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

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

MERIT SYSTEMS PROTECTION BOARD

5 CFR Part 1201

Civil Monetary Penalty Inflation Adjustment

AGENCY: Merit Systems Protection Board.

ACTION: Final rule.

SUMMARY: This final rule adjusts the level of civil monetary penalties (CMPs) in regulations maintained and enforced by the Merit Systems Protection Board (MSPB) with an annual adjustment under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) and Office of Management and Budget (OMB) guidance.

DATES: This final rule is effective on February 22, 2019.

FOR FURTHER INFORMATION CONTACT: Jennifer Everling, Acting Clerk of the Board, Merit Systems Protection Board, 1615 M Street NW, Washington, DC 20419; Phone: (202) 653–7200; Fax: (202) 653–7130; or email: *mspb@mspb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Civil Penalties Inflation Adjustment Act of 1990 (the 1990 Act), Public Law 101–410, provided for the regular evaluation of CMPs by Federal agencies. Periodic inflationary adjustments of CMPs ensure that the consequences of statutory violations adequately reflect the gravity of such offenses and that CMPs are properly accounted for and collected by the Federal Government. In April 1996, the 1990 Act was amended by the Debt Collection Improvement Act of 1996 (the 1996 Act), Public Law 104–134, requiring Federal agencies to adjust their CMPs at least once every four years. However, because inflationary adjustments to CMPs were statutorily capped at ten percent of the maximum penalty amount, but only required to be calculated every four years, CMPs in many cases did not correspond with the true measure of inflation over the preceding four-year period, leading to a decline in the real value of the penalty. To remedy this decline, the 2015 Act (section 701 of Pub. L. 114–74) requires agencies to adjust CMP amounts with annual inflationary adjustments through a rulemaking using a methodology mandated by the legislation. The purpose of these adjustments is to maintain the deterrent effect of civil penalties.

A civil monetary penalty is ''any penalty, fine, or other sanction'' that: (1) ''is for a specific amount'' or ''has a maximum amount'' under Federal law; and (2) a Federal agency assesses or enforces ''pursuant to an administrative proceeding or a civil action in the Federal courts.'' 28 U.S.C. 2461 note.

The MSPB is authorized to assess CMPs pursuant to 5 U.S.C. 1215(a)(3) and 5 U.S.C. 7326 in disciplinary actions brought by the Special Counsel. The corresponding MSPB regulation for both CMPs is 5 CFR 1201.126(a). As required by the 2015 Act, and pursuant to guidance issued by the OMB, the MSPB is now making an annual adjustment for 2019, according to the prescribed formulas.

II. Calculation of Adjustment

The CMP listed in 5 U.S.C. 1215(a)(3) was established in 1978 with the enactment of the Civil Service Reform Act of 1978 (CSRA), Public Law 95–454, section 202(a), 92 Stat. 1121–30 (Oct. 13, 1978), and originally codified at 5 U.S.C. 1207(b). That CMP was last amended by section 106 of the Whistleblower Protection Enhancement Act of 2012, Public Law 112–199, 12 Stat. 1468 (Nov. 27, 2012), now codified at 5 U.S.C. 1215(a)(3), which provided for a CMP ''not to exceed $1,000.'' The CMP authorized in 5 U.S.C. 7326 was established in 2012 by section 4 of the Hatch Act Modernization Act of 2012 (Hatch Act), Public Law 112–230, 126 Stat. 1617 (Dec. 28, 2012), which provided for a CMP ''not to exceed $1,000.'' On January 10, 2018, the MSPB issued a final rule which increased the maximum CMP allowed under both 5 U.S.C. 1215(a)(3) and 5 U.S.C. 7326 to $1,066 for the year 2018. *See* 83 FR 1173 (Jan. 10, 2018). This increase reflected the annual increase for the year 2018 mandated by the 2015 Act.

On December 14, 2018, OMB issued guidance on calculating the annual inflationary adjustment for 2019. *See* Memorandum from Mick Mulvaney, Dir., OMB, to Heads of Executive Departments and Agencies re: Implementation of Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, M–19–04 (Dec. 14, 2018). Therein, OMB notified agencies that the annual adjustment multiplier for 2019, based on the Consumer Price Index for All Urban Consumers (CPI–U), is 1.02522 and that the 2019 annual adjustment amount is obtained by multiplying the 2018 penalty amount by the 2019 annual adjustment multiplier, and rounding to the nearest dollar. Therefore, the new maximum penalty under the CSRA and the Hatch Act is $1,066 × 1.02522 = $1,092.88, which rounds to $1,093.

III. Effective Date of Penalties

The revised CMP amounts will go into effect on February 22, 2019. All violations for which CMPs are assessed after the effective date of this rule will be assessed at the adjusted penalty level regardless of whether the violation occurred before the effective date.

IV. Procedural Requirements

A. Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b), the MSPB has determined that good cause exists for waiving the general notice of proposed rulemaking and public comment procedures as to these technical amendments. The notice and comment procedures are being waived because Congress has specifically exempted agencies from these requirements when implementing the 2015 Act. The 2015 Act explicitly requires the agency to make subsequent annual adjustments notwithstanding 5 U.S.C. 553, the section of the Administrative Procedure Act that normally requires agencies to engage in notice and comment. It is also in the public interest that the adjusted rates for CMPs under the CSRA and the Hatch Act become effective as soon as possible to maintain their effective deterrent effect.

B. Regulatory Impact Analysis: E.O. 12866

The MSPB has determined that this is not a significant regulatory action under E.O. 12866. Therefore, no regulatory impact analysis is required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. *See* 5 U.S.C. 603(a) and 604(a). As discussed above, the 2015 Act does not require agencies to first publish a proposed rule when adjusting CMPs within their jurisdiction. Thus, the RFA does not apply to this final rule.

D. Paperwork Reduction Act

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. Chapter 35).

List of Subjects in 5 CFR Part 1201

Administrative practice and procedure, Civil rights, Government employees.

For the reasons set forth above, 5 CFR part 1201 is amended as follows:

PART 1201—PRACTICES AND PROCEDURES

■ 1. The authority citation for part 1201 continues to read as follows:

Authority: 5 U.S.C. 1204, 1305, and 7701, and 38 U.S.C. 4331, unless otherwise noted.

§ 1201.126 [Amended]

■ 2. Section 1201.126 is amended in paragraph (a) by removing ''$1,066'' and adding in its place ''$1,093.''

Jennifer Everling,

Acting Clerk of the Board.

[FR Doc. 2019–03018 Filed 2–21–19; 8:45 am]

BILLING CODE 7400–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0508; Product Identifier 2018–NM–012–AD; Amendment 39–19563; AD 2019–03–11]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Airbus SAS Model A350–941 and -1041 airplanes. This AD was prompted by a determination that more restrictive maintenance requirements and airworthiness limitations are necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive maintenance requirements and airworthiness limitations. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective March 29, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of March 29, 2019.

ADDRESSES: For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAL, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *continued-airworthiness.a350@airbus.com;* internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Standards 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 on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0508.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0508; 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 regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus SAS Model A350–941 airplanes. The NPRM published in the **Federal Register** on June 11, 2018 (83 FR 26884). The NPRM was prompted by a determination that more restrictive maintenance requirements and airworthiness limitations are necessary. The NPRM proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive maintenance requirements and airworthiness limitations.

We issued a supplemental NPRM (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus SAS Model A350–941 and –1041 airplanes. The SNPRM published in the **Federal Register** on November 6, 2018 (83 FR 55496). We issued the SNPRM because the service information referenced in the NPRM had been further revised to include new or more restrictive maintenance requirements and airworthiness limitations. We also revised the applicability of the proposed AD by adding Airbus SAS Model A350–1041 airplanes.

We are issuing this AD to address safety-significant latent failures that would, in combination with one or more other specific failures or events, result in a hazardous or catastrophic failure condition.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0179, dated August 23, 2018, to correct an unsafe condition on all Airbus SAS Model A350–941 and –1041 airplanes. EASA AD 2018–0179 states:

Certification Maintenance Requirements (CMR) for the Airbus A350, which are approved by EASA, are currently defined and published in the Airbus A350 ALS [Airworthiness Limitations Section] Part 3 document. These instructions have been

identified as mandatory for continued airworthiness.

Failure to accomplish these instructions could result in an unsafe condition.

EASA previously issued AD 2018–0004 to require the actions as specified in Airbus A350 ALS Part 3 Revision 04.

Since this [EASA] AD was issued, Airbus published variation 4.2 of Airbus A350 ALS Part 3, to introduce new and more restrictive CMRs.

For the reason described above, this [EASA] AD requires accomplishment of the actions specified in the ALS.

EASA previously issued AD 2018–0004, dated January 9, 2018, to correct an unsafe condition on all Airbus SAS Model A350–941 airplanes. EASA AD 2018–0004 states:

Certification Maintenance Requirements (CMR) for the Airbus A350, which are approved by EASA, are currently defined and published in the Airbus A350 ALS Part 3 document. These instructions have been identified as mandatory for continued airworthiness.

Failure to accomplish these instructions could result in an unsafe condition.

EASA previously issued AD 2017–0029 to require the actions as specified in Airbus A350 ALS Part 3 Revision 03.

Since this [EASA] AD was issued, Airbus published Revision 04 of Airbus A350 ALS Part 3, to introduce new and more restrictive CMRs.

For the reason described above, this [EASA] AD retains the requirements of EASA AD 2017–0029, which is superseded, and requires accomplishment of the actions specified in the ALS.

EASA ADs 2018–0004 and 2018–0179 are collectively referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0508.

Comments

We gave the public the opportunity to participate in developing this final rule. The following presents the comment received on the SNPRM and the FAA's response to that comment.

Support for the SNPRM

An anonymous commenter stated support for the SNPRM.

Request To Clarify the Cost of Compliance

The anonymous commenter wondered how the total cost of $7,650 per worker was reached and expressed concern that the cost would create inefficient use of workers' time if they are checking the airplane more than they should be.

From these statements, we infer that the commenter was requesting that we clarify the proposed Costs of Compliance. We agree to clarify the Costs of Compliance in this final rule. As we explained in the Costs of Compliance section, the cost estimate comes from the $85 per work-hour labor rate multiplied by the 90 work-hours for incorporating the new, more restrictive maintenance requirements and airworthiness limitations into the operator's maintenance or inspection program, although this figure may vary from operator to operator. In the past, we have estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), we have determined that a per-operator estimate is more accurate than a per-airplane estimate. The cost does not include the estimated time for each inspection because this AD only requires revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). We have not changed this final rule in this regard.

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the SNPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the SNPRM.

Related Service Information Under 1 CFR Part 51

Airbus has issued A350 Airworthiness Limitations Section (ALS) Part 3, Certification Maintenance Requirements (CMR), Revision 04, dated December 15, 2017, as supplemented by Airbus A350 ALS Part 3, Certification Maintenance Requirements (CMR), Variation 4.2, dated July 26, 2018. These documents describe mandatory maintenance requirements and airworthiness limitations that operators must perform at specified intervals. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 11 airplanes of U.S. registry.

We estimate the following costs to comply with this AD. We have determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although this figure may vary from operator to operator. In the past, we have estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), we have determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, we estimate the total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

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.

We are 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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

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) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

(4) 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.

Adoption of 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 (AD):

2019–03–11 Airbus SAS: Amendment 39–19563; Docket No. FAA–2018–0508; Product Identifier 2018–NM–012–AD.

(a) Effective Date

This AD is effective March 29, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category, with an original certificate of airworthiness or original export certificate of airworthiness issued on or before July 26, 2018.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Reason

This AD was prompted by a determination that more restrictive maintenance requirements and airworthiness limitations are necessary. We are issuing this AD to address safety-significant latent failures that would, in combination with one or more other specific failures or events, result in a hazardous or catastrophic failure condition.

(f) Compliance

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

(g) Maintenance or Inspection Program Revision

Within 90 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate Airbus A350 Airworthiness Limitations Section (ALS) Part 3, Certification Maintenance Requirements (CMR), Revision 04, dated December 15, 2017, as supplemented by Airbus A350 ALS Part 3, Certification Maintenance Requirements (CMR), Variation 4.2, dated July 26, 2018. The initial compliance time for accomplishing the actions is at the applicable times specified in Airbus A350 Airworthiness Limitations Section (ALS) Part 3, Certification Maintenance Requirements (CMR), Revision 04, dated December 15, 2017, as supplemented by Airbus A350 ALS Part 3, Certification Maintenance Requirements (CMR), Variation 4.2, dated July 26, 2018; or within 90 days after the effective date of this AD; whichever occurs later.

(h) No Alternative Actions or Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals, may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (i)(1) of this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@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.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0179, dated August 23, 2018; and EASA AD 2018–0004, dated January 9, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0508.

(2) For more information about this AD, contact Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

(k) Material Incorporated by Reference

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

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

(i) Airbus A350 Airworthiness Limitations Section (ALS) Part 3, Certification Maintenance Requirements (CMR), Revision 04, dated December 15, 2017.

(ii) Airbus A350 ALS Part 3, Certification Maintenance Requirements (CMR), Variation 4.2, dated July 26, 2018.

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *continued-airworthiness.a350@airbus.com;* internet *http://www.airbus.com.*

(4) You may view this service information at the FAA, Transport Standards 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 service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on February 7, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–02924 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0580; Product Identifier 2018–NM–025–AD; Amendment 39–19558; AD 2019–03–06]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 737–300, –400, and –500 series airplanes. This AD was prompted by a report indicating the passenger service units (PSUs) became separated from their attachments during several survivable accident sequences. This AD requires installing lanyard assemblies on the PSU and, for certain airplanes, on the life vest panel. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective March 29, 2019.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of March 29, 2019.

ADDRESSES: For service information identified in this final rule, 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; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Transport Standards 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 on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0580.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0580; 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 regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Scott Craig, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216 St., Des Moines, WA 98198; phone and fax: 206–231–3566; email: *Michael.S.Craig@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We 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 737–300, –400, and –500 series airplanes. The NPRM published in the **Federal Register** on July 6, 2018 (83 FR 31507). The NPRM was prompted by a report indicating that the PSUs became separated from their attachments during several survivable accident sequences. The NPRM proposed to require installing lanyard assemblies on the PSU and, for certain airplanes, on the life vest panel.

We are issuing this AD to address the PSU becoming detached and falling into the cabin, which could lead to passenger injuries and impede egress during an evacuation.

Comments

We gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA's response to each comment.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that the installation of winglets per Supplemental Type Certificate (STC) ST01219SE does not affect the accomplishment of the manufacturer's service instructions.

We agree with the commenter that STC ST01219SE does not affect the accomplishment of the manufacturer's service instructions. Therefore, the installation of STC ST01219SE does not affect the ability to accomplish the actions required by this AD. We have not changed this AD in this regard.

Request To Revise the Applicability

Atlas Air Inc. requested that certain airplanes be removed from the applicability. Atlas Air Inc. stated that if any affected airplanes specified in Boeing Service Bulletin 737–25–1728, dated October 10, 2016, are converted from passenger configuration to a freighter configuration after October 10, 2016, the release date of the service bulletin, then those airplanes should be excluded from the applicability of the proposed AD. Atlas Air Inc. commented that, after freighter conversion, an airplane is no longer equipped with passenger service units or passenger life vest panels.

We partially agree with the commenter's request. We agree with Atlas Air Inc. that passenger service units or passenger life vest panels might not be installed on an airplane that has gone through a freighter conversion because they may no longer be required in an airplane that has been fully converted to a freighter and has no passengers. We disagree with modifying the applicability of the AD because it is possible that the freighter conversion could still include some passenger seating with passenger service units. However, we will consider specific configurations, and operators may request approval of an alternative method of compliance (AMOC) under the provisions of paragraph (i) of this AD. We have not changed this AD regarding this issue.

Request To Revise Certain Language in the Proposed AD

Boeing requested that we revise the proposed AD to state that the NPRM ''was prompted by a report indicating that the passenger service unit (PSU) became separated from their attachments during the survivable accident sequences.'' Boeing stated that this wording aligns with standardized language used in previous documentation of this unsafe condition, including the National Transportation Safety Board (NTSB) safety recommendation, A–12–2.

We agree with the commenter that the new wording aligns with standard language used in previous documentation of this unsafe condition, including the NTSB safety recommendation, A–12–2. We have revised the final rule accordingly.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Service Bulletin 737–25–1728, dated October 10, 2016. The service information describes procedures for installing lanyard assemblies on the PSU and life vest panel.

We reviewed Boeing Requirements Bulletin 737–25–1758 RB, dated November 8, 2017. The service information describes procedures for installing lanyard assemblies on the PSU.

These documents are distinct since they apply to airplanes in different configurations.

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

Costs of Compliance

We estimate that this AD affects 227 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Installation of lanyard assemblies.	Up to 76 work-hour × $85 per hour = $6,460.	Up to $11,000	Up to $17,460	Up to $3,963,420.

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.

We are 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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

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) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

(4) 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.

Adoption of 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 (AD):

2019–03–06 The Boeing Company: Amendment 39–19558; Docket No. FAA–2018–0580; Product Identifier 2018–NM–025–AD.

(a) Effective Date

This AD is effective March 29, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 737–300, –400, and –500 series airplanes, certificated in any category, as identified in the service information specified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Boeing Service Bulletin 737–25–1728, dated October 10, 2016.

(2) Boeing Requirements Bulletin 737–25–1758 RB, dated November 8, 2017.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a report indicating the passenger service units (PSUs) became separated from their attachments during several survivable accident sequences. We are issuing this AD to address the PSU becoming detached and falling into the cabin, which could lead to passenger injuries and impede egress during an evacuation.

(f) Compliance

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

(g) Required Actions

(1) For airplanes identified in Boeing Service Bulletin 737–25–1728, dated October 10, 2016: Except as required by paragraph (h)(1) of this AD, at the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Service Bulletin 737–25–1728, dated October 10, 2016, do all applicable actions identified as ''RC'' (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Service Bulletin 737–25–1728, dated October 10, 2016.

(2) For airplanes identified in Boeing Requirements Bulletin 737–25–1758 RB, dated November 8, 2017: Except as required by paragraph (h)(2) of this AD, at the applicable times specified in the ''Compliance'' paragraph of Boeing Requirements Bulletin 737–25–1758 RB, dated November 8, 2017, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing

Requirements Bulletin 737–25–1758 RB, dated November 8, 2017.

Note 1 to paragraph (g)(2) of this AD: Guidance for accomplishing the actions required by paragraph (g)(2) of this AD can be found in Boeing Service Bulletin 737–25–1758, dated November 8, 2017, which is referred to in Boeing Requirements Bulletin 737–25–1758 RB, dated November 8, 2017.

(h) Exceptions to Service Information Specifications

(1) For purposes of determining compliance with the requirements of this AD: Where Boeing Service Bulletin 737–25–1728, dated October 10, 2016, uses the phrase ''the original issue date of this service bulletin,'' this AD requires using ''the effective date of this AD.''

(2) For purposes of determining compliance with the requirements of this AD: Where Boeing Requirements Bulletin 737–25–1758 RB, dated November 8, 2017, uses the phrase ''the original issue date of the Requirements Bulletin (RB),'' this AD requires using ''the effective date of this AD.''

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO 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 certification office, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@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.

(3) 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 Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO 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.

(4) For service information that contains steps that are labeled as RC, the provisions of paragraphs (i)(4)(i) and (i)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(j) Related Information

For more information about this AD, contact Scott Craig, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3566; email: *Michael.S.Craig@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) Boeing Service Bulletin 737–25–1728, dated October 10, 2016.

(ii) Boeing Requirements Bulletin 737–25–1758 RB, dated November 8, 2017.

(3) For service information 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; internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Standards 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 service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on February 1, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–02932 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0409; Product Identifier 2017–NM–120–AD; Amendment 39–19559; AD 2019–03–07]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2017–16–05, which applied to certain The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes. AD 2017–16–05 required a one-time detailed visual inspection for discrepancies in the Krueger flap bullnose attachment hardware, and related investigative and corrective actions if necessary. This AD adds airplanes and an additional inspection to determine if any Krueger flap no. 1, 2, 3, or 4 has been replaced, and related investigative and corrective actions. Since this is a rotable parts issue, the applicability of this AD has been expanded beyond the airplanes listed in the related service bulletin to include all airplanes on which a Krueger flap bullnose may be installed. This AD was prompted by a report of a Krueger flap bullnose departing an airplane during taxi, which caused damage to the wing structure and thrust reverser, and a report of a missing no. 2 Krueger flap bullnose hinge bolt from an airplane that was not included in the effectivity of AD 2017–16–05. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective March 29, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of March 29, 2019.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; phone: 562–797–1717; internet: *https://www.myboeingfleet.com.* You may view this service information at the FAA, Transport Standards 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 on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0409.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0409; 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 regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West

Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

Alan Pohl, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3527; email: *alan.pohl@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2017–16–05, Amendment 39–18982 (82 FR39344, August 18, 2017) (''AD 2017–16–05''). AD 2017–16–05 applied to certain The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes. The NPRM published in the **Federal Register** on May 15, 2018 (83 FR22420). The NPRM was prompted by a report of a Krueger flap bullnose departing an airplane during taxi, which caused damage to the wing structure and thrust reverser, and a report of a missing no. 2 Krueger flap bullnose hinge bolt from an airplane that was not included in the effectivity of AD 2017–16–05. The NPRM proposed to continue to require a one-time detailed visual inspection for discrepancies in the Krueger flap bullnose attachment hardware, and related investigative and corrective actions, if necessary. The NPRM also proposed to add airplanes and an additional inspection to determine if any Krueger flap no. 1, 2, 3, or 4 has been replaced, and related investigative and corrective actions. Since this is a rotable parts issue, the applicability of this AD has been expanded beyond the airplanes listed in the related service bulletin to include all airplanes on which a Krueger flap bullnose may be installed. We are issuing this AD to address missing Krueger flap bullnose hardware. Such missing hardware could result in the Krueger flap bullnose departing the airplane during flight, which could damage empennage structure and lead to the inability to maintain continued safe flight and landing.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA's response to each comment.

Support for the NPRM

Boeing concurred with the content of the NPRM. Delta Air Lines (DAL) and American Airlines (AAL) concurred with the intent of the NPRM.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that accomplishing the Supplemental Type Certificate (STC) ST00830SE does not affect the actions specified in the NPRM.

We concur with the commenter. We have redesignated paragraph (c) of the proposed AD as paragraph (c)(1) of this AD and added paragraph (c)(2) to this AD to state that installation of STC ST00830SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST00830SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Request To Remove Airplanes From the Applicability

All Nippon Airways (ANA) requested that we remove the airplanes identified in paragraph (c)(3) of the proposed AD. ANA stated that those airplanes are not required to do the actions specified in paragraph (g) of the proposed AD.

We disagree with the request. Although the airplanes identified in paragraph (c)(1)(iii) of this AD (paragraph (c)(3) of the proposed AD) are not required to do the actions specified in paragraph (g) of this AD, those airplanes must still comply with the parts installation limitation specified in paragraph (i) of this AD. We have not changed this AD in this regard.

Request for a Different Method of Compliance

DAL requested that we include an option in paragraph (i) of the proposed AD to install the Krueger flap before accomplishing the required actions. DAL mentioned that it has updated its manuals to inspect after installation on the airplane, not prior to installation.

We agree that clarification is necessary. The required inspection of the Krueger flap bullnose can only be accomplished after installation on the Krueger flap assembly, either prior to or after installation on the airplane. We have revised paragraph (i) to specify that the actions required by paragraph (g) of this AD must be accomplished after installation but prior to further flight.

Request To Clarify Which Krueger Flaps Are Affected

DAL and AAL requested that we clarify paragraph (i) of the proposed AD to specify affected Krueger flap(s) and Krueger flap bullnose(s). DAL stated that not all four positions need to be inspected, only the Krueger flap(s) and Krueger flap bullnose(s) being installed. AAL suggested that we reword paragraph (i) of the proposed AD to improve clarity.

We agree with the request because it is not necessary to perform the actions specified in paragraph (i) of this AD on all four Krueger flap(s) or Krueger flap bullnose(s). Only the Krueger flap(s) or Krueger flap bullnose(s) being installed must be inspected. We have revised paragraph (i) of this AD to specify: ''These actions are required only for the Krueger flap(s) or Krueger flap bullnose(s) being installed.''

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously, and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737–57A1327, Revision 2, dated July 25, 2017. This service information describes procedures for a one-time detailed visual inspection for discrepancies in the Krueger flap bullnose attachment hardware, and related investigative and corrective actions; and an inspection to determine if any Krueger flap no. 1, 2, 3, or 4 has been replaced, and related investigative and corrective actions. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 1,814 airplanes of U.S. registry. We estimate 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 the Krueger flap bullnose hardware (1,495 airplanes) (retained actions from AD 2017–16–05).	3 work-hours × $85 per hour = $255.	$0	$255	$381,225
Inspection to determine if any Krueger flap no. 1, 2, 3, or 4 has been replaced (1,814 airplanes) (new action).	3 work-hours × $85 per hour = $255.	0	255	462,570

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all available costs in our cost estimate.

Authority for This Rulemaking

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

We are 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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

We have determined that 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) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

(4) 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.

Adoption of 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 removing Airworthiness Directive (AD) 2017–16–05, Amendment 39–18982 (82 FR 39344, August 18, 2017), and adding the following new AD:

2019–03–07 The Boeing Company: Amendment 39–19559; Docket No. FAA–2018–0409; Product Identifier 2017–NM–120–AD.

(a) Effective Date

This AD is effective March 29, 2019.

(b) Affected ADs

This AD replaces AD 2017–16–05, Amendment 39–18982 (82 FR 39344, August 18, 2017) (''AD 2017–16–05'').

(c) Applicability

(1) This AD applies to all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes, certificated in any category, as specified in paragraphs (c)(1)(i) through (c)(1)(iii) of this AD.

(i) Airplanes in Groups 1 and 2 as identified in Boeing Alert Service Bulletin 737–57A1327, Revision 2, dated July 25, 2017 (''BASB 737–57A1327, R2'').

(ii) Airplanes in Group 3, as identified in BASB 737–57A1327, R2, except where this service bulletin specifies the groups as line numbers 6422 through 6465 inclusive, this AD specifies those groups as line number 6422 through any line number airplane with an original Certificate of Airworthiness or an original Export Certificate of Airworthiness dated on or before the effective date of this AD.

(iii) All Model 737–600, –700, –700C, –800, –900 and –900ER series airplanes with an original Certificate of Airworthiness or an original Export Certificate of Airworthiness dated after the effective date of this AD.

(2) Installation of Supplemental Type Certificate (STC) ST00830SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST00830SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a report of a Krueger flap bullnose departing an airplane during taxi, which caused damage to the wing structure and thrust reverser, and a report of a missing no. 2 Krueger flap bullnose hinge bolt from an airplane that was not included in the effectivity of AD 2017–16–05. We are issuing this AD to address missing Krueger flap bullnose hardware. Such missing hardware could result in the Krueger flap bullnose departing the airplane during flight, which could damage empennage structure and lead to the inability to maintain continued safe flight and landing.

(f) Compliance

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

(g) Required Actions

For airplanes identified in paragraphs (c)(1)(i) and (c)(1)(ii) of this AD: Except as required by paragraph (h) of this AD, at the applicable times specified in paragraph 1.E., ''Compliance,'' of BASB 737–57A1327, R2, do all applicable actions identified as ''RC''

(required for compliance) in, and in accordance with, the Accomplishment Instructions of BASB 737–57A1327, R2.

(h) Exceptions to Service Information Specifications

(1) For purposes of determining compliance with the requirements of this AD: Where BASB 737–57A1327, R2 uses the phrase ''the original issue date of this service bulletin,'' this AD requires using September 22, 2017 (the effective date of AD 2017–16–05).

(2) For purposes of determining compliance with the requirements of this AD: Where BASB 737–57A1327, R2 uses the phrase ''the Revision 2 date of this service bulletin,'' 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 a Krueger flap or Krueger flap bullnose on any airplane identified in paragraph (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of this AD, unless the actions required by paragraph (g) of this AD have been accomplished on the Krueger flap bullnose after installation but prior to further flight. These actions are required only for the Krueger flap(s) or Krueger flap bullnose(s) being installed.

(j) Credit for Previous Actions

(1) This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before September 22, 2017 (the effective date of AD 2017–16–05), using Boeing Alert Service Bulletin 737–57A1327, dated May 20, 2016.

(2) This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD, using Boeing Alert Service Bulletin 737–57A1327, Revision 1, dated September 28, 2016.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO 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 certification office, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@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.

