured participants aged 18 to 64 with a prescription based on adherence status (see Table 10 below).[417] Observing the average number of distinct medical events, such as inpatient hospitalizations or office-based visits to physicians, the data suggests that across most categories of healthcare, cost-related non-adherence is associated with higher utilization of care. Adherent participants, for example, averaged 8.7 medical office visits in 2023, compared with an average of 14.5 office visits for non-adherent participants. This data supports other research suggesting medication adherence and compliance can reduce adverse health outcomes and healthcare utilization.

[409] Christine Cuny, Omri Even-Tov, & Edward Watts, *From Implicit to Explicit: The Impact of Disclosure Requirements on Hidden Transaction Costs,* Journal of Accounting Research (2021), available at *https://onlinelibrary.wiley.com/doi/10.1111/1475-679X.12340?msockid=18d7b391c5d560f015c7a5a9c4c7616c;* Dominique Badoer, Charles Costello, & Christopher Jones, *I Can See Clearly Now: The Impact of Disclosure Requirements on 401(k) Fees,* Journal of Financial Economics 136(2), (2020), *https://www.sciencedirect.com/science/article/abs/pii/S0304405X19302466.*

[410] Estimate is based on the Department's tabulations of the March 2025 Current Population Survey (CPS) Auxiliary Data.

[411] This estimate is calculated as: 52,882,418 individuals aged 18–64 in large, self-insured plans × 67.8 percent reporting having a prescription medication × 8 percent cost-related non-adherence = 2,868,342 cost-related non-adherent individuals aged 18–64 in large, self-insured plans.

[412] *https://pubmed.ncbi.nlm.nih.gov/18180484/.* This estimate is calculated as: 2,868,342 × 21.05 prescriptions per prescribed adult 18–64 with private health insurance = 60,371,715 prescriptions for individuals aged 18–64 in large, self-insured plans that are non-adherent due to cost. Total may not sum due to rounding.

[413] Abe Dunn, *Health Insurance and the Demand for Medical Care: Instrumental Variable Estimates Using Health Insurer Claims Data,* Journal of Health Economics, Vol 48, (2016).

[414] This estimate is calculated as: 60,371,715 prescriptions × −0.01 price change × −0.358 price elasticity of demand = 216,131 additional prescriptions for individuals aged 18–64 in large, self-insured plans that are non-adherent due to cost. Additionally, 216,131 additional prescriptions ÷ 21.05 prescriptions per prescribed non-adherent individual = 10,269 individuals aged 18–64 in large, self-insured plans improving their adherence. Total may not sum due to rounding.

[415] In the estimate provided here, the Department applies the price change and elasticity of demand to only the non-adherent population. This produces an estimate of 216,131 additional prescriptions that is utilized for the QALY analysis and the analysis of reductions in medical spending. In the primary analysis where direct WTP is utilized, the estimate results from applying the price change and elasticity of demand to the entire affected population, then attributing the change in demand for prescriptions entirely to non-adherent individuals, resulting in 1,344,165 additional prescriptions. As such, the QALY and medical spending estimates in the Uncertainty section likely have a tendency toward underestimating these impacts of the rule.

[416] Michael C. Sokol, Kimberly A. McGuigan, Robert R. Verbrugge, & Robert S. Epstein, *Medication Adherence on Hospitalization Risk and Healthcare Costs,* Medical Care Vol 43(6) (June 2008), available at *https://pubmed.ncbi.nlm.nih.gov/15908846/.*

[417] Based on self-reporting of delaying taking or being unable to afford their medication. Department of Health and Human Services, Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey* (2024).

TABLE 10. Average Annual Healthcare Events Per Person, by Adherence Status

	Average Utilization, Adherent	Average Utilization, Non-Adherent
Emergency Room Visits	0.24	0.32
Hospital, Inpatient Admissions	0.08	0.06
Hospital, Outpatient Admission	1.10	1.36
Office-Based Visits	8.72	14.45
Prescribed Medicines Filled	11.12	21.05

Note: The MEPS-HC data on healthcare utilization above represents the average number of distinct medical events in 2023 by facility type, based on the participants reported adherence status for those that have prescribed medication. The table above does not include all the healthcare utilization categories analyzed, such as telehealth or dental visits.

The Department further examined the cost savings of reduced utilization of medical services resulting from improved cost-related prescription adherence (see Table 11). Using 2023 MEPS–HC data on healthcare expenditures of privately insured patients aged 18 to 64 with a prescription medication, the Department estimated the impact of adherence on health expenditures for those costs paid by the issuer. The reduced utilization of medical services for these 10,269 participants could lower the reimbursement requirements of private issuers to healthcare providers by approximately $9.6 million annually.[418]

TABLE 11. Estimated Healthcare Expenditures and Savings, by Adherence Status

	Estimated Issuer Health Expenditures	
	Adherent	Non-Adherent
Emergency Room	$3,800,352	$4,692,132
Hospital, Inpatient	$20,082,785	$10,280,994
Hospital, Outpatient	$11,625,740	$7,832,828
Office-Based Visit	$17,924,314	$31,160,192
Prescription Medicine	$23,118,435	$31,446,902
All Medical Expenditures	$83,372,984	$93,022,353
Total Cost Savings	$9,649,369	

Note: These calculations utilize the average expenditure by payer for those indicating having a prescription medication based on reported adherence status. This average expenditure is then applied to the estimated number of participants improving adherence (10,269) in self-insured group health plans. The estimated cost-savings represent the expenditures for those improving adherence based on their adherence status (expenditures at non-adherence – expenditures at adherence = cost savings). Columns may not sum to total due to rounding. Not all sources of expenditure are listed.
Source: Agency for Healthcare Quality and Research, MEPS-HC, 2023.

Increased prescription adherence is also associated with a decreased risk of adverse health outcomes.[419] For patients with chronic or severe diseases, the mortality risk associated with non-adherence to their medication can be considerable.[420] [421] Additionally, health-related quality of life data from MEPS indicates that adherence is also

[418] Based on data reporting insurer expenditures for privately insured patients aged 18–64 with a prescription medication. Department of Health and Human Services, Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey* (2024).

[419] Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality,* BMJ (2006), *https://pubmed.ncbi.nlm.nih.gov/16790458/;* P. Michael Ho, John Rumsfeld, Frederick Masoudi, David McClure, Mary Plomondon, John F. Steiner, & David Magid, *Effect of Medication Nonadherence on Hospitalization and Mortality Among Patients with Diabetes Mellitus,* Archives of Internal Medicine, (2022), *https://pubmed.ncbi.nlm.nih.gov/17000939/;* Donald Pittman, William Chen, Steven Bowlin, & JoAnne Foody, *Adherence to Statins, Subsequent Healthcare Costs, and Cardiovascular Hospitalizations,* American Journal of Cardiology (2011).

[420] Sarah Van Alsten & Jenine Harris, *Cost-Related Nonadherence and Mortality in Patients with Chronic Disease: A Multiyear Investigation, National Health Interview Survey, 2000–2014,* Preventing Chronic Disease, Center for Disease Control and Prevention (2020), *https://pubmed.ncbi.nlm.nih.gov/33274701/.*

[421] Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality,* BMJ (2006), *https://pubmed.ncbi.nlm.nih.gov/16790458/.* See also, P. Michael Ho, John Rumsfeld, Frederick Masoudi, David McClure, Mary Plomondon, John F. Steiner, & David Magid, *Effect of Medication Nonadherence on Hospitalization and Mortality Among Patients with Diabetes Mellitus,* Archives of Internal Medicine (2022), *https://pubmed.ncbi.nlm.nih.gov/17000939/.*

associated with significantly higher health-related quality of life scores for both mental and physical health.[422]

To assess the value of these health benefits, the Department estimates the changes in health status through a single metric: quality-adjusted life-years (QALYs), which quantify the changes to morbidity for affected participants.[423] To calculate the QALY, the health utility metric, *Short Form Six-Dimension* (SF–6D),[424] is estimated for participants aged 18–64 with private health insurance. The average score for such participants that were adherent to their medication was approximately 0.82. An analysis of MEPS data by the Department indicated that non-adherence to medication for reasons of cost was associated with a 0.05 decrease in SF–6D scores. [425] The Department estimates that QALY gains in each year will be equivalent to this 0.05 estimate for participants that improve their adherence.[426] [427] The calculations are provided in Table 12 below.

TABLE 12. Annual QALY Estimates

Years →	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
N=	10,269	10,269	10,269	10,269	10,269	10,269	10,269	10,269	10,269	10,269
QALY Gains	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
Total QALY Gains	531	531	531	531	531	531	531	531	531	531

Note: QALYs are estimated from the 2023 MEPS-HC as 0.05 per participant lower for participants that are non-adherent to their medication and aged 18 to 64 with private health insurance. Total may not sum due to rounding.

The difference between the baseline and post-rule estimates indicates that, each year, increased medication adherence among the 10,269 participants will result, on average, in 531 additional QALYs.[428] The Department uses an estimate for the central value of a QALY (VQALY) of approximately $763,000,[429] [430] suggesting an average total annual value of approximately $405.3 million from improvements to quality of life arising from a one percent reduction in prescription drug prices. These calculations and estimates are provided in Table 13 below.

[422] Physical Health Summary Scores (PCS) and Mental Health Summary Scores (MCS) showed significant variation between adherent and non-adherent respondents aged 18 to 64 with private health insurance. Department of Health and Human Services, Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey* (2024).

[423] A quality-adjusted life-year is standardized on a scale of 0 to 1, where 1 represents a perfect state of health and 0 represents the worst state of health (death).

[424] SF–6D is a value indicating the quality of a participant's life based on health determinants derived from physical health and mental health summary scores of the 2023 MEPS.

[425] Based on a regression analysis of calculated SF–6D values derived from 2023 MEPS–HC data for participants reflecting reported cost-related non-adherence and controlling for mental and physical health status, race, income, sex, ethnicity, age, and insurance status.

[426] The MEPS Mental Health Score (MCS) and Physical Health Score (PCS) are standardized health-related quality of life scores from the VR–12 Assessment. The scores are adapted to a health utility metric, SF–6D using a peer-reviewed methodology. (*Source:* Hyun Song, Ji Haeng Heo, Debbie Wilson, Bui Shao, Haesuk Park, *National Catalog of Mapped Short-Form Six-Dimension Utility Scores for Chronic Conditions in the United States from 2010 to 2015,* Value in Health 25(8), (2022), (2003)).

[427] Hyun Jin Song, Ji Haeng Heo, Debbie L.Wilson, Hui Shao, & Haesuk Park, *A National Catalog of Mapped Short-Form Six-Dimension Utility Scores for Chronic Conditions in the United States From 2010 to 2015,* Value in Health, (2022).

[428] This estimate is calculated as: 10,269 participants improving adherence × 0.05 QALYs = 531 QALYs gained annually. Total may not sum due to rounding.

[429] The value of a quality-adjusted life-year (VQALY) utilizes the central estimate and is derived from *HHS, Standard Values for Regulatory Impact Analysis, 2026,* Office of Science and Data Policy, Department of Health and Human Services (2026).

[430] HHS values for a QALY, discounted at 3 percent, are utilized for this analysis. The value of a QALY in year one is estimated as $725,872 and is adjusted upward 1.1 percent each year to account for projected earnings growth. This results in an average value of QALY of $763,467 over the 10 years observed. Source: *HHS Standard Values for Regulatory Analysis 2025—Supplemental Tables,* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. February 2025.