(3) 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 Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO 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.

(4) AMOCs approved previously for AD 2017–16–05 are approved as AMOCs for the corresponding provisions of BASB 737–57A1327, R2 that are required by paragraph (g) of this AD.

(5) For service information that contains steps that are labeled as RC, the provisions of paragraphs (k)(5)(i) and (k)(5)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Operators may deviate from steps not labeled as RC by using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(l) Related Information

(1) For more information about this AD, contact Alan Pohl, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3527; email: *alan.pohl@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (m)(3) and (m)(4) of this AD.

(m) Material Incorporated by Reference

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

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

(i) Boeing Alert Service Bulletin 737–57A1327, Revision 2, dated July 25, 2017.

(ii) [Reserved]

(3) For service information 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; phone: 562–797–1717; internet: *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Standards 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 service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on February 7, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–02930 Filed 2–21–19; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0906; Product Identifier 2018–NM–122–AD; Amendment 39–19561; AD 2019–03–09]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus SAS Model A310–304, –322, –324, and –325 airplanes. This AD was prompted by an evaluation by the design approval holder (DAH) indicating that certain wing skin stringer joints are subject to widespread fatigue damage (WFD). This AD requires a rototest inspection of the fastener holes in the affected areas and repair if necessary, and modifying the fastener holes. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective March 29, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of March 29, 2019.

ADDRESSES: For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAW, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Standards 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 on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0906.

Examining the AD Docket

You may examine the AD docket on the internet at *http://*

www.regulations.gov by searching for and locating Docket No. FAA–2018–0906; 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 regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus SAS Model A310–304, –322, –324, and –325 airplanes. The NPRM published in the **Federal Register** on November 5, 2018 (83 FR 55294). The NPRM was prompted by an evaluation by the DAH indicating that certain wing skin stringer joints are subject to WFD. The NPRM proposed to require a rototest inspection of the fastener holes in the affected areas and repair if necessary, and modifying the fastener holes.

We are issuing this AD to address any cracking of the top wing skin stringer joints at rib 19, which could result in reduced structural integrity of the wing.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0174, dated August 14, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus SAS Model A310–304, –322, –324, and –325 airplanes. The MCAI states:

> In response to US 14 CFR part 26 concerning Widespread Fatigue Damage (WFD), Airbus assessed all wing structural items of the Airbus A310 design deemed potentially susceptible to WFD. The top [wing] skin stringer joints at rib 19 at level of the first fastener row were highlighted as an area of uniform stress distribution, indicating that cracks may develop in adjacent stringers at the same time, which is known as Multi Element Damage.
>
> This condition, if not corrected, could reduce the structural integrity of the wing.
>
> Prompted by the conclusion of WFD analysis, Airbus issued the SB [Service Bulletin A310–57–2108, dated November 9, 2017] to provide modification instructions. The accomplishment of this modification at the specified time will extend the life of the fastener holes in the affected area in order to reach the Limit of Validity.
>
> For the reasons described above, this [EASA] AD requires a one-time inspection of the [fastener] holes in the affected area, accomplishment of applicable corrective action(s) [contacting the manufacturer], depending on findings, and modification.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0906.

Comments

We gave the public the opportunity to participate in developing this final rule. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A310–57–2108, dated November 9, 2017. This service information describes procedures for accomplishing a rototest inspection of the fastener holes in the affected areas and repair if necessary, and modifying the fastener holes.

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

Costs of Compliance

We estimate that this AD affects 14 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
43 work-hours × $85 per hour = $3,655	$0	$3,655	$51,170

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

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.

We are 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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

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) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

(4) 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.

Adoption of 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 (AD):

2019–03–09 Airbus SAS: Amendment 39–19561; Docket No. FAA–2018–0906; Product Identifier 2018–NM–122–AD.

(a) Effective Date

This AD is effective March 29, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS Model A310–304, –322, –324, and –325 airplanes, certificated in any category.

(d) Subject

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

(e) Reason

This AD was prompted by an evaluation by the design approval holder (DAH) indicating that top wing skin stringer joints at rib 19 are subject to widespread fatigue damage (WFD). We are issuing this AD to address any cracking of the top wing skin stringer joints at rib 19, which could result in reduced structural integrity of the wing.

(f) Compliance

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

(g) Definitions

(1) The affected areas are defined as the top wing skin stringers, 9 to 15, at the stringer joints, outboard of rib 19, on both wings.

(2) The average flight time (AFT) is defined as flight hours (FH) divided by flight cycles (FC) accumulated by an individual airplane since the airplane's first flight, specified in hours and hundredths of an hour. Refer to the Airbus A310 Maintenance Review Board Report Section D2 for guidance on determining the AFT.

(h) Inspection

Within the applicable compliance times specified in figure 1 to paragraph (h) of this AD, accomplish a rototest inspection of the fastener holes in the affected areas in accordance with the Accomplishment Instructions of Airbus Service Bulletin A310–57–2108, dated November 9, 2017.

Figure 1 to paragraph (h) of this AD – *Compliance times for rototest inspection*

AFT	Compliance Time (FC or FH, whichever occurs first since the airplane's first flight)
Special (long) Range: AFT > 4.0 FH/FC	34,500 FC or 172,600 FH
Normal (short) Range: AFT ≤ 4.0 FH/FC	42,100 FC or 117,800 FH

(i) Corrective Actions

If, during the inspection required by paragraph (h) of this AD, any discrepancy (*i.e.,* cracking or discrepant hole diameter) or existing repair is detected, before further flight, obtain corrective actions approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus SAS's EASA Design Organization Approval (DOA); and accomplish the corrective actions within the compliance time specified therein. If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Modification

If, during the inspection required by paragraph (h) of this AD, no existing repair or discrepancy is detected, before further flight, modify the fastener holes in accordance with the Accomplishment Instructions of Airbus Service Bulletin A310–57–2108, dated November 9, 2017.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (l)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@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.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the EASA; or Airbus SAS's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0174, dated August 14, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0906.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (m)(3) and (m)(4) of this AD.

(m) Material Incorporated by Reference

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

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

(i) Airbus Service Bulletin A310–57–2108, dated November 9, 2017.

(ii) [Reserved]

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.*

(4) You may view this service information at the FAA, Transport Standards 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 service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on February 7, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–02925 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0907; Product Identifier 2018–NM–118–AD; Amendment 39–19562; AD 2019–03–10]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2017–07–05, which applied to all Airbus SAS Model A300 series airplanes; and Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes). AD 2017–07–05 required repetitive detailed visual inspections of the main landing gear (MLG) leg components and replacement of the MLG leg if cracked components are found. This AD retains the requirements of AD 2017–07–05 and removes the credit for doing an MLG overhaul in lieu of the initial inspection of the MLG leg components. This AD was prompted by further investigation after AD 2017–07–05 was issued, which revealed that overhaul of the MLG does not alleviate the need for inspecting the MLG hinge arm/barrel pin for cracking. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective March 29, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of March 29, 2019.

ADDRESSES: For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAW, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Standards 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 on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0907.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0907; 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 regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2017–07–05, Amendment 39–18843 (82 FR 16101, April 3, 2017) (''AD 2017–07–05''). AD 2017–07–05 applied to all Airbus SAS Model A300 series airplanes; and Model A300–600 series airplanes. The NPRM published in the **Federal Register** on November 6, 2018 (83 FR 55498). The NPRM was prompted by further investigation after AD 2017–07–05 was issued, which revealed that overhaul of the MLG does not alleviate the need for inspecting the MLG hinge arm/barrel pin for cracking. The NPRM proposed to retain the requirements of AD 2017–07–05 and remove the credit for doing an MLG overhaul in lieu of the initial inspection of the MLG leg components. We are issuing this AD to address cracking of certain components in the MLG leg, which could result in an MLG collapse, and consequent damage to the airplane and injury to the airplane occupants.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0170, dated August 6, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus SAS Model A300 series airplanes; and Model A300–600 series airplanes. The MCAI states:

Two cases were reported of finding a cracked MLG hinge arm/barrel pin, one was discovered in service during a maintenance

task and the other one was identified during MLG overhaul.

This condition, if not detected and corrected, could lead to MLG collapse, possibly resulting in damage to the aeroplane and injury to occupants.

To address this potential unsafe condition, Airbus issued [Alert Operators Transmission] AOT A32W008–16 (original issue) to provide instructions for detailed visual inspections (DET) to detect cracks and EASA issued AD 2016–0058 accordingly [which corresponds to FAA AD 2017–07–05], requiring repetitive DET of the affected parts and, depending on findings, replacement of the affected MLG leg.

Since that [EASA] AD was issued, further investigation results highlighted that, the overhaul of the MLG cannot alleviate the inspection need of the hinge arm/barrel pin.

For the reasons described above, this [EASA] AD retains the requirement of EASA AD 2016–0058, which is superseded, removing the credit of MLG overhaul for the first inspection of the pin.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0907.

Comments

We gave the public the opportunity to participate in developing this final rule. We have considered the comments received. Air Line Pilots Association, International and Madeline Roach each indicated support for the NPRM.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Airbus has issued Alert Operators Transmission (AOT) A32W008–16, Rev 01, dated July 30, 2018. This service information describes procedures for inspecting the MLG hinge arm/barrel pin for cracking, and replacement of the MLG leg if cracking is detected.

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

Costs of Compliance

We estimate that this AD affects 128 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85, per inspection cycle.	$0	$85, per inspection cycle	$10,880, per inspection cycle.

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
20 work-hours × $85 per hour = $1,700 per MLG	$3,400,000 per MLG	$3,401,700 per MLG.

We estimate that it will take about 1 work-hour per product to comply with the reporting requirement in this AD. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of reporting the inspection results on U.S. operators to be $85 per product.

The new requirements of this AD add no additional economic burden.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW, Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES–200.

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.

We are 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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

We determined that 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. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. 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.

Adoption of 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 removing Airworthiness Directive (AD) 2017–07–05, Amendment 39–18843 (82 FR 16101, April 3, 2017), and adding the following new AD:

2019–03–10 Airbus SAS: Amendment 39–19562; Docket No. FAA–2018–0907; Product Identifier 2018–NM–118 AD.

(a) Effective Date

This AD is effective March 29, 2019.

(b) Affected ADs

This AD replaces AD 2017–07–05, Amendment 39–18843 (82 FR 16101, April 3, 2017) (''AD 2017–07–05'').

(c) Applicability

This AD applies to Airbus SAS airplanes, certificated in any category, all manufacturer serial numbers, identified in paragraphs (c)(1) through (c)(5) of this AD.

(1) Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.

(2) Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes.

(3) Model A300 B4–605R and B4–622R airplanes.

(4) Model A300 F4–605R and F4–622R airplanes.

(5) Model A300 C4–605R Variant F airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing Gear.

(e) Reason

This AD was prompted by reports of cracks in main landing gear (MLG) leg components. We are issuing this AD to address cracking of certain components in the MLG leg, which could result in an MLG collapse, and consequent damage to the airplane and injury to the airplane occupants.

(f) Compliance

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

(g) Definition

For the purpose of this AD an affected part is an MLG hinge arm/barrel pin having part number (P/N) C66441–(X) and P/N C65543–(X), where the X is representing a variable number.

(h) Repetitive Inspections

At the applicable compliance time specified in figure 1 to paragraph (h) of this AD, and thereafter at intervals not to exceed 100 flight cycles, accomplish a detailed visual inspection of the internal diameter of each affected MLG hinge arm/barrel pin for cracking, in accordance with the instructions of Airbus Alert Operators Transmission (AOT) A32W008–16, Rev 01, dated July 30, 2018 (''AOT A32W008–16, Rev 01'').

Figure 1 to paragraph (h) of this AD – *Compliance time for initial inspection*

Compliance time (whichever occurs later between A and B, or between A and C, as applicable)	
A	Within 30 months since the pin's first flight on an airplane.
B (For airplanes on which an inspection specified in Airbus AOT A32W008-16 has not been done as of the effective date of this AD)	Within 30 days after the effective date of this AD, without exceeding the later of (1) Within 30 months since the pin's first flight on an airplane, or since the pin's first flight on an airplane after overhaul, as applicable and (2) Within 30 days after May 8, 2017 (the effective date of AD 2017-07-05).
C (For airplanes on which an inspection specified in Airbus AOT A32W008-16 has been done as of the effective date of this AD)	Within 30 days after the effective date of this AD, without exceeding 100 flight cycles since the most recent inspection.

(i) Corrective Action

If any crack is found during any inspection required by paragraph (h) of this AD: Before further flight, replace the MLG leg in accordance with the instructions of Airbus AOT A32W008–16, Rev 01. Replacement of an MLG leg does not constitute terminating action for the repetitive inspections required by paragraph (h) of this AD.

(j) Reporting

At the applicable time specified in paragraph (j)(1) or (j)(2) of this AD, report the inspection results required by paragraph (h) of this AD to Airbus SAS. This can be accomplished using the instructions of Airbus AOT A32W008–16, Rev 01.

(1) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after each inspection required by paragraph (h) of this AD.

(2) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(k) Credit for Previous Actions

This paragraph provides credit for the initial inspection required by paragraph (h) of this AD and corrective actions required by paragraph (i) of this AD, if those actions were performed before the effective date of this AD using the instructions of Airbus AOT A32W008–16, dated February 25, 2016.

(l) Other FAA AD Provisions

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (m)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@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.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW, Washington, DC 20591, Attn: Information Collection Clearance Officer, AES 200.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0170, dated August 6, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0907.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (n)(3) and (n)(4) of this AD.

(n) Material Incorporated by Reference

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

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

(i) Airbus Alert Operators Transmission A32W008–16, Rev 01, dated July 30, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.*

(4) You may view this service information at the FAA, Transport Standards 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 service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on February 8, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–02938 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2017–0735; FRL–9989–99–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Nonattainment New Source Review Requirements for 2008 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision submitted by the Commonwealth of Pennsylvania. This revision was in response to EPA's February 3, 2017 Findings of Failure to Submit for various requirements relating to the 2008 8-hour ozone national ambient air quality standards (NAAQS). This SIP revision is specific to nonattainment new source review (NNSR) requirements. EPA is approving this revision in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on March 25, 2019.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2017–0735. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov*, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Amy Johansen, (215) 814–2156, or by email at *johansen.amy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 6, 2018 (83 FR 62774), EPA published a notice of proposed rulemaking (NPRM) for the Commonwealth of Pennsylvania. In the NPRM, EPA proposed approval of Pennsylvania's NNSR Certification for the 2008 Ozone Standard. This SIP

revision is in response to EPA's final 2008 8-hour ozone NAAQS Findings of Failure to Submit for NNSR requirements. See 82 FR 9158 (February 3, 2017). Specifically, Pennsylvania is certifying that its existing NNSR program, covering the Allentown-Bethlehem-Easton, PA Nonattainment Area (which includes Carbon, Lehigh, and Northampton Counties), the Lancaster, PA Nonattainment Area (which includes Lancaster County), the Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE Nonattainment Area (which includes Bucks, Chester, Delaware, Montgomery, and Philadelphia Counties), Pittsburgh-Beaver Valley, PA Nonattainment Area (which includes Allegheny, Beaver, Butler, Fayette, Washington, and Westmoreland Counties) and the Reading, PA Nonattainment Area (which includes Berks County) for the 2008 8-hour ozone NAAQS, is at least as stringent as the requirements at 40 CFR 51.165, as amended by the final rule titled ''Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements'' (SIP Requirements Rule), for ozone and its precursors.[1] [2] See 80 FR 12264 (March 6, 2015). The formal SIP revision was submitted by Pennsylvania on October 30, 2017.

A. 2008 8-Hour Ozone NAAQS

On March 12, 2008, EPA promulgated a revised 8-hour ozone NAAQS of 0.075 parts per million (ppm). See 73 FR 16436 (March 27, 2008). Under EPA's regulations at 40 CFR 50.15, the 2008 8-hour ozone NAAQS is attained when the three-year average of the annual fourth-highest daily maximum 8-hour average ambient air quality ozone concentrations is less than or equal to 0.075 ppm.

Upon promulgation of a new or revised NAAQS, the CAA requires EPA to designate as nonattainment any area that is violating the NAAQS based on the three most recent years of ambient air quality data at the conclusion of the designation process. The Allentown-Bethlehem-Easton, PA Nonattainment Area, the Lancaster, PA Nonattainment Area, the Pittsburgh-Beaver Valley, PA Nonattainment Area, and the Reading, PA Nonattainment Area were classified as marginal nonattainment areas for the 2008 8-hour ozone NAAQS on May 21, 2012 (effective July 20, 2012) using 2009–2011 ambient air quality data. See 77 FR 30088. The Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE Nonattainment Area was classified as a marginal nonattainment area for the 2008 8-hour ozone NAAQS on May 21, 2012 (effective July 20, 2012) using 2008–2010 ambient air quality data. See 77 FR 30088. On March 6, 2015, EPA issued the final SIP Requirements Rule, which establishes the requirements that state, tribal, and local air quality management agencies must meet as they develop implementation plans for areas where air quality exceeds the 2008 8-hour ozone NAAQS. See 80 FR 12264. Areas that were designated as marginal ozone nonattainment areas were required to attain the 2008 8-hour ozone NAAQS no later than July 20, 2015, based on 2012–2014 monitoring data. See 40 CFR 51.1103. The Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE and the Pittsburgh-Beaver Valley, PA Nonattainment Areas did not attain the 2008 8-hour ozone NAAQS by July 20, 2015; however, these areas did meet the CAA section 181(a)(5) criteria, as interpreted in 40 CFR 51.1107, for a one-year attainment date extension. See 81 FR 26697 (May 4, 2016). Therefore, on April 11, 2016, the EPA Administrator signed a final rule extending the Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE and the Pittsburgh-Beaver Valley, PA Nonattainment Area 8-hour ozone NAAQS attainment dates from July 20, 2015 to July 20, 2016. *Id.* Based on initial nonattainment designations for the 2008 8-hour ozone standard, as well as the March 6, 2015 final SIP Requirements Rule, Pennsylvania was required to develop a SIP revision addressing certain CAA requirements for the Allentown-Bethlehem-Easton, PA, the Lancaster, PA, the Philadelphia-Wilmington-Atlantic City, PA–NJ–MD, DE, the Pittsburgh-Beaver Valley, PA, and the Reading, PA Nonattainment Areas, and submit to EPA a NNSR Certification SIP or SIP revision no later than 36 months after the effective date of area designations for the 2008 8-hour ozone NAAQS (*i.e.,* July 20, 2015). See 80 FR 12264 (March 6, 2015). EPA is approving Pennsylvania's October 30, 2017 NNSR Certification SIP revision.

B. 2017 Findings of Failure To Submit SIP for the 2008 8-Hour Ozone NAAQS

Areas designated nonattainment for the ozone NAAQS are subject to the general nonattainment area planning requirements of CAA section 172 and also to the ozone-specific planning requirements of CAA section 182. States in the ozone transport region (OTR), such as Pennsylvania, are additionally subject to the requirements outlined in CAA section 184.

Ozone nonattainment areas in the lower classification levels have fewer and/or less stringent mandatory air quality planning and control requirements than those in higher classifications. For marginal areas, such as the Allentown-Bethlehem-Easton, PA, the Lancaster, PA, the Philadelphia-Wilmington-Atlantic City, PA-NJ-MD, DE, the Pittsburgh-Beaver Valley, PA, and the Reading, PA Areas, a state is required to submit a baseline emissions inventory, adopt a SIP requiring emissions statements from stationary sources and implement a NNSR program for the relevant ozone standard. See CAA section 182(a). For each higher ozone nonattainment classification, a state needs to comply with all lower area classification requirements, plus additional emissions controls and more expansive NNSR offset requirements.

The CAA sets out specific requirements for states in the OTR. Upon promulgation of the 2008 8-hour ozone NAAQS, states in the OTR were required to submit a SIP revision addressing reasonably available control technology (RACT). See 40 CFR 51.1116. This requirement is the only recurring obligation for an OTR state upon revision of a NAAQS, unless that state also contains some portion of a nonattainment area for the revised NAAQS. In that case, the nonattainment requirements described previously also apply to those portions of that state.

In the March 6, 2015 SIP Requirements Rule, EPA detailed the requirements applicable to ozone nonattainment areas, as well as requirements that apply in the OTR, and provided specific deadlines for SIP submittals. See 80 FR 12264.

On February 3, 2017, EPA found that 15 states and the District of Columbia failed to submit SIP revisions in a timely manner to satisfy certain requirements for the 2008 8-hour ozone NAAQS that apply to nonattainment areas and/or states in the OTR. See 82

[1] The SIP Requirements Rule addresses a range of nonattainment area SIP requirements for the 2008 8-hour ozone NAAQS, including requirements pertaining to attainment demonstrations, reasonable further progress (RFP), reasonably available control technology, reasonably available control measures, major new source review, emission inventories, and the timing of SIP submissions and of compliance with emission control measures in the SIP. The rule also revokes the 1997 ozone NAAQS and establishes anti-backsliding requirements.

[2] On February 16, 2018, the United States Court of Appeals for the District of Columbia Circuit (D.C. Cir. Court or Court) issued an opinion on the EPA's SIP Requirements Rule. *South Coast Air Quality Mgmt. Dist.* v. *EPA,* 882 F.3d 1138, 2018 U.S. App. LEXIS 3636 (D.C. Cir. Feb. 16, 2018). The D.C. Cir. Court found certain provisions from the SIP Requirements Rule, including certain provisions relating to anti-backsliding, to be inconsistent with the statute or unreasonable and vacated those provisions. *Id.* The Court found other parts of the SIP Requirements Rule unrelated to anti-backsliding and this action reasonable and denied the petition for appeal on those provisions. *Id.*

FR 9158. As explained in that rulemaking action, consistent with the CAA and EPA regulations, these Findings of Failure to Submit established certain deadlines for the imposition of sanctions, if a state does not submit a timely SIP revision addressing the requirements for which the finding is being made, and for the EPA to promulgate a Federal implementation plan (FIP) to address any outstanding SIP requirements.

EPA found, *inter alia,* that the Commonwealth of Pennsylvania failed to submit SIP revisions in a timely matter to satisfy NNSR requirements for its marginal nonattainment areas, specifically the Allentown-Bethlehem-Easton, PA, the Lancaster, PA, the Philadelphia-Wilmington-Atlantic City, PA-NJ-MD, DE, the Pittsburgh-Beaver Valley, PA, and the Reading, PA Areas. Pennsylvania submitted its October 30, 2017 SIP revision to address the specific NNSR requirements for the 2008 8-hour ozone NAAQS, located in 40 CFR 51.160–165, as well as its obligations under EPA's February 3, 2017 Findings of Failure to Submit.

II. Summary of SIP Revision and EPA Analysis

This rulemaking action is specific to Pennsylvania's NNSR requirements. NNSR is a preconstruction review permit program that applies to new major stationary sources or major modifications at existing sources located in a nonattainment area. The specific NNSR requirements for the 2008 8-hour ozone NAAQS are located in 40 CFR 51.160–165.

Pennsylvania's SIP approved NNSR program, established in the Pennsylvania Code of Regulations (Pa. Code) Rule 25 Pa. Code Chapter 127—*Construction, Modification, Reactivation, and Operation of Sources,* applies to the construction and modification of major stationary sources in nonattainment areas. In its October 30, 2017 SIP revision, Pennsylvania certified that the version of 25 Pa. Code Chapter 127 in the SIP is at least as stringent as the Federal NNSR requirements for the Allentown-Bethlehem-Easton, PA, the Lancaster, PA, the Philadelphia-Wilmington-Atlantic City, PA-NJ-MD, DE, the Pittsburgh-Beaver Valley, PA, and the Reading, PA Nonattainment Areas.

Other specific requirements for the 2008 8-hour ozone NAAQS, specific to NNSR requirements and the rationale for EPA's proposed action are explained in the NPRM and will not be restated here.

EPA received one comment in response to the December 6, 2018 NPRM. The comment did not concern any of the specific issues raised in the NPRM, nor did it address EPA's rationale for the proposed approval of this SIP revision. Therefore, EPA is not responding to that comment.

III. Final Action

EPA is approving Pennsylvania's October 30, 2017 SIP revision addressing the NNSR requirements for the 2008 ozone NAAQS for the Allentown-Bethlehem-Easton, PA, the Lancaster, PA, the Philadelphia-Wilmington-Atlantic City, PA-NJ-MD, DE, the Pittsburgh-Beaver Valley, PA, and the Reading, PA Nonattainment Areas. EPA has concluded that the Commonwealth's submission fulfills the 40 CFR 51.1114 revision requirement, meets the requirements of CAA sections 110 and 172 and the minimum SIP requirements of 40 CFR 51.165, as well as its obligations under EPA's February 3, 2017 Findings of Failure to Submit. See 82 FR 9158.

IV. Statutory and Executive Order Reviews

A. General Requirements

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 23, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and

shall not postpone the effectiveness of such rule or action. This action pertaining to Pennsylvania's NNSR program and the 2008 8-hour ozone NAAQS may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: February 12, 2019.

Cecil Rodrigues,

Acting Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart NN—Pennsylvania

■ 2. In § 52.2020, the table in paragraph (e)(1) is amended by adding an entry for ''2008 8-Hour Ozone National Ambient Air Quality Standard Nonattainment New Source Review Requirements'' at the end of the table. The added text reads as follows:

§ 52.2020 Identification of plan.

* * * * *

(e) * * *

(1) * * *

EPA-APPROVED NONREGULATORY AND QUASI-REGULATORY MATERIAL

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
*	*	*	*	*
2008 8-Hour Ozone NAAQS Nonattainment New Source Review Requirements.	Allentown-Bethlehem-Easton, PA area (includes Carbon, Lehigh, and Northampton Counties), Lancaster, PA area (includes Lancaster County), Pittsburgh-Beaver Valley, PA area (includes Allegheny, Beaver, Butler, Fayette, Washington, and Westmoreland Counties), Reading, PA area (includes Berks County), and Pennsylvania's portion of the Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE area (includes Bucks, Chester, Delaware, Montgomery, and Philadelphia Counties).	10/30/17	2/22/2019, *[Insert **Federal Register** citation].*	

* * * * *

[FR Doc. 2019–03109 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2018–0675; FRL–9989–61–Region 6]

Air Plan Approval; Texas; Reasonably Available Control Technology

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is converting its September 22, 2017 conditional approval of revisions to the Texas State Implementation Plan (SIP), addressing Oxides of Nitrogen (NO_X) Reasonably Available Control Technology (RACT) for the TXI Operations, LP (Texas Industries, Inc., TXI) cement manufacturing plant in Ellis County, to full approval. We are approving an August 21, 2018 SIP submittal which satisfies Texas' commitment which was the basis for our conditional approval. We are taking this action in accordance with the Clean Air Act (CAA, the Act).

DATES: The final rule is effective on March 25, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R06–OAR–2018–0675. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Planning Section (6MM–AA), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. The file will be made available by appointment for public inspection in the Region 6 FOIA Review Room between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Alan Shar (6MM–AA), telephone (214) 665–2164, email *shar.alan@epa.gov.*

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

I. Background
II. Final Actions
III. Incorporation by Reference
IV. Statutory and Executive Order Reviews

I. Background

The background for this action is discussed in detail in the November 14, 2018 (83 FR 56770) Proposal.[1] The November 14, 2018 (83 FR 56770) action proposed approval of TCEQ's August 21, 2018 submittal as a revision to Texas SIP addressing NO_X RACT for the TXI cement manufacturing plant in Ellis County as a part of its Dallas Fort Worth (DFW) 2008 8-Hour Ozone National Ambient Air Quality Standards (NAAQS) SIP update. The August 21, 2018 SIP submittal contained both an Agreed Order (AO) concerning TXI and a SIP narrative update for DFW NO_X RACT. The Technical Support Document (TSD)[2] also provided a detailed description and rationale for the proposed action.

[1] See the Proposal, document ID No. EPA–R06–OAR–2018–0675–0001 at *Regulations.gov.*

[2] See the TSD, document ID No. EPA–R06–OAR–2018–0675–0002 at *Regulations.gov.*

The public comment period closed on December 14, 2018, and we received no adverse comments. We received two comments, including one from TCEQ, that were supportive of our action. We received one additional comment that was also generally supportive of our proposed action ''if chemical knowledge for community safety is taken into consideration.'' The commenter's discussion of chemical hazards, however, is outside the scope of our November 14, 2018 (83 FR 56770) Proposal taken under the CAA. We acknowledge that the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 was created to help communities plan for chemical emergencies and requires industry to report on the storage, use and releases of hazardous substances to federal, state, and local governments. EPCRA requires state and local governments, and Indian tribes to use this information to prepare their community from potential risks.