TABLE 13. Estimated Value of QALY Improvements

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
VQALY	$725,872	$733,980	$742,179	$750,469	$758,852	$767,328	$775,899	$784,566	$793,330	$802,191
QALY Gains (1.0%)	531	531	531	531	531	531	531	531	531	531
Total Value (1.0%)*	$385.4	$389.7	$394.0	$398.4	$402.9	$407.4	$411.9	$416.5	$421.2	$425.9

Note: *Value illustrated is reported in millions of dollars.

In total, the final rule is estimated to generate approximately $415.0 million in undiscounted benefits annually when considering QALYs. This total includes averted medical costs and improved health outcomes from greater treatment adherence.[431]

11.6.1.2 WTP Sensitivity Analysis

The Department has provided a sensitivity analysis of the WTP benefit estimates, utilizing the same approach as described in the benefits section. Table 14 presents the estimates of annual benefits and transfers under a 0.5 percent and 2.0 percent reduction in the average net retail prescription drug price. The Department estimates that the annualized WTP benefits range from approximately $146.5 million to $586.0 million.

TABLE 14. Participant Annual Welfare Gains Measured by Willingness-to-Pay under Varying Assumptions about Reductions in Average Net Retail Prescription Drug Price

Decrease in Average Net Retail Prescription Price	Prescription Quantity in Baseline	Price Elasticity Estimate	Additional Prescriptions Filled	Average Price per Prescription ($)	Monetized Value of Willingness-to-Pay ($ million)	Transfers to Participants: Reduced Rx Spending ($ million)
(A)	(B)	(C)	(D)	(E)	(F) = (D × E)	(G) = Baseline spending ($81.8 B) x (A)
-0.5%	375,465,168	-0.358	672,083	$217.98	$146,500,576	$409.2
-1.0%	375,465,168	-0.358	1,344,165	$217.98	$293,001,152	$818.4
-2.0%	375,465,168	-0.358	2,688,331	$217.98	$586,002,305	$1,636.9

11.6.1.3 QALY Sensitivity Analysis

The Department analyzes the impact of health improvements arising from 0.5 and 2.0 percent reductions in the price of prescription drugs. Applying a one percent price reduction and an estimate price elasticity of demand of −0.358 for prescription drugs, [432] the Department estimates that between 108,065 and 432,261 additional prescriptions will be purchased by this group resulting in approximately 5,134 to 20,537 additional such participants improving their adherence to medication.[433] [434]

[431] This estimate is calculated as: $405,330,037 quality-adjusted life years + $9,649,359 in averted healthcare expenditures = $414,979,405 in total undiscounted benefits.

[432] Abe Dunn, *Health Insurance and the Demand for Medical Care: Instrumental Variable Estimates Using Health Insurer Claims Data,* Journal of Health Economics, Vol 48, (2016).

[433] This estimate is calculated as: 60,371,715 prescriptions × −0.005 price change × −0.358 price elasticity of demand = 108,065 additional prescriptions for individuals aged 18–64 in large, self-insured plans that are non-adherent due to cost. Additionally, 108,065 additional prescriptions ÷ 21.05 prescriptions per prescribed individual = 5,134 individuals aged 18–64 in large, self-insured plans improving their adherence. Total may not sum due to rounding.

[434] This estimate is calculated as: 60,371,715 prescriptions × −0.02 price change × −0.358 price elasticity of demand = 432,262 additional prescriptions for individuals aged 18–64 in large, self-insured plans that are non-adherent due to cost. Additionally, 432,262 additional prescriptions ÷ 21.05 prescriptions per prescribed individual = 20,537 individuals aged 18–64 in large, self-insured plans improving their adherence. Total may not sum due to rounding.

Table 15. Estimated Adherence Improvements under Different Assumptions of Price Reduction in Average Net Retail Prescription Drug Price

Price Reduction	Price Elasticity of Demand	Non-Adherent Population	Prescriptions for Non-Adherent Participants	Additional Prescriptions Arising from Rule	Estimated Population Experiencing Adherence Improvement
-0.5%	-0.358	2,868,342	60,371,715	108,065	5,134
-1.0%	-0.358	2,868,342	60,371,715	216,131	10,269
-2.0%	-0.358	2,868,342	60,371,715	432,261	20,537

The calculations of the QALY estimates follow the same methodology as described earlier in the Uncertainty section, utilizing the estimated population experiencing adherence improvement from Table 15. The sensitivity analysis for 0.5 percent and 2.0 percent reductions in the average net retail price is stated in Table 16.

Table 16. Annualized QALY and Benefit Estimates under Different Assumptions of Price Reduction in Average Net Retail Prescription Drug Prices

Decrease in Average Net Retail Prescription Price	Prescription Quantity in Baseline	Price Elasticity Estimate	Additional Prescriptions Filled	Average Price per Prescription ($)	Monetized Value of Willingness-to-Pay ($ million)	Transfers to Participants: Reduced Rx Spending ($ million)
(A)	(B)	(C)	(D)	(E)	(F) = (D × E)	(G) = Baseline spending ($81.8 B) x (A)
-0.50%	5,134	2,654	$202.70	$4.80	$207.50	$409.2
-1.00%	10,269	5,309	$405.30	$9.60	$415.00	$818.4
-2.00%	20,537	10,618	$810.60	$19.30	$829.90	$1,636.9

The value of the QALY benefits are estimated in the same manner as the benefit section and provided below in Table 17.

Table 17. Estimated Value of QALY Improvements under Different Assumptions of Price Reduction in Average Net Retail Prescription Drug Prices

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
VQALY	$725,872	$733,980	$742,179	$750,469	$758,852	$767,328	$775,899	$784,566	$793,330	$802,191
Total Value (0.5%) *	$192.7	$194.8	$197.0	$199.2	$201.4	$203.7	$206.0	$208.3	$210.6	$212.9
Total Value (1.0%) *	$385.4	$389.7	$394.0	$398.4	$402.9	$407.4	$411.9	$416.5	$421.2	$425.9
Total Value (2.0%) *	$770.7	$779.3	$788.0	$796.8	$805.7	$814.7	$823.8	$833.0	$842.3	$851.7

*Values are stated in millions of dollars.

In total, the estimates of improved health outcomes for the final rule are estimated to generate approximately between $207.5 million and $829.9 million in undiscounted benefits annually under an estimated range of 0.5 percent and 2.0 percent price reductions for prescription drugs. This total includes averted medical costs, reduced prescription drug expenditures, and improved health outcomes from greater treatment adherence.[435]

12. Alternatives

In addition to the regulatory approach outlined in the final rule, the Department considered an alternative approach during the development of the final rule. It is discussed in greater detail below.

12.1. Inclusion of Fully Insured Group Health Plans

The Department considered applying the proposed regulation to fully insured group health plans. In doing so, the full universe of ERISA -covered group health plans could benefit from these disclosures, which would aid responsible plan fiduciaries in fulfilling their fiduciary responsibilities, assist them in monitoring service providers to ensure that only reasonable costs are paid and that any conflicts of interest are disclosed and mitigated. This would in turn benefit plan participants and their beneficiaries.

Upon review, the Department found that fully insured group health plans generally do not enter into separate agreements for prescription drug benefits through carve-out arrangements but rather contract with issuers for comprehensive health insurance coverage with prescription drug benefits bundled into the larger package. A 2023 study on vertical integration in the Medicare Part D market finds that consolidation of PBMs and insurers can raise premiums for non-integrated insurers and lowers premiums for vertically integrated insurers. This research suggests that vertical integration may limit competition and increase costs even in markets, such as the fully insured group market, where prescription drugs benefits are bundled rather than separately carved out.[436] As such, it is not clear that responsible plan fiduciaries would find the disclosures required under this final rule helpful when negotiating or monitoring their benefit plan as to justify the costs associated with the disclosures (both to the covered service provider providing the disclosures and the responsible plan fiduciary reviewing and analyzing the disclosures). Therefore, the required disclosures under the final rule may not meaningfully reduce information asymmetry in the fully insured group health plan market, given that prescription drug benefits are bundled and negotiated at the issuer level rather than directly by plan fiduciaries. Based on these considerations, the Department has instead reserved obligations with respect to fully insured group health plans for future action.

12.2. Inclusion of Smaller Self-Insured Group Health Plans

The Department considered including smaller self-insured group health plans, such as level-funded plans, within the scope of the final rule. Level-funded plans, in particular, tend to rely on TPAs and issuers to carry out their claims, administrative, and pharmacy benefit management functions. Requiring PBMs to furnish the required disclosures to these plans would impose additional administrative burdens associated with reviewing and analyzing these disclosures. The Department estimates there are approximately 953,420 level-funded group health plans, accounting for 90 percent of affected ERISA-covered group health plans.[437]

The Department determined not to include small, self-insured group health plans for several reasons, including aligning the covered plan definition with ERISA section 726. ERISA section 726 also includes a requirement that small group health plans receive a summary document. Small, self-insured group health plans will also still receive the generalized compensation disclosures pursuant to ERISA section 408(b)(2)(B). In addition, the disclosures in the final rule will be most useful to responsible plan fiduciaries of large plans, who are more likely to have

[435] This estimate is calculated as: $202,657,700 quality-adjusted life years + $4,824,510 in averted healthcare expenditures = $207,482,211 in total undiscounted benefits under a price reduction of 0.5 percent. Additionally, $810,632,677 quality-adjusted life years + $19,298,085 in averted healthcare expenditures = $829,930,762 in total undiscounted benefits under a price reduction of 2.0 percent.

[436] Gray, Charles, Abby E. Alpert, & Neeraj Sood, *Disadvantaging Rivals: Vertical Integration in the Pharmaceutical Market,* National Bureau of Economic Research (2023), available at *https://www.nber.org/system/files/working_papers/w31536/w31536.pdf.*

[437] Additionally, the Department estimates there are 953,420 small, level-funded ERISA-covered group health plans based on the 20254 KFF Employer Health Benefits Survey, the 2024 Medical Expenditure Panel Survey Insurance Component (MEPS–IC) and the 20221 County Business Patterns from the Census Bureau. Large is defined as having 100 or more participants and beneficiaries in the plan.

compliance staff and sufficient resources to analyze the disclosures and take appropriate action. Limiting the scope of the final rule is intended to avoid unintended negative consequences to smaller plans as described by some commenters. Accordingly, the Department determined not to include these small plans within the scope of the final rule.

12.3. Annual Disclosures From PBMs

The Department considered requiring annual disclosures from PBMs but determined that this information needed to be provided more frequently. Requiring disclosures only on an annual basis would delay actionable information for a substantial portion of the market, increasing the likelihood of inefficient pricing, foregone renegotiations opportunities, and higher plan costs. Semiannual disclosures reduce these market inefficiencies by improving the timeliness and useful of information available to plan fiduciaries. Therefore, under the final rule the Department requires that PBMs or covered service providers furnish disclosures on a semiannual basis within 30 calendar days following the conclusion of each six-month period starting from the contract or arrangement initiation date.

The Department requested comments on the proposed frequency of these disclosures. Some commenters expressed strong support for requiring semi-annual disclosures for the specific compensation categories estimated in the annual disclosures. One commenter supported the proposed semi-annual timeframe because it aligns with the statutory reporting requirements under the CAA, 2026. The Department appreciates these comments for providing additional insight into the optimal frequency of disclosures.