II. Final Actions

We find that TCEQ's August 21, 2018 SIP submittal satisfies its obligation under the September 22, 2017 (82 FR 44320) conditional approval and are converting the September 22, 2017 (82 FR 44320) final rule to full approval. We are also approving the August 21, 2018 SIP submittal, including the AO as a source-specific NO_X RACT revision to the SIP. Our approval will incorporate these changes into the SIP for Texas.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the revisions to the Texas source specific requirements as described in the Final Actions section above. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 6 Office (please contact Mr. Alan Shar, (214) 665–2164, *shar.alan@epa.gov* for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. If a portion of the plan revision meets all the applicable requirements of this chapter and Federal regulations, the Administrator may approve the plan revision in part. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices that meet the criteria of the Act, and to disapprove state choices that do not meet the criteria of the Act. Accordingly, this final action approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this final action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA;
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994); and
- Does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 23, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposed of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: February 14, 2019.

Anne Idsal,

Regional Administrator, Region 6.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart SS—Texas

■ 2. In § 52.2270:

■ a. In paragraph (d), the table titled ''EPA-Approved Texas Source-Specific Requirements'' is amended by adding an entry for ''TXI Operations LP (Texas Industries, Inc., TXI), Kiln #5, Ellis County, Texas'' at the end of the table.

■ b. In paragraph (e), the second table titled ''EPA Approved Nonregulatory Provisions and Quasi-Regulatory Measures in the Texas SIP'' is amended by:

■ i. Removing the entry ''Conditional approval of NO_X RACT finding for the Martin Marietta (formerly Texas Industries, Inc., or TXI) cement manufacturing plant under the 2008 8-Hour ozone NAAQS'' and

■ ii. Adding an entry titled ''NO_X RACT finding under the 2008 8-Hour ozone NAAQS'' at the end of the table.

The additions read as follows:

§ 52.2270 Identification of plan.

* * * * *

(d) * * *

EPA-APPROVED TEXAS SOURCE-SPECIFIC REQUIREMENTS

Name of source	Permit or order No.	State effective date	EPA approval date	Comments
*	*	*	*	*
TXI Operations LP (Texas Industries, Inc., TXI), Kiln #5, Ellis County, Texas.	Agreed Order No. 2017–1648–SIP.	08/21/18	02/22/19 [Insert **Federal Register** citation].	DFW 2008 8-Hour ozone standard.

(e) * * *

EPA APPROVED NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES IN THE TEXAS SIP

Name of SIP provision	Applicable geographic or non-attainment area	State submittal/ effective date	EPA approval date	Comments
*	*	*	*	*
NO_X RACT finding under the 2008 8-Hour ozone NAAQS.	Collin, Dallas, Denton, Tarrant, Ellis, Johnson, Kaufman, Parker, Rockwall, and Wise Counties, TX.	8/21/2018	02/22/19 [Insert **Federal Register** citation].	DFW as Moderate and Serious, also converts conditional approval 09/22/17, 82 FR 44322 to full approval.

[FR Doc. 2019–03096 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA–R04–RCRA–2018–0255; FRL–9989–93–Region 4]

Georgia: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is granting Georgia final authorization for changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The Agency published a notice of proposed rulemaking on August 13, 2018, and provided for public comment. No comments were received on Georgia's proposed revisions. No further opportunity for comment will be provided.

DATES: This final authorization is effective February 22, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R04–2018–0255. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Thornell Cheeks, Materials and Waste Management Branch, RCR Division, U.S. Environmental Protection Agency, Atlanta Federal Center, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960; telephone number: (404) 562–8479; fax number: (404) 562–9964; email address: *cheeks.thornell@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. What changes to Georgia's hazardous waste program is EPA authorizing with this action?

On September 22, 2015, September 12, 2016, and November 7, 2017, Georgia submitted final complete program revision applications seeking authorization of changes to its hazardous waste program in accordance with 40 CFR 271.21. EPA now makes a final decision that Georgia's hazardous waste program revisions that are being authorized are equivalent to, consistent with, and no less stringent than the Federal program, and therefore satisfy all of the requirements necessary to qualify for final authorization. For a list of State rules being authorized with this Final Rule, please see the Proposed Rulemaking published in the **Federal Register** 83 FR 39975, August 13, 2018.

B. What is codification and is EPA codifying Georgia's hazardous waste program as authorized in this rule?

Codification is the process of placing citations and references to the State's statutes and regulations that comprise the State's authorized hazardous waste program into the Code of Federal Regulations (CFR). EPA does this by adding those citations and references to the authorized State rules in 40 CFR part 272. EPA is not codifying the authorization of Georgia's revisions at this time. However, EPA reserves the ability to amend 40 CFR part 272, subpart L, for the authorization of Georgia's program changes at a later date.

C. Statutory and Executive Order Reviews

This final authorization revises Georgia's authorized hazardous waste management program pursuant to Section 3006 of RCRA and imposes no requirements other than those currently imposed by State law. For further information on how this authorization complies with applicable executive orders and statutory provisions, please

see the Proposed Rule published in the **Federal Register** 83 FR 39975, August 13, 2018. The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this document and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This final action will be effective February 22, 2019.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of Sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

Dated: December 21, 2018.

Mary S. Walker,

Acting Regional Administrator, Region 4.

[FR Doc. 2019–03106 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 84, No. 36
Friday, February 22, 2019

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 21

[Docket No.: FAA–2018–1052; Notice No. 18–09]

RIN 2120–AL10

Foreign Civil Aviation Authority Certifying Statements

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to revise a regulation that imposes a duplicative requirement on foreign applicants for type certificates of import products. Existing FAA regulations require all applicants to submit two documents: A compliance listing to document the means of compliance with applicable standards; and a corresponding statement of compliance from the applicant certifying that all the requirements in the certification basis have been complied with. These compliance documents are duplicative and redundant to the certifying statement that the FAA already requires from the foreign civil aviation authority of the country or jurisdiction having State of Design responsibility for the design approval holder of the product. The FAA proposes to no longer require either the compliance listing or the accompanying statement of compliance from the foreign applicant.

DATES: Send comments on or before April 23, 2019.

ADDRESSES: Send comments identified by docket number FAA–2018–1052 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov,* including any personal information the commenter provides. Using the search function of the docket website, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477), as well as at *http://DocketsInfo.dot.gov*.

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: For questions concerning this action, contact Steve Flanagan, Policy and Innovation Division Certification Procedures Branch (AIR–6C0), Aircraft Certification Service, Federal Aviation Administration, 800 Independence Ave. SW, Washington, DC 20027; telephone (202) 267–1602; email *steve.flanagan@faa.gov*.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701. Under that section, the FAA is charged with promoting safe flight of civil airplanes in air commerce by prescribing minimum standards required in the interest of safety for the design and performance of airplanes. The FAA also has the authority to prescribe regulations for other practices, methods, and procedures it finds necessary for safety in air commerce. This rulemaking is within the scope of that authority because the proposed rule would eliminate duplication and promote efficiency in the issuance of type certificate approvals for import products certified by bilateral partners of the FAA, while continuing to meet the FAA's charge to promote safe flight.

I. Overview of the Proposal

The FAA proposes to amend 14 CFR 21.20, ''Compliance with applicable requirements,'' to exclude its applicability to import products that have been type certificated outside of the United States by a bilateral partner civil aviation authority (''CAA''). These products are validated by the FAA consistent with the requirements in 14 CFR 21.29, ''Issue of type certificate: import products.'' This proposed rule change would eliminate the necessity for redundant compliance documents to the FAA by both the CAA and the foreign applicant. The FAA would no longer require the foreign applicant to submit either the means of compliance listing or the accompanying statement of compliance because the FAA already requires that the applicant provide technical data to show compliance and for the bilateral partner CAA to provide a certifying statement of compliance. In addition to streamlining the application process for import products, this proposal would eliminate a burden to the FAA of accepting and reviewing redundant and duplicative information. This rule does not propose any changes to substantive type certification requirements applicable to foreign applicants.

II. Background

The United States has bilateral aviation agreements with numerous foreign countries for the acceptance of aeronautical products for export and import. The FAA and the foreign civil aviation authority (CAA) are responsible for implementing these agreements. Before making an agreement, the FAA thoroughly reviews the certification and production systems of the foreign

authority, including its organization, personnel, processes and regulations. Approval of the bilateral agreement makes the foreign authority (the CAA) a bilateral partner. The FAA does not sign an agreement unless the FAA has confidence in the CAA's system for certifying aviation products and overseeing the design organizations and manufacturers under its authority. Under these bilateral agreements, the CAA's type certification of a product is accepted by the FAA for import through a ''validation'' process to ensure all applicable requirements are met, including the procedural requirements in § 21.29, ''Issue of type certificate: import products.'' [1]

Section 21.29(a)(1) provides in pertinent part that the FAA may issue a type certificate (''TC'') for an import product if the applicable State of Design (*i.e.* the bilateral partner) ''certifies that the product has been examined, tested, and found to meet,'' applicable requirements for aircraft noise, fuel venting, exhaust emissions, and airworthiness. Therefore, in order for a product to receive a validated TC from the FAA for import of the product, the applicable foreign CAA must submit to the FAA a certifying statement that the product complies with the requirements and standards which are identified in the product's certification basis.

In accordance with § 21.29(a)(2), the FAA requires further that the foreign applicant provide to the CAA technical data to show that the product meets the applicable airworthiness and environmental requirements. In practice, this requirement is accomplished when the applicant submits to its CAA the technical data necessary for the CAA to certificate the product. Through the typical terms of a bilateral agreement, the FAA has access to this compliance data upon request to the CAA.

Section 21.20, ''Compliance with applicable requirements,'' was issued in 2009 rule (74 FR 53385, October 16, 2009). That provision requires an applicant for a type certificate, including an amended or supplemental type certificate, to show and certify compliance with all applicable requirements by submitting to the FAA two different compliance documents: A compliance listing (§ 21.20(a)); and a corresponding applicant statement of compliance [2] (§ 21.20(b)) certifying the applicant complies with the applicable requirements in its certification basis. In most cases, the § 21.20(a) statement takes the form of a compliance listing to document the means of compliance, as described in Advisory Circular (AC) No. 21–51, *Applicant's Showing of Compliance and Certifying Statement of Compliance* (Sep. 28, 2011). At a minimum, the compliance listing contains the following information: The design data; all the requirements to be complied with; the means of compliance, whether by analysis, test (flight, ground, or other), design similarity, equivalent level of safety, or exemption, etc.; and a reference to the substantiating data and documentation used to show compliance.

Section 21.20(b) establishes the FAA requirement for the TC applicant's statement of compliance with applicable requirements, the second of the two documents required by § 21.20 from an applicant for an FAA TC. An FAA TC applicant typically submits this statement of compliance upon completion of its FAA TC program.[3] Like the § 21.29(a)(1) certifying statement from the foreign CAA, the § 21.20(b) applicant statement of compliance contributes to product safety and compliance by the FAA applicant's certification document stating that the product being certified complies with minimum safety, environmental, and other requirements identified in the product's FAA certification basis.

As written, § 21.20 requires compliance documents from all applicants for type certificates, including foreign applicants seeking validation by the FAA of the foreign CAA's TC of the import product under § 21.29. Section 21.20, therefore, requires foreign applicants to generate and submit to the FAA the two applicant compliance documents described above. These redundant and duplicative data are in addition to the § 21.29(a)(1) and (2) requirements which request the same information.

III. Discussion of the Proposal

The FAA proposes to eliminate the requirement on foreign applicants of import products to submit the compliance listing and applicant statement of compliance. Both of these documents are duplicative and redundant of the foreign CAA certifying statement. The FAA is amending § 21.20 to specifically exclude its applicability to those applicants seeking FAA validation TCs for import products under § 21.29.

The foreign CAA's certifying statement required in § 21.29(a)(1) and the applicant's statement of compliance required in § 21.20(b) are substantively the same and duplicative. They both provide certification that a product complies with the applicable airworthiness, environmental, and other requirements in its certification basis. Whether it is the foreign applicant or the CAA that makes the statement is of no regulatory or legal significance. Regardless of which person submits the statement, a fraudulent, intentionally false, or misleading statement is a basis for denying issuance of a type certificate and suspending or revoking an existing type certificate. *See* 14 CFR 21.2, ''Falsification of applications, reports, or records.'' Moreover, as stated above, the FAA enters into a bilateral aviation agreement only if it has confidence in the foreign CAA's certification system. This confidence extends to that CAA's capability to certify that an import product has been examined, tested, and found to meet applicable requirements. The additional statement of compliance to the FAA by the foreign applicant is superfluous in light of the bilateral partner's responsibilities.

The compliance listing required under § 21.20(a) is also unnecessary for foreign applicants of type certificates of import products. When a foreign applicant seeks type certification through the validation process set forth in § 21.29, it will have already acquired, or is concurrently applying for, type certification through its own CAA. As required by § 21.29(a)(2), the foreign applicant must have provided, or is concurrently providing, technical data to its own CAA to show that the product meets all applicable airworthiness, environmental, and other requirements documented in the certification basis of the TC issued by the CAA. This information is available to the FAA during validation if needed under the terms of the bilateral agreement. Therefore, an additional compliance listing from the foreign applicant is redundant in light of the requirements

[1] For additional information on the validation process, *see* FAA Order 8110.52B, *Type Validation and Post-type Validation Procedures,* available online at *https://www.faa.gov/regulations_policies/orders_notices/index.cfm/go/document.information/documentid/1031946.*

[2] The FAA has previously referred to the statement required under § 21.20(b) as the applicant ''certifying statement.'' However, in order to distinguish between the foreign CAA ''certifying statement'' under § 21.29(a), the FAA now refers to the § 21.20(b) statement as the applicant ''statement of compliance.''

[3] For additional information on type certification programs, *see* FAA Order 8110.4C, *Type Certification,* available online at *https://www.faa.gov/regulations_policies/orders_notices/index.cfm/go/document.information/documentid/15172.*

in § 21.29(a) and the CAA's work during its TC program.

This proposed rule would eliminate the burden on foreign applicants to produce and submit redundant documentation and would relieve the FAA from the administrative burden associated with processing this redundant paperwork. This proposal would apply to all type certificate applications under § 21.29, including product type, amended type, supplemental, and amended supplemental type certificates. This proposal would streamline the TC process for import products, thereby facilitating U.S. industry access to aeronautical products.

IV. Regulatory Notices and Analyses

Changes to Federal regulations must undergo several economic analyses. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as codified in 5 U.S.C. 603 *et seq.,* requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended, 19 U.S.C. Chapter 13, prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as codified in 2 U.S.C. 1532, requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with a base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this proposed rule.

In conducting these analyses, the FAA has determined that this proposal is not a ''significant regulatory action,'' as defined in section 3(f) of Executive Order 12866. The rule is also not ''significant'' as defined in the Department of Transportation's (DOT's) Regulatory Policies and Procedures. The proposed rule will not have a significant economic impact on a substantial number of small entities, will not create unnecessary obstacles to international trade, and will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector.

A. Regulatory Evaluation

DOT Order 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits a statement to that effect and the basis for it to be included in the preamble if a full regulatory evaluation of the costs and benefits is not prepared. Such a determination has been made for this proposed rule. The reasoning for this determination follows:

By adding rule language which excludes the applicability of 14 CFR 21.20 ''Compliance with applicable requirements'' to products type certificated outside of the United States by a bilateral partner, this proposed rule will result in minor cost savings to the FAA.

The FAA may issue a type certificate for a product that is type certificated outside of the United States by a foreign CAA with which the United States has a bilateral agreement. Validation of the CAA's TC allows import of the product into the U.S. if the applicant and its CAA complies with 14 CFR 21.29. These applicants have also been required to comply with § 21.20,[4] which requires the applicant show compliance with all applicable requirements and provide its statements to the FAA showing and certifying compliance. Changing the rule to exclude applications for type certificates of import products under § 21.29 from having to comply with § 21.20 will have a small reduction in burden on the FAA and on the manufacturer of such products.

These manufacturers will not have to submit documentation to the FAA under § 21.20, which is redundant to documentation provided by the CAA to the FAA under § 21.29. This will result in small cost savings to the FAA, which will no longer have to accept and review the documentation.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354, ''RFA'') establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

As discussed above, this proposed rule would result in minor cost savings to foreign applicants and to the FAA. Because savings to foreign entities are not relevant to this analysis and the FAA is not a small entity there are no small entities affected and the impacts are minor cost savings.

Therefore, as provided in section 605(b), the head of the FAA certifies that this rulemaking will not result in a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended, prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to this Act, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

[4] While the current § 21.20 does not specify whether the applicants who must comply with that section are domestic, foreign, or both, AC 21–51 indicates that foreign applicants need to comply with 21.20 and make a statement directly to the FAA. AC 21–51 is being revised, and will reflect this proposed rule change.

The FAA has assessed the potential effect of this proposed rule and has determined that the rule is in accord with the Trade Agreements Act as to the rule expectations and responsibilities for domestic and foreign persons engaged in aviation activities under 14 CFR.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) 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 (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $155 million in lieu of $100 million.

This proposed rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there is no new requirement for information collection associated with this proposed rule.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and has identified no differences with this regulation.

C. barcasEnvironmental Analysis

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6(d), which covers the issuance of regulatory documents covering administrative or procedural requirements and involves no extraordinary circumstances.

V. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this proposed rule under the principles and criteria of Executive Order 13132, ''Federalism.'' The agency determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have Federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this proposed rule under Executive Order 13211, ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use'' (May 18, 2001). The agency has determined that it is not a ''significant energy action'' under the executive order and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, International Cooperation

Executive Order 13609, ''Promoting International Regulatory Cooperation,'' promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action would have no adverse effect on international regulatory cooperation.

D. Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

VI. This Proposed Rule Is Not Expected To Be an E.O. 13771 Regulatory Action Because This Proposed Rule Is Not Significant Under E.O. 12866. How To Obtain Additional Information

A. Rulemaking Documents

An electronic copy of a rulemaking document may be obtained from the internet by—

1. Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);

2. Visiting the FAA's Regulations and Policies web page at *http://www.faa.gov/regulations_policies/;* or

3. Accessing the Government Printing Office's web page at *http://www.gpo.gov/fdsys/.*

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9680.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document, may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 21

Aircraft, Aviation safety, Exports, Imports, Reporting and recordkeeping requirements.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend chapter I of title 14, Code of Federal Regulations as follows:

PART 21—CERTIFICATION PROCEDURES FOR PRODUCTS AND ARTICLES

■ 1. The authority citation for part 21 continues to read as follows:

Authority: 42 U.S.C. 7572; 49 U.S.C. 106(f), 106(g), 40105, 40113, 44701–44702, 44704, 44707, 44709, 44711, 44713, 44715, 45303.

■ 2. Amend § 21.20 by revising the introductory text to read as follows:

§ 21.20 Compliance with applicable requirements.

Except for applications for type certificates of import products under § 21.29, the applicant for a type certificate, including an amended or supplemental type certificate, must—

* * * * *

Issued under authority provided by 49 U.S.C. 106(f) and 44701(a) in Washington, DC, on February 7, 2019.

Earl Lawerence,

Executive Director, Aircraft Certification Service.

[FR Doc. 2019–02634 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0019; Product Identifier 2018–NM–130–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. This proposed AD was prompted by reports of low clearance between the variable frequency generator (VFG) power feeder cables and adjacent hydraulic lines and/or fuel lines in the aft equipment bay, which could cause chafing damage. This proposed AD would require modifying the routing of the VFG power feeder cables and harnesses in the aft equipment bay. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by April 8, 2019.

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

For service information identified in this NPRM, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone: 514–855–5000; fax: 514–855–7401; email: *thd.crj@aero.bombardier.com;* internet: *http://www.bombardier.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0019; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Steven Dzierzynski, Aerospace Engineer, Avionics and Electrical Systems Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7367; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2019–0019; Product Identifier 2018–NM–130–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2018–22, dated August 2, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. The MCAI states:

> Several aircraft have been discovered with low clearance between the Variable Frequency Generator (VFG) cables and hydraulic/fuel lines in the Aft Equipment Bay which may lead to chafing between the VFG cables and the hydraulic/fuel lines. Chafing may result in damage that could lead to a hydraulic/fuel leak and electrical arcing as an ignition source. This condition, if not corrected, could result in an in-flight fire.
>
> This [Canadian] AD mandates a modification to the routing of the VFG power feeder cables and harnesses, to ensure the required clearance between the VFG cables and hydraulic/fuel lines in the Aft Equipment Bay.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0019.

Related Service Information Under 1 CFR Part 51

Bombardier has issued the following service information for Bombardier, Inc. Model BD–700–1A10 airplanes.

- Service Bulletin 700–24–089, Revision 01, dated August 21, 2018.
- Service Bulletin 700–24–6014, Revision 01, dated August 21, 2018.

Bombardier has issued the following service information for Bombardier, Inc. Model BD–700–1A11 airplanes.

- Service Bulletin 700–1A11–24–028, Revision 01, dated August 21, 2018.
- Service Bulletin 700–24–5014, Revision 01, dated August 21, 2018.

This service information describes procedures for modifying the routing of the VFG power feeder cables and harnesses in the aft equipment bay to ensure the required clearance between the cables and the hydraulic lines and/or fuel lines. These documents are distinct since they apply to different airplane models and configurations.

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

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed Requirements of This NPRM

This proposed AD would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

We estimate that this proposed AD affects 112 airplanes of U.S. registry. We

estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 5 work-hours × $85 per hour = Up to $425	Up to $606	Up to $1,031	Up to $115,472.

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.

We are 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.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Bombardier, Inc.: Docket No. FAA–2019–0019; Product Identifier 2018–NM–130–AD.

(a) Comments Due Date

We must receive comments by April 8, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes, certificated in any category, serial numbers 9002 through 9831 inclusive, and 9998.

(d) Subject

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

(e) Reason

This AD was prompted by reports of low clearance between the variable frequency generator (VFG) power feeder cables and adjacent hydraulic lines and/or fuel lines in the aft equipment bay, which could cause chafing damage. We are issuing this AD to address this unsafe condition, which could result in a hydraulic/fuel leak and electrical arcing as an ignition source, and could cause an in-flight fire.

(f) Compliance

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

(g) Routing Modification

Within 24 months after the effective date of this AD: Modify the routing of the VFG power feeder cables and harnesses in the aft equipment bay to ensure the required clearance between the cables and the hydraulic lines and/or fuel lines, in accordance with the Accomplishment Instructions of the applicable service information listed in figure 1 to paragraph (g) of this AD.

Figure 1 to paragraph (g) of this AD – *Service information for modification*

Airplane Model/Serial No.	Bombardier Service Information
BD-700-1A10 9002 through 9312 inclusive; 9314 through 9380 inclusive; 9384 through 9429 inclusive	Service Bulletin 700-24-089, Revision 01, dated August 21, 2018
BD-700-1A10 9313, 9381, and 9432 through 9831 inclusive	Service Bulletin 700-24-6014, Revision 01, dated August 21, 2018
BD-700-1A11 9127 through 9383 inclusive; 9389 through 9400 inclusive; 9404 through 9431 inclusive; and 9998	Service Bulletin 700-1A11-24-028, Revision 01, dated August 21, 2018
BD-700-1A11 9386, 9401, and 9445 through 9831 inclusive	Service Bulletin 700-24-5014, Revision 01, dated August 21, 2018

(h) Credit for Previous Actions

(1) This paragraph provides credit for the modification required by paragraph (g) of this AD for airplanes on which the modification specified in Bombardier Service Bulletin 700–24–6014, dated April 25, 2018, was performed before the effective date of this AD using Bombardier Service Request for Product Support Action (SRPSA) 000236314.

(2) This paragraph provides credit for the modification required by paragraph (g) of this AD, if the modification was performed before the effective date of this AD using the service information specified in paragraphs (h)(2)(i) through (h)(2)(iv) of this AD.

(i) Bombardier Service Bulletin 700–24–089, dated April 25, 2018.

(ii) Bombardier Service Bulletin 700–24–6014, dated April 25, 2018.

(iii) Bombardier Service Bulletin 700–1A11–24–028, dated April 25, 2018.

(iv) Bombardier Service Bulletin 700–24–5014, dated April 25, 2018.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO 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 certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. 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.

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

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2018–22, dated August 2, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0019.

(2) For more information about this AD, contact Steven Dzierzynski, Aerospace Engineer, Avionics and Electrical Systems Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7367; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone: 514–855–5000; fax: 514–855–7401; email: *thd.crj@aero.bombardier.com;* internet: *http://www.bombardier.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on February 1, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–02937 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0016; Product Identifier 2018–NM–168–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Airbus SAS Model A350–941 and –1041 airplanes. This proposed AD was prompted by reports of loss of retention of the regulator inlet filter retainer on certain crew oxygen cylinder assemblies. This proposed AD would require an operational check of the crew oxygen cylinder assembly, replacement of an affected assembly, and eventual replacement of all affected assemblies with redesigned serviceable assemblies.

We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by April 8, 2019.

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

For the incorporation by reference (IBR) material described in the ''Related IBR material under 1 CFR part 51'' section in **SUPPLEMENTARY INFORMATION**, contact European Aviation Safety Agency (EASA), Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Transport Standards 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 in the AD docket on the internet at *http://www.regulations.gov.*

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0016; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2019–0016; Product Identifier 2018–NM–168–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0245R1, dated December 5, 2018 (''EASA AD 2018–0245R1'') (also referred to as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus SAS Model A350–941 and –1041 airplanes. The MCAI states:

> Several occurrences were reported of loss of retention of the regulator inlet filter retainer on affected assemblies. The filter retainer detached from the regulator and dropped within the cylinder internal volume. The technical investigation identified a design defect which was the cause of these events.
>
> This condition, if not detected and corrected, could lead to particle ingestion into the regulator during ground handling, possibly resulting in ignition/fire during system ground operational testing following cylinder (re)installation on an aeroplane.
>
> To address this potential unsafe condition, Airbus issued the AOT [Airbus Alert Operators Transmission A35P010–17, dated December 20, 2017] to provide instructions for an operational check (OPC). Airbus also developed an improved oxygen cylinder assembly and issued the SB [Airbus Service Bulletin A350–35–P012, dated July 12, 2018] accordingly, to provide replacement instructions.
>
> For the reasons described above, EASA issued AD 2018–0245 to require a one-time OPC of each affected assembly and, depending on findings, replacement. This [EASA] AD also requires replacement of all affected assemblies with improved serviceable assemblies.
>
> Prompted by operator requests for clarification after that [EASA] AD was issued, this [EASA] AD is revised to introduce a new definition for 'Groups' of aeroplanes affected by this [EASA] AD, amending the [EASA] AD accordingly to reflect the intended requirements for each Group.

Related IBR Material Under 1 CFR Part 51

EASA AD 2018–0245R1 describes procedures for an operational check of the crew oxygen cylinder assembly, replacement of an affected assembly, and eventual replacement of all affected assemblies with redesigned serviceable assemblies. 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, and it is publicly available through the EASA website.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Proposed Requirements of This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2018–0245R1 described previously, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. As a result, EASA AD 2018–0245R1 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with the provisions specified in EASA AD 2018–0245R1, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information specified in EASA AD 2018–0245R1 that is required for compliance with EASA AD 2018–0245R1 will be available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0016 after the FAA final rule is published.

Costs of Compliance

We estimate that this proposed AD affects 11 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
10 work-hours × $85 per hour = $850	* $0	$850	$9,350

* We have received no definitive data regarding the parts cost.

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

Authority for This Rulemaking

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

We are 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.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus SAS: Docket No. FAA–2019–0016; Product Identifier 2018–NM–168–AD.

(a) Comments Due Date

We must receive comments by April 8, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 35, Oxygen.

(e) Reason

This AD was prompted by reports of loss of retention of the regulator inlet filter retainer on certain crew oxygen cylinder assemblies. We are issuing this AD to address loss of retention of the regulator inlet filter retainer on certain crew oxygen cylinder assemblies. This condition could lead to particle ingestion into the regulator during ground handling, possibly resulting in ignition/fire during system ground operational testing following crew oxygen cylinder (re)installation on an airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2018–0245R1.

(h) Exceptions to EASA AD 2018–0245R1

(1) For purposes of determining compliance with the requirements of this AD: Where EASA AD 2018–0245R1 refers to its effective date, or the effective date of EASA AD 2018–0245, dated November 13, 2018, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2018–0245R1 does not apply to this AD.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2018–0245R1 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@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.

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

(3) *Required for Compliance (RC):* For any service information referenced in EASA AD 2018–0245R1 that contains RC procedures and tests: Except as required by paragraph (h)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

(1) For information about EASA AD 2018–0245R1, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this EASA AD at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. EASA AD 2018–0245R1 may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0016.

(2) For more information about this AD, contact Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

Issued in Des Moines, Washington, on February 1, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–02931 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0022; Product Identifier 2018–NM–162–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 737–200, –200C, –300, –400, and –500 airplanes. This proposed AD was prompted by reports of cracking in the lower lobe skin panel assemblies of the fuselage. This proposed AD would require replacement of lower lobe skin panel assemblies, and detailed inspections for scribe lines and applicable on-condition actions. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by April 8, 2019.

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

For service information identified in this NPRM, 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; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Standards 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 on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0022.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0022; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: James Guo, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5357; fax: 562–627–5210; email: *james.guo@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2019–0022; Product Identifier 2018–NM–162–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

Fatigue damage can occur locally, in small areas or structural design details, or globally, in widespread areas. Multiple-site damage is widespread damage that occurs in a large structural element such as a single rivet line of a lap splice joining two large skin panels. Widespread damage can also occur in multiple elements such as adjacent frames or stringers. Multiple-site damage and multiple-element damage cracks are typically too small initially to be reliably detected with normal inspection methods. Without intervention, these cracks will grow, and eventually compromise the structural integrity of the airplane. This condition is known as widespread fatigue damage (WFD). It is associated

with general degradation of large areas of structure with similar structural details and stress levels. As an airplane ages, WFD will likely occur, and will certainly occur if the airplane is operated long enough without any intervention.

The FAA's WFD final rule (75 FR 69746, November 15, 2010) became effective on January 14, 2011. The WFD rule requires certain actions to prevent structural failure due to WFD throughout the operational life of certain existing transport category airplanes and all of these airplanes that will be certificated in the future. For existing and future airplanes subject to the WFD rule, the rule requires that DAHs establish a limit of validity (LOV) of the engineering data that support the structural maintenance program. Operators affected by the WFD rule may not fly an airplane beyond its LOV, unless an extended LOV is approved.

The WFD rule (75 FR 69746, November 15, 2010) does not require identifying and developing maintenance actions if the DAHs can show that such actions are not necessary to prevent WFD before the airplane reaches the LOV. Many LOVs, however, do depend on accomplishment of future maintenance actions. As stated in the WFD rule, any maintenance actions necessary to reach the LOV will be mandated by airworthiness directives through separate rulemaking actions.

In the context of WFD, this action is necessary to enable DAHs to propose LOVs that allow operators the longest operational lives for their airplanes, and still ensure that WFD will not occur. This approach allows for an implementation strategy that provides flexibility to DAHs in determining the timing of service information development (with FAA approval), while providing operators with certainty regarding the LOV applicable to their airplanes.

We have received a report indicating that an operator of a 737–300 airplane reported a chem-milled step crack above stringer S–15 on the left side between station (STA) 360 and STA 380. The airplane had a lap splice modification done in accordance with Boeing Service Bulletin 737–53A1177 and had logged 48,537 total flight cycles and 67,505 total flight hours. The 5-inch crack was found by visual inspection during airplane maintenance. On these skin panel assemblies, the bonded doubler is chemically milled to create pockets. At these locations, the loads could cause a condition where cracks could form along the longitudinal edges of the doubler at the step of the chem-milled pockets. Without skin panel assembly replacement, the skin cracks could grow and multiple adjacent cracks in the fuselage skin could link up with each other. This condition, if not addressed, could lead to decompression or loss of structural integrity of the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Requirements Bulletin 737–53A1379 RB, dated September 4, 2018. The service information describes procedures for replacement of lower lobe skin panel assemblies, and detailed inspections for scribe lines and applicable on-condition actions.

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

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishment of the actions identified in Boeing Alert Requirements Bulletin 737–53A1379 RB, dated September 4, 2018, described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0022.

Explanation of Requirements Bulletin

The FAA worked in conjunction with industry, under the Airworthiness Directive Implementation Aviation Rulemaking Committee (AD ARC), to enhance the AD system. One enhancement is a process for annotating which steps in the service information are ''required for compliance'' (RC) with an AD. Boeing has implemented this RC concept into Boeing service bulletins.

In an effort to further improve the quality of ADs and AD-related Boeing service information, a joint process improvement initiative was worked between the FAA and Boeing. The initiative resulted in the development of a new process in which the service information more clearly identifies the actions needed to address the unsafe condition in the ''Accomplishment Instructions.'' The new process results in a Boeing Requirements Bulletin, which contains only the actions needed to address the unsafe condition (*i.e.,* only the RC actions).

Explanation of Compliance Time

The compliance time for the modification specified in this proposed AD for addressing WFD was established to ensure that discrepant structure is replaced before WFD develops in airplanes. Standard inspection techniques cannot be relied on to detect WFD before it becomes a hazard to flight. We will not grant any extensions of the compliance time to complete any AD-mandated service bulletin related to WFD without extensive new data that would substantiate and clearly warrant such an extension.

Costs of Compliance

We estimate that this proposed AD affects 171 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS *

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection and replacement	688 work-hours × $85 per hour = $58,480.	(*)	$58,480	$10,000,080

* Parts cost unavailable.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD.

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.

We are 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.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

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

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2019–0022; Product Identifier 2018–NM–162–AD.

(a) Comments Due Date

We must receive comments by April 8, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 737–200, –200C, –300, –400, and –500 airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin 737–53A1379 RB, dated September 4, 2018.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of cracking in the lower lobe skin panel assemblies of the fuselage. We are issuing this AD to address the possibility of multiple adjacent cracks at chem-milled steps in the fuselage skin linking up with each other, which could lead to decompression or loss of structural integrity 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 737–53A1379 RB, dated September 4, 2018, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 737–53A1379 RB, dated September 4, 2018.

Note 1 to paragraph (g) of this AD: Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 737–53A1379, dated September 4, 2018, which is referred to in Boeing Alert Requirements Bulletin 737–53A1379 RB, dated September 4, 2018.

(h) Exceptions to Service Information Specifications

(1) For purposes of determining compliance with the requirements of this AD: Where Boeing Alert Requirements Bulletin 737–53A1379 RB, dated September 4, 2018, uses the phrase ''the original issue date of Requirements Bulletin 737–53A1379 RB,'' this AD requires using ''the effective date of this AD.''

(2) Where Boeing Alert Requirements Bulletin 737–53A1379 RB, dated September 4, 2018, specifies contacting Boeing for work instructions or for scribe line repair and skin panel replacement work instructions: This AD requires doing the work and the scribe line repair and skin panel replacement before further flight using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO 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 certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@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.

(3) 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 Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO 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) Related Information

(1) For more information about this AD, contact James Guo, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5357; fax: 562–627–5210; email: *james.guo@faa.gov*.

(2) For service information 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; internet *https://www.myboeingfleet.com*. You may view this referenced service information at the FAA,

Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on February 8, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–02923 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0018; Product Identifier 2018–NM–116–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2016–07–12, which applies to certain Airbus SAS Model A318, A319, A320, and A321 series airplanes. AD 2016–07–12 requires repetitive inspections for damage and cracking of the aft fixed fairing (AFF) of the pylons, and repair if necessary. Since we issued AD 2016–07–12, we have received reports of cracks on a certain rib of a modified AFF of the pylons. This proposed AD would retain the repetitive inspections required by AD 2016–07–12, and require additional repetitive inspections at the upper spar at a certain rib area and corrective actions if necessary. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by April 8, 2019.

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

For the incorporation by reference (IBR) material described in the ''Related IBR material under 1 CFR part 51'' section in **SUPPLEMENTARY INFORMATION**, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email *ADs@easa.europa.eu*; internet *www.easa.europa.eu*. You may find this IBR material on the EASA website at *https://ad.easa.europa.eu*. You may view this IBR material at the FAA, Transport Standards 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 in the AD docket on the internet at *http://www.regulations.gov*.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0018; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2019–0018; Product Identifier 2018–NM–116–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

We issued AD 2016–07–12, Amendment 39–18457 (81 FR 19482, April 5, 2016) (''AD 2016–07–12''), for certain Airbus SAS Model A318, A319, A320, and A321 series airplanes. AD 2016–07–12 requires repetitive inspections for damage and cracking of the AFF of the pylons, and repair if necessary. AD 2016–07–12 resulted from reports of cracking of the AFF of the pylons due to fatigue damage of the structure. We issued AD 2016–07–12 to address such damage and cracking of the AFF of the pylons, which could result in detachment of a pylon and consequent reduced structural integrity of the airplane.

Actions Since AD 2016–07–12 Was Issued

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0137, dated June 28, 2018 (''EASA AD 2018–0137'') (also referred to as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus SAS Model A318–111, –112; Model A319–111, –112, –113, –114, –115; Model A320–211, –212, –214, –216; and Model A321–111, –112, –211, –212, –213 airplanes. The MCAI states:

> On aeroplanes equipped with post-mod 33844 CFM pylons, several operators reported finding cracks on the Aft Fixed Fairing (AFF). After material analysis, it appeared that the pylon AFF structure, especially on this configuration, was subject to fatigue-induced damage which could lead to pylon AFF cracks.
>
> This condition, if not detected and corrected, could lead to detachment of a pylon AFF from the aeroplane, possibly resulting in injury to persons on the ground.
>
> To address this unsafe condition, Airbus published Alert Operators Transmission (AOT) A54N002–12, providing inspection instructions. Thereafter, Airbus issued Service Bulletin (SB) A320–54–1027, later revised, superseding AOT A54N002–12. EASA issued AD 2014–0154 [which corresponds to FAA AD 2016–07–12] to require repetitive inspections of the pylon AFF and, depending on findings, replacement.
>
> Since that [EASA] AD was issued, Airbus developed mod 156593 to increase the fatigue life of the pylon AFF structure by using a different material and introducing thermal treatment of the aluminium sheets parts. Prompted by new findings of cracks on rib 15, it was determined that this area also needs to be inspected to ensure the structural integrity of the new pylon AFF. Airbus further revised SB A320–54–1027, including instructions for repetitive inspection of that area. Repetitive inspections are also required on post-mod 156593 aeroplanes.

Airbus also developed mod 159806 and 156765, redesigning the corner fittings at the junction upper spar and rib 15, which constitutes terminating action for the repetitive inspections. For retrofit purposes, Airbus issued SB A320–54–1035 and SB A320–54–1036, later revised, providing instructions to modify and re-identify the pylon AFF, which constitutes terminating action for the repetitive inspections.

For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2014–0154, which is superseded, and requires repetitive inspections of the upper spar at rib 15 area and, depending on findings, accomplishment of applicable corrective action(s). This [EASA] AD also includes references to optional terminating actions, and provides installation requirements for the new pylon AFF.

Model A320–216 Airplanes

The Airbus SAS Model A320–216 was U.S. type certificated on December 19, 2016. Before that date, any EASA ADs that affected Model A320–216 airplanes were included on the Required Airworthiness Actions List (RAAL). One or more Model A320–216 airplanes have subsequently been placed on the U.S. Register, and will now be included in FAA AD actions. For Model A320–216 airplanes, the requirements that correspond to AD 2016–07–12 were mandated by the MCAI via the RAAL. Although that RAAL requirement is still in effect, for continuity and clarity we have identified Model A320–216 airplanes in paragraph (c) of this AD; the MCAI that is specified in paragraph (g) in this proposed AD includes restated requirements, which would therefore apply to those airplanes.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2016–07–12, this proposed AD would retain all of the requirements of AD 2016–07–12. Those requirements are referenced in EASA AD 2018–0137, dated June 28, 2018, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related IBR Material Under 1 CFR Part 51

EASA AD 2018–0137, dated June 28, 2018, describes procedures for repetitive inspections for pre- and post-Airbus SAS modification 156593 airplanes, corrective actions, and optional terminating actions for the repetitive inspections. Corrective actions include modifications and 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 and it is publicly available through the EASA website.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. As a result, EASA AD 2018–0137 will be incorporated by reference in the FAA final rule. This proposed AD would therefore require compliance with the provisions specified in EASA AD 2018–0137, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information specified in EASA AD 2018–0137 that is required for compliance with EASA AD 2018–0137 will be available at *http://www.regulations.gov* under Docket No. FAA–2019–0018 after the FAA final rule is published.

Differences Between This Proposed AD and the Service Information/MCAI

Although paragraph (3) of EASA AD 2018–0137 and Airbus Service Bulletin A320–54–1027, Revision 04, dated June 4, 2018, specify accomplishing the initial detailed and special detailed inspections of the AFF of the pylons on aircraft, or the detailed inspection of the AFF of the pylons on bench before exceeding 10,000 flight cycles or 15,000 flight hours since airplane first flight, whichever occurs first, this proposed AD would require operators to accomplish these inspections before exceeding 10,000 flight cycles or 15,000 flight hours since embodiment of Airbus modification 156593, whichever occurs first. This difference has been coordinated with EASA.

Where paragraph (5) of EASA AD 2018–0137 provides credit for actions accomplished in accordance with Airbus Service Bulletin A320–54–1027, Revision 02, dated January 12, 2017; or Airbus Service Bulletin A320–54–1027, Revision 03, dated September 22, 2017; this proposed AD would not provide credit for actions accomplished in accordance with the above referenced service information because of the additional work required by Airbus Service Bulletin A320–54–1027, Revision 04, dated June 4, 2018.

Costs of Compliance

We estimate that this proposed AD affects 205 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2016–07–12.	4 work-hours × $85 per hour = $340	$0	$340	$69,700.
New proposed actions	Up to 21 work-hours × $85 per hour = $1,785	0	Up to $1,785	Up to $365,925.

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Labor cost	Parts cost	Cost per product
Up to 70 work-hours × $85 per hour = $5,950	Up to $32,800	Up to $38,750.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD.

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

Authority for This Rulemaking

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

We are 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.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2016–07–12, Amendment 39–18457 (81 FR 19482, April 5, 2016), and adding the following new AD:

Airbus SAS: Docket No. FAA–2019–0018; Product Identifier 2018–NM–116–AD.

(a) Comments Due Date

We must receive comments by April 8, 2019.

(b) Affected ADs

This AD replaces AD 2016–07–12, Amendment 39–18457 (81 FR 19482, April 5, 2016) (''AD 2016–07–12'').

(c) Applicability

This AD applies to Airbus SAS Model A318–111, –112; Model A319–111, –112, –113, –114, –115; Model A320–211, –212, –214, –216; and Model A321–111, –112, –211, –212, –213 airplanes, certificated in any category, as identified in the European Aviation Safety Agency (EASA) AD 2018–0137, dated June 28, 2018 (''EASA AD 2018–0137'').

(d) Subject

Air Transport Association (ATA) of America Code 54, Nacelles/pylons.

(e) Reason

This AD was prompted by reports of cracking of the aft fixed fairing (AFF) of the pylons due to fatigue damage of the structure and reports of cracks on a certain rib of a modified AFF of the pylons. We are issuing this AD to address damage and cracking of the AFF of the pylons, which could result in detachment of a pylon and consequent reduced structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2018–0137.

(h) Exceptions to EASA AD 2018–0137

(1) For purposes of determining compliance with the requirements of this AD, use the following paragraphs.

(i) Where EASA AD 2018–0137 refers to its effective date, this AD requires using the effective date of this AD.

(ii) Where EASA AD 2018–0137 refers to a compliance time of after July 16, 2014, this AD requires using May 10, 2016, (the effective date of AD 2016–07–12).

(2) The ''Remarks'' section of EASA AD 2018–0137 does not apply.

(3) Where paragraph (3) of EASA AD 2018–0137 requires that airplanes that have embodied Airbus modification 156593 accomplish the initial inspection of the AFF of the pylons before exceeding 10,000 flight cycles or 15,000 flight hours, whichever occurs first since airplane first flight, this AD requires inspection of those airplanes before exceeding 10,000 flight cycles or 15,000 flight hours since embodiment of Airbus modification 156593, whichever occurs first.

(4) The provisions of paragraph (5) of EASA AD 2018–0137 are not allowed in this AD.

(5) Where paragraph (6) of EASA AD 2018–0137 gives credit for ''the initial requirements of paragraph (4)'' of EASA AD 2018–0137, this AD gives credit for ''the requirements of paragraph (4)'' of EASA AD 2018–0137.

(6) Where EASA AD 2018–0137 requires any approval from EASA or Airbus's Design Organization Approval (DOA), this AD requires approval by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus SAS's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2018–0137 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*.

(i) 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.

(ii) AMOCs approved previously for AD 2016–07–12 are approved as AMOCs for this AD.

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

(3) *Required for Compliance (RC):* For any service information referenced in EASA AD 2018–0137 that contains RC procedures and tests: RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

(1) For information about EASA AD 2018–0137, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email *ADs@easa.europa.eu*; Internet *www.easa.europa.eu*. You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu*. You may view this EASA AD at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. EASA AD 2018–0137 may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0018.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

Issued in Des Moines, Washington, on February 1, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–02926 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0021; Product Identifier 2018–NM–038–AD]

RIN 2120–AA64

Airworthiness Directives; AmSafe Inc. Seatbelts

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all AmSafe Inc. seatbelts, as installed in, but not limited to, various airplanes and rotorcraft. This proposed AD was prompted by reports of multiple failed keepers on seatbelt hook assemblies. This proposed AD would require an inspection for affected parts, repetitive general visual inspections of the seatbelt hook assembly for damage, repetitive functional checks, and replacement of all affected parts. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by April 8, 2019.

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

For service information identified in this NPRM, contact AmSafe Inc., 1043 N 47th Avenue, Phoenix, AZ 85043; telephone: 602–850–2850; fax: 602–850–2812; internet: *https://www.amsafe.com*. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0021; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Patrick Farina, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5344; fax: 562–627–5210; email: *Patrick.Farina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2019–0021; Product Identifier 2018–NM–038–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

We have received a report indicating that failed keepers on seatbelt hook assemblies have been found on multiple transport category airplanes. These seatbelt hook assemblies might also be installed on other types of aircraft. The keepers have been found with the metal bridge above the spring bent or broken in a way that does not allow the seatbelt hook assemblies to be securely fastened to the seat structure. Failure of keepers on seatbelt hook assemblies, if not addressed, could result in the seatbelt disengaging from and detaching from the seat structure under certain conditions, and could result in injury to passengers or flightcrew.

Related Service Information Under 1 CFR Part 51

We reviewed AmSafe Safety Bulletin SB505960–01, Issue 5, dated August 6, 2018. The service information describes procedures for an inspection for affected

parts, repetitive general visual inspections of the seatbelt hook assembly for damage (including compressed springs, bends, rotation or deformation of the bridge), repetitive functional checks and replacement. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type designs.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between this Proposed AD and the Service Information.''

Differences Between This Proposed AD and the Service Information

AmSafe Safety Bulletin SB505960–01, Issue 5, dated August 6, 2018, specifies to return parts to the manufacturer. This proposed AD would not include that requirement.

Costs of Compliance

We estimate that this proposed AD affects 100,000 appliances installed on, but not limited to, various airplanes and rotorcraft of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection for affected part	1 work-hour × $85 per hour = $85.	$0	$85	$8,500,000.
Repetitive inspections and functional checks.	1 work-hour × $85 per hour = $85 per inspection cycle.	0	$85 per inspection cycle	$8,500,000 per inspection cycle.
Replacement	1 work-hour × $85 per hour = $85.	28	$113	$11,300,000.

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have 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	1 work-hour × $85 per hour = $85	$28	$113

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

Authority for This Rulemaking

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

We are 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.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

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

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

AmSafe Inc. Seatbelts: Docket No. FAA–2019–0021; Product Identifier 2018–NM–038–AD.

(a) Comments Due Date

We must receive comments by April 8, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to AmSafe Inc. seatbelts installed on various airplanes and rotorcraft, certificated in any category, including, but not limited to, the airplanes of the manufacturers specified in paragraphs (c)(1) through (c)(5) of this AD.

(1) Airbus SAS
(2) The Boeing Company
(3) Bombardier, Inc.
(4) Embraer S.A.
(5) Fokker Services B.V.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by reports of multiple failed keepers on seatbelt hook assemblies. We are issuing this AD to address failed keepers on seatbelt hook assemblies. Failure of keepers on seatbelt hook assemblies, if not addressed, could result in the seatbelt disengaging from and detaching from the seat structure under certain conditions, and could result in injury to passengers or flightcrew.

(f) Compliance

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

(g) Inspection for Affected Parts

For any seatbelt buckle half and connector half having a part number listed in Table 1 of paragraph ''1.1., Effectivity'' of AmSafe Safety Bulletin SB505960–01, Issue 5, dated August 6, 2018: Within 180 days after the effective date of this AD, do a general visual inspection of each seatbelt buckle half and connector half to determine whether the seatbelt hook assembly has exposed springs, in accordance with AmSafe Safety Bulletin SB505960–01, Issue 5, dated August 6, 2018.

(1) An affected part is any seatbelt buckle half or connector half that has a seatbelt hook assembly with exposed springs.

(2) An unaffected part is any seatbelt buckle half or connector half that has a seatbelt hook assembly without exposed springs.

(h) Repetitive Inspections and Functional Checks

Within 180 days after the effective date of this AD, do a general visual inspection of each affected part for damage to the seatbelt hook assembly and do a functional check in accordance with AmSafe Safety Bulletin SB505960–01, Issue 5, dated August 6, 2018.

(1) If any seatbelt hook assembly is damaged or the part fails the functional check, before further flight, replace the part with a new or serviceable part. If an affected part is installed, repeat the inspection and functional check at intervals not to exceed 24 months or at the next scheduled heavy maintenance check, whichever occurs first, until the actions specified in paragraph (i) of this AD are done.

(2) If an affected part is undamaged and passes the functional check, repeat the inspection and functional check at intervals not to exceed 24 months or at the next scheduled heavy maintenance check, whichever occurs first, until the actions specified in paragraph (i) of this AD are done.

(i) Terminating Action

Within 58 months after the effective date of this AD, replace all affected parts with unaffected parts in accordance with AmSafe Safety Bulletin SB505960–01, Issue 5, dated August 6, 2018. Replacing all affected parts with unaffected parts on a seatbelt hook assembly terminates the repetitive inspections and functional checks specified in paragraph (h) of this AD for that seatbelt hook assembly. Replacing all affected parts with unaffected parts on an airplane or rotorcraft terminates the repetitive inspections and functional checks specified in paragraph (h) of this AD for that airplane or rotorcraft.

(j) Parts Installation Prohibition

No person may install on any seat an affected part as of the time specified in paragraph (j)(1), (j)(2), or (j)(3) of this AD, as applicable.

(1) For seats on which, as of the effective date of this AD any affected part is found during the inspection required by paragraph (g) of this AD: After replacement of the affected part(s) with unaffected part(s).

(2) For seats on which no affected parts are found during the inspection required by paragraph (g) of this AD: As of the date of the inspection required by paragraph (g) of this AD.

(3) For seats on which both the seatbelt buckle half and connector half have part numbers not listed in Table 1 of paragraph ''1.1., Effectivity'' of AmSafe Safety Bulletin SB505960–01, Issue 5, dated August 6, 2018: As of the effective date of this AD.

(k) No Return of Parts

Although AmSafe Safety Bulletin SB505960–01, Issue 5, dated August 6, 2018, specifies to return parts to the manufacturer, this AD does not require the return of the parts to the manufacturer.

(l) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraphs (g), (h), and (i) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraphs (l)(1) or (l)(2), of this AD.

(1) AmSafe Safety Bulletin SB505960–01, Issue 3, dated April 19, 2018.

(2) AmSafe Safety Bulletin SB505960–01, Issue 4, dated July 12, 2018.

(m) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO 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 certification office, send it to the attention of the person identified in paragraph (n)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@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.

(n) Related Information

(1) For more information about this AD, contact Patrick Farina, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5344; fax: 562–627–5210; email: *Patrick.Farina@faa.gov.*

(2) For service information identified in this AD, contact AmSafe Inc., 1043 N 47th Avenue, Phoenix, AZ 85043; telephone: 602–850–2850; fax: 602–850–2812; internet: *https://www.amsafe.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on February 8, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–02933 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0037; Airspace Docket No. 19–ACE–2]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Denison, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace extending

upward from 700 feet above the surface at Denison Municipal Airport, Denison, IA. The FAA is proposing this action due to the decommissioning of the Denison non-directional radio beacon (NDB). Additionally, the geographic coordinates are being updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before April 8, 2019.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2019–0037; Airspace Docket No. 19–ACE–2, at the beginning of your comments. You may also submit and review comments through the internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741–6030, or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

FOR FURTHER INFORMATION CONTACT: John Witucki, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5900.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2019–0037; Airspace Docket No. 19–ACE–2.'' The postcard will be date/time stamped and returned to the commenter.

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

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air-traffic/publications/airspace-amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by amending Class E airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Denison Municipal Airport, Denison, IA and within 2.0 miles each side of the 124° bearing from the Denison Municipal Airport extending from the 6.5-mile radius to 10.9 miles southeast of the airport. This action is necessary due to the decommissioning of the Denison NDB and for the safety and management of instrument flight rules (IFR) operations at the airport. Additionally, the geographic coordinates are being updated to coincide with the FAA's aeronautical database.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11C, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant

preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

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

* * * * *

ACE IA E5 Denison, IA [Amended]

Denison Municipal Airport, IA
(Lat. 41°59′12″ N, long. 95°22′50″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Denison Municipal Airport and within 2.0 miles, each side of the 124° bearing from the Denison Municipal Airport extending from the 6.5-mile radius to 10.9 miles southeast of the airport.

Issued in Fort Worth, Texas, on February 15, 2019.

Wayne Eckenrode,

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

[FR Doc. 2019–03093 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–13–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Parts 1601 and 1626

RIN 3046–AB07

Procedural Regulations Under Title VII, ADA, and GINA; Procedures—Age Discrimination in Employment Act

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Equal Employment Opportunity Commission (EEOC or Commission) is proposing to amend its procedural regulations to explicitly provide for digital transmissions of documents, to clarify the process for deferral to state and local agencies, to update no cause determination procedures, and to correct typographical errors.

DATES: Comments on the notice of proposed rulemaking must be received on or before April 23, 2019.

ADDRESSES: You may submit comments by any of the following methods—please use only one method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions on the website for submitting comments.
- *Mail:* Comments may be submitted by mail to Bernadette B. Wilson, Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, 131 M Street NE, Washington, DC 20507.
- *Fax:* Comments totaling six or fewer pages can be sent by facsimile (''fax'') machine to (202) 663–4114. (This is not a toll-free number.) Receipt of fax transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663–4070 (voice) or 800–669–6820 (TTY). (These are not toll-free telephone numbers.)

Instructions: All comments received must include the agency name or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. However, the EEOC reserves the right to refrain from posting libelous or otherwise inappropriate comments, including those that contain obscene, indecent, or profane language; that contain threats or defamatory statements; that contain hate speech directed at race, color, sex, national origin, age, religion, disability, or genetic information; or that promote or endorse services or products.

All comments received, including any personal information provided, also will be available for public inspection during normal business hours by appointment only at the EEOC Headquarters' Library, 131 M Street NE, Washington, DC 20507. Upon request, individuals who require assistance viewing comments are provided appropriate aids such as readers or print magnifiers. To schedule an appointment to inspect the comments at the EEOC's library, contact the library staff at (202) 663–4630 (voice) or 800–669–6820 (TTY). (These are not toll-free numbers.)

FOR FURTHER INFORMATION CONTACT: Kathleen Oram, Assistant Legal Counsel, (202) 663–4681 (voice) or *kathleen.oram@eeoc.gov;* Erin Norris, Senior Attorney, Office of Legal Counsel, (704) 954–6491 or *erin.norris@eeoc.gov.*

SUPPLEMENTARY INFORMATION:

Digital Submissions of Charge Documents

The Equal Employment Opportunity Commission is building a fully digital system for charges of discrimination filed with the EEOC. The system enables the EEOC, charging parties who file charges, and respondents against whom charges are filed to communicate and to transmit documents, including notices of charges, digitally through a secure online portal. It allows potential charging parties to submit online inquiries to the EEOC and to schedule intake interviews through the online system. The EEOC now has the capacity to make its charge processing and records system fully digital. In furtherance of that effort, the EEOC proposes to amend portions of its regulations in 29 CFR parts 1601 and 1626 to explicitly provide for digital or online transmission of charge-related documents. Specifically, the EEOC proposes to amend the following sections to explicitly provide for digital transmission and service of EEOC documents: Sections 1601.3 Other definitions, 1601.8 Where to make a charge, 1601.13(a)(4)(i)(A) and (B) Filing; deferrals to State and local agencies, 1601.14(a) Service of charge or notice of charge, 1601.21, Reasonable cause determination: Procedure and authority, 1626.5 Where to submit complaints and charges, 1626.7(b) Timeliness of charge, and 1626.15(c) Commission enforcement.