12.4. Enhanced Disclosure for Bundled Services

The Department considered enhanced disclosures regarding direct compensation for bundled services. As proposed, the initial disclosure requirements would require a description of direct compensation that the covered service provider, an affiliate, agent, or subcontractor reasonably expects to receive in connection with the pharmacy benefit management services under the contract or arrangement. The term ''direct compensation'' means compensation received directly from the self-insured group health plan, or from the plan sponsor on behalf of the self-insured group health plan, regardless of whether such compensation is paid from plan assets. The proposal would require a description of the amount of all direct compensation, both in the aggregate and by service, that the covered service provider, an affiliate, agent, or subcontractor reasonably expects to receive on a quarterly basis in connection with pharmacy benefit management services under the contract or arrangement.

The Department considered whether to require the description of direct compensation for a bundled services option to include additional information, such as the bundled discounted value along with a description of services provided in the bundle. Greater additional disclosures could further reduce information asymmetries associated with bundled pricing by enabling fiduciaries to better compare compensation arrangements across providers. However, the Department was uncertain whether this level of detail would provide additional benefits to self-insured group health plan fiduciaries beyond the other disclosure requirements in the proposal, particularly given potential increases in compliance and administrative costs. The Department requested comments on this alternative but did not receive any.

12.5. Other Alternatives Suggested by Commenters

One commenter suggested requiring standardized Application Programming Interface (APIs), such as Fast Healthcare Interoperability Resources (FHIR), to allow automated real-time compliance checks and make data easier to use. The Department considered this recommendation and recognizes that it could improve efficiency and reduce compliance checks over time. However, the Department also recognizes that creating and maintaining these systems could be costly and difficult.

Another commenter recommended that the Department provide standardized disclosure templates to improve consistency and make information easier to compare. The Department considered this recommendation and recognizes that standardized templates could reduce confusion and lessen the reporting burden for employers. However, the Department also notes that standardized templates may not work equally well for all entities and could create implementation challenges for organizations with different reporting systems.

Finally, one commenter suggested expanding disclosure requirements to include brokers and consultants who advise plan sponsors because of potential conflicts of interest. The Department considered this recommendation and acknowledges that greater transparency could help plan sponsors make more informed decisions. However, expanding disclosure requirements could also increase administrative and compliance costs for affected entities. Nevertheless, to the extent PBMs or their affiliates also act as brokers or consultants with respect to pharmacy benefit management services, they may be covered under the final rule as covered service providers.

12.6. Conclusion

The final rule is intended to allow responsible plan fiduciaries of self-insured group health plans to better fulfill their statutorily mandated role to determine that the service contracts or arrangements are reasonable under ERISA section 408(b)(2). The Department is of the view that increased transparency in PBM practices will empower responsible plan fiduciaries to increase market competition, negotiate more favorable contractual terms, reduce PBMs' conflicts of interest, and promote greater competition across the prescription drug supply chain. The final rule is expected to result in more accurate prescription drug classifications by PBMs, leading to more cost-effective and clinically appropriate formularies. Taken together, these outcomes will enhance market efficiency and ultimately improve access to affordable prescription drugs for consumers.

G. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), the Departments solicited comments concerning the information collection requests (ICRs) included in the proposed rules. At the same time, the Department also submitted ICRs to OMB, in accordance with 44 U.S.C. 3507(d). The Department received comments that specifically addressed the paperwork burden analysis of the ICRs contained in the proposed rules.

One commenter argued the proposed rule raised concerns under the PRA regarding duplication, burden, and practical utility. The commenter stated that the proposal overlaps with the existing CAA reporting requirements for rebates and fees, creating a risk of duplicative and inconsistent reporting. The Department acknowledges the concern regarding potential overlap with the CAA. However, to prevent unnecessary burden, the Department has harmonized the disclosure requirements in this final rule with the

existing CAA reporting framework. This harmonization avoids inconsistent reporting and minimizes additional compliance costs. Therefore, the Department concludes that the final rule provides necessary practical utility without creating an unwarranted duplicative burden.

Another commenter suggested updating Schedule C of Form 5500 to capture the compensation disclosures required under the final rule and the CAA 2026. The commenter noted that Schedule C currently does not reflect the expanded disclosure obligations for group health plan service providers. The Department believes that this rulemaking under ERISA section 408(b)(2) is properly focused on disclosures to responsible plan fiduciaries of covered plans. This rulemaking does not establish a new reporting framework for information to be submitted to the Department, other than the reporting provision in the administrative exemption in paragraph (n), which is discussed in greater detail in the preamble. Accordingly, changes to Schedule C of the Form 5500 are outside the scope of this rulemaking.

The changes made by this final rule affect the existing OMB control number, 1210–0173. A copy of the ICR for OMB Control Number 1210–0173 may be obtained by contacting the PRA addressee listed in the following sentence or at *www.RegInfo.gov.* For additional information contact, U.S. Department of Labor, Employee Benefits Security Administration, Office of Research and Analysis, Attention: PRA Officer, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210; or send to *ebsa.opr@dol.gov.*

The final rule is intended to help responsible plan fiduciaries better monitor prescription drug costs and benefit administration. The final rule requires PBMs and other covered service providers, and their affiliates, and agents, and subcontractors, to disclose pricing structures and potential conflicts of interest before entering, extending or renewing a service agreement and on a semiannual basis afterward. PBMs and other covered service providers must also make available all the information needed for responsible plan fiduciaries to audit their disclosures provided under the regulation. Please see Table 18 for a summary of the hour and cost burden. For a description of how the estimates are obtained please see the Cost section of the RIA.

TABLE 18. Summary of Hour and Cost Burden

	Hour Burden	Cost Equivalent of Hour Burden	Cost Burden
IT Infrastructure (first year)	474,500	$80,300,000	$0
IT Infrastructure (subsequent years)	94,900	$21,900,000	$0
Disclosure (annual)	95,087	$12,547,664	$0
Audit (annual)	109,253	$15,959,168	$0
First Year Total	**678,839**	**$108,806,832**	**$0**
Subsequent Year Total	**299,239**	**$50,406,832**	**$0**
Three-Year Average Total	**425,773**	**$69,873,499**	**$0**

Below is a summary of the burden associated with the information collection.

Type of Review: New.

Agency: Employee Benefits Security Administration, U.S. Department of Labor.

Title: PBM Fee Disclosure Regulation under 408(b)(2).

OMB Control Number: 1210–0173.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 131,175 (3-year average).

Estimated Number of Annual Responses: 424,111 (3-year average).

Frequency of Response: Annual, Semi-annual.

Estimated Total Annual Burden Hours: 425,773 (3-year average).

Estimated Total Annual Burden Cost: $0.

H. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[438] imposes certain requirements with respect to Federal rules that are subject to the notice-and-comment requirements of section 553(b) of the Administrative Procedure Act and are likely to have a significant economic impact on a substantial number of small entities. Unless the head of an agency determines that a final rule is not likely to have a significant economic impact on a substantial number of small entities, section 604[439] of the RFA requires the agency to present a final regulatory flexibility analysis of the final rule.

The final rule only applies to self-insured plans of specified large employers and self-insured group health plans that are specified large plans. Small group health plans are not affected by the final rule. However, the final rule may still affect small, covered service providers, including PBMs and indirectly TPAs and issuers.

The Department has limited data to determine if this final rule would have a significant impact on a substantial number of small entities. As the Department is not able to certify that the final rule will not have a significant economic impact on a substantial number of small entities the Department has prepared this Final Regulatory Flexibility Analysis (FRFA) to evaluate the rule's potential effects on small entities.

1. Need for the Rule

Research suggests that PBMs contribute to high prescription drug prices in the United States by extracting

[438] 5 U.S.C. 601 *et seq.* (1980).

[439] 5 U.S.C. 604 (1980).

economic rents in their role as intermediaries between self-insured group health plans and prescription drug manufacturers. PBMs are often responsible for developing prescription drug formularies and benefit designs for self-insured group health plans, negotiating rebates with drug manufacturers for placement on those formularies, establishing preferred pharmacy networks, and processing prescription drug claims. In providing these services, PBMs often operate in ways that make it difficult for plans and plan sponsors to compare different PBM services, due to the non-transparent nature of the information.[440] These information asymmetries may also affect competition within the PBM market, including the ability of smaller PBMs to enter the market and compete with larger PBMs. Currently, the three largest PBMs—CVS Caremark, Express Scripts, and Optum Rx—account for 80 percent of the market.[441] As a result, reduced competition within the PBM market may contribute to higher prescription prices.

2. Objective of the Rule

The final rule aims to improve transparency in PBM arrangements by requiring covered service providers, including PBMs, to disclose detailed information to responsible plan fiduciaries. This will help them assess the reasonableness of compensation and fulfill their duties under ERISA.

PBMs and other covered service providers would be required to disclose, both before entering into an agreement and throughout the term of the contract, the full range of services provided, including those delivered through affiliates, agents, and subcontractors. They must also report all compensation, including manufacturer payments, spread pricing, copay claw-backs, and incentives related to formulary placement or price protection agreements. Disclosures must include enough information to allow responsible plan fiduciaries to independently estimate the cost of each drug by pharmacy channel. On a semiannual basis, PBMs and other covered service providers must provide updated disclosures summarizing the actual amounts received in manufacturer payments, spread pricing, copay claw-backs, and any other compensation received or reasonably expected to be received. They must also provide additional information upon request from the responsible plan fiduciary.

The final rule also specifies the responsible plan fiduciary's right to audit PBM and other covered service providers compliance once per year. Although the self-insured group health plan is responsible for audit costs, PBMs and other covered service providers must provide access to all necessary records, including contracts with pharmacies, drug manufacturers, and affiliates. The covered service provider must confirm receipt of the audit request within 10 business days and must provide the information within a commercially reasonable period.

The Department expects that the final rule would increase transparency in PBM compensation arrangements and enable self-insured group health plans to better understand these practices. This increased transparency would allow responsible plan fiduciaries to compare offerings across PBMs more effectively, helping them enter into the most appropriate PBM contracts for their needs. The final rule is intended to allow fiduciaries of self-insured group health plans to fulfill their statutorily mandated role to determine that the service contracts or arrangements are reasonable under ERISA section 408(b)(2).

Some commenters stated that small and mid-sized employers are particularly disadvantaged in contract negotiations because they lack the market power, expertise, and resources to negotiate effectively with large, vertically integrated PBMs. The Department agrees that greater transparency from PBMs is needed to address these concerns and has therefore issued this final rule.

3. Affected Small Entities

The final rule will affect small, covered service providers, including PBMs and indirectly TPAs and issuers. These entities are discussed in greater detail in this FRFA.

3.1. Group Health Plans

For the purposes of the FRFA, the Department considers employee benefit plans with fewer than 100 participants to be small entities.[442] The basis of this definition is found in ERISA Section 104(a)(2), which permits the Secretary of Labor to prescribe simplified annual reports for plans that cover fewer than 100 participants. Under ERISA Section 104(a)(3), the Secretary may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Pursuant to the authority of Section 104(a)(3), the Department has previously issued (see 29 CFR 2520.104–20, § 2520.104–21, § 2520.104–41, § 2520.104–46, and § 2520.104b–10) simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans, that and satisfy certain requirements.

For purposes of this analysis, small group health plans would not be affected by the final rule. The final rule requires PBMs to provide disclosures only to large, self-insured group health plans with 100 or more participants and beneficiaries.

3.2. TPAs and Issuers

The Department also estimates that the final rule will indirectly affect 205 TPAs and 373 issuers in the group market with 809 issuers/State combinations.[443] These are service providers acting on behalf of level-funded group health plans and self-insured group health plans, who typically provide plan management, regulatory compliance, and administrative services.