Deferrals to State and Local Agencies

The EEOC proposes to clarify the application of the charge-filing time periods for charges arising in jurisdictions having a State or local fair

employment practice (FEP) agency. Under section 706(e)(1) of Title VII of the Civil Rights Act of 1964, charging parties have 300 days after the alleged unlawful employment practice occurred to file a charge in jurisdictions having an FEP agency with authority to grant or seek relief from such practice. Charging parties have 180 days in jurisdictions with no FEP agency. 42 U.S.C. 2000e–5(e)(1). The EEOC's regulations address the circumstances in which an FEP agency exists but does not have jurisdiction over the particular basis of discrimination alleged in the charge (for example, if the FEP agency does not have authority to investigate sex discrimination), and provide that when such a charge is filed, it is treated as being filed in a jurisdiction having no FEP agency and thus is timely filed only if received within 180 days. Currently, the regulation uses the phrase, ''without subject matter jurisdiction over a charge'' to describe such a situation. The proposed revision replaces ''subject matter jurisdiction over a charge'' with ''jurisdiction over the statutory basis alleged in the charge'' in §§ 1601.13(a)(2) and (3).

In some instances, respondents have argued that even though a charge alleges the same type or basis of discrimination prohibited by state law, such as disability discrimination, it is untimely because the state law would not have applied to the particular circumstances or theory of relief, such as a failure to accommodate theory. The EEOC believes that this interpretation is incorrect and unworkable. Charging parties may assert multiple theories of relief or related claims, or may not know what theory ultimately will apply to their statutory claims, and it would be inappropriate to require an evaluation of the merits of the charge in light of state law before deciding what filing deadline applies. Conditioning the timeliness of their filing on the interpretation of ''complicated issues of state law'' would be contrary to the Supreme Court's decision in *EEOC* v. *Commercial Office Products Co.,* 486 U.S. 107, 123–24 (1988). The Supreme Court discouraged interpreting the filing periods in ways that would involve the interpretation of ''complicated issues of state law'' particularly because in discrimination cases, ''laymen, unassisted by trained lawyers, initiate the process.'' The Court emphasized that rules should be ''both easily understood by complainants and easily administered by the EEOC.'' *See id.* at 124. The proposed revision to §§ 1601.13(a)(2) and (3) thus expresses more clearly that the charge-filing time period is determined simply by looking to the general bases on which the FEP agency's statute prohibits discrimination. Thus, if the FEP agency's statute covers the same general basis or category of discrimination alleged by the charging party (for example, age or disability discrimination), the charging party has 300 days to file a charge. This information about the FEP agency's general statutory coverage will normally be readily available to the public, and it will be easier for charging parties to determine which filing deadline applies.

Clarity of the Communication Closing an Investigation and Delegation

The EEOC proposes changes to §§ 1601.18(a) and 1601.19(a) to serve two purposes: (1) To more clearly communicate to charging parties and respondents the import of the EEOC's decision to close a charge investigation, and (2) to bring greater efficiencies to charge closures by permitting further delegation.

Clarity of Communication

The EEOC proposes to amend § 1601.18(a) to add language clearly communicating that a dismissal includes notice of the charging party's statutory right to file a lawsuit.

The EEOC also proposes to amend § 1601.19(a) to add language clarifying the meaning and import of the EEOC's issuance of a ''no cause'' determination. Some have misunderstood the ''no cause determination'' and the language in the EEOC's current ''Dismissal and Notice of Rights.'' Hence, the EEOC proposes to revise 1601.19(a) to more clearly communicate that the EEOC's ''no cause'' closure of a charge does not mean the claims have no merit. The purpose of this proposed amendment is to ensure that charging parties, respondents, and courts understand that the extent of an EEOC investigation can vary widely from charge to charge, and therefore should not be viewed as a final evaluation of whether discrimination occurred or is occurring. The EEOC recognizes that, even after the EEOC has decided not to proceed further with its investigation, private proceedings or litigation may lead to court findings of discrimination or settlements favorable to charging parties.

Similarly, parties can misunderstand the meaning of the language in the EEOC's current ''Dismissal and Notice of Rights;'' therefore, the EEOC also proposes to revise the language on this form to clarify its purpose. The current language in the EEOC's ''Dismissal and Notice of Rights'' states:

''The EEOC issues the following determination: Based on its investigation, the EEOC is unable to conclude that the information obtained establishes violations of the statutes. This does not certify that the respondent is in compliance with the statutes. No finding is made as to any other issues that might be construed as having been raised by this charge.''

The EEOC proposes to revise the above language to read as follows:

''The EEOC issues the following determination: Based on its investigation, the EEOC has sufficient information to conclude that further investigation is not likely to result in a cause finding. This does not certify that the respondent is in compliance with the statutes. The EEOC makes no finding as to the merits of any issues that might be construed as having been raised by this charge.''

The Commission does not propose to make the form part of the regulation, but invites public comment on the above-proposed revised ''Dismissal and Notice of Rights'' language.

Delegation of Authority To Issue ''Dismissal and Notice of Rights''

The EEOC proposes to amend §§ 1601.18(b) and 1601.19(a) to allow District, Field, Area, and Local Office Directors to delegate to ''their designees'' their authority to issue a ''Dismissal and Notice of Rights.'' This change will permit EEOC employees other than office directors to issue dismissals and determinations, freeing office directors' time for other enforcement efforts.

Agency experience has shown that this level of delegation is appropriate. Established procedures and quality standards will support the increased efficiencies gained by permitting this delegation, while ensuring continued focus on charges that may lead to determinations of reasonable cause. In concert with that change, the EEOC proposes to amend § 1601.19(b) to permit the director of an office issuing a ''Dismissal and Notice of Rights'' to reconsider that determination, upon request or on his or her own initiative, and to issue a notice of intent to reconsider. In those instances where an EEOC employee other than the office director issues a ''Dismissal and Notice of Rights,'' only the office director will have authority to reconsider the determination.

As noted above, determinations are contained in a document titled ''Dismissal and Notice of Rights'' because they combine the no cause determination with the notice of right to sue under § 1601.19. Accordingly, the

EEOC proposes to remove the term ''letter of'' wherever it precedes the word ''determination'' in § 1601.19 No cause determinations: Procedure and authority.

Miscellaneous Updates

The EEOC proposes the following clarifying changes and updates to the regulations:

1. In § 1601.2 adding ''as amended'' to ''the Americans with Disabilities Act of 1990'';
2. In § 1601.3 removing Maryland from the area served by the Washington Field Office to reflect field office restructuring that occurred in 2006;
3. In § 1601.4 replacing ''Vice Chairman'' and ''Chairman'' with the current titles ''Vice Chair'' and ''Chair'' and replacing ''disability'' with ''incapacity'';
4. In § 1601.5 correcting typographical errors by replacing ''field'' with ''field office'' and ''area'' with ''area office'';
5. In §§ 1601.7(a) and (b), 1601.12, and 1626.8, replacing references to ''address and telephone number'' and ''address'' with the more general ''contact information'';
6. In § 1601.16(b) identifying two kinds of petitions to revoke or modify subpoenas to clarify that such petitions should be served on the issuing director except that, if the subpoena was issued by a Commissioner, the petition should be served on the General Counsel;
7. In § 1601.16(d) replacing the misspelled word ''Council'' with ''Counsel'';
8. In § 1601.21(d) replacing the words ''a copy of the determination'' with ''the determination or a copy of the determination'' to allow for digital transmission;
9. In § 1601.28(c) removing an obsolete footnote;
10. In § 1601.28(e)(3) replacing ''A copy of the charge'' with ''The charge or a copy of the charge'' to allow for digital transmission;
11. In § 1601.70(a)(1) adding genetic information to the list of prohibited bases of discrimination;
12. In § 1601.75(b)(2) updating an office title and removing an obsolete reference to Order 916;
13. In § 1601.76 and 1601.78 removing an obsolete reference to Order 916;
14. In § 1626.15(c) replacing ''A copy of the signed agreement'' with ''The signed agreement or a copy of the signed agreement'' to allow for digital transmission;
15. In § 1626.15(e) and 1626.16(b) replacing ''Field Directors'' with ''Field Directors, Area Directors, and Local Directors''; and
16. In § 1626.17(a)(2) adding a reference to the Genetic Information Nondiscrimination Act.

Regulatory Procedures

Executive Order 12866

This is not a ''significant regulatory action'' within the meaning of section 3 of Executive Order 12866.

Paperwork Reduction Act

This regulation contains no new information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

Regulatory Flexibility Act

The Commission certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities because it primarily affects the EEOC. To the extent that it affects small entities by allowing for electronic transmission of documents, it will save resources of those entities.

Unfunded Mandates Reform Act of 1995

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

Congressional Review Act

This action concerns agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties and, accordingly, is not a ''rule'' as that term is used by the Congressional Review Act (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

List of Subjects in 29 CFR Parts 1601 and 1626

Administrative practice and procedure, Equal employment opportunity.

Approved by the Commission December 4, 2018.

Dated: February 12, 2019.

For the Commission.

Victoria A. Lipnic,

Acting Chair.

Accordingly, for the reasons set forth in the preamble, the Equal Employment Opportunity Commission proposes to amend 29 CFR parts 1601 and 1626 as follows:

PART 1601—PROCEDURAL REGULATIONS

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

Authority: 42 U.S.C. 2000e to 2000e–17; 42 U.S.C. 12111 to 12117; 42 U.S.C. 2000ff to 2000ff–11.

■ 2. Amend § 1601.2 by revising the second sentence to read as follows:

§ 1601.2 Terms defined in title VII of the Civil Rights Act, the Americans with Disabilities Act, and the Genetic Information Nondiscrimination Act.

* * * The term *disability* shall have the meaning set forth in section 3 of the Americans with Disabilities Act, as amended. * * *

■ 3. Amend § 1601.3 by:

■ a. Removing the words ''and surrounding Maryland'' from paragraph (a);

■ b. Redesignating paragraph (b) as paragraph (c); and

■ c. Adding a new paragraph (b).

The addition reads as follows:

§ 1601.3 Other definitions.

* * * * *

(b) For the purposes of this part, the terms *file, serve, submit, receive, transmit, present, send,* and *notify* shall include all forms of digital transmission.

* * * * *

■ 4. Revise § 1601.4 to read as follows:

§ 1601.4 Vice Chair's functions.

The member of the Commission designated by the President to serve as Vice Chair shall act as Chair in the absence or incapacity of the Chair or in the event of a vacancy in that office.

■ 5. Amend § 1601.5 by revising the section heading and the sixth and eighth sentences to read as follows:

§ 1601.5 District; field; area; local authority.

* * * The term ''field director'' shall refer to that person designated as the Commission's chief officer in each field office. * * * The term ''area director'' shall refer to that person designated as the Commission's chief officer in each area office. * * *

■ 6. Amend § 1601.7 by revising the fourth sentence of paragraph (a) and paragraph (b) to read as follows:

§ 1601.7 Charges by or on behalf of persons claiming to be aggrieved.

(a) * * * The person making the charge, however, must provide the Commission with the name and contact information of the person on whose behalf the charge is made. * * *

(b) The person claiming to be aggrieved has the responsibility to provide the Commission with notice of any change in contact information so that the Commission may communicate with him or her during the Commission's consideration of the charge.

■ 7. Revise § 1601.8 to read as follows:

§ 1601.8 Where to make a charge.

A charge may be made using the EEOC's designated digital system, in person, or by mail to any EEOC office or to any designated representative of the Commission. The addresses of the EEOC's offices appear at *www.eeoc.gov.*

■ 8. Amend § 1601.12 by revising paragraphs (a)(1) and (2) to read as follows:

§ 1601.12 Contents of charge; amendment of charge.

(a) * * *

(1) The full name and contact information of the person making the charge except as provided in § 1601.7;

(2) The full name and contact information of the person against whom the charge is made, if known (hereinafter referred to as the respondent);

* * * * *

■ 9. Amend § 1601.13 by:

■ a. Revising paragraphs (a)(2) and (3), (a)(4) introductory text, (a)(4)(i)(A) and (a)(4)(i)(B);

■ b. Removing the word ''filing'' and adding in its place the word ''filed'' in the second sentence of paragraph (a)(4)(ii)(B); and

■ c. Removing the word ''certified'' and adding in its place the word ''registered'' in paragraph (b)(2)(iii).

The revisions read as follows:

§ 1601.13 Filing; deferrals to State and local agencies.

(a) * * *

(2) A jurisdiction having a FEP agency without jurisdiction over the statutory basis alleged in the charge (*e.g.,* an agency that does not have enforcement authority over sex discrimination) is equivalent to a jurisdiction having no FEP agency. Charges over which a FEP agency has no jurisdiction over the statutory basis alleged are filed with the Commission upon receipt and are timely filed if received by the Commission within 180 days from the date of the alleged violation.

(3) Charges arising in jurisdictions having a FEP agency with jurisdiction over the statutory basis alleged in the charge are to be processed in accordance with the Commission's deferral policy set forth below and the procedures in paragraph (a)(4) of this section.

(4) The following procedures shall be followed with respect to charges which arise in jurisdictions having a FEP agency with jurisdiction over the statutory basis alleged in the charge:

(i) * * *

(A) The document shall reflect the date and time it was received by the EEOC.

(B) A copy of the original document shall be transmitted by registered mail, return receipt requested, to the appropriate FEP agency, or by any other means acceptable to the FEP agency. State or local proceedings are deemed to have commenced on the date such document is transmitted.

* * * * *

■ 10. Amend § 1601.14(a) by revising the first two sentences to read as follows:

§ 1601.14 Service of charge or notice of charge.

(a) Within ten days after the filing of a charge in the appropriate Commission office, the Commission shall serve respondent the charge or a copy of the charge by digital transmission, by mail, or in person, except when it is determined that providing the charge or a copy of the charge would impede the law enforcement functions of the Commission. Where the charge or a copy of the charge is not provided, the respondent will be served with a notice of the charge within ten days after the filing of the charge. * * *

* * * * *

■ 11. Amend § 1601.16 by revising paragraph (b)(1), and in paragraph (d), removing the word ''Council'' wherever it appears and adding in its place the word ''Counsel.''

The revision reads as follows:

§ 1601.16 Access to and production of evidence; testimony of witnesses; procedure and authority.

* * * * *

(b)(1) Any person served with a district director-issued subpoena who intends not to comply shall petition the issuing director to seek its revocation or modification. Any person served with a Commissioner-issued subpoena who intends not to comply shall petition the General Counsel to seek its revocation or modification. Petitions must be mailed or transmitted digitally to the issuing director at the address stated on the subpoena (or, if the subpoena was issued by a Commissioner, to the General Counsel) within five days (excluding Saturdays, Sundays, and Federal legal holidays) after service of the subpoena. Petitions to the General Counsel pertaining to subpoenas issued by a Commissioner may be transmitted digitally or mailed to 131 M Street NE, Washington, DC 20507 and a copy of the petition shall also be served upon the issuing Commissioner.

* * * * *

■ 12. Amend § 1601.18 by:

■ a. In paragraph (b), adding a new sentence after the first sentence; and

■ b. In paragraph (c), in the second sentence adding ''or their designees,'' after ''Local Directors''.

The addition reads as follows:

§ 1601.18 Dismissal: Procedure and authority.

* * * * *

(b) * * * The dismissal shall include a notice of rights informing the person claiming to be aggrieved or the person on whose behalf a charge was filed of the right to sue in Federal district court within 90 days of receipt of the determination.* * *

* * * * *

■ 13. Revise § 1601.19 to read as follows:

§ 1601.19 No cause determinations: Procedure and authority.

(a) Where the Commission completes its investigation of a charge and finds that there is not reasonable cause to believe that an unlawful employment practice has occurred or is occurring as to all issues addressed in the determination, the Commission shall issue a determination to all parties to the charge indicating the finding. This determination does not mean the claims in the charge have no merit. The Commission's determination shall be the final determination of the Commission, unless a final determination of no reasonable cause is vacated pursuant to § 1601.19(b). The determination shall inform the person claiming to be aggrieved or the person on whose behalf a charge was filed of the right to sue in Federal district court within 90 days of receipt of the determination. The Commission hereby delegates authority to the Director of the Office of Field Programs, or upon delegation to the Director of Field Management Programs, and District Directors or upon delegation to Field Directors, Area Directors, or Local Directors, or their designees, except in those cases involving issues currently designated by the Commission for priority review, to issue no cause determinations.

(b) The Commission may on its own initiative reconsider a final determination of no reasonable cause and a director of the issuing office may, on his or her own initiative, reconsider a final determination of no reasonable cause. If the Commission or the director

of the issuing office decides to reconsider a final no cause determination, a notice of intent to reconsider shall promptly issue to all parties to the charge. If such notice of intent to reconsider is issued within 90 days of receipt of the final no cause determination, and the person claiming to be aggrieved or the person on whose behalf a charge was filed has not filed suit and did not request and receive a notice of right to sue pursuant to § 1601.28(a)(1) or (2), the notice of intent to reconsider shall vacate the determination and shall revoke the charging party's right to bring suit within 90 days. If the 90-day suit period has expired, the charging party has filed suit, or the charging party had requested a notice of right to sue pursuant to § 1601.28(a)(1) or (2), the notice of intent to reconsider shall vacate the determination, but shall not revoke the charging party's right to sue within 90 days. After reconsideration, the Commission or a director of the issuing office shall issue a new determination. In those circumstances where the charging party's right to bring suit within 90 days was revoked, the determination shall include notice that a new 90-day suit period shall begin upon the charging party's receipt of the determination. Where a member of the Commission has filed a Commissioner charge, he or she shall abstain from making a determination in that case.

§ 1601.21 [Amended]

■ 14. Amend § 1601.21(d) by removing the words ''a copy of the determination'' and adding in their place ''the determination or a copy of the determination.''

■ 15. Amend § 1601.28 by removing footnote 1 from paragraph (c) and revising paragraph (e)(3) to read as follows:

§ 1601.28 Notice of right to sue: Procedure and authority.

* * * * *

(e) * * *

(3) The charge or a copy of the charge;

* * * * *

■ 16. Amend § 1601.70 by revising paragraph (a)(1) to read as follows:

§ 1601.70 FEP agency qualifications.

(a) * * *

(1) That the state or political subdivision has a fair employment practice law which makes unlawful employment practices based upon race, color, religion, sex, national origin, disability, or genetic information; and

* * * * *

■ 17. Amend § 1601.75 by:

■ a. Revising paragraph (b)(2); and

■ b. In paragraph (c), by removing the word ''cetification'' and adding in its place the word ''certification.''

The revision reads as follows:

§ 1601.75 Certification of designated FEP agencies

* * * * *

(b) * * *

(2) That the State or local designated FEP agency's work product has been evaluated within the past 12 months by State and Local Programs, Office of Field Programs, and found to be in conformance with the Commission's Substantial Weight Review Procedures.

§ 1601.76 [Amended]

■ 18. Amend § 1601.76 by removing the words ''(EEOC Order 916)''.

§ 1601.78 [Amended]

■ 19. Amend § 1601.78, by removing the words ''(EEOC Order 916)'' in the introductory text.

PART 1626—PROCEDURES—AGE DISCRIMINATION IN EMPLOYMENT ACT

■ 20. The authority citation for part 1626 continues to read as follows:

Authority: Sec. 9, 81 Stat. 605, 29 U.S.C. 628; sec. 2, Reorg. Plan No. 1 of 1978, 3 CFR 1978 Comp., p. 321.

■ 21. Amend § 1626.3 by:

■ a. Designating the text as paragraph (a);

■ b. In newly redesignated paragraph (a), removing the words ''For purpose of this part'' and adding in their place the words ''For the purposes of this part''; and

■ c. Adding a new paragraph (b).

The addition reads as follows:

§ 1626.3 Other definitions.

* * * * *

(b) For the purposes of this part, the terms *file, serve, submit, receive, transmit, present, send,* and *notify* shall include all forms of digital transmission.

■ 22. Revise § 1626.5 to read as follows:

§ 1626.5 Where to submit complaints and charges.

Complaints and charges may be made through the EEOC's designated digital system, in person, by telephone, or by mail to any EEOC office or any designated representative of the Commission. The current addresses of the EEOC's offices appear at *www.eeoc.gov.*

■ 23. Amend § 1626.7 by redesignating paragraphs (b)(1), (2), and (3) as paragraphs (b)(2), (3), and (4), and adding a new paragraph (b)(1) to read as follows:

§ 1626.7 Timeliness of charge.

* * * * *

(b) * * *

(1) Charges filed digitally: Date of transmission.

* * * * *

■ 24. Amend § 1626.8 by revising paragraphs (a)(1) and (2), and adding new paragraphs (d) and (e) to read as follows:

§ 1626.8 Contents of charge; amendment of charge.

(a) * * *

(1) The full name and contact information of the person making the charge except as provided in § 1626.8(d);

(2) The full name and contact information of the person against whom the charge is made, if known (hereinafter referred to as the respondent);

* * * * *

(d) A charge that any person has engaged in or is engaging in an unlawful employment practice within the meaning of the ADEA may be made by or on behalf of any person claiming to be aggrieved. A charge on behalf of a person claiming to be aggrieved may be made by any person, agency, or organization. The written charge need not identify by name the person on whose behalf it is made. The person making the charge, however, must provide the Commission with the name and contact information of the person on whose behalf the charge is made. During the Commission investigation, Commission personnel shall verify the authorization of such charge by the person on whose behalf the charge is made. Any such person may request that the Commission shall keep his or her identity confidential. However, such request for confidentiality shall not prevent the Commission from disclosing the identity to Federal, State or local agencies that have agreed to keep such information confidential. If this condition is violated by a recipient agency, the Commission may decline to honor subsequent requests for such information.

(e) The person claiming to be aggrieved has the responsibility to provide the Commission with notice of a change in contact information so that he or she can be contacted when necessary during the Commission's consideration of the charge.

■ 25. Amend § 1626.15 by revising the last sentence of paragraph (c), and in paragraph (e), removing the words ''the Field Directors'' and adding in their place the words ''Field Directors, Area Directors, and Local Directors.''

The revision reads as follows:

§ 1626.15 Commission enforcement.

* * * * *

(c) * * * The signed agreement or a copy of the signed agreement shall be sent to all the signatories thereto.

* * * * *

§ 1626.16 [Amended]

■ 26. Amend § 1626.16(b) by removing the words ''the Field Directors'' and adding in their place the words ''Field Directors, Area Directors, and Local Directors''.

§ 1626.17 [Amended]

■ 27. Amend § 1626.17(a)(2) by removing the words ''or the Americans with Disabilities Act (ADA),'' and adding in their place the words ''or the Americans with Disabilities Act (ADA) or the Genetic Information Nondiscrimination Act (GINA)'' and removing the words ''or the ADA.'' and adding in their place the words '', the ADA, or GINA.''.

[FR Doc. 2019–02664 Filed 2–21–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ46

Veterans Community Care Program

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its medical regulations to implement its authority for covered veterans to receive necessary hospital care, medical services, and extended care services from non-VA entities or providers in the community. Section 101 of the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Network Act of 2018 directs VA to implement a program to furnish such care and services to covered veterans through eligible entities and providers. This proposed rule would establish the criteria for determining when covered veterans may elect to receive such care and services through community health care entities or providers, as well as other parameters of this program.

DATES: Comments must be received on or before March 25, 2019.

ADDRESSES: Written comments may be submitted by email through *http://www.regulations.gov;* by mail or hand-delivery to Director, Office of Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW, Room 1063B, Washington, DC 20420; or by fax to (202) 273–9026. (This is not a toll-free number.) Comments should indicate that they are submitted in response to ''RIN 2900–AQ46, Veterans Community Care Program.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joseph Duran, Office of Community Care (10D), Veterans Health Administration, Department of Veterans Affairs, Ptarmigan at Cherry Creek, Denver, CO 80209; *Joseph.Duran2@va.gov,* (303) 370–1637. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Summary

Purpose of This Regulatory Action: We propose to create new regulations to define and implement the Veterans Community Care Program authorized by section 1703 of title 38, United States Code (U.S.C.), as that statute will be amended by section 101 of the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018, effective upon VA's issuance of implementing regulations. The Veterans Community Care Program will permit eligible veterans to elect to receive hospital care, medical services, and extended care services from eligible entities and providers. The Veterans Community Care Program would replace the Veterans Choice Program and would be used as the exclusive authority that determines eligibility under which VA would authorize covered veterans (as defined later in this rulemaking) to receive community care through eligible entities or providers.

Summary of the Major Provisions of This Regulatory Action: This proposed rule—

- Would establish the exclusive authority under which VA would authorize covered veterans to receive care in the community from eligible entities or providers at VA expense when such veterans meet established eligibility criteria.
- Would define key terms used throughout the regulation. Many of these terms would be substantively similar to those defined in the Veterans Choice Program.
- Would define eligibility criteria, including conditions under which covered veterans could elect to have VA authorize non-VA care through eligible entities or providers, subject to the availability of appropriations. In general, covered veterans would have to be enrolled in the VA health care system (or be eligible for care and services without enrolling) and would have to require care or services from an eligible entity or provider, as proposed to be defined in sections 17.4005 and 17.4030 of title 38, Code of Federal Regulations (CFR), because VA determined at least one of the following six conditions was met:
  - VA does not offer the required care or services;
  - VA does not operate a full-service medical facility in the State in which the veteran resides;
  - the veteran was eligible to receive care under the Veterans Choice Program and is eligible to receive care under certain grandfathering provisions;
  - VA is not able to furnish care or services to a veteran in a manner that complies with VA's designated access standards;
  - the veteran and the referring clinician determine it is in the best medical interest of the veteran to receive care or services from an eligible entity or provider based on consideration of certain criteria VA proposes to establish; or
  - the veteran is seeking care or services from a VA medical service line that VA has determined is not providing care that complies with VA's standards for quality.
- Would describe the process VA would use to identify medical service lines that are underperforming and that could be the basis for eligibility to receive non-VA care.
- Would describe how non-VA care could be authorized through the election of a covered veteran who is eligible to receive non-VA care. Eligible veterans could also identify a specific entity or provider to furnish such care. VA would be able to authorize emergency care under certain conditions within 72 hours of such care being furnished.
- Would describe the effect of the Veterans Community Care Program on other benefits and services available to covered veterans. In general, no provision in this section would be

construed to alter or modify any other provision of law establishing specific eligibility criteria for certain hospital care, medical services, or extended care services. VA would continue to pay for and fill prescriptions written by non-VA health care providers to the extent such prescriptions were immediately required and were covered by the VA medical benefits package. VA would continue to calculate veterans' VA copayments under applicable regulations.

- Would establish those non-VA health care entities and providers that would be permitted to furnish care under the Veterans Community Care Program. The types of eligible entities or providers would be substantively identical to those presently permitted to participate under the Veterans Choice Program or in VA's other existing community care program.
- Would clarify payment rates and methodologies for care and services furnished by non-VA health care entities and providers through the Veterans Community Care Program, to include rates for Critical Access Hospitals as allowable under 42 U.S.C. 1395m, and other types of providers, including Federally Qualified Health Centers.
- Would designate access standards that would be a basis for eligibility for non-VA care.

Costs and Benefits: As further detailed in the *Regulatory Impact Analysis,* which can be found as a supporting document at *http://www.regulations.gov* and is available on VA's website at *http://www.va.gov/orpm/,* by following the link for ''VA Regulations Published From FY 2004 Through Fiscal Year to Date,'' this proposed rule would affect covered veterans and eligible health care entities and providers. Covered veterans who meet at least one of the eligibility criteria may elect to receive, at VA expense and upon VA's authorization, care and services from an eligible entity or provider of their choice. Participating eligible entities and providers would be paid for furnishing authorized hospital care, medical services, and extended care services to covered veterans under the Veterans Community Care Program in accordance with payment rates as described in this rulemaking.

General Discussion: On June 6, 2018, the President signed into law the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018 (hereafter referred to as the ''MISSION Act,'' Public Law 115–182, 132 Stat. 1395). This proposed rule would implement section 101 of the MISSION Act, which requires VA to implement a Veterans Community Care Program to furnish required care and services to covered veterans through eligible entities and providers. Section 101, which amends 38 U.S.C. 1703 upon the effective date of final regulations implementing this provision, further establishes the conditions under which VA would determine if covered veterans are eligible to elect to receive such care and services through eligible entities or providers, as well as other parameters of the Veterans Community Care Program. For the sake of convenience and understanding, we will refer to provisions of section 1703, as section 101 of the MISSION Act will amend it, although we recognize that section 1703 as so amended is not legally effective until VA has published a final rule implementing the Veterans Community Care Program. (Where we are referring to a provision in current section 1703, we will state ''current section 1703.'').

We additionally clarify that throughout this rulemaking, the abbreviation ''U.S.C.'' or the term ''section'' will be used to indicate discussion of or reference to a statutory provision in the United States Code (*e.g.,* ''section 1703'') or in another statute, while the abbreviation ''CFR'' or the section symbol ''§ '' will be used to indicate discussion of or reference to an existing or proposed regulatory provision in the Code of Federal Regulations (*e.g.,* ''proposed § 17.4005''). There may be instances where the term ''section'' rather than the section symbol must be used at the beginning of a sentence to discuss or reference a regulatory provision, but it should be clear in the sentence that a regulatory provision is at issue. In general, any reference to a section that uses a period in it (*e.g.,* § 17.55) is a reference to the CFR, while any reference without such a period (*e.g.,* section 1703) is a reference to the U.S.C.

This proposed rule would implement in a regulatory framework the requirements in section 1703, consistent with the mandate that VA promulgate regulations to carry out the Veterans Community Care Program. Although VA is required to promulgate regulations, some of the provisions established in section 1703 are either self-executing and would not be more specifically interpreted by VA in regulation, or would be most appropriately established in the contracts, agreements, or other arrangements VA would use to purchase care under the Veterans Community Care Program. For instance, section 1703(h)(3)(A) establishes certain grounds for termination of a contract. There is no need to regulate this requirement, as section 1703 does not alter or amend VA's existing authority to enter into, modify, or terminate a contract. This rulemaking generally will not promulgate regulations that merely restate the substantive provisions in section 1703 that are clear and unambiguous, although such provisions would apply to the Veterans Community Care Program regardless. VA proposes to codify the new Veterans Community Care Program regulations at 38 CFR 17.4000 through 17.4040.

Conforming Revisions to Regulations That Reference the Veterans Choice Program

Subsection (p) of section 101 of the Veterans Access, Choice, and Accountability Act of 2014 (Pub. L. 113–146; 38 U.S.C. § 1701 note), as amended by section 143 of the MISSION Act, does not permit VA to furnish care and services through the Veterans Choice Program after June 6, 2019. However, this does not mean that all of the regulatory provisions under which the Veterans Choice Program is implemented (generally, 38 CFR 17.1500–17.1540) would be legally inoperative after June 6, 2019. There are some provisions in the Veterans Choice Program regulations (such as those provisions related to payment rates and limits on authorized care) that would need to continue to be in effect for resolution of claims arising from the Veterans Choice Program that would be in process after June 6, 2019 (for episodes of care performed under the Veterans Choice Program prior to June 6, 2019). We therefore do not propose to rescind the Veterans Choice Program regulations at this time, as VA will continue paying claims under such regulations for a period of time after the authority for the Veterans Choice Program expires, and we do not want to create any confusion as to how those claims should be processed or adjudicated. We anticipate further amendments to our regulations in the future to repeal the regulations governing the Veterans Choice Program and to remove references to the Veterans Choice Program in other regulations.

We similarly do not propose to remove references to the Veterans Choice Program in other applicable VA regulations at this time, but would add references to the Veterans Community Care Program in such regulations. Specifically, we would amend §§ 17.108(b)(4), 17.108(c)(4), and 17.110(b)(4) to include references to the Veterans Community Care Program under §§ 17.4000 through 17.4040 to ensure that copayments for inpatient

hospital care, outpatient medical care, and for medications reference the new Veterans Community Care Program in the same way these regulations currently reference the Veterans Choice Program. We also would amend § 17.111(b)(3) to include a reference to extended care services furnished through the Veterans Community Care Program under §§ 17.4000 through 17.4040 to ensure that copayments for extended care services (both institutional (*i.e.,* continuous care occurring in a professional long-term care setting such as a nursing home) and non-institutional (*i.e.,* non-continuous care occurring in non-professional settings such as a patient's home) under the new Veterans Community Care Program are treated the same way as copayments for non-institutional extended care services under the Veterans Choice Program.

Finally, we would delete the list of authorities for §§ 17.108, 17.110, and 17.111 to comply with the guidelines of the Office of the Federal Register and would add the complete list of authorities for these regulations, including 38 U.S.C. 1703, among the authority citations listed for part 17.

Conforming Amendments for Revisions to 38 U.S.C. 1703

We propose to make a number of conforming amendments to several existing regulations to reflect the consolidation of care and the initiation of the new Veterans Community Care Program. In general, for each of the regulations referenced below, we would also revise these regulations to remove specific authority citations in each section and instead to refer generally to these sections under the authority citation for part 17 to conform with publishing guidelines established by the Office of the Federal Register. We would generally impose sunset provisions on these regulations to ensure that they do not continue to apply to VA's decisions regarding community care after the new Veterans Community Care Program begins on June 6, 2019. We do not propose to rescind these regulations at this time to allow VA to close out any bills or claims for care or services furnished prior to June 6, 2019, and to continue to refer to the existing regulations while processing these claims. VA will rescind any elements of these regulations at a later point in time when we are confident that such rescissions will not affect operations or create confusion for veterans or providers.

First, we propose to amend § 17.46. Section 17.46 governs how VA furnishes hospital care under 38 U.S.C. 1710(a)(1), which generally requires VA to furnish hospital care and medical services the Secretary determines to be needed to any veteran for a service-connected disability and to any veteran who has a service-connected disability rated at 50 percent or more. Section 17.46 specifically requires VA to furnish care in a VA facility, or if that facility is incapable of furnishing care, arrange to admit the veteran to another VA facility, a DoD facility with which VA has a sharing agreement, or arrange for care on a contract basis if authorized by 38 U.S.C. 1703 and 38 CFR 17.52, if the veteran is in immediate need of hospitalization. If the veteran does not need immediate hospitalization, § 17.46 further provides that VA will schedule the veteran for admission at a VA facility or refer the veteran to a DoD facility with which VA has a sharing agreement. We propose to amend § 17.46 to clarify that paragraph (a) of this provision would no longer apply after June 6, 2019. We do not propose to make any changes to paragraph (b) of § 17.46, which deals with eligibility for domiciliary care. While we do not generally believe that § 17.46(a) is used or relied upon to authorize care in the community for eligible veterans, we believe it is important to avoid creating any confusion by establishing a sunset for this provision to ensure that any decisions regarding eligibility for a covered veteran to receive care in the community are made under the regulations proposed in this rulemaking.

Second, we propose to amend § 17.52 to add a new paragraph (c) that would similarly establish a sunset provision for this regulation. Section 17.52 generally establishes eligibility for community care under the existing 38 U.S.C. 1703. Upon the effective date of a final rule for this rulemaking, the current section 1703 will no longer exist. As a result, § 17.52 would no longer apply to care furnished after June 6, 2019, as it would be implementing a statute that no longer exists.

Third, we propose to amend § 17.55 to clarify the scope of its applicability. Section 17.55 currently establishes payment rates and standards for hospital care furnished by non-VA entities or providers. Proposed § 17.4035 as presented in this rulemaking would establish general parameters for payment, and thus would eliminate the need for this rule in part. However, it would not do so entirely. Current § 17.55 establishes payment rates for care that VA pays on a reimbursement basis, most notably emergency care under 38 U.S.C. 1728 and 38 CFR 17.120 and 17.128, as well as payment for care for eligible family members of veterans stationed at Camp Lejeune under 38 U.S.C. 1787 and 38 CFR 17.410. Because these programs will continue to operate independently from the new Veterans Community Care Program, VA is proposing to add language that would sunset the applicability of § 17.55 only for care and services furnished to covered veterans. Payments for care and services furnished under the Veterans Community Care Program would be subject to § 17.4035 as proposed in this rule. We would also make a technical change to § 17.55 to remove the reference to the Health Care Financing Administration and instead refer to the Centers for Medicare & Medicaid Services (CMS) given the change in this agency's name. We would make a similar revision to § 17.1004(b) where an HCFA form is referenced to instead refer to a CMS form.

Finally, we propose to modify § 17.56 to include a new paragraph (e). Similar to the changes above regarding § 17.55, VA proposes to amend the current regulation to clarify that payments for care furnished under 38 U.S.C. 1725 and 38 CFR 17.1005, which govern VA's other authority to reimburse for emergency treatment, payments under 38 U.S.C. 1728 and 38 CFR 17.120 and 17.128, and payments under 38 U.S.C. 1787 and 38 CFR 17.410 would continue under this regulation, while this section would no longer generally establish payment rates for care in the community after June 6, 2019.

§ 17.4000, Purpose and Scope

Proposed § 17.4000(a) would establish that the purpose of proposed regulations §§ 17.4000–17.4040 would be to implement the Veterans Community Care Program authorized by section 1703. As previously stated, we will refer to section 1703 as amended by section 101 of the MISSION Act for clarity and convenience, even though those amendments technically will not come into effect until final regulations are effective to implement the Veterans Community Care Program.

Section 17.4000(b) would state that the Veterans Community Care Program establishes when a covered veteran could elect to have VA authorize an episode of care for hospital care, medical services, or extended care services with eligible entities or providers. Section 17.4000(b) would further state that §§ 17.4000–.4040 do not affect eligibility for non-VA care under sections 1724, 1725, 1725A, or 1728 of title 38, United States Code. Sections 1724, 1725, 1725A, and 1728 establish other methods for accessing community care without requiring

express authorization from VA prior to the receipt of such care. Because sections 1724, 1725, 1725A, and 1728 establish distinct eligibility criteria that determine when VA can reimburse for care and services in the community as specified under those statutes, such criteria would not be affected by this proposed rule. This would relieve an individual that does meet the eligibility criteria under section 1725A, for instance, from also having to meet the eligibility criteria under section 1703 in order to receive care under section 1725A. As another example, this clarification would not amend VA's authority to furnish care to veterans participating in VA's Foreign Medical Program under section 1724. Similarly, some veterans receive care from the Indian Health Service (IHS) and Tribal Health Programs (THP) under a sharing agreement with VA. VA has existing reimbursement agreements with IHS and THPs under which VA reimburses IHS and THPs for certain care provided to eligible American Indian/Alaskan Native veterans. Care provided under these agreements (generally referred to as ''other arrangements'' in statute) would not be affected by this proposed rule. This proposal also would not modify VA's existing statutory authorities to furnish care in the community at VA expense to anyone who is not a covered veteran (generally, non-veteran beneficiaries) who may be eligible for such care pursuant to other authorities, such as sections 1786 or 1787, because such individual would not meet the definition of covered veteran (as would be defined in proposed § 17.4005). The requirements of those statutes and their implementing regulations would continue to apply, and VA would use those specific authorities when appropriate to furnish community care for non-veteran beneficiaries of care under chapter 17 of title 38, U.S.C.

§ 17.4005, Definitions

Proposed § 17.4005 would define terms for purposes of §§ 17.4000 through 17.4040. In general, these would be defined in the same way, or very similar ways, to terms used in VA's Veterans Choice Program regulation at § 17.1505, where such definitions would support the same or similar concepts in the Veterans Community Care Program. Certain terms defined in § 17.1505 would no longer be applicable in the Veterans Community Care Program and so would be excluded here. Other terms would be new to this section. The explanation that follows of the proposed definitions in § 17.4005 is presented by comparison to what is in current § 17.1505, to provide a clearer understanding of whether or to what extent definitions or concepts are proposed to change from the Veterans Choice Program to the future Veterans Community Care Program. We do not propose to explain the omission of certain terms from § 17.1505, but will instead explain the definitions we propose to adopt in § 17.4005 by reference to § 17.1505.

The term appointment is currently defined in § 17.1505 to mean an authorized and scheduled encounter with a health care provider for the delivery of hospital care or medical services. Under § 17.1505, a visit to an emergency room or an unscheduled visit to a clinic is not an appointment. The proposed definition of appointment in § 17.4005 would be slightly revised, to include the term extended care services, as all types of extended care services would be available for covered veterans who otherwise qualify for such care under the Veterans Community Care Program in accordance with sections 1703, 1710, and 1710A. Also, the proposed definition of appointment would not include the sentence in current § 17.1505 excluding emergency room visits and unscheduled visits, as certain forms of emergency care would be otherwise addressed in proposed § 17.4020(c). We would further recognize that ad hoc telehealth encounters or same day care would be considered an appointment, even though these are not always scheduled in advance. The term appointment would be used primarily in proposed § 17.4010, related to veteran eligibility to receive care or services through the Veterans Community Care Program.

The term covered veteran would be newly defined in proposed § 17.4005 to mean a veteran enrolled under the system of patient enrollment in § 17.36, or a veteran who otherwise meets the criteria to receive care and services notwithstanding his or her failure to enroll under 38 U.S.C. 1705(c)(2). This definition would be consistent with how the term covered veteran is defined in section 1703(b) and would be relevant for determinations of veteran eligibility for community care under proposed § 17.4010. We note that certain veterans are not required to enroll to receive care and services, although many would only qualify for a narrow range of services without enrolling. Section 1705(c)(2) directs VA to provide hospital care and medical services for the 12 month period following the veteran's discharge or release from service to any veteran referred to in sections 1710(a)(1) (which refers to furnishing hospital care and medical services determined to be needed for a service-connected disability and to any veteran with a service-connected disability rated at 50 percent or more) and (a)(2)(B) (which refers to furnishing hospital care, medical services, and nursing home care determined to be necessary to a veteran whose discharge or release from active military, naval, or air services was for a disability that was incurred or aggravated in the line of duty) for a disability specified in those provisions of law, notwithstanding the failure of the veteran to enroll in the VA health care system. Any veteran meeting these conditions would be considered a covered veteran under this definition. Moreover, there are a number of special treatment authorities, such as sections 1702, 1710(a)(2)(F) and (e), 1720D, and 1720E, that direct VA to provide certain care and services to certain veterans. Although the conditions that can be treated under these special treatment authorities are not technically service-connected, as VA explained in a prior rulemaking titled ''Third Party Billing for Medical Care Provided under Special Treatment Authorities'' (RIN 2900–AP20), veterans eligible under these special treatment authorities are eligible for treatment of specific conditions, which although not adjudicated as service-connected, are treated as the practical equivalent for medical care purposes. 83 FR 31452, 31453 (July 6, 2018). As a result, we believe it would be consistent with our interpretation of these special treatment authorities under other laws and regulations to regard these as the practical equivalent of service-connected conditions as described in 1705(c)(2). Similarly, section 2 of Public Law 95–126, as amended (38 U.S.C. 5303 note), directs VA to provide the type of health care and related benefits authorized to be provided under chapter 17 for any disability incurred or aggravated during active military, naval, or air service in the line of duty by a person other than one statutorily barred from receiving benefits under section 5303(a), but prohibits VA from providing such health care and related benefits pursuant to this section for any disability incurred or aggravated during a period of service from which such person was discharged by reason of a bad conduct discharge. We would, similar to the special treatment authorities, regard persons eligible under section 2 of Public Law 95–126 as satisfying the condition of not needing to enroll. Consequently, veterans who are not enrolled but who qualify for services under section 1705(c)(2),

section 2 of Public Law 95–126, or any of the special treatment authorities would be considered covered veterans for purposes of this definition and would be subject to the eligibility criteria in proposed § 17.4010.

The term eligible entity or provider would be newly defined in proposed § 17.4005 to mean a health care entity or provider that meets the requirements of § 17.4030. The section of this rule that discusses proposed § 17.4030 will describe those requirements, but we note here that the potentially eligible entities and providers under the Veterans Community Care Program would be substantively identical to those expressly identified as eligible to participate in the Veterans Choice Program under current § 17.1510. This proposed definition is not intended to make any substantive changes from the Veterans Choice Program in terms of the entities or providers that would participate in the Veterans Community Care Program, and any entities or providers furnishing care and services through VA's existing community care program would similarly be eligible if they enter into a contract, agreement, or other arrangement to furnish such care and services. This would include private providers that are typically thought of in relation to furnishing VA community care, as well as non-VA Federal or other health care providers such as the Department of Defense or the Indian Health Service. As described in further detail in proposed § 17.4030, the critical elements that must be met for an entity or provider to be an eligible entity or provider are (1) that the entity or provider must have entered into a contract, agreement, or other arrangement to furnish care and services under the Veterans Community Care Program; (2) the entity or provider not be a part of, or an employee of, VA; and (3) the entity or provider must be accessible to the covered veteran.

The term episode of care is currently defined in § 17.1505 to mean a necessary course of treatment, including follow-up appointments and ancillary and specialty services, which lasts no longer than 1 calendar year from the date of the first appointment with a non-VA health care provider. The proposed definition of episode of care in § 17.4005 would vary from the definition under current § 17.1505 by removing the reference to the date of the first appointment with a non-VA health care provider. The phrase seems unnecessary, as the episode of care would necessarily begin with the first such appointment. This change would not, however, create a broader standard than presently exists in the Veterans Choice Program in terms of the possible duration of an episode of care, because the definition of episode of care in proposed § 17.4005 still means a necessary course of treatment, including follow-up appointments and ancillary and specialty services for identified health care needs. VA would therefore retain the responsibility for care coordination with eligible entity or providers in this proposed revised definition to determine whether ancillary and specialty care of any duration up to 1 year would be needed in the course of a veteran's care. For care or services that would need to extend beyond one year, additional care would need to be authorized by VA. In addition, it is possible that any one episode of care may not capture all care or treatment fully necessary to improve, restore, or promote a veteran's health, as a veteran may have multiple conditions that could require VA to authorize several episodes of care at the same time. While some episodes of care require only a single visit, and others may require multiple visits, in all cases VA would continue to authorize, as part of care coordination, only care that is clinically necessary over the course of treatment. If an eligible entity or provider believed that a veteran needed additional care beyond the authorized episode of care, the eligible entity or provider would be required to contact VA prior to administering or referring such care to ensure that this care was authorized and therefore would be paid for by VA. In short, under the revised definition of episode of care in proposed § 17.4005, whether additional care constituted a new episode of care would continue to be a clinical determination based on generally acceptable clinical practices and protocols, whenever possible, as part of care coordination conducted by VA in close consultation with eligible entities or providers.

The term extended care services would be newly defined in proposed § 17.4005 to include the same services as described in 38 U.S.C. 1710B(a). This definition would be required as section 1703(a)(1) makes extended care services available under the Veterans Community Care Program, whereas only certain non-institutional extended care services are available as medical services under the Veterans Choice Program. This proposed definition to include those services described is section 1710B(a) would be sufficiently broad to capture all extended care services offered by VA.

The term full-service VA medical facility would be newly defined in proposed § 17.4505 to mean a VA medical facility that provides hospital care, emergency medical services, and surgical care and having a surgical complexity designation of at least standard. This proposed definition would also include a note that would state that VA maintains a website with a list of the facilities that have been designated with at least a surgical complexity of ''standard,'' which can be accessed on VA's website. This proposed definition would be relevant for determinations of certain veteran eligibility under proposed § 17.4010 and is consistent with how a VA facility is characterized for purposes of similar veteran eligibility under current § 17.1510(b)(3). The current location for information regarding the surgical complexity levels of VA facilities is on VA's website: *www.va.gov/health/surgery*. We do not propose to identify a specific URL in our regulations in the event that this information is ultimately moved to another page on VA's website.

The terms hospital care and medical services would be newly defined in proposed § 17.4005 by cross referencing to the applicable statutory definitions for these terms at 38 U.S.C. 1701(5) and (6), respectively, to sufficiently capture those types of care furnished by VA. These terms would be used throughout these proposed regulations, as section 1703(a)(1) requires the furnishing of hospital care, medical services, and extended care services through the Veterans Community Care Program. We have interpreted these terms through VA's medical benefits package in § 17.38, and this benefits package would be available to covered veterans under the Veterans Community Care Program when clinically necessary, as required by section 1703(n)(1) and § 17.38(b). Section 1703(n)(1) prohibits VA from limiting the types of care or services covered veterans may receive under this section if it is in the best medical interest of the veteran to receive such care or services as determined by the veteran and the veteran's health care provider. We interpret section 1703(n)(1) to reinforce the requirement currently in regulation at § 17.38(b) that care referred to in the medical benefits package will be provided to individuals only if it is determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice.

The term health-care plan is currently defined in § 17.1505 to mean an insurance policy or contract, medical or hospital service agreement, membership or subscription contract, or similar arrangement not administered by the Secretary of Veterans Affairs, under

which health services for individuals are provided or the expenses of such services are paid; and does not include any such policy, contract, agreement, or similar arrangement pursuant to title XVIII or XIX of the Social Security Act (42 U.S.C. 1395 *et seq.*) or chapter 55 of title 10, United States Code. We would propose minor changes in proposed § 17.4005 to rename this term as other health-care plan contract because other health-care plan contract is the term that appears in section 1703(j). This term would be relevant for purposes of proposed § 17.4010(c) related to when covered veterans participating in the Veterans Community Care Program would have to report on their third-party health care insurance, similar to how the term health-care plan is used in current § 17.1510(d).

The term residence is currently defined in § 17.1505 to mean a legal residence or personal domicile, even if such residence is seasonal. Section 17.1505 further provides that a person may maintain more than one residence but may only have one residence at a time. It also states that if a veteran lives in more than one location during a year, the veteran's residence is the residence or domicile where the person is staying at the time the veteran wants to receive hospital care or medical services through the Program. Finally, it states that a post office box or other non-residential point of delivery does not constitute a residence. We would propose minor edits to this definition in proposed § 17.4005 to refer consistently to covered veterans instead of person or veteran, as this is the term used in these regulations. We also would include extended care services for the reasons described above. This term would be used in proposed § 17.4010, and the section of this rulemaking that explains proposed § 17.4010 would explain VA's proposed revisions to certain geographic conditions that can establish eligibility for community care.

The term schedule is currently defined in § 17.1505 to mean identifying and confirming a date, time, location, and entity or health care provider for an appointment. We would clarify in proposed § 17.4005 that schedule requires identifying and confirming a date, time, and location for an appointment in advance of such appointment. We would further add a note explaining that a VA telehealth encounter would be considered to be scheduled even if such encounter is conducted on an ad hoc basis. In the years since the Veterans Choice Program was established, VA's telehealth program has grown, and its authority to furnish care has been buttressed through regulation (see § 17.417) and statute (see section 1730C, as added by section 151 of the MISSION Act). Some telehealth encounters are scheduled well in advance of the appointment, while others are made available to eligible and interested veterans on an ad hoc basis (for example, if a veteran cancelled an appointment or did not show up to an appointment, VA schedulers may follow up with the veteran and ask the veteran if he or she would like to participate in a telehealth encounter at that moment). This note would clarify that in either scenario, a telehealth encounter would be considered scheduled and would thus qualify as an appointment under the definition of appointment described above. As described in further detail later in this regulation, if VA is able to furnish a covered veteran with care or services through telehealth, whether through a telehealth encounter that was scheduled well-in advance or one conducted on an ad hoc basis, and the veteran accepts the use of this modality for care, VA would determine that it was able to furnish such care or services in a manner that complies with designated access standards. We would similarly consider same-day services provided to a veteran who did not schedule an appointment in advance as scheduled. This is also a new service that VA has only begun routinely offering in the past several years and is distinct from the unscheduled visits we referred to in the Veterans Choice Program regulations at § 17.1505, as those were primarily concerned with open clinics (such as general group counseling or services, like access to a gymnasium, that do not have or require an appointment). Just as with telehealth, if VA were able to offer the care or services a veteran required on a same-day basis, we would determine that VA was able to furnish the care or services in a manner that complies with designated access standards. The term schedule would be used throughout the proposed regulations, primarily in proposed § 17.4010 related to veteran eligibility for care under the Veterans Community Care Program.

The term VA facility would be newly defined in proposed § 17.4005 to mean a VA facility that offers hospital care, medical services, or extended care services, although the similar term VA medical facility was defined in § 17.1505. This definition would be required in relation to certain veteran eligibility under the Veterans Community Care Program in proposed § 17.4010. We note that we propose different definitions for full-service VA medical facility and VA facility, as these terms would be applied to discrete proposed eligibility criteria to furnish care under the Veterans Community Care Program. We propose to refer in this definition of VA facility to the types of care and services that a facility provides, rather than the designations of the facilities (*e.g.,* VA medical center, community-based outpatient clinic (CBOC), etc.) to ensure that any future descriptions of VA facilities would not result in a gap in our regulations for this Program. VA has multiple types of facilities from which VA care and services are furnished, including but not limited to medical centers, CBOCs, outreach clinics, and mobile clinics, among others. By defining VA facility broadly in terms of the types of care or services that could be provided, we would avoid the need to revise a specific list of facility types in the event that VA develops new types of facilities or renames existing types of facilities. We note that the term VA facility intends to capture a single site of care, and not for instance a grouping of multiple facilities that are under the direction of one administrative VA parent facility. We further note that Vet Centers, which were expressly excluded from the definition of a VA medical facility under § 17.1505, would still be excluded, as Vet Centers do not furnish hospital care, medical services, or extended care services.

The term VA medical service line would be newly defined in proposed § 17.4005 to mean a specific medical service or set of services delivered in a VA facility. We believe this is consistent with but also more appropriately descriptive than the definition of the term in section 1703(o)(2). We propose to refer to VA facilities, rather than only VA medical centers, because this definition is relevant for purposes of establishing eligibility under section 1703(e), and paragraph (1)(B) of that subsection specifically refers to comparisons of timeliness and quality at a facility of the Department, rather than just a medical center. Moreover, reports from the Veterans' Affairs Committees of the Senate and the House of Representatives both consistently refer to this provision affecting VA facilities, rather than only VA medical centers. See S. Rpt. 115–212, p. 10; see also H. Rpt. 115–671, Part 1, pp. 5, 51. In this context, we believe using the term facility is appropriate. This definition would apply for purposes of proposed §§ 17.4010(a)(6) and 17.4015.

§ 17.4010, Veteran Eligibility

Section 1703(d) establishes the conditions under which, at the election of the veteran and subject to the

availability of appropriations, VA must furnish care in the community through eligible entities and providers. Section 1703(d)(3) requires VA to make determinations regarding whether these conditions are met for sections 1703(d)(1)(A)–(D). Section 1703(e) authorizes VA to furnish care in the community through eligible entities and providers. VA proposes to establish a single section of regulations, § 17.4010, that would cover these three provisions of law under the general mantle of eligibility for ease of understanding and review and to align with dozens of other VA health care regulations. We emphasize that while we describe this as eligibility, covered veterans do not need to do anything other than contact VA to request care and provide the information required in paragraphs (b) and (c), as they typically would. It is VA's responsibility to determine whether the veteran has met any of the conditions described here and would be eligible to make an election to have VA authorize the care in the community.

Similar to the definitions section above, portions of the following explanation of veteran eligibility in proposed § 17.4010 will be presented by comparison to current veteran eligibility under the Veterans Choice Program at § 17.1510, to provide a clearer understanding of whether eligibility is proposed to change under the future Veterans Community Care Program. We will also note where the proposed eligibility criteria align with informal criteria used in VA's existing community care program. We additionally reiterate that, for the sake of convenience and understanding, we will refer to provisions of section 1703, as section 101 of the MISSION Act will amend it, although we recognize that section 1703 as so amended is not legally effective until VA has published a final rule implementing the Veterans Community Care Program. When we do refer to the current section 1703 to describe current eligibility criteria, we will refer to it as such.

Consistent with the structure of veteran eligibility determinations under the Veterans Choice Program at 38 CFR 17.1510, as well as the structure of veteran eligibility under 38 U.S.C. 1703(b), (d), and (e), proposed § 17.4010 would establish that determinations of veteran access to care or services through the Veterans Community Care Program would be based on a two-part assessment. First, the introductory text of proposed § 17.4010 would establish that a veteran must meet the definition of covered veteran, which as previously explained in the definitions section would mean that the veteran is enrolled under the system of patient enrollment in § 17.36, or the veteran must otherwise meet the criteria to receive care and services notwithstanding his or her failure to enroll under 38 U.S.C. 1705(c)(2). This requirement to establish a threshold eligibility related to a veteran's enrollment status would be consistent with definition of a covered veteran in section 1703(b), and would be consistent generally with the Veterans Choice Program (which was only available to enrolled veterans). The proposed definition of covered veteran would clarify that the Veterans Community Care Program would include veterans under section 1705(c)(2) not subject to the requirement to enroll. Veterans meeting either of these requirements would be considered a covered veteran. The second part of the assessment is for VA to determine whether any of the six conditions described in proposed § 17.4010(a) are met. Moreover, such eligible veterans would have to provide VA with the information that would be required by proposed § 17.4010(b) and (c) as a condition for receiving care and services through this Program.