3.3. PBMs

In 2023, there were 73 full-service PBMs in the marketplace.[444] These PBMs may also provide brokerage services to self-insured group health plans with respect to pharmacy benefit management services. PBMs fall under the NACIS Code 524292, or ''Pharmacy Benefit Management and Other Third-Party Administration of Insurance and Pension Funds,'' and the SBA considers businesses with up to $45.5 million in annual receipts to be small.[445] Notably,

[440] Véronique C. Raimond, William B. Feldman, Benjamin N. Rome, & Aaron S. Kesselheim, *Why France Spends Less than the United States on Drugs: A Comparative Study of Drug Pricing and Pricing Regulation,* The MilBank Quarterly (Mar. 22, 2021), available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7984670/.*

[441] Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

[442] The Department consulted with the Small Business Administration in making this determination, as required by 5 U.S.C. 601(3) and 13 CFR 121.903(c). Memorandum received from the U.S. Small Business Administration, Office of Advocacy on July 10, 2020.

[443] An ''issuer/state combination'' refers to a health insurance issuer and the state in which it offers coverage, such that the same issuer operating in multiple states is treated as separate issuer/state combinations. Data source: Centers for Medicare and Medicaid Services, *2023 Medical Loss Ratio Data, https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources.*

[444] The PCMA article estimated the total number of PBMs in 2023 in the following manner: 70 full-service PBMs + 6 new full-service PBMs—8 acquired PBMs + 5 PBMs that expanded services = 73 full-service PBMs.

[445] SBA, *Table of Size Standards* (last updated Mar. 2023), available at *https://www.sba.gov/sites/*

Continued

92 percent of businesses within this industry are small businesses according to the SBA size standards. However, the Department believes that the distribution of revenue for this entire category does not reflect the distribution of PBM revenues. This is because the size distribution for TPAs is different than the size distribution for PBMs—PBMs are larger than TPAs and the annual receipts of most PBMs exceed this threshold. In particular, the three largest PBMs which account for 80 percent of the market, CVS Caremark, Express Scripts, and Optum Rx respectively reported $180.9 billion,[446] $216.7 billion,[447] and $154.7 billion[448] in revenue in 2025, according to the SEC 10–K filings. Even for ''small'' PBMs, the Department expects that annual receipts would not be significantly below the SBA threshold. The Department requested, but did not receive, comments on this assumption.

4. Cost of Final Rule

The Department expects small PBMs to review the final rule, evaluate their current disclosure practices, and make any necessary changes to ensure compliance. Increased transparency may reveal concern with revenue strategies, causing some PBMs to shift toward fee-based compensation models and renegotiate contracts with manufacturers, and wholesalers. The Department notes that these second-order effects are not reflected in the cost estimates presented in this analysis.

Under the final rule, PBMs must provide fee disclosures to self-insured group health plans and permit self-insured group health plans to audit the covered service provider at least once per year. The Department estimates that only one-third of self-insured group health plans will submit an annual request for all information necessary to conduct such an audit. While self-insured plans are not expected to make these requests directly, the Department anticipates that issuers or TPAs providing services to self-insured group health plans will submit audit requests on their behalf.

4.1. Responses to Comments

One commenter stated the Department underestimated the burden on small group health plans, since the reporting requirements are complex and that many contractual agreements will have to be reviewed and revised at a high cost. The Department acknowledges the commenter's concern that the complexity of the reporting requirements and the need to review and revise contractual agreements could impose significant costs on small entities. However, the Department notes that the final rule does not affect small group health plans. Therefore, small group health plans are not expected to incur any burden. The Department has received comments regarding the impact on smaller PBMs. Some commenters contend that the disclosure requirements in the NPRM are duplicative and would require PBMs to divert substantial resources toward compliance activities rather than innovation or competition. They argue that these demands could disproportionately burden smaller PBMs and diminish their ability to compete with larger entities. One commenter further asserts that smaller PBMs lack the economies of scale necessary to distribute these costs across large enrollee populations or to absorb them while remaining competitive on an administrative-cost basis. According to this commenter, the requirements could create new barriers to market entry and expansion, discouraging innovation and reducing competition. Another commenter states that the machine-readable format requirement would impose substantial infrastructure costs, which would have a particularly pronounced impact on smaller PBMs serving regional and community employer markets.

The Department acknowledges these concerns, but believes that the benefits of the disclosure requirements justify the associated costs. The Department notes that transparency is essential for enabling plans, plan sponsors, and other stakeholders to better assess PBM practices and negotiate more effectively. Additionally, the Department believes that increased transparency may enhance rather than diminish market competition by reducing information asymmetries and enabling smaller PBMs to compete on clearer and more consistent negotiation terms.

4.2. Illustration of Costs for Small PBMs

Tables 19 and 20 illustrate how the estimated costs for PBMs compare to revenue in the first year and subsequent years, respectively. Table 19 specifically presents a range of potential cost impacts at different revenue levels. The Department does not have data on the revenue distribution of PBMs or on how many self-insured group health plans a small PBM typically provides services for. Since both the disclosure and audit costs depend on the number of self-insured group health plans, these tables present a range of per-entity costs as a percentage of revenue, varying both the average number of self-insured group health plans serviced by a PBM and the revenue relative to the SBA small business threshold.

As previously discussed, while the Department uses the SBA threshold for NACIS Code 524292, or ''Pharmacy Benefit Management and Other Third-Party Administration of Insurance and Pension Funds'' in this analysis, the Department expects that the size distribution for TPAs to be different than the size distribution for PBMs. Based on these assumptions, the Department estimates that the final rule's costs for small PBMs would represent at least 2.5 percent of revenues in the first year and at least 1 percent of revenues in subsequent years. The Department requested comments on the parameters used in this illustration, particularly any data on the revenues of small PBMs and how many self-insured group health plans a small PBM typically provides services self-insured plans. No comments were received that addressed these topics.

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default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf.

[446] The Form 10–K does not directly report the revenue for CVS Caremark. However, it provides revenue for the pharmacy services within the Health Services segment, which includes the pharmacy network, mail order pharmacies, and specialty pharmacies, and these services are generally managed by the PBM. Securities and Exchange Commission, *Form 10–K, CVS Health Corporation, Annual Report* (Fe. 10, 2026), available at *https://www.sec.gov/Archives/edgar/data/64803/000006480325000007/cvs-20241231.htm.*

[447] The Form 10–K does not directly report the revenue for Express Scripts. However, it provides revenue for the pharmacy services, and these services are generally managed by the PBM. (*Source:* SEC, *Form 10–K, Cigna. Annual Report* (Feb. 26, 2026), available at *https://d18rn0p25nwr6d.cloudfront.net/CIK-0001739940/64c4c39f-1b4e-4979-8b4a-bfc403377665.pdf.*

[448] The Form 10–K directly reports revenue for Optum Rx. Securities and Exchange Commission, *Form 10–K, UnitedHealth Group, Annual Report* (Mar. 2, 2026), available at *https://www.unitedhealthgroup.com/content/dam/UHG/PDF/investors/2024/UNH-Q4-2024-Form-10-K.pdf.*

TABLE 19. PBM Per Entity Costs as a Percentage of Revenue, First Year

	Per-Entity Cost	Cost as a Percent of 100% of SBA Threshold	Cost as a Percent of 75% of SBA Threshold	Cost as a Percent of 50% of SBA Threshold	Cost as a Percent of 25% of SBA Threshold	Cost as a Percent of 10% of SBA Threshold
PBMs						
Dollar Amount of Percent of SBA Small Business Threshold ($ millions)		$45.5 million	$34.1 million	$22.8 million	$11.4 million	$4.6 million
Rule Familiarization	$3,752 [a]	0.008%	0.011%	0.016%	0.033%	0.082%
IT Infrastructure	$1,100,000 [b]	2.418%	3.223%	4.835%	9.670%	24.176%
Disclosure [c]						
Servicing 50 Plans	$3,969	0.009%	0.012%	0.017%	0.035%	0.087%
Servicing 100 Plans	$7,938	0.017%	0.023%	0.035%	0.070%	0.174%
Servicing 150 Plans	$11,907	0.026%	0.035%	0.052%	0.105%	0.262%
Servicing 200 Plans	$15,876	0.035%	0.047%	0.070%	0.140%	0.349%
Audit [d]						
Servicing 50 Plans	$15,141	0.033%	0.044%	0.067%	0.133%	0.333%
Servicing 100 Plans	$30,282	0.067%	0.089%	0.133%	0.266%	0.666%
Servicing 150 Plans	$45,423	0.100%	0.133%	0.200%	0.399%	0.998%
Servicing 200 Plans	$60,564	0.133%	0.177%	0.266%	0.532%	1.331%
Total						
Servicing 50 Plans	**$1,122,862**	**2.468%**	**3.290%**	**4.936%**	**9.871%**	**24.678%**
Servicing 100 Plans	**$1,141,972**	**2.510%**	**3.346%**	**5.020%**	**10.039%**	**25.098%**
Servicing 150 Plans	**$1,161,082**	**2.552%**	**3.402%**	**5.104%**	**10.207%**	**25.518%**
Servicing 200 Plans	**$1,180,192**	**2.594%**	**3.458%**	**5.188%**	**10.375%**	**25.938%**

Note:

[a] Calculated as 20 hours per PBM x an hourly labor cost of $187.58.

[b] Calculated as an hourly labor cost of $131.29 for project management specialists x 2,250 hours + $659.15 for outside legal counsel x 160 hours + an hourly labor cost of $124.74 business operations specialists x 750 hours + an hourly labor cost of $178.08 for software developers, programmers, and testers x 3,500 hours.

[c] The costs associated with the initial disclosure are calculated as: 0.5 hour per PBM x an hourly labor cost of $156.16 for legal professionals and benefit specialists x 1/3 x the number of self-insured group health plans serviced by the PBM. The costs associated with the semiannual disclosure are calculated as: 0.25 hour x an hourly labor cost of $124.74 for benefit specialist x 2 x the number of self-insured group health plans serviced by the PBM. The costs associated with the quarterly disclosures upon request are calculated as: 0.25 hour x an hourly labor cost of $124.74 for benefit specialist x 2 x the number of self-insured group health plans serviced by the PBM, The costs associated with providing missing information are calculated as: 0.25 hour x an hourly wage rate of $124.74 for benefit specialist x 3.3 percent x the number of self-insured group health plans serviced by the PBM.

[d] Calculated as: 2 hours x an hourly labor cost of $151.41 for benefit specialist and IT professional x 1/3 x the number of self-insured group health plans serviced by the PBM.