Proposed § 17.4010(a) would state that the covered veteran would have to require hospital care, medical services, or extended care services. This is a core requirement for VA to furnish any care under the medical benefits package at 38 CFR 17.38(b), as such care must be necessary to promote, preserve, or restore the health of the veteran. In addition, one of the six conditions identified in sub-paragraphs (1) through (6) would have to be met. These conditions in proposed § 17.4010(a)(1)–(a)(6) would reflect the specific six conditions under sections 1703(d) and (e) for covered veterans to receive care through the Veterans Community Care Program, which generally are:

- VA does not offer the care or services the veteran requires;
- VA does not operate a full-service medical facility in the State in which the veteran resides;
- The veteran was eligible to receive care under the Veterans Choice Program and is eligible to receive care under certain grandfathering provisions;
- VA is not able to furnish care or services to a veteran in a manner that complies with VA's designated access standards;
- The veteran and the veteran's referring clinician determine it is in the best medical interest of the veteran to receive care or services from an eligible entity or provider based on consideration of certain criteria that VA would establish; or
- The veteran is seeking care or services from a VA medical service line that VA has determined is not providing care that complies with VA's standards for quality.

The explanation that follows will provide more specific interpretations of these general conditions from sections 1703(d) and (e), and we note that each condition would be an independent means by which a covered veteran could access care or services through the Veterans Community Care Program. For instance, if a covered veteran did not qualify for community care under proposed § 17.4010(a)(1), such veteran might still qualify under proposed § 17.4010(a)(2)–(a)(6). The conditions in proposed § 17.4010(a)(1)–(a)(6) would also not be mutually exclusive in an absolute sense. While VA proposes to distinguish each condition meaningfully, it may be the case that veterans could be considered eligible under more than one proposed criterion. For example, a veteran who resides in a State without a full-service VA medical facility might also require care or services that VA does not offer. Some of the conditions, such as residing in a State without a full-service VA medical facility, or qualifying under the grandfathering provision related to 40-mile eligibility and residence in one of the five States with the lowest population density in the 2010 census, would qualify a veteran to receive any clinically necessary hospital care, medical services, or extended care services that is in accord with generally accepted standards of medical practice and that is needed to promote, preserve, or restore the veteran's health. Other conditions, such as VA not offering the care or service a covered veteran requires, would only qualify the veteran to receive a particular episode of care in the community for that care or service. We will describe these general parameters of eligibility as we explain each specific criterion.

Proposed § 17.4010(a)(1) would establish eligibility for a covered veteran to access care and services through the Veterans Community Care Program if VA determined that no VA facility offered the hospital care, medical services, or extended care services the veteran requires. Proposed § 17.4010(a)(1) would implement the eligibility criterion under section 1703(d)(1)(A) related to when the Department does not offer the care or services. VA proposes to interpret this criterion to capture certain care and services that VA does not offer at any of its facilities, (such as full obstetrics care, the limited provision of certain in vitro fertility services, and certain non-

institutional extended care services such as homemaker/home health aide services) and that VA exclusively relies on non-VA health care entities or providers to furnish. Covered veterans requiring such care and services would be considered eligible for the Veterans Community Care Program under proposed § 17.4010(a)(1) for the specific care or service they require. Although this criterion would be an assessment of VA facilities at large, VA would capture whether a VA facility does not offer the specific care and service that a covered veteran requires in relation to the residence of the covered veteran, for instance, during the consultation with the VA clinician or member of the VA care coordination team at the time when access to care in the community is determined. We intend that proposed § 17.4010(a)(1) would be a simple qualifier for covered veterans that need certain types of care that VA simply does not provide in any of its facilities. Any covered veteran requiring such care or services would not have to be assessed any further under other proposed eligibility criteria for community care. This would provide clarity for veterans and would be administratively simpler for VA. We note that proposed § 17.4010(a)(1) would not be used to limit access to community care generally in instances where a single VA facility offers the care or services required; covered veterans would simply be assessed under one of the other five eligibility criteria in proposed § 17.4010(a)(2)–(a)(6). We reiterate that each of the eligibility criteria in proposed § 17.4010(a)(1)–(a)(6) would be an independent means by which a covered veteran could be considered eligible to receive required care or services through the Veterans Community Care Program. Because proposed § 17.4010(a)(4) would separately assess eligibility for community care in a manner that considered whether individual VA facilities offered the required care or services in relation to individual covered veterans, the interpretation in proposed § 17.4010(a)(1) to consider the availability of care or services anywhere in the VA system would allow VA to give meaning to every community care eligibility criterion under section 1703(d), and would prevent any one criterion from subsuming others. Proposed § 17.4010(a)(1) does not have an analogous or substantively similar eligibility criterion under current § 17.1510, but would reflect current practice through both the Veterans Choice Program and VA's traditional community care program. Under the Veterans Choice Program, eligible veterans requiring services that VA does not provide in any location would qualify under the wait-time criteria, as the wait-time to receive that care in a VA facility would be infinite. Under the current section 1703(a), VA may contract with non-VA facilities to furnish care and services when VA facilities are not capable of furnishing the care or services required. Covered veterans would only be eligible under proposed § 17.4010(a)(1) for the specific care or service they require that VA does not furnish.

Proposed § 17.4010(a)(2) would establish eligibility for a covered veteran to receive care and services through the Veterans Community Care Program if VA has determined that it does not operate a full-service VA medical facility in the State in which such covered veteran resides. Proposed § 17.4010(a)(2) would implement the eligibility criterion in section 1703(d)(1)(B). Proposed § 17.4010(a)(2) would be analogous to current § 17.1510(b)(3)(i), although proposed § 17.4010(a)(2) would not retain the 20-mile qualifying criterion in current 38 CFR 17.1510(b)(3)(ii), to be consistent with section 1703(d)(1)(B). VA has determined that this change would only affect a small portion of veterans residing in New Hampshire along the border with Vermont, and the effect would be to establish their eligibility to elect to receive community care under this new Program. We reiterate from the definitions section that VA would interpret a full-service VA medical facility to mean a VA medical facility that provides hospital care, emergency medical services, and surgical care and having a surgical complexity designation of at least ''standard,'' which is how a VA facility is characterized in current § 17.1510(b)(3)(i) for purposes of assessing the capabilities of a VA facility within a State to provide care and services. Currently, Alaska, Hawaii, New Hampshire, and most of the U.S. territories (American Samoa, the Northern Mariana Islands, Guam, and the U.S. Virgin Islands) qualify as States without a full-service VA medical facility. Eligibility under this criterion would qualify a covered veteran to elect to receive in the community any hospital care, medical services, or extended care services that is needed to promote, preserve, or restore the health of the veteran and that is in accord with generally accepted standards of medical practice.

Proposed § 17.4010(a)(3) would establish eligibility for a covered veteran to receive care and services through the Veterans Community Care Program if VA has determined that the covered veteran was eligible to receive care and services from an eligible entity or provider under section 101(b)(2)(B) of the Veterans Access, Choice, and Accountability Act of 2014 (Public Law 113–146; 38 U.S.C.1701 note) as of June 5, 2018, and continues to reside in a location that would have qualified the veteran under section 101(b)(2)(B), and one of two additional conditions is met: The veteran (i) resides in one of the five States with the lowest population density as determined by data from the 2010 decennial census (Alaska, Montana, North Dakota, South Dakota, or Wyoming); or (ii) does not reside in one of these States, but received care or services under title 38 U.S.C. in the year preceding June 6, 2018, and is seeking care before June 6, 2020. For purposes of this latter category, we note that receipt of care or services under title 38, U.S.C., would include literally any hospital care, medical service, or extended care service VA furnished to the veteran, whether in a VA facility or not. Proposed § 17.4010(a)(3) would implement the eligibility criterion in section 1703(d)(1)(C), to effectively grandfather eligibility for those veterans who qualify for care under the Veterans Choice Program under current § 17.1510(b)(2) based on the 40-mile distance criterion. We note that, consistent with section 1703(d)(1)(C), the grandfathering of eligibility in proposed § 17.4010(a)(3) would be carried forward indefinitely for only those covered veterans that reside in Alaska, Montana, North Dakota, South Dakota, or Wyoming. Any covered veterans that did not reside in one of these States would only be considered to have this grandfathered eligibility related to the 40-mile criterion in current § 17.1510(b)(2) for the first two years after the date of enactment of the MISSION Act, until June 6, 2020. Eligibility under this proposed criterion would qualify a covered veteran to elect to receive in the community any hospital care, medical service, or extended care service that is needed to promote, preserve, or restore the health of the veteran and that is in accord with generally accepted standards of medical practice.

Proposed § 17.4010(a)(4) would establish conditions for a covered veteran to access care and services through the Veterans Community Care Program if the covered veteran has contacted an authorized VA official to request the care or services the veteran requires, but VA has determined it is not able to furnish such care or services

in a manner that complies with designated VA access standards that would be established in proposed § 17.4040. Proposed § 17.4010(a)(4) would implement the eligibility criterion in section 1703(d)(1)(D). The proposed access standards themselves are explained in the section of this rule that discusses proposed § 17.4040, which would implement both section 1703(d)(1)(D) and portions of section 1703B. Access to care in the community based upon this criterion generally would only qualify a covered veteran to receive a specific care or service within an episode of care, but in practice could amount to general eligibility for any care or service within multiple episodes of care. While described in greater detail in our discussion of proposed § 17.4040, VA's designated access standards consider both wait-times to receive care or services, as well as the average driving time from the covered veteran's residence to such care and services. Because both the wait-time and the average driving time standards are specific to the type of care required, these would generally only qualify a veteran for a specific type of care or service. However, if a covered veteran resided in a location that was beyond the average driving time standard for any service, that covered veteran would effectively qualify for any clinically necessary hospital care, medical service, or extended care service (except for nursing home care, as described below). This criterion is essentially a permutation of the existing distance and wait-time criteria in the Veterans Choice Program under current § 17.1510(b)(1) and (b)(2), as well as the general standards under current section 1703(a).

Proposed § 17.4010(a)(5) would establish eligibility for a covered veteran to receive care and services through the Veterans Community Care Program if the veteran and the veteran's referring clinician (either a VA or non-VA clinician) determine it is in the best medical interest of the veteran—for the purpose of achieving improved clinical outcomes—to receive the care or services the veteran requires from an eligible entity or provider, based on factors that could be considered under proposed § 17.4010(a)(5)(i)–(vii). We note that we propose to qualify a determination of best medical interest in proposed § 17.4010(a)(5) by expressly stating that such a determination would be for the purpose of the veteran achieving improved clinical outcomes by receiving the care or services in the community, versus from a VA health care provider. VA intends this distinction to clarify that the factors proposed in § 17.4010(a)(5)(i)–(vii) would be considered in the context of clinical decision making. This is well-supported by the reference in section 1703(d)(1)(E) to the determination being based on the best medical interest of the covered veteran based on criteria developed by the Secretary. The inclusion of language referencing improved clinical outcomes would clarify that other factors (such as mere convenience), when unconnected to any clinical outcome, would not be a basis for determining that receipt of care in the community is in the covered veteran's best medical interest.

Sections 1703(d)(1)(E) and (d)(2) require VA to develop criteria to be used in determining the best medical interest of the veteran. Proposed § 17.4010(a)(5) would implement the eligibility criterion in section 1703(d)(1)(E), and proposed § 17.4010(a)(5)(i)–(vii) would describe the criteria that VA proposes to guide determinations of whether it is in the best medical interest that a veteran be furnished care or services by an eligible entity or provider. Section 1703(d)(2) identifies specific criteria that VA must consider in developing these factors; this list is not exhaustive, as demonstrated by the statute's direction to ensure that the criteria developed under paragraph (1)(E) include consideration of the criteria that follow. This language makes the most sense when subsection (d)(2) is understood as a minimum description of the criteria that must be considered by VA. Thus, the additional factors VA is proposing to adopt in proposed § 17.4010(a)(5)(v)–(vii), discussed further below, would be an exercise of discretion authorized by Congress.

The specific factors that a veteran and a veteran's referring clinician could consider in proposed § 17.4010(a)(5)(i)–(iv) would mirror those expressly listed in section 1703(d)(2)(A)–(D), and we note that two of these proposed factors (related to the nature of the care and services, and frequency that the care and services would be needed) are presently assessed in the Veterans Choice Program under § 17.1510(b)(4)(ii)(A)–(B). We would make a minor clarification to the statutory criteria in proposed paragraph (a)(5)(i) to refer to a facility or facilities where care could be provided, in case there is more than one location that could furnish the care. The language concerning a facility or facilities is intended to include both VA and non-VA facilities.

Proposed § 17.4010(a)(5)(v) would not mirror a statutory criteria, but is proposed in the Secretary's discretion to permit the additional consideration of whether there would be the potential for improved continuity of care if a non-VA health care provider furnished the care, such as instances where the veteran might have an existing relationship with a non-VA health care provider that would make adherence to a clinical regimen more likely than if a VA health care provider were to start newly furnishing care or services. Proposed § 17.4010(a)(5)(vi) would similarly not mirror a statutory factor in section 1703(d)(2), but would permit the additional consideration of whether the quality of care provided by an eligible entity or provider might be considered more clinically appropriate for a veteran, such as when an eligible entity or provider might have more expertise in furnishing a specialized procedure than a VA health care provider.

Proposed § 17.4010(a)(5)(vii) would implement the factor in section 1703(d)(2)(E) to consider it in the best medical interest of the covered veteran to receive care or services from an eligible entity or provider if the veteran faces an unusual or excessive burden in accessing a VA facility. Proposed § 17.4010(a)(5)(vii)(A)–(D) would implement the express considerations in section 1703(d)(2)(E)(i)–(iv), many of which mimic the unusual or excessive travel burden criteria in current § 17.1510(b)(4)(ii). The unusual and excessive travel burden would apply to travel to a VA facility for any type or category of care and services under VA's medical benefits package. Proposed § 17.4010(a)(5)(vii)(E) would implement the substantively similar consideration in current § 17.1510(b)(4)(ii)(C), that a covered veteran's need for an attendant to travel to a VA medical facility to receive care and services could be assessed as a factor in the best medical interest determination.

Proposed § 17.4010(a)(6) would establish eligibility for a covered veteran to receive care and services through the Veterans Community Care Program if, in accordance with proposed § 17.4015, explained later in this rule, VA has determined that a VA medical service line that would furnish the care or services the veteran requires is not providing such care or services in a manner that complies with VA's standards for quality. Proposed § 17.4010(a)(6) would implement the eligibility criterion for community care in section 1703(e), which permits but does not compel VA to furnish hospital care, medical services, or extended care services through the Veterans Community Care Program. We note this difference between the discretionary eligibility in section 1703(e) and the eligibility in section 1703(d), which is

required subject to the availability of appropriations, at the outset here, and will explain more fully in the discussion below that addresses proposed § 17.4015 how VA would designate medical service lines based on data related to VA's standards for quality, and how this would be applied to eligibility decisions under this section.

Proposed § 17.4010(b) and (c) would incorporate without substantive change two requirements from the Veterans Choice Program at current § 17.1510(c) and (d), respectively, related to veterans alerting VA of a change of residence, and veterans providing VA with information about any other health-care plan contract under which the veteran is covered. This information would continue to be needed in the Veterans Community Care Program so that VA could make accurate eligibility determinations under proposed § 17.4010(a)(2)–(6) that would rely on a veteran's place of residence, and so that VA could continue to recover or collect reasonable charges for care and services furnished in the community for a non-service connected disability from a health plan contract, consistent with section 1703(j). The only changes from current § 17.1510(c) and (d) would be referring to covered veterans instead of only veterans in both provisions and, proposed § 17.4010(c), referring to care and services the veteran requires instead of care under the Veterans Choice Program, as well as referring to other health-care plan contracts instead of health-care plans, as previously explained in the definitions section of this rulemaking.

Proposed § 17.4010(d) would implement the requirements in section 1703(f) that any decisions concerning eligibility for community care under sections 1703(d) and (e) be subject to VA's clinical appeals process, and not be appealable to the Board of Veterans' Appeals. Proposed § 17.4010(d) would refer to all eligibility determinations under proposed § 17.4010(a) as being subject to VA's clinical appeals process. We note that VA's current clinical appeals process is established in VHA Directive 1041, titled ''Appeal of VHA Clinical Decisions,'' and any successor VHA policy would equally apply. The current Directive and any future policies are and will be made available on VA's website *https://www.va.gov/vhapublications/publications.cfm?pub=1.*

§ 17.4015, Designated VA Medical Service Lines

Proposed § 17.4015 would establish the process by which VA would identify its medical service lines that were not able to furnish care or service in a manner that complied with VA's standards for quality, so that veterans who would receive care or services through such VA medical service lines could be considered eligible for the Veterans Community Care Program under proposed § 17.4010(a)(6).

Consistent with section 1703(e)(1)(A)–(B), proposed § 17.4015(a) would establish that VA's permissive authority to consider covered veterans as eligible for community care under proposed § 17.4010(a)(6) would be based on whether VA medical service lines were identified by VA as underperforming in accordance with timeliness standards when compared with the same VA medical service lines at other VA facilities and based on two or more distinct and appropriate quality measures of VA's standards for quality when compared with non-VA medical service lines. Proposed § 17.4015(b) would further clarify that VA's identification of its underperforming medical service lines would be based on the data that VA would analyze under proposed § 17.4015(a), VA's standards for quality themselves, as well as factors in proposed § 17.4015(e) that would guide how VA would assess the information it gathered related to VA and non-VA medical service lines.

Consistent with section 1703(e)(4), proposed § 17.4015(c) would establish that VA would announce any VA medical service lines identified under proposed § 17.4015(a) in a document in the **Federal Register** and would identify and describe the standards for quality VA used to inform its determination under proposed § 17.4015(a), as well as how the data described in proposed § 17.4015(a) and the factors identified in proposed § 17.4015(e) were used to make the determinations. The announcement of this information through a document in the **Federal Register** would provide clear information to the public regarding how VA arrived at its choice of standards, while additionally allowing VA to remain nimble (subject to existing legal authorities, such as the Paperwork Reduction Act, as applicable) with its gathering and analysis of data related to its standards for quality, and possible identification of its medical service lines that are underperforming. Consistent with section 1703(e)(2), proposed § 17.4015(c) would also establish that this document in the **Federal Register** would identify limitations, if any, concerning when and where covered veterans can receive qualifying care and services at their election in the community, which could include defined timeframes in which such care and services could be available, defined geographic areas in which such care and services may be provided, and a defined scope of services that veterans may elect to receive. Finally, in accordance with section 1703(e)(4), VA would be required to take all reasonable steps to provide direct notice to covered veterans affected under this section. Such direct notice would generally include written correspondence and could include electronic messages or direct contact (in person or by phone).

Proposed § 17.4015(d) would restate the requirement from section 1703(e)(1)(C)(ii) that VA could not identify more than 3 of its medical service lines in any single VA facility, and not more than 36 such service lines throughout VA nationally, when determining those underperforming service lines that might create eligibility for community care. We believe these provisions to be clear in the statute, but in the interest of being comprehensive, we have included these requirements in regulation to avoid confusion. To provide some scope of the relative impact of designating up to 36 service lines, we note that 36 services lines would be a very small number of those that exist nationally. For instance, it is possible that a single VA medical center could have as many as 20 service lines itself, and VA operates more than 1,200 sites of care.

Proposed § 17.4015(e) would establish the factors that VA would consider when determining whether one of its medical service lines should be identified as underperforming; we clarify that the threshold requirements, in accordance with section 1703(e)(1)(B) are performance on timeliness standards when compared with medical services lines at other VA facilities and on quality standards when compared with non-VA medical service lines when external benchmarks are available. The data on performance for these timeliness and other quality standards will identify potential service lines that could be designated, and VA would apply the factors described in this paragraph to determine which service lines to designate. These same factors would also be used in the event that one of the limitations in proposed § 17.4015(d) restricted VA's ability to designate all VA medical service lines that might be considered underperforming under proposed § 17.4015(a). Proposed § 17.4015(e)(1) would establish that VA would consider whether the differences between performance of individual VA medical service lines (concerning timeliness) and performance of VA

medical service lines and non-VA medical service lines (concerning quality) are clinically significant. This factor would allow VA to appropriately discern small differences in performance metrics as not evidencing underperformance per se.

Proposed § 17.4015(e)(2) would establish that VA would consider the likelihood or ease of remediation of a medical service line within a short timeframe in identifying whether it is underperforming, to permit VA to be selective as remediation would require further considerations of VA resource management or allocation. Section 1706A requires VA to develop plans and to remediate VA medical service lines that are identified as underperforming under section 1703(e). We therefore propose to consider the likelihood and ease of remediation in designating such service lines in the first place, as it would be illogical to designate a VA medical service line as underperforming and in need of the kind of intensive remediation envisioned by section 1706A when a simple action (such as the purchase of new equipment) would be sufficient and is likely to occur. This view is further reinforced by the limited number of VA medical service lines VA could designate under this authority; VA should not use a limited authority when other options are already available.

Proposed § 17.4015(e)(3) would establish that VA would consider any recent trends (as they were known) that might concern a VA or non-VA medical service line, as such trends could be more contemporary than the data or information upon which VA would be basing a determination of underperformance. Given the requirements to gather, analyze, and verify quality data, there may be a considerable period of time (sometimes up to 18–24 months) between when the data are first collected and when decisions can be made on that data. If VA had reason to believe, based on more contemporaneous information, that some of the factors that contributed to poor performance on quality metrics had already been corrected, VA would factor such evidence into its decision making.

Proposed § 17.4015(e)(4) would establish that VA would consider the number of veterans served by the medical service line or that could be affected by the designation. This could be considered in several ways. For example, this is likely to be a relevant consideration to allow VA to properly assess data about its own medical service lines, and for comparing a particular medical service line to other VA or to non-VA medical service lines. For example, a VA medical service line that only treated a few patients may be more likely to be adversely affected by a single negative outcome than would be other VA or non-VA service lines with larger numbers of patients. It could also be relevant when deciding whether to designate a VA medical service line at all, or in a situation where VA had to choose which service line to designate because one of the limitations in paragraph (d) applied. For example, if VA could only choose one of two VA medical service lines to designate, and one of those service lines only treated one patient within the past year, while another treated 1,000 patients, it would likely make more sense to designate the VA medical service line with a greater patient volume to ensure the maximum number of covered veterans receive access to community care.

Proposed § 17.4015(e)(5) would establish that VA would consider the potential impact on patient outcomes when considering whether a VA medical service line was underperforming. Some medical service lines, by the nature of their clinical area of responsibility, deal with more significant health concerns than others.

Finally, proposed § 17.4015(e)(6) would allow VA to take into account the effect that designating one VA medical service line would have on other VA medical service lines. For example, if VA identified a surgical line as underperforming, that could have collateral effects on a range of other service lines, such as cardiology, orthopedics, or gastroenterology. For instance, a cardiology service line would be less likely to undertake complex interventional procedures if there is not appropriate surgical support in the event of a procedural complication. VA could consider these secondary effects and weigh the relative costs and benefits associated with designating one VA medical service line as it would affect other service lines within the VA facility.

We reiterate that proposed § 17.4015 would establish a process by which VA would determine, announce, and explain the VA medical service lines it determines are underperforming based on an assessment of the timeliness of its care compared with other VA facilities and the quality of that service line's care when compared with two or more distinct and appropriate quality measures of VA's standards for quality. Proposed § 17.4015 would not itself list VA's standards for quality as these standards and measures are dynamic and will evolve based on new discoveries and innovations as well as wider adoption of standardized quality measures across the U.S. health care industry; VA is submitting a report to Congress detailing its standards for quality no later than March 4, 2019. It also would not announce any VA medical service lines that VA might identify as underperforming in accordance with such standards, as this would be done through a document in the **Federal Register** under proposed § 17.4015(c) and direct notice to affected veterans. The process in proposed § 17.4015 would be the means of identifying those VA medical service lines that would be the basis for the eligibility determination under proposed § 17.4010(a)(6).

§ 17.4020, Authorized Non-VA Care

Proposed § 17.4020 would describe the process and requirements for authorizing non-VA care under this Program, similar to current § 17.1515.

Proposed § 17.4020(a) and (b) would implement, without substantive change, two provisions from the Veterans Choice Program at § 17.1515 (a) and (b), respectively, related to a covered veteran's election to receive care in the community, and related to a covered veteran's selection of an eligible entity or provider. These provisions would be carried over to the Veterans Community Care Program to confirm a veteran's ability to elect to receive community care under appropriate circumstances, consistent with section 1703(d)(3), and to ensure continuity of veteran experience from the Veterans Choice Program in being able to choose an eligible entity or provider, while also being consistent with section 1703(g)(2). Section 1703(g)(2) provides that VA may not prioritize providers in a manner that limits the choice of a covered veteran in selecting an eligible entity or provider. The only non-substantive changes from current § 17.1515(a) would be referring to covered veterans in proposed § 17.4020(a) and removing language related to a veteran's election to be placed on an electronic waiting list for VA care because such a waiting list is not an express option in section 1703 related to a veteran's election to receive VA care versus VA community care. Proposed § 17.4020(a) would retain the premise in the Veterans Choice Program that the covered veteran who has been determined to be eligible for community care could elect to still receive such care through VA, or could elect to receive such care through an eligible entity or provider. We would clarify that any authorized care must be determined to be clinically necessary. This is a requirement both of existing § 17.38(b), as well as section 1703(n)(1), but adding

this language would be particularly critical for determinations by a non-VA referring clinician that receiving care or services would be in the best medical interest of the covered veteran. VA must ultimately determine that such care is clinically necessary. Section 17.4020(b) would also refer now to covered veterans for the reasons previously explained.

In paragraph (c) of § 17.4020, we would clarify the timelines associated with the authorization of care and services. In general, care furnished under the Veterans Community Care Program must be furnished following an authorization by VA that such care and services are to be provided to a covered veteran. However, we recognize that emergency care will be needed in applicable situations. VA currently permits emergency care, in certain situations, to be considered as authorized for purpose of current section 1703 through regulation at § 17.54. We propose to rescind and reserve the existing § 17.54 and instead establish a comparable rule in paragraph (c) of § 17.4020. We believe this is authorized under the new section 1703 amendments. Section 1703(a)(3) states that covered veterans may only receive care or services under this section upon the authorization of such care or services by VA, but it does not state that such authorization must occur in advance. We presume Congress was aware of the existing provisions allowing for authorizations within 72 hours, and did not consider it necessary to require prior authorization to allow VA to continue this practice. This presumption is based on the principle of statutory interpretation that Congress does not make sweeping changes to existing practice without explicitly stating so. We would state clearly, though, that this paragraph would not affect eligibility for, or create any new rules or conditions affecting, reimbursement for emergency treatment under sections 1725 or 1728. These authorities permit VA to reimburse eligible veterans for the receipt of emergency treatment under certain conditions, and no aspect of the VA MISSION Act of 2018 affected eligibility for care under these authorities. Care that cannot be authorized under this paragraph would be considered for reimbursement under 1725 or 1728, as applicable.

Paragraph (c)(1) would state that VA could authorize emergency treatment after it has been furnished to a covered veteran. This is consistent with the description of the scope of this provision above. We would define the term emergency treatment to be consistent with the definition of section 1725(f)(1). We would not reproduce the definition in this regulation in the event that any future changes are made to the statute; by cross-referencing, this would ensure that our regulations and statutes remain consistent on this point. In general, emergency treatment under section 1725(f)(1) means medical care or services furnished that, in the judgment of VA, meet three conditions. First, that VA or other Federal facilities are not feasibly available and an attempt to use them beforehand would not be reasonable. Second, that the care or services are rendered in a medical emergency of such nature that a prudent layperson reasonably expects that delay in seeking immediate medical attention would be hazardous to life or health. Third, emergency treatment continues until such time that the veteran can be transferred safely to a VA facility or other Federal facility and such facility is capable of accepting such transfer, or such time as the VA facility or other Federal facility accepts such transfer if at the time the veteran could have been transferred safely to a VA or other Federal facility, no VA or other Federal facility agreed to accept such transfer and the non-VA facility in which such medical care or services were furnished made and documented reasonable attempts to transfer the veteran to a VA or other Federal facility.