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TABLE 20. PBM Per Entity Costs as a Percentage of Revenue, Subsequent Years

	Per-Entity Cost	SBA Small Business Threshold ($ millions)	Cost as a Percent of Threshold (100%)	Cost as a Percent of 75% of Threshold	Cost as a Percent of 50% of Threshold	Cost as a Percent of 25% of Threshold	Cost as a Percent of 10% of Threshold
PBMs		$45.5					
IT Infrastructure	$300,000 [a]		0.659%	0.879%	1.319%	2.637%	6.593%
Disclosure Cost	[b]						
Servicing 50 Plans	$3,969		0.009%	0.012%	0.017%	0.035%	0.087%
Servicing 100 Plans	$7,938		0.017%	0.023%	0.035%	0.070%	0.174%
Servicing 150 Plans	$11,907		0.026%	0.035%	0.052%	0.105%	0.262%
Servicing 200 Plans	$15,876		0.035%	0.047%	0.070%	0.140%	0.349%
Audit	[c]						
Servicing 50 Plans	$15,141		0.033%	0.044%	0.067%	0.133%	0.333%
Servicing 100 Plans	$30,282		0.067%	0.089%	0.133%	0.266%	0.666%
Servicing 150 Plans	$45,423		0.100%	0.133%	0.200%	0.399%	0.998%
Servicing 200 Plans	$60,564		0.133%	0.177%	0.266%	0.532%	1.331%
Total							
Servicing 50 Plans	**$319,110**		**0.701%**	**0.935%**	**1.403%**	**2.805%**	**7.013%**
Servicing 100 Plans	**$338,220**		**0.743%**	**0.991%**	**1.487%**	**2.973%**	**7.433%**
Servicing 150 Plans	**$357,330**		**0.785%**	**1.047%**	**1.571%**	**3.141%**	**7.853%**
Servicing 200 Plans	**$376,440**		**0.827%**	**1.103%**	**1.655%**	**3.309%**	**8.273%**

Note:

[a] Calculated as 73 PBMs x an hourly labor cost of $131.29 for project management specialist x 500 hours + an hourly labor rate of $659.15 for outside legal counsel x 100 hours + an hourly labor cost of $124.74 business operations specialists x 50 hours + an hourly labor cost of $178.08 for software developers, programmers, and testers x 750 hours.

[b] The costs associated with the initial disclosure are calculated as: 0.5 hours per PBM x an hourly labor cost of $156.16 for legal professionals and benefit specialists x 1/3 x the number of self-insured group health plans serviced by the PBM. The costs associated with the semiannual disclosure are calculated as: 0.25 hours x an hourly labor cost of $124.74 for benefit specialist x 2 x the number of self-insured group health plans serviced by the PBM. The costs associated with the quarterly disclosures upon request are calculated as: 0.25 hours x an hourly labor cost of $124.74 for benefit specialist x 2 x the number of self-insured group health plans serviced by the PBM. The costs associated with providing missing information are calculated as: 0.25 hours x an hourly wage rate of $124.74 for benefit specialist x 3.3 percent x the number of self-insured group health plans serviced by the PBM.

[c] Calculated as: 2 hours x an hourly labor cost of $151.41 for benefit specialist and IT professional x 1/3 x the number of self-insured group health plans serviced by the PBM.

5. Steps Taken To Minimize Compliance Costs to Small Entities

The Department considered including smaller self-insured group health plans, such as level-funded plans, within the scope of the final rule. However, the Department determined not to include small, self-insured group health plans for several reasons, including aligning the covered plan definition with ERISA section 726. ERISA section 726 also includes a requirement that small group health plans receive a summary document. Small, self-insured group health plans will also still receive the generalized compensation disclosures pursuant to ERISA section 408(b)(2)(B). In addition, the disclosures in the final rule will be most useful to responsible plan fiduciaries of large plans, who are more likely to have compliance staff and sufficient resources to analyze the disclosures and take appropriate action. Limiting the scope of the final rule is intended to avoid compliance costs and unintended negative consequences to smaller plans as described by some commenters.

The final rule applies only to self-insured group health plans offered by ''specified large employers'' and self-insured group health plans that are ''specified large plans.'' The exclusion of small plans from the final rule will likely help small PBMs. While the Department lacks explicit information on the clients of small PBMs, small PBMs likely have small plans for which they will not have to provide required disclosures or other items covered by the final rule.[449]

Comments and the Department's rationale for limiting to large self-insure plans is discussed in more detail in the section of the preamble titled, ''Limitation to Large, Self-insured Group Health Plans.''

6. Duplicate, Overlapping, or Relevant Federal Rules

There are no duplicate, overlapping, or relevant Federal rules.

[449] Drug Channels, *Plan Sponsors Like More Transparent PBMs—Yet Not All Choose Transparency,* (December 2016), *https://www.drugchannels.net/2016/12/plan-sponsors-like-more-transparent.html.*

I. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation with the base year 1995) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector.[450] For purposes of the UMRA, this rulemaking is expected to have such an impact on the private sector. For the purposes of this rulemaking, the RIA shall meet the UMRA obligations.

J. Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on the States, the relationship between the Federal Government and States, or on the distribution of power and responsibilities among the various levels of government.[451] Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the final rule. Federal agencies must also ensure that ''National action limiting the policymaking discretion of the States shall be taken only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance.'' [452]

Although this final rule is not intended to have any 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, this rule may have federalism implications. Section 514 of ERISA provides, with certain exceptions specifically enumerated, that the provisions of Titles I and IV of ERISA supersede any and all laws of the States as they relate to any employee benefit plan covered under ERISA. Whether ERISA preempts any particular State law is decided on a facts-and-circumstances basis by Federal courts and remains governed by relevant case law and Supreme Court precedent.

In the proposed rule, the Department stated that the rule may have some implications for States, particularly if the rule is found to preempt State laws affecting PBMs providing services to self-insured group health plans. The Department requested input from affected States regarding this assessment. The Department received a comment letter from the National Association of Attorneys General, joined by attorneys general from 43 States, Washington, DC, and American Samoa, in support of the rulemaking, calling it an important step towards transparency. This comment offered feedback on, and a proposed clarification of, the Department's assessment of the rule's federalism implications. Specifically, this comment requested that it be clarified that neither does the Department intend that this rule preempts State law, nor does this rule in fact preempt State law. The commenters also urged the Department to reiterate its ongoing commitment to continued coordination and information sharing with State regulators and attorneys general.

The Department acknowledges these concerns and recognizes that State attorneys general play an important role in overseeing PBM practices under applicable State laws. Nothing in this rule precludes the Department from consulting, coordinating, sharing information as permitted by law, or referring matters to State attorneys general where the Department determines that State laws may be violated or that such cooperation would promote effective oversight and enforcement. Furthermore, this final rule does not alter, expand, or modify the scope of ERISA preemption.

K. Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act,5 U.S.C. 801–808), OIRA has determined that this rule meets the criteria set forth in 5 U.S.C. 804(2). Therefore, this rule shall be submitted to each House of the Congress and to the Comptroller General as part of a report containing a copy of the rule along with other information specified in 5 U.S.C. 801(a)(1).

List of Subjects in 29 CFR Part 2550

Employee benefit plans, Individual retirement accounts, Pensions, Plans.

For the reasons set forth in the preamble, the Department amends part 2550 of subchapter F of chapter XXV of title 29 of the Code of Federal Regulations as follows:

Subchapter F—Fiduciary Responsibility Under the Employee Retirement Income Security Act of 1974

PART 2550—RULES AND REGULATIONS FOR FIDUCIARY RESPONSIBILITY

■ 1. The authority citation for part 2550 continues to read as follows:

Authority: 29 U.S.C. 1135, sec. 102, Reorganization Plan No. 4 of 1978, 5 U.S.C. App. at 727 (2012) and Secretary of Labor's Order No. 1–2011, 77 FR 1088 (Jan. 9, 2012). Section 2550.401c–1 also issued under 29 U.S.C. 1101. Sections 2550.404a–2 and 2550.404a–3 also issued under sec. 657, Pub. L. 107–16, 115 Stat. 38. Sections 2550.404a–5, 2550.404c–1 and 2550.404c–5 also issued under 29 U.S.C. 1104. Sec. 2550.408b–1 also issued under 29 U.S.C. 1108(b)(1). Sec. 2550.408b–19 also issued under sec. 611, Pub. L. 109–280, 120 Stat. 780, 972. Sec. 2550.412–1 also issued under 29 U.S.C. 1112.

■ 2. Amend § 2550.408b–2 by revising paragraph (c)(2) to read as follows:

§ 2550.408b–2 General statutory exemption for services or office space.

* * * * *

(c) * * *

(2) *Welfare plan disclosure.* See § 2550.408b–22.

* * * * *

■ 3. Add § 2550.408b–22 to read as follows:

§ 2550.408b–22 Compensation transparency; pharmacy benefit management services.

(a) *General.* Section 408(b)(2) of the Employee Retirement Income Security Act of 1974 (the Act) exempts from the prohibitions of section 406(a) of the Act payment by a plan to a party in interest, including a fiduciary, for office space or any service (or a combination of services) if such office space or service is furnished under a contract or arrangement which is reasonable. No contract or arrangement for services between a covered plan and a covered service provider, nor any extension or renewal, is reasonable within the meaning of section 408(b)(2) of the Act unless, in addition to meeting the general requirements in § 2550.408b–2, the requirements of section 408(b)(2)(B) of the Act are met. This section implements section 408(b)(2)(B) of the Act with respect to the covered service providers defined in this section. A contract or arrangement between a covered plan and a covered service provider as defined in this section that satisfies the requirements of this section also satisfies the requirements of section 408(b)(2)(B) of the Act.

[450] 2 U.S.C. 1501 *et seq.* (1995).

[451] Federalism, 64 FR 43255 (Aug. 4, 1999).

[452] Id. at section 3(b), 64 FR at 43256.

(b) *Covered plan.* For purposes of this section, a ''covered plan'' means a group health plan as defined in section 733(a) of the Act that is offered by a specified large employer or that is a specified large plan, each as defined in paragraph (m) of this section, other than:

(1) A group health plan in which all of the benefits are provided exclusively through a contract or policy of insurance issued by a health insurance issuer as defined in § 2590.701–2 of this chapter; and

(2) A group health plan established by a plan sponsor that is, or that is affiliated with, a drug manufacturer, distributor, wholesaler, pharmacy benefit manager, rebate aggregator (or other purchasing entity designed to aggregate rebates).

(c) *Covered service provider.* (1) For purposes of this section, a ''covered service provider'' means a service provider that enters a contract or arrangement with the covered plan and reasonably expects $1,000 or more in compensation, direct or indirect, to be received in connection with:

(i) Providing any pharmacy benefit management services, as defined in paragraph (d) of this section, pursuant to the service contract or arrangement, regardless of whether such services will be performed, or such compensation received, by the covered service provider, an affiliate, an agent, or a subcontractor; or

(ii) Providing advice, recommendations, or referrals regarding the provision of pharmacy benefit management services, as defined in paragraph (d) of this section, pursuant to the service contract or arrangement, and is the entity described in paragraph (c)(1)(i) of this section or an affiliate of such entity.

(2) No person or entity is a ''covered service provider'' solely on the basis of providing services as an affiliate, an agent, or a subcontractor of the covered service provider, with respect to performing one or more of the services described in paragraph (c)(1)(i) or (ii) of this section under the contract or arrangement with the covered plan.

(3) Nothing in this section requires disclosure of the compensation of an individual who is an officer, director, employee, or partner of a covered service provider, an affiliate, an agent or a subcontractor, received for their duties performed as set forth in their job description or as expected in their role in connection with the provision of pharmacy benefit management services described in paragraph (d) of this section.

(d) *Pharmacy benefit management services*—(1) *General.* For purposes of this section, the term ''pharmacy benefit management services'' means services necessary for the management or administration of a covered plan's prescription drug benefits (including the covered plan's provision of prescription drugs through the plan's medical benefit), regardless of whether the person, business, or entity performing the service identifies itself as a ''pharmacy benefit manager.''

(2) *Examples.* Pharmacy benefit management services include but are not limited to:

(i) Acting as a negotiator or aggregator of rebates, fees, discounts, and other price concessions for prescription drugs.

(ii) Establishing or maintaining prescription drug formularies.

(iii) Establishing or maintaining pharmacy networks, through contract or otherwise, including a mail order pharmacy, a specialty pharmacy, a retail pharmacy, a nursing home pharmacy, a long-term care pharmacy, and an infusion or other outpatient pharmacy, to provide prescription drugs.

(iv) Performing utilization review and management, including the instituting or processing of prior authorization requests for drugs, step therapy protocols, patient compliance analyses, conducting therapeutic intervention, and administering generic and biosimilar substitution programs.

(v) In conjunction with any of these other services, processing and payment of claims for prescription drugs; adjudicating appeals or grievances related to the covered plan's prescription drug benefits; recordkeeping related to the covered plan's prescription drug benefits; or performing regulatory compliance with respect to the covered plan's prescription drug benefits under the service contract or arrangement.

(e) *Initial disclosure requirements.* A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following information in paragraphs (e)(1) through (9) of this section, not later than the date that is reasonably in advance of the date on which the service contract or arrangement is entered, and extended or renewed (for extensions and renewals, 90 calendar days in advance is deemed to be a reasonable period of time):

(1) *Description of services.* A description of each pharmacy benefit management service, or of the advice, recommendations, or referrals regarding the provision of pharmacy benefit management services, to be provided to the covered plan pursuant to the service contract or arrangement.

(2) *Direct compensation.* A description of the amount of all direct compensation, both in the aggregate and by service, that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive on a semiannual (or at the request of the covered plan, quarterly) basis in connection with services under the service contract or arrangement. For purposes of this paragraph (e)(2), the term ''direct compensation'' means compensation received directly from a covered plan or from the plan sponsor on behalf of the plan (regardless of whether such compensation is paid from plan assets). An example is an administrative fee calculated on a per-participant, per-month basis. In the case of a bundled service or aggregated compensation arrangement, the description must include a reasonable and good faith allocation of the compensation associated with each service in the bundle.

(3) *Indirect compensation.* A description of the following, which shall include compensation based on a structure of incentives not solely related to the contract or arrangement with the covered plan:

(i) *Manufacturer payments.* A description of the amount of any rebate, fee, alternative discount or other remuneration, both in the aggregate and for each drug on the formulary, reasonably expected to be received from any drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), by the covered service provider, an affiliate, an agent, or a subcontractor in connection with the service contract or arrangement, for the semiannual period (or quarter):

(A) For claims incurred during the period; and

(B) Related to utilization of such drug or spending on such drug during the period, specifying both the amount that is reasonably expected to be passed on to the covered plan and, if applicable, plan sponsor and the amount that will be retained by the covered service provider, an affiliate, an agent, or a subcontractor.

(ii) *Spread compensation.* (A) A list of drugs on the formulary and with respect to each such drug on such list:

(*1*) The contracted compensation to be paid by the covered plan for each drug (identified by the National Drug Code) to the covered service provider, an affiliate, an agent, or a subcontractor on behalf of the covered plan;

(*2*) The contracted compensation to be paid to the pharmacy by the covered service provider, an affiliate, an agent, or a subcontractor on behalf of the covered plan for each drug (identified by the National Drug Code); and

(*3*) For each drug, the difference between the amount to be paid under paragraph (e)(3)(ii)(A)(*1*) of this section and the amount paid under paragraph (e)(3)(ii)(A)(*2*) of this section (spread compensation);

(B) A description of the amount of spread compensation reasonably expected to be received by the covered service provider, an affiliate, an agent, or a subcontractor in connection with the service contract or arrangement, for claims filed during each semiannual period (or quarter) both in the aggregate and for each drug on the formulary, and for each pharmacy channel (*i.e.*, retail, mail order, and specialty pharmacy); and

(C) A description of arrangements, incentives, contractual provisions, and policies that will be implemented under the service contract or arrangement that direct patients to pharmacies that are affiliates of the covered service provider.

(iii) *Pharmacy recoupment.* A description of the amount of copay claw-back compensation and any other retroactive adjustment to pharmacy reimbursement reasonably expected to be recouped from a pharmacy by a covered service provider, an affiliate, an agent, or a subcontractor in connection with prescription drugs dispensed under the service contract or arrangement for each semiannual period (or quarter), specifying the anticipated total number of transactions resulting in recoupment. For purpose of this paragraph (e)(3)(iii), copay claw-back compensation means the dollar amount of the difference between a copayment or coinsurance amount paid to the pharmacy by a plan participant or beneficiary and the reimbursement to the pharmacy.

(iv) *Price protection agreements.* A description of any inflation protection or price protection agreements that the covered service provider, an affiliate, an agent, or a subcontractor has entered with any drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), in connection with prescription drugs dispensed under the service contract or arrangement, specifying the amount reasonably expected to be retained by the covered service provider, an affiliate, an agent, or a subcontractor in connection with each such inflation protection or price protection contract or arrangement for each semiannual period (or quarter):

(A) For claims incurred during the period; and

(B) That is related to utilization of such drug or spending on such drug during the period, and the amount that will be passed on to the plan and, if applicable, plan sponsor.

(4) *Compensation for termination of service contract or arrangement.* A description of any compensation that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive in connection with termination of the service contract or arrangement, and how any prepaid amounts will be calculated and refunded upon such termination.

(5) *Description of other compensation.* To the extent not already disclosed under paragraphs (e)(1) through (4) of this section—

(i) A description of any compensation that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive in connection with the service contract or arrangement for the semiannual period (or quarter), regardless of whether such compensation is paid regularly or irregularly or from plan assets or is subject to any contingency or other condition;

(ii) The identification of the payer of such compensation;

(iii) An identification of the services for which such compensation will be received; and

(iv) A description of the arrangement between the payer and the covered service provider, an affiliate, an agent, or a subcontractor, as applicable, pursuant to which such compensation is paid.

(6) *Description of formulary placement incentives.* (i) A description of any formulary placement incentives and arrangements that the covered service provider, an affiliate, an agent, or a subcontractor has entered with any drug manufacturer in connection with the service contract or arrangement, along with an explanation of how the incentives and arrangements affect services to and are aligned with the interests of the plan and/or its participants and beneficiaries (*e.g.*, incentives or arrangements are to control prescription drug costs, provide clinically superior drugs, or both).

(ii) For any drug on the formulary with respect to which the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive any payment by the manufacturer or aggregator in connection with the service contract or arrangement (and that is not passed through to the plan), an identification of any reasonably available therapeutically equivalent alternatives (including biosimilar biological products), and the reason for omitting the alternatives from the formulary.

(iii) If the covered service provider, an affiliate, an agent, or a subcontractor retains authority to modify the formulary during the term of the service contract or arrangement, such as by adding or deleting drugs or changing their tiering, an explanation of the reasons for retaining such authority, the expected frequency of such changes, and that the responsible plan fiduciary will be notified reasonably in advance of any modifications that, individually or in the aggregate, are reasonably expected to have a material impact on the reasonableness of compensation under the service contract or arrangement, as well as the covered plan's right to terminate the service contract or arrangement on reasonably short notice under the circumstances. For purposes of this paragraph (e)(6)(iii), the term ''material'' means an amount that is 5 percent or more, or such lower percentage or dollar amount as may be agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement, of the aggregate compensation (on a semiannual basis, or at the request of the covered plan, quarterly basis) disclosed pursuant to paragraph (e)(3)(i) of this section, adjusted for any increases previously disclosed under this paragraph (e)(6).

(7) *Drug pricing methodology.* A description of the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, to the covered plan of each drug on the formulary, as defined by National Drug Code, after rebates, fees, alternative discounts, or other remuneration received from drug manufacturers, distributors, wholesalers, or rebate aggregators (or other purchasing entities designed to aggregate rebates), for each pharmacy channel, expressed as a monetary amount. If a monetary amount is not ascertainable, the covered service provider must disclose the methodology used by the covered service provider, an affiliate, an agent, or a subcontractor, under the service contract or arrangement, to determine the net price per course of treatment or single fill, the covered plan will pay for each drug on the formulary, for each pharmacy channel, along with an objective means to verify the accuracy.

(8) *Statement of fiduciary status.* If applicable, a statement that the covered service provider, an affiliate, an agent, or a subcontractor will provide, or reasonably expects to provide, services pursuant to the service contract or arrangement directly to the covered plan as a fiduciary (within the meaning of section 3(21) of the Act).

(9) *Statement of audit right.* A statement of the covered plan's right to

the audit described in paragraph (j) of this section and the procedures for requesting such an audit.

(f) [Reserved]

(g) *Semiannual disclosure requirements.* A covered service provider shall disclose to a responsible plan fiduciary, in writing, on a semiannual basis (or at the request of the covered plan, quarterly) no later than 30 calendar days after the end of each six-month period or quarter beginning on the date the service contract or arrangement is entered, the following information with respect to the preceding six-month period (or quarter):

(1) *Direct compensation.* A description of all direct compensation (within the meaning of paragraph (e)(2) of this section), both in the aggregate and by service, that the covered service provider, an affiliate, an agent, or a subcontractor received or reasonably expects to receive for the semiannual period (or quarter) in connection with services under the service contract or arrangement. In the case of a bundled service or aggregated compensation arrangement, the description must include a reasonable and good faith allocation of the compensation associated with each service in the bundle.

(2) *Indirect compensation.* A description of the following, which shall include compensation based on a structure of incentives not solely related to the contract or arrangement with the covered plan:

(i) *Manufacturer payments.* A description of all rebates, fees, alternative discounts or other remuneration, both in the aggregate and for each drug on the formulary, received or reasonably expected to be received from any drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), by the covered service provider, an affiliate, an agent, or a subcontractor in connection with the service contract arrangement for the semiannual period (or quarter):

(A) For claims incurred during the period; and

(B) That are related to utilization of such drug or spending on such drug during such period, specifying both the amount passed on to the plan and, if applicable, plan sponsor and the amount retained by the covered service provider, an affiliate, and agent, or a subcontractor.

(ii) *Spread compensation.* (A) A list of drugs for which a claim was filed during the semiannual period or quarter, and with respect to each drug on the list:

(*1*) The contracted compensation paid by the covered plan for each drug (identified by the National Drug Code) to the covered service provider, an affiliate, an agent, or a subcontractor on behalf of the covered plan;

(*2*) The contracted compensation paid to the pharmacy by the covered service provider, an affiliate, an agent, or a subcontractor on behalf of the covered plan for each drug (identified by the National Drug Code); and

(*3*) For each such claim, the difference between the amount paid under paragraph (g)(2)(ii)(A)(*1*) of this section and the amount paid under paragraph (g)(2)(ii)(A)(*2*) of this section (spread compensation); and

(B) A description of the amount of all spread compensation (within the meaning of paragraph (e)(3)(ii) of this section) received for the semiannual period (or quarter) by the covered service provider, an affiliate, an agent, or a subcontractor in connection with the service contract or arrangement, both in the aggregate and for each drug, and for each pharmacy channel (*i.e.*, retail, mail order, and specialty pharmacy).

(iii) *Pharmacy recoupment.* A description of all amounts of copay claw-back compensation (as described in paragraph (e)(3)(iii) of this section) and any other retroactive adjustment to pharmacy reimbursement recouped for the semiannual period (or quarter) from a pharmacy by a covered service provider, an affiliate, an agent, or a subcontractor in connection with prescription drugs dispensed under the service contract or arrangement, specifying the total number of transactions resulting in recoupment.