Proposed paragraph (c)(2) would state that VA could only authorize emergency treatment under this paragraph if the covered veteran, someone acting on the covered veteran's behalf, or the eligible entity or provider notifies VA within 72 hours of such care or services being furnished and VA approves the furnishing under paragraph (c)(3). This would be consistent with existing § 17.54(a), with the specific inclusion of an eligible entity or provider being a possible entity that could notify VA; § 17.54(a) only refers to notification by the veteran or by others in his or her behalf, so our proposed language in paragraph (c)(2) would still provide flexibility while recognizing that an eligible entity or provider might be the most appropriate party to notify VA given their contractual relationship to furnish care on VA's behalf. This 72-hour requirement is consistent with the window for approval under existing § 17.54(a). We believe the 72-hour requirement continues to be a reasonable period of time as it would allow notification upon stabilization of the patient or upon the next business day in the overwhelming majority of cases. We would not retain the language from § 17.54(a)(2) concerning non-contiguous States because, as noted in proposed paragraph (c)(3)(i), this rule would only apply to emergency care furnished by eligible entities or providers who have a contract or agreement to furnish care on VA's behalf; this relationship would provide the means for notifying VA in a timely manner, while the prior rule in § 17.54 did not require such a relationship.

Notification, however, would not guarantee that care would be approved by VA as authorized; paragraph (c)(2) would note that paragraph (c)(3) would further describe the conditions under which VA would approve such care. Paragraph (c)(3) would explain that VA would approve care as authorized only if three conditions are met. First, the veteran must be receiving emergency treatment from an eligible entity or provider. This is a requirement for the care to be furnished under section 1703 and these proposed regulations. It would also ensure that all care furnished is subject to the payment rates established in a contract or agreement. VA would further require the notification be submitted appropriately, as further described in paragraph (c)(4), and provided within 72 hours of the beginning of such treatment. This would ensure that VA is able to make an appropriate determination as soon as possible as to whether or not the emergency treatment is qualifying care under these authorities. Finally, VA would limit emergency treatment to services covered by VA's medical benefits package. This would ensure VA does not authorize any care or services it lacks the authority to furnish at all.

Paragraph (c)(4) would stipulate requirements that the notice must satisfy to be accepted as notice for purposes of this paragraph. The notice would need to contain three elements. First, it would have to be made to an appropriate VA official at the nearest VA medical facility. While we would not define how this official would be defined through the regulation, we believe that either through the contract or agreement the eligible entity or provider has with VA or through another means (like each VA medical facility's website), the eligible entity or provider would know the right official to contact. Veterans or other parties could simply contact their VA medical center to provide this information. This would ensure that the appropriate officials are notified and can make determinations under this authority. Second, the notice would have to identify the covered veteran. This would ensure VA could review and determine the veteran actually meets the definition of a covered veteran for

purposes of these regulations. Finally, the notice would have to identify the eligible entity or provider furnishing the emergency treatment. This would ensure that the entity or provider is in fact eligible to furnish care and services for VA pursuant to a contract or agreement authorizing such entity or provider to furnish care and services on our behalf.

We note that we have not included language in this proposed rule to address the provisions in section 1703(l) regarding organ and bone marrow transplants. VA will address this through a subsequent rulemaking. Section 1703(l) provides that the Secretary shall determine whether to authorize an organ or bone marrow transplant for a covered veteran at a non-VA facility. If the rulemaking focused on organ and bone marrow transplants is not effective by the time this rule for the Veterans Community Care Program is effective, the Secretary will effectively have exercised his discretion to determine that the election of a covered veteran eligible under § 17.4010(a) on where to receive organ or bone marrow transplant care controls.

We further note that section 153 of the MISSION Act added a new section 1788 to title 38, U.S.C., specifically authorizing VA to provide for an operation on a live donor to carry out a transplant procedure for an eligible veteran, notwithstanding that the live donor may not be eligible for VA health care. VA will issue separate regulations concerning this new authority. Any comments on care for living donors will be considered outside the scope of this rulemaking.

§ 17.4025, Effect on Other Provisions

Proposed § 17.4025 would address the effect of the Veterans Community Care Program on other provisions and programs administered by VA, similar to current § 17.1520.

Proposed § 17.4025(a) would provide that, consistent with section 1703(n)(2), no provision in these sections may be construed to alter or modify any other provision of law establishing specific eligibility criteria for hospital care, medical services, or extended care services. If particular services, such as dental benefits under §§ 17.160–17.169, have unique eligibility standards, only veterans who are eligible under proposed § 17.4010 and meet the eligibility standards for those services can elect to receive them through the Veterans Community Care Program. Nothing in section 1703 or these regulations would waive the eligibility requirements established in other applicable statutes or regulations. This is substantively similar to the first sentence of current § 17.1520(a).

Similar to the second sentence of current § 17.1520(a), proposed § 17.4025(b) would address VA's paying for and filling of prescriptions obtained by covered veterans from eligible entities and providers, but would clarify VA's current practice that distinguishes circumstances under which VA pays for (versus fills) such prescriptions. Proposed § 17.4025(b)(1) would retain the practice in the Veterans Choice Program that VA will pay for prescriptions, including prescription drugs, over the counter drugs, and medical and surgical supplies written by non-VA health care providers furnishing services through VA community care, but would clarify that such payment would be for a course of treatment that lasts no longer than 14 days. This current practice to limit payment for non-VA prescriptions is reasonable, as it would allow VA to ensure that any amount of medication in excess of 14 days would be filled through VA's Consolidated Mail Order Pharmacy system to ensure cost and quality controls. VA believes that the economies of scale related to bulk purchase of medications allow for the best maximization of Federal resources. Proposed § 17.4025(b)(2) would establish the correlate rule from the Veterans Choice Program, that VA would fill longer-term prescriptions for courses of treatment that exceed 14 days if they are filled through VA's Consolidated Mail Order Pharmacy system.

Proposed § 17.4025(b)(3) and (b)(4) would further clarify current practice under the Veterans Choice Program regarding VA paying for or filling prescriptions written by non-VA health care providers for durable medical equipment (DME) and devices. Although not expressly stated in current § 17.1520, the Veterans Choice Program currently permits VA to pay for such prescriptions to be furnished by a community provider only when there is an urgent or emergent need for the durable medical equipment or medical device, meaning the veteran has a medical condition of acute onset or exacerbation manifesting itself by severity of symptoms including pain, soft tissues symptomatology, bone injuries, etc. Urgent or emergent DME or medical devices may include, but are not limited to: Splints, crutches, canes, slings, soft collars, walkers, and manual wheelchairs. This current practice to limit payment for non-VA prescriptions of DME or medical devices to only what is immediately needed is reasonable, as VA must ensure administrative oversight as well as clinical appropriateness of all other DME and medical devices prescribed by non-VA health care providers. DME and medical devices are specific to a particular clinical need and in most cases are further specifically tailored to fit or serve an individual, and as such require direct provision by VA (except when urgently needed) to ensure clinical appropriateness and the best use of Federal resources. Proposed § 17.4025(b)(3) would establish that VA would pay for prescriptions written by eligible entities or providers for covered veterans that have an immediate need for durable medical equipment and medical devices to address urgent or emergent conditions, and would parenthetically reference a non-exhaustive list of such devices to include splints, crutches, and manual wheelchairs. Proposed 38 CFR 17.4025(b)(4) would then establish a correlate rule that VA would fill prescriptions written by eligible entities or providers for covered veterans for DME and medical devices without any limitation related to the equipment being required for an urgent or emergent need.

Proposed § 17.4025(c) would restate with slight revision the last sentence of current § 17.1520(b), as veterans would continue to be liable as applicable under §§ 17.108(b)(4) and (c)(4), 17.110(b)(4), and 17.111(b)(3) for copayments for community care that is furnished through the Veterans Community Care Program. The Veterans Community Care Program would not alter the current treatment of veteran copayments for community care as exists in the Veterans Choice Program. We are not including the language in the first sentence of 17.1520(b), concerning VA's liability for deductibles, cost-shares, or copayments required by an eligible veterans' health-care plan, because that language was originally included in the Veterans Choice Program regulations when VA was a secondary payer to an eligible veteran's other health insurance. That language was needed to ensure veterans faced no additional liability for using the Veterans Choice Program, as opposed to VA's traditional community care programs where VA was and is the primary payer. Under the Veterans Community Care Program, VA will be the primary payer, so this language is unnecessary.

§ 17.4030, Eligible Entities and Providers

Similar to current § 17.1530 under the Veterans Choice Program, proposed § 17.4030 would establish requirements for non-VA entities and providers to be

eligible to furnish hospital care, medical services, and extended care services to covered veterans under the Veterans Community Care Program. We would not identify specific lists of health care entities or providers (*e.g.,* Department of Defense, Medicare providers, etc.), as section 1703(c) already provides VA broad authority to include additional health care providers who enter into contracts or agreements to furnish care and services under this Program. Proposed § 17.4030(b) would establish conditions that non-VA entities and providers must meet to be considered eligible to furnish care or services under the Veterans Community Care Program. We note that the requirements in this paragraph are not exhaustive, as there are other provisions established in law (namely, in 1703(h)(3)(A)(IV) and section 108 of the MISSION Act) that must be met to be a participating eligible entity or provider.

Proposed § 17.4030(a) would require the non-VA entity or provider to enter into a contract, agreement, or other arrangement to furnish care and services under the Veterans Community Care Program established by these regulations. The terms of the contract, agreement, or other arrangement will impose additional requirements that must be met, particularly concerning additional qualifications, but it is not necessary to regulate these conditions because entities or providers will agree to be bound by them through the contract, agreement, or other arrangement.

Proposed § 17.4030(b) would be consistent with existing § 17.1530(a), which prohibits an entity or provider that is part of VA, or providers who are employed by VA from furnishing care or services while acting within the scope of their VA employment, from being an eligible entity or provider. As we explained in the Veterans Choice Program regulations, the purpose of VA's use of community providers to furnish care is to ensure that veterans are able to access non-VA entities or providers, so it would be contrary to the purpose of the statute to include VA entities or providers within the definition of eligible entities or providers for community care. This same rationale applies to the Veterans Community Care program for covered veterans.

Proposed § 17.4030(c) would require that the non-VA entity or provider be accessible to an eligible veteran. VA would make determinations regarding accessibility by considering the length of time the veteran would have to wait to receive care or services from the entity or provider; the qualifications of the entity or provider; and the distance between the eligible veteran's residence and the entity or provider. This language would be substantively identical to § 17.1530(c), which requires that non-VA entities or providers in the Veterans Choice Program be accessible to veterans eligible under that Program. As the Veterans Community Care Program is intended, like the Veterans Choice Program, to expand access to care, we believe that imposing the same assurance of accessibility is appropriate. We would make minor edits to include references to extended care services for the reasons explained above.

§ 17.4035, Payment Rates

Similar to current § 17.1535 for the Veterans Choice Program, proposed § 17.4035 would establish the rate structure for payment for hospital care, medical services, and extended care services furnished pursuant to a contract or an agreement authorized by section 1703A would be the rates set forth in the terms of such contract or agreement. Such payment rates would comply with parameters defined in proposed § 17.4035(a)–(e), as described below, and would be analogous to the parameters established in section 1703(i).

Proposed § 17.4035(a) would establish that, except as otherwise provided in proposed § 17.4035, payment rates would not exceed the applicable Medicare fee schedule (including but not limited to allowable rates under 42 U.S.C. 1395m) or prospective payment system amount (hereafter referred to as ''Medicare rate''), if any, for the period in which the service was provided (without any changes based on the subsequent development of information under Medicare authorities). This would be analogous to the general provision in section 1703(i)(1), that, with exceptions, the rates paid for care and services may not exceed the applicable Medicare rate. This would also be similar to current § 17.1535(a)(1). The parenthetical language in proposed § 17.4035(a), to indicate that VA's rates would be based on Medicare rates without any changes based on the subsequent development of information under Medicare authorities is intended to limit VA's rate adjustments to an annual basis in line with Medicare's annual payment update, versus other adjustments that Medicare may make to its rates throughout any given year that is typically provider-specific and is based on provider and other reporting.

Proposed § 17.4035(b) would establish that, with respect to services furnished in a State with an All-Payer Model Agreement under section 1814(b)(3) of the Social Security Act (42 U.S.C. 1395f(b)(3)) that became effective on or after January 1, 2014, the Medicare rate under paragraph (a) would be calculated based on the payment rates under such agreement. This is consistent with section 1703(i)(4) and § 17.1535(a)(4).

Proposed § 17.4035(c) would establish, consistent with section 1703(i)(2)(A), that payment rates for services furnished in a highly rural area may exceed the limitations set forth in proposed § 17.4035(a)–(b). Proposed § 17.4035(c) would further establish that the term highly rural area means an area located in a county that has fewer than seven individuals residing in that county per square mile, consistent with the definition of highly rural area in section 1703(i)(2)(B).

Proposed § 17.4035(c) would further interpret that the assessment of a highly rural area would be made in relation to the areas where the services are furnished, and not the areas where the individuals receiving the care or services may reside as provided under section 1703(i)(2)(A). We believe this interpretation is reasonable because the typical laws of supply and demand dictate that in highly rural areas, the scarcity of health care providers and other health care resources tends to create increased prices for delivery of health care services. Additionally, it may not be accurate that, in all cases, individuals who reside in highly rural areas are receiving care and services in those same areas, and VA would not want to adopt an interpretation that would permit payment of higher rates to health care providers in other than highly rural areas. Attempting to tie payment rates to particular patients, rather than setting general rates for particular health care providers, would be administratively cumbersome and could lead to selective acceptance of patients that would adversely affect other patients.

Proposed § 17.4035(d) would establish that VA may deviate from the parameters set forth in proposed § 17.4035(a)–(c) when VA determines that, based on patient needs, market analyses, health care provider qualifications, or other factors, it is not practicable to limit payments as would be dictated by application of proposed § 17.4035(a)–(d). This general exception would be consistent with the provision in section 1703(i)(1) that authorizes VA to pay at rates not to exceed the Medicare rate to the extent practicable. Proposed § 17.4035(d) would afford VA the flexibility to ensure it can reach agreement with non-VA entities or providers to furnish necessary services when factors that drive costs may shift

faster than established Medicare rates. This flexibility would not be a guarantee of payments above applicable Medicare rates because the introductory language in proposed § 17.4035 would establish that payment rates are ultimately set forth in the terms of the contract or agreement under which the care and services are furnished. Such contracts or agreements will provide for the relevant procedures and review process for any payments that might utilize the exception in proposed § 17.4035(d), to ensure a consistent level of VA oversight.

Finally, proposed § 17.4035(e) would establish, consistent with section 1703(i)(3), that payment rates for services furnished in Alaska would not be subject to paragraphs (a) through (d) and would be set forth in the terms of the procurement contract or agreement authorized by section 1703A, pursuant to which such services are furnished. Proposed § 17.4035(e) would further state that, if no payment rate is set forth in the terms of such a contract or agreement to which services are furnished, payment rates for services furnished in Alaska would follow the Alaska Fee Schedule of the Department of Veterans Affairs. Under the VA Alaska Fee Schedule, as described in § 17.56(b), the amount paid in Alaska for each code will be 90 percent of the average amount VA actually paid in Alaska for the same services in Fiscal Year (FY) 2003. For services that VA provided less than eight times in Alaska in FY 2003, for services represented by codes established after FY 2003, and for unit-based codes prior to FY 2004, VA will take the Centers for Medicare and Medicaid Services' (CMS) rate for each code and multiply it times the average percentage paid by VA in Alaska for CMS-like codes. VA will increase the amounts on the VA Alaska Fee Schedule annually in accordance with the published national Medicare Economic Index (MEI). For those years where the annual average is a negative percentage, the Fee Schedule will remain the same as the previous year.

§ 17.4040, Designated Access Standards

Proposed § 17.4040 would establish the designated access standards by which VA would assess the availability of VA care and services in relation to individual covered veterans for purposes of eligibility determinations under proposed § 17.4010(a)(4). As we explained in the context of § 17.4015, this section would not establish all of VA's access standards, just as § 17.4015 would not establish VA's standards for quality. Proposed § 17.4040 would implement both section 1703(d)(1)(D) related to VA's eligibility determinations for community care, and portions of section 1703B related to VA's establishment of access standards. Section 1703(d)(1)(D) refers specifically to eligibility based on an inability to furnish care or services in a manner that complies with VA's designated access standards. This section would establish these designated access standards, which cover all care or services under VA's medical benefits package (with the exception of institutional extended care services, or nursing home care), to allow VA to determine whether the condition under proposed § 17.4010(a)(4) has been met. In publishing these standards through a final rule implementing this section, we would also satisfy part of the requirement in section 1703B(g); VA will also publish the final designated access standards on its website when they are effective.

In developing these proposed designated access standards, VA researched access standards established by Federal- and State-level agencies, consulted with the Department of Defense (DoD), the Department of Health and Human Services (HHS), as well as several commercial entities to identify best practices and acceptable standards for consideration, as required by section 1703B(c). On June 29, 2018, VA published a Notice in the **Federal Register** requesting public comments, and on July 13, 2018, VA held a public meeting to provide an additional opportunity for public comment. Results of these consultations will be discussed in a report to Congress detailing the access standards, which is required by 38 U.S.C. 1703B(d)(1).

A prime consideration were the existing standards in the Veterans Choice Program; these standards measure timeliness of and distance to receive care. Other access standards that VA researched measured the distance from the patient's home to the service needed, whereas VA currently measures, under the Veterans Choice Program, the distance from the patient's home to the nearest VA medical facility with a full-time primary care physician. This difference means that veterans, particularly in rural areas, currently must often travel farther to receive specialty care than they would under the proposed rule, if finalized, because they do not qualify for community care under the Veterans Choice Program distance criterion Changing VA's distance-related measurement for community care to be the distance from the patient's home to the care or service needed would assist VA in determining when covered veterans can be served directly by VA and when covered veterans can choose community care, thereby helping to ensure adequate health care access for covered veterans.

Further changing the standard to refer to an average driving time would recognize that distance is often a poor indicator of actual conditions; veterans in large metropolitan areas may be physically closer to VA facilities than their counterparts in rural areas, but may actually face more significant challenges in accessing care based on traffic. Adopting access standards based on average driving time would result in more equitable access for all covered veterans. VA's proposal to use the average driving time is premised on the use of a personal vehicle, but we believe this applies to many of the veterans we serve, and that it would be too difficult to fairly and consistently implement and operationalize a system that considered the variety of transportation options potentially available to an individual veteran. We note that the proposed approach is similar to that taken by DoD.

Using the results of its access standards analysis, VA developed and modeled several options using VA's Enrollee Health Care Projection Model. After considering this information, VA determined that its access standards should reflect a driving time-based criterion that considers the care or services needed in relation to the veteran's residence and should reflect a wait-time criterion that would be considered in tandem with the driving time criterion. VA used the same rationale as TRICARE Prime in proposing its standards related to travel standards, opting to use time versus distance. To reiterate, distance-based criteria do not recognize the inherent variation of driving speeds in rural versus urban areas. Traffic levels and speed limits allow rural residents to travel farther and faster than urban residents. The switch to average drive-time criteria versus distance provides a more consistent standard of access for urban and rural veterans. More specific analyses showed trends of 30-minute drive times for primary care and 60-minute drive times for specialty care in TRICARE, State Medicaid plans, State insurance departments, and commercial health plans. VA determined that it would be reasonable to fall in line with these other network expectations throughout the industry. The proposed wait-time standards would similarly fall within the range of appointment wait-time standards found in other government organizations, State programs, and commercial entities (*e.g.,* 7–28 days for primary care and 15–30 days for specialty care). Further, the

proposed wait-time standards are achievable in most VA facilities and are consistent with capabilities identified in the private sector. On average, VA national wait times (as of December 2018) for new appointments (*e.g.,* the first appointment in a new episode of care versus a subsequent appointment in the continuation of an existing episode of care) are approximately 21.6 days for primary care, 11.2 days for mental health care, and 23.2 days for specialty care. We note that data presented in VA's report to Congress, and that VA has provided previously to Congress, includes different averages, but this variance is due simply to when the data were collected; the information in the report to Congress and what has previously been provided was from the fall of 2018. The proposed wait-time standard of 20 days for primary care and mental health, for example, is both in line with other similar industry standards and is a manageable goal for access to VA care.

The following access standards would therefore be designated in proposed § 17.4040(a) to apply for purposes of eligibility determinations under § 17.4010(a)(4). For primary care, mental health care, and non-institutional extended care services, proposed § 17.4040(a)(1) would establish that the access standard would not be met if VA cannot schedule an appointment for a covered veteran with a VA health care provider that can furnish the required care or services within 30 minutes average driving time of the veteran's residence, and within 20 days of the date of request, unless a later date has been agreed to by the veteran in consultation with the VA provider. For specialty care, proposed § 17.4040(a)(2) would establish that the designated access standard would not be met if VA cannot schedule an appointment for the covered veteran with a VA health care provider that can furnish the required care or services within 60 minutes average driving time of the veteran's residence, and within 28 days of the date of request, unless a later date has been agreed to by the veteran in consultation with the VA provider.

The later date that a veteran could agree to be scheduled for an appointment would be determined through the veteran's consultation with a VA health care provider. This consultation would ensure that the veteran's preferred date to be seen, as well as clinical considerations regarding the appropriate time for an appointment, were taken into account. For instance, veterans might agree to a later date because they prefer to be seen after the 20 or 28 days (as applicable) from the date they contact VA to request an appointment, such as if the veteran expects to be traveling. In such a case, the veteran might discuss this later date with a provider to ensure that it was clinically appropriate to delay the appointment.

A veteran might also agree to a later date because the provider has consulted with the veteran, and the provider has determined that an appointment would not be clinically useful until after the 20 or 28 days (as applicable) from the date the veteran might contact VA to request an appointment. This scenario most often arises in the context of follow-up appointments, where a veteran might contact VA to schedule an appointment that is, for instance, no sooner than 30 days away to accommodate the completion of necessary diagnostic tests that were ordered by the provider as part of the veteran's prior appointment. This scenario can also arise outside of the context of typical follow-up care, such as for regularly scheduled, routine care or treatment that typically occurs perhaps only once or twice a year. For instance, a veteran could agree to a later date for a routine dental cleaning that the veteran typically schedules to receive every six months.

The option in proposed § 17.4040(a)(1)(ii) and (a)(2)(ii) for a veteran to agree to a later date is similar to the definition of the term wait-time goals of the Veterans Health Administration in current § 17.1505, because the veteran's preference as well as clinical appropriateness would continue to be considered in determining the later date. We believe that proposed § 17.4040(a)(1)(ii) and (a)(2)(ii) are more simply stated than current § 17.1505, and are framed in a more veteran-centric manner because these provisions propose to shift the decision for the later date entirely to the veteran. In practice, we do not believe that this proposed shift would create significant changes in veteran eligibility for VA community care based on the wait-time standard, because the veteran's agreement to a later date would still be informed by consultation with the VA health care provider. However, as proposed § 17.4040(a)(1)(ii) and (a)(2)(ii) would be a significant technical change from the way the wait-time goals of the Veterans Health Administration are written in current § 17.1505, we invite comment on this issue as with other changes as described in this rulemaking.

A full explanation of the estimated impact of these proposed access standards, when compared to the distance-based and wait-time based standards in current § 17.1510(b)(1) and (b)(2), can be found in the *Regulatory Impact Analysis* that accompanies this proposed rule, which can be found as a supporting document at *http://www.regulations.gov* and is available on VA's website at *http://www.va.gov/orpm/,* by following the link for ''VA Regulations Published From FY 2004 Through Fiscal Year to Date.'' For purposes of this rulemaking, VA believes these proposed access standards are reasonable applications of VA's discretion to establish access standards in 38 U.S.C. 1703B. Section 1703B confers broad authority on the Secretary to establish access standards, and sections 1703B and 1703(d)(1)(D) further authorize the Secretary to designate certain access standards as the basis for eligibility for community care.

Proposed § 17.4040(b) would establish, similar to current § 17.1510(e), that for purposes of calculating the distance from the veteran's residence to a VA facility for eligibility determinations, VA would use geographic information system software. As with current § 17.1510(e), proposed § 17.4040(b) cannot be more specific in naming the system software or describing its methodology because it is proprietary. The most substantive change from current § 17.1510(e) is that proposed § 17.4040(b) would use the phrase average driving time instead of driving distance, because the access standards under proposed § 17.4040(a) would be based on average driving time. The average driving time in proposed § 17.4040(a) and (b) would be calculated by using the geographic information system software to calculate the average drive time from the veteran's residence to the applicable VA facility, based on predictive traffic patterns from historical data, as opposed to real-time traffic conditions.

We note that we do not propose to regulate the process described in section 1703B(h), which must be followed to review requests from veterans to determine whether or not VA can furnish care or services within the designated access standards. Because this is a procedural requirement relating to VA's operations and will not affect veteran eligibility, we are not proposing to include this process in this rulemaking, but will establish such a process through internal policy. However, we anticipate that veterans would contact VA to request such reviews in the same manner they would contact VA to seek care generally that then might be referred to the community under an access standard.

We further note that we have considered whether VA would want to ensure the continued utilization of VA

care and services that VA has particular expertise in directly providing, such as VA's specialized care models for veterans with disabilities such as traumatic brain injury, posttraumatic stress disorder, and military sexual trauma. VA Centers of Excellence, such as the Polytrauma Rehabilitation Centers, deliver certain types of specialized care that may improve quality of care or reduce costs when compared with similar care that might be furnished in the community. However, there are far fewer Centers of Excellence than VA medical centers, and as there would be fewer locations in relation to the total number of veterans nationwide, travel distances for veterans to these Centers of Excellence could in many cases exceed the designated access standards in this rule. At this time, VA does not propose to designate (or not designate) particular access standards for these or other types of more specialized care; the general specialty care access standards would apply. Moreover, veterans would be made aware if such care was available from VA outside of the designated access standards to be fully informed of their options prior to electing to receive care in the community or in VA. Similarly, VA does not propose at this time to designate particular access standards for care that it might consider to be its foundational services. VA will continue to sharpen its focus on directly providing those services that are most important to the coordination and management of a veteran's overall medical and health needs, while purchasing services that can be as effectively or more conveniently delivered by non-VA providers. VA will continue to examine whether its proposed designated access standards should be revised with future rulemakings to account for such specialized areas of expertise as the care provided by Centers of Excellence or other similar organizations within VA (such as the War Related Illness and Injury Study Center), as well as VA's foundational services, and we welcome public comment on whether any of these services, or others, should be further considered in terms of designated access standards for purposes of eligibility for community care.

We note that institutional extended care services (nursing home care) are not the subject of a designated access standard; the designated access standards in paragraphs (a) and (b) only cover primary care, mental health, non-institutional extended care, and specialty care, but nursing home care does not fit within any of these categories. Nursing home care is distinct from specialty care—it is a form of extended care services, and is subject to copayments related to extended care services under § 17.111 (as opposed to specialty care, which is subject to copayments under § 17.108). We have not included a designated access standard for nursing home care because of the unique nature of this care, as it is VA's anecdotal experience in referring nursing home care to the community that the relative scarcity of such resources in the community, the variability in quality in community nursing homes, and the expense associated with such care are all variables that make the assignment of a standardized wait time, for instance, impracticable. Any covered veteran requiring nursing home care may still qualify to receive such care in the community, but the veteran would have to qualify for non-VA care under this section under a different eligibility criterion in § 17.1410(a).

Section 17.4040 would establish access standards that would be applicable until further rulemaking amended them. VA has preliminarily determined that its goal is to revise over time the access standards that would be designated in proposed § 17.4040, after designated access standards are made effective through final rulemaking, in order to reduce the maximum wait-times for primary and mental health care services from 20 days to 14 days no sooner than June 2020. This reduction from 20 days to 14 days is not proposed in this rulemaking, and VA would need to publish a future rulemaking should it proceed with this goal. Presently, implementing a 14-day wait-time standard would be difficult for VA due to the current availability of primary care providers and variability in primary care appointment wait-times across VA facilities. However, we share this goal with the public at this time, as it may influence the comments submitted by the public on the current proposed designated access standard of 20 days.

Improving VA

While this proposed rulemaking has focused on the new Veterans Community Care Program required by the MISSION Act, we believe it is important to note that the MISSION Act also improves care furnished directly in VA facilities in a number of ways. For example, section 1703C of title 38, U.S.C. as added by section 104 of the MISSION Act, requires VA to establish standards for quality. VA is proposing standards for quality in a report that will be submitted to Congress no later than March 4, 2019. If VA designated a medical service line under proposed § 17.4015, we would also be required to begin remediation efforts for that service line under section 1706A. However, VA's remediation efforts will not be limited to just those service lines designated under § 17.4015. In addition to establishing standards for quality, section 1703C requires VA to publish the quality