(iv) *Price protection agreements.* A description of all amounts received or reasonably expected to be received from a drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), by the covered service provider, an affiliate, an agent, or a subcontractor for the semiannual period (or quarter):

(A) For claims incurred during the period; and

(B) That is related to the utilization of such drug or spending on such drug during the period pursuant to any inflation protection or price protection agreements that the covered service provider, an affiliate, an agent, or a subcontractor entered with any drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), in connection with prescription drugs dispensed under the service contract or arrangement, specifying both the amount passed on to the plan and, if applicable, plan sponsor and the amount retained by the covered service provider, an affiliate, and agent, or a subcontractor.

(3) *Other compensation.* To the extent not already disclosed under paragraph (g)(1) or (2) of this section—

(i) A description of any compensation that the covered service provider, an affiliate, an agent, or a subcontractor received or reasonably expects to receive in connection with services under the service contract or arrangement for the semiannual period (or quarter), regardless of whether such compensation is paid regularly or irregularly or from plan assets or is subject to any contingency or other condition;

(ii) The identification of the payer of indirect compensation;

(iii) An identification of the services for which indirect compensation was received; and

(iv) A description of the arrangement between the payer and the covered service provider, an affiliate, an agent, or a subcontractor, as applicable, pursuant to which such compensation was paid.

(4) *Overage explanation.* If any category of compensation to the covered service provider, an affiliate, an agent, or a subcontractor described in this paragraph (g), in the aggregate, materially exceeds the corresponding semiannual (or quarterly) estimate described in paragraph (e) of this section, an identification of the amount of the overage (in the aggregate) and the reason for the overage. For purposes of this paragraph (g)(4), the term ''materially'' means 5 percent or more, or such lower percentage or dollar amount as may be agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement.

(5) *Statement of fiduciary status.* To the extent not previously disclosed under paragraph (e) of this section, if applicable, a statement that the covered service provider, an affiliate, an agent, or a subcontractor will provide, or reasonably expects to provide, services pursuant to the service contract or arrangement directly to the covered plan as a fiduciary (within the meaning of section 3(21) of the Act).

(6) *Statement of audit right.* A statement of the covered plan's right to the audit described in paragraph (j) of this section and the procedures for requesting such an audit.

(h) [Reserved]

(i) *Information on request.* (1) Upon the written request of the responsible plan fiduciary, the covered service

provider must furnish any other information relating to the contract or arrangement that is required for the covered plan to comply with the reporting and disclosure requirements of Title I of the Act, the regulations in this chapter, and forms and schedules issued under Title I.

(2) The covered service provider must disclose the information required by paragraph (i)(1) of this section reasonably in advance of the date upon which such responsible plan fiduciary states that it must comply with the applicable reporting or disclosure requirement, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, in which case the information must be disclosed as soon as practicable.

(j) *Right to audit*—(1) *Frequency and scope.* Not less than once per year, at the written request of the covered plan, the covered service provider shall allow for an audit of the covered service provider for accuracy of any disclosure made to comply with this section.

(2) *Auditor.* A responsible plan fiduciary of the covered plan shall have the right to select an auditor. The covered service provider shall not impose any limitations on the selection of such auditor.

(3) *Provision of information.* The covered service provider shall make available to the auditor all records, claims and transaction-level data, and other information reasonably necessary to confirm the accuracy of any disclosure made to comply with this section, including contracts with retail pharmacies, drug manufacturers, and rebate aggregators, subject to reasonable confidentiality agreements to prevent redisclosure of such information and to limit use of such information for purposes related to the covered plan's contract or arrangement.

(4) *Fees.* The covered plan shall bear responsibility for all expenses related to the selection and retention of the auditor. The covered service provider shall bear the cost of providing the requested information.

(5) *Timing.* The covered service provider shall confirm receipt of a request for an audit under this section no later than ten (10) business days after the information is requested. The covered service provider shall provide the information required under paragraph (j)(3) of this section within a commercially reasonable period but in no event later than 60 calendar days absent extraordinary circumstances beyond their control.

(6) *Restrictions.* The covered service provider may not impose conditions that would restrict the covered plan's right to conduct an audit under this section, including restrictions on the period of the audit, the location of the audit, or the number of records to be provided, except that the scope of the audit is limited to the period covered by the disclosures under this section.

(7) *Information from affiliates and subcontractors.* The covered service provider shall be responsible for providing such auditor with the information required under paragraph (j)(3) of this section that is owned or held by an affiliate, an agent, or a subcontractor of the covered service provider.

(k) *Manner of disclosure*—(1) *General.* All disclosures under this section must be clear and concise, free of misrepresentations, and contain sufficient specificity to permit evaluation of the reasonableness of the service contract or arrangement. For example, the Department will consider the use of generic industry terms, jargon, or legalese, without definition, to lack the sufficient specificity required under the preceding sentence unless the language in question specifically refers to objectively determinable definitions, standards, or other similar guidelines, that are publicly available or will be provided by the covered service provider to the responsible plan fiduciary free of charge and within a reasonable period of time following the request.

(2) *Descriptions of compensation.* Descriptions of compensation or amounts required under this section must be expressed as a monetary amount (*e.g.*, $1,000) and may be estimated to the extent that the actual amount is not reasonably ascertainable but shall contain sufficient information and specificity to permit evaluation of the reasonableness of the compensation received by the covered service provider, an affiliate, an agent, or a subcontractor. Estimates shall be grounded in good faith assumptions based on contractually defined methodologies, historical utilization and rebate experience, or other information reasonably available at the time of disclosure.

(3) *Machine-readability format.* Upon request of a responsible plan fiduciary of a covered plan, descriptions of compensation required under this section must also be provided, within a reasonable time after such request, in a standard machine-readable file. For purposes of this paragraph (k)(3), ''machine-readable file'' means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost. Drugs must be referred to using an industry standard name and include a useful, non-proprietary identifier such as the National Drug Code, promulgated by the U.S. Food and Drug Administration.

(4) *Confidentiality agreements.* (i) Except as provided in paragraph (j)(3) of this section, the covered service provider and its affiliates, agents, and subcontractors may not impose restrictions on the covered plan's use of disclosures required under this section, or the contract or arrangement described in paragraph (c)(1) of this section, except that the covered contract or arrangement may require the responsible plan fiduciary to require third parties to whom it rediscloses such information and any subcontractors of those third parties to execute reasonable confidentiality agreements preventing redisclosure by such parties and limiting use of such information to purposes related to the covered plan's contract or arrangement.

(ii) Neither this paragraph (k)(4) nor paragraph (j)(3) of this section restrict a covered plan, auditor, or a third party hired by the plan, or their subcontractors, from sharing information with State or Federal Government regulators or with legal counsel, even if the activities of those entities are unrelated to the purpose of a covered plan's contract or arrangement.

(l) *Disclosure errors.* No service contract or arrangement will fail to be reasonable under this section solely because the covered service provider, acting in good faith and with reasonable diligence, makes an error or omission in disclosing the information required pursuant to paragraph (e), (g), or (j) of this section, provided that the covered service provider discloses the correct information to the responsible plan fiduciary as soon as practicable, but not later than 30 calendar days from the date on which the covered service provider knows of such error or omission.

(m) *Definitions*—(1) *Affiliate.* A person's or entity's ''affiliate'' directly or indirectly (through one or more intermediaries) controls, is controlled by, or is under common control with such person or entity; or is an officer, director, or employee of, or partner in, such person or entity. Unless otherwise specified, an ''affiliate'' in this section refers to an affiliate of the covered service provider.

(2) *Agent.* An ''agent'' is any person or entity authorized (whether that authorization is expressed or implied) to

represent or act on behalf of another person or entity. Unless otherwise specified, an ''agent'' in this section refers to an agent of the covered service provider.

(3) *Compensation.* The term ''compensation'' means anything of monetary value but does not include any item or service valued at $250 or less, in the aggregate, during the term of the service contract or arrangement.

(4) *Responsible plan fiduciary.* A ''responsible plan fiduciary'' is a fiduciary with authority to cause the covered plan to enter, extend, or renew the service contract or arrangement.

(5) *Subcontractor.* A ''subcontractor'' is any person or entity (or an affiliate of such person or entity) that is not an affiliate of the covered service provider and that, pursuant to a contract or arrangement with the covered service provider or an affiliate, reasonably expects to receive $1,000 or more in compensation for performing one or more services described pursuant to paragraph (d) of this section provided for by the service contract or arrangement with the covered plan.

(6) *Specified large employer.* The term ''specified large employer'' means, in connection with a group health plan established or maintained by a single employer, with respect to a calendar year, an employer who employed an average of at least 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the calendar year. Whether an employer is a specified large employer shall be determined in accordance with the rules for counting employees and employer aggregation under section 4980H of the Internal Revenue Code and its implementing regulations at 26 CFR 54.4980H.

(7) *Specified large plan.* The term ''specified large plan'' means a group health plan established or maintained by a plan sponsor described in 29 U.S.C. 1002(16)(B)(ii) or (iii) that had an average of at least 100 participants on business days during the preceding plan year. Whether a group health plan is a specified large plan is determined by taking the sum of the total number of participants (not including beneficiaries) for each calendar month in the preceding plan year, and dividing by 12. The result, if not a whole number, is then rounded to the next lowest whole number.

(n) *Exemption for responsible plan fiduciary*—(1) *General.* Pursuant to section 408(a) of the Act, the restrictions of section 406(a)(1)(C) and (D) of the Act shall not apply to a responsible plan fiduciary, notwithstanding any failure by a covered service provider to meet the requirements in paragraphs (e) through (l) of this section, if the following conditions are met:

(i) The responsible plan fiduciary did not know that the covered service provider failed or would fail to meet the requirements in paragraphs (e) through (l) of this section and reasonably believed that such requirements had been met.

(ii) The responsible plan fiduciary, upon discovering that the covered service provider failed to meet any requirement in paragraphs (e) through (l) of this section, requests in writing that the covered service provider correct the failure, *e.g.*, to furnish required information or comply with the audit requirement.

(iii) If the covered service provider fails to comply with the written request described in paragraph (n)(1)(ii) of this section within 90 calendar days of the request, the responsible plan fiduciary notifies the Secretary of the covered service provider's failure, in accordance with paragraphs (n)(2) and (3) of this section.

(2) *Notice content.* The notice to the Secretary shall contain—

(i) The name of the covered plan;

(ii) The plan number used for the annual report on the covered plan;

(iii) The plan sponsor's name, address, and employer identification number;

(iv) The name, address, and telephone number of the responsible plan fiduciary;

(v) The name, address, phone number, and, if known, employer identification number of the covered service provider;

(vi) A description of the services provided to the covered plan;

(vii) A description of the covered service provider's failure;

(viii) The date on which the corrective action described in paragraph (n)(1)(ii) of this section was requested in writing from the covered service provider; and

(ix) A statement as to whether the covered service provider continues to provide services to the plan.

(3) *Notice timing.* The notice described in paragraph (n)(2) of this section shall be filed with the Department not later than 30 calendar days following the earlier of:

(i) The covered service provider's refusal to correct the failure identified in the written request described in paragraph (n)(1)(ii) of this section; or

(ii) 90 calendar days after the written request described paragraph (n)(1)(ii) of this section is made.

(4) *Where to file notice.* The notice described in paragraph (n)(2) of this section shall be furnished to the U.S. Department of Labor electronically in accordance with instructions published by the Department; or may be sent to the following address: U.S. Department of Labor, Employee Benefits Security Administration, Office of Enforcement, P.O. Box 75296, Washington, DC 20013.

(5) *Termination of service contract or arrangement.* If the covered service provider fails to comply with the written request under paragraph (n)(1)(ii) of this section within 90 calendar days of such request, the responsible plan fiduciary shall determine whether to terminate or continue the service contract or arrangement consistent with its duty of prudence under section 404 of the Act and shall document the basis for that determination.

(o) *Severability.* If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof.

(p) *Effective and applicability dates.* (1) This section is effective January 4, 2027.

(2) This section shall apply to plan years beginning on or after July 1, 2027.

Signed at Washington, DC, on this 28th day of October 2026.

Daniel Aronowitz,

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2026–22306 Filed 10–30–26; 8:45 am]

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Part IV

The President

Proclamation 11077—Adjusting Imports of Robotics, Industrial Machinery, and Their Parts and Components Into the United States

Memorandum of October 28, 2026—Delegation of Authority Under Section 8335 of the National Defense Authorization Act for Fiscal Year 2026

Federal Register
Vol. 91, No. 210
Monday, November 2, 2026

Presidential Documents

Title 3—

The President

Proclamation 11077 of October 28, 2026

Adjusting Imports of Robotics, Industrial Machinery, and Their Parts and Components Into the United States

By the President of the United States of America

A Proclamation

1. Within the past 90 days, the Secretary of Commerce (Secretary) transmitted to me a report on his investigation into the effects of imports of robotics and industrial machinery, as well as their parts and components (together, components), on the national security of the United States under section 232 of the Trade Expansion Act of 1962, as amended, 19 U.S.C. 1862 (section 232). Based on the facts considered in that investigation, and taking into account the close relation of the economic welfare of the Nation to our national security and other relevant factors, see section 232(d) (19 U.S.C. 1862(d)), the Secretary found and advised me of his opinion that robotics, industrial machinery, and their components are being imported into the United States in such quantities and under such circumstances as to threaten to impair the national security of the United States.

2. Nearly all modern defense systems and critical infrastructure sectors require the use of robotics or industrial machinery to function or be manufactured effectively and efficiently. Robotics and industrial machinery are critical to virtually all modern manufacturing processes, including for defense, commercial, and dual-use purposes. Robotics and industrial machinery enable defense readiness and design, production, and sustainment activities across a wide range of defense applications. Furthermore, robotics and industrial machinery generate substantial economic value and support important economic activities, including approximately $7.1 trillion in shipments of manufactured goods in 2024 and the production of approximately $86 billion worth of equipment in 2024.

3. The Secretary found that robotics and industrial machinery support the production of essential, state-of-the-art defense systems, such as aircraft, tanks, ships, weapons, and munitions, as well as certain military and law enforcement activities. For example, advanced robots—such as autonomous robots, humanoid and quadruped robots, and autonomous ground vehicles—provide combat support to the United States military, including by conducting intelligence, surveillance, and reconnaissance missions and by handling dangerous tasks, such as casualty extraction and mine detection and clearing. Robotics and industrial machinery also enable the defense industry to automate the building of essential defense products, such as missiles, aircraft, and ships, allowing production activities to last longer and for repetitive tasks to be performed with minimal error. Indeed, the defense industrial base's ability to surge production, including during wartime or armed conflict, relies on industrial robotics and machinery.

4. The Secretary found that robotics and industrial machines are also crucial to the United States' critical infrastructure sectors and other key aspects of the United States economy. Industrial robots and machines are used to create products and parts that are used across all 16 critical infrastructure sectors of the United States. For example, industrial robots are heavily used in the automotive, electrical, and electronics industries and are also

meaningfully used in the metal and machinery, plastic and chemical products, and food and beverage industries. Similarly, industrial machinery carries out critical functions across various industries and in the manufacturing process for a range of goods, including construction equipment, electronics, medical devices, metal fabrication, motor vehicles, and aircraft. And because industrial robots and machinery serve end-use industries and contribute to equipment manufacturing and product creation efforts, they carry expansive downstream implications for the United States economy. Thus, robotics and industrial machines are a driving force behind critical infrastructure sectors and are crucial to the national and economic security interests of the United States.

5. The Secretary found that the United States relies on foreign imports for most types of robotics and industrial machinery and for their components. The value of robotics, industrial machinery, and their components imported into the United States has increased over the last decade and is projected to continue to increase. This import reliance poses risks to the United States industrial base and threatens the long-term competitiveness of the United States in a sector that is increasingly vital to national security.

6. The Secretary also found that robotics, industrial machinery, and their components from certain foreign entities pose unique security and safety risks. Robotics and industrial machinery are integrated into many manufacturing and defense systems and routinely process and store sensitive data. These technologies, when sourced from foreign entities, can pose significant cybersecurity vulnerabilities that can result in severe consequences to the United States.

7. The Secretary found that the domestic industry does not produce enough robotics, industrial machinery, and their components to meet national security needs, and that the need for domestically produced robotics, industrial machinery, and their components will only increase. Despite a recent surge in investments in manufacturing facilities in the United States, the United States still produces less robotics and industrial equipment than it consumes, lacks the capacity to satisfy the need for robotics and industrial machinery with domestic sources, and underutilizes its manufacturing capacity for robotics, industrial equipment, and their components. According to the Secretary, without intervention, challenges for United States manufacturers investing in robotics and industrial machinery will likely continue. In the Secretary's opinion, it is vital to take action to strengthen, expand, and modernize the domestic manufacturing and industrial base for robotics, industrial machinery, and their components.

8. In light of these findings and other findings in the Secretary's report, the Secretary recommended various actions to adjust the imports of robotics, industrial machinery, and their components so that such imports will not threaten to impair the national security.

9. After considering the Secretary's report, the factors in section 232(d) (19 U.S.C. 1862(d)), and other relevant factors and information, I concur with the Secretary's finding that robotics, industrial machinery, and their components are being imported into the United States in such quantities and under such circumstances as to threaten to impair the national security of the United States. In my judgment, and in light of the Secretary's report, the factors in section 232(d) (19 U.S.C. 1862(d)), and other relevant factors and information, I determine that it is necessary and appropriate to enter into negotiations with trading partners to adjust imports of robotics, industrial machinery, and their components so that such imports will not threaten to impair the national security of the United States.

10. I therefore direct the Secretary and the United States Trade Representative (Trade Representative) to jointly pursue negotiations of agreements or continue any current negotiations of agreements to address the threatened impairment of the national security with respect to imported robotics, industrial machinery, and their components, with any foreign trading partner the Secretary and the Trade Representative deem appropriate, and to update me

on the progress of such negotiations within 180 days of the date of this proclamation. Under current circumstances and in light of future requirements of the United States, this course of action is necessary and appropriate to address the threatened impairment of the national security.

11. Section 232 authorizes the President to take action to adjust the imports of an article and its derivatives that are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security. Section 232 includes the authority to adopt and carry out a plan of action, with adjustments over time, to address the national security threat. That initial plan of action may include negotiations of agreements along with other actions to adjust imports to address the national security threat, including tariffs, duties, quotas, and fees. If action under section 232 includes the negotiation of an agreement, such as one contemplated in section 232(c)(3)(A)(i) (19 U.S.C. 1862(c)(3)(A)(i)), the President may also take other actions he deems necessary to adjust imports to eliminate the threat that the imported article poses to the national security, including if such an agreement is not entered into within 180 days of the date of this proclamation, is not being carried out, or is ineffective. *See* 19 U.S.C. 1862(c)(3)(A).

12. Section 604 of the Trade Act of 1974, as amended (19 U.S.C. 2483) (section 604), authorizes the President to embody in the Harmonized Tariff Schedule of the United States the substance of statutes affecting import treatment, and actions thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States, including section 232; section 604; and section 301 of title 3, United States Code, do hereby proclaim as follows:

(1) The Secretary and the Trade Representative shall jointly pursue or continue pursuing negotiations of agreements to address the threatened impairment of the national security with respect to imports of robotics, industrial machinery, and their components. Depending on the status or outcome of such negotiations, I may consider alternative remedies in the future, including imposing or modifying tariffs, duties, quotas, and fees; and establishing a program to incentivize new investment in United States production of robotics and industrial machinery, as well as their parts and components.

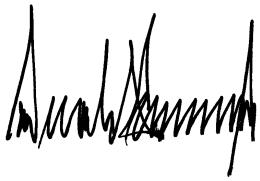
(2) The Secretary and the Trade Representative, in consultation with any other senior executive branch official they deem appropriate, shall, from time to time, update me on the status or outcome of the negotiations described in this proclamation. The Secretary and the Trade Representative shall provide one of these updates within 180 days of the date of this proclamation.

(3) The Secretary shall continue to monitor imports of robotics, industrial machinery, and their components and shall, from time to time, in consultation with any senior executive branch officials the Secretary deems appropriate, review the status of such imports with respect to the national security. The Secretary shall inform me of any circumstances that, in the Secretary's opinion, might indicate the need for further action by the President under section 232.

(4) Any provision of previous proclamations and Executive Orders that is inconsistent with this proclamation is superseded to the extent of such inconsistency. If any provision of this proclamation or the application of any provision of this proclamation to any individual or circumstance is held to be invalid, the remainder of this proclamation and the application of its provisions to any other individual or circumstance shall not be affected.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of October, in the year of our Lord two thousand twenty-six, and

of the Independence of the United States of America the two hundred and fifty-first.



[FR Doc. 2026–22385
Filed 10–30–26; 11:15 am]
Billing code 3395–F4–P

Presidential Documents

Memorandum of October 28, 2026

Delegation of Authority Under Section 8335 of the National Defense Authorization Act for Fiscal Year 2026

Memorandum for the Secretary of State [and] the Secretary of the Treasury

By the authority vested in me as President by the Constitution and the laws of the United States, including section 301 of title 3, United States Code, I hereby direct:

Section 1. (a) I hereby delegate to the Secretary of the Treasury, in consultation with the Secretary of State, the functions and authorities vested in the President by section 8335(a) of the National Defense Authorization Act for Fiscal Year 2026 (the ''Act'') (22 U.S.C. 10704(a)). Once sanctionable foreign persons are identified by the Secretary of State, I delegate to the heads of relevant executive departments and agencies, commensurate with their respective areas of responsibility, the authority to implement such sanctions.

(b) I hereby delegate to the Secretary of the Treasury the functions and authorities vested in the President by sections 8335(c)(1) and 8335(d)(1) of the Act.

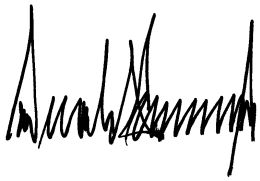
(c) I hereby delegate to the Secretary of the Treasury, in consultation with the Secretary of State, the functions and authorities vested in the President by section 8335(f) of the Act.

(d) I hereby delegate to the Secretary of State the functions and authorities vested in the President by section 8335(g) of the Act.

(e) I hereby delegate to the Secretary of the Treasury the functions and authorities vested in the President by section 8335(i) of the Act.

Sec. 2. The delegations in this memorandum shall apply to any provision of any future public law that is the same or substantially the same as the provision referenced in this memorandum. Any reference in this memorandum to any act shall be deemed to be a reference to such act as amended from time to time.

Sec. 3. The Secretary of the Treasury is authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, October 28, 2026

[FR Doc. 2026–22386
Filed 10–30–26; 11:15 am]
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A new table will be published in the first issue of each month.

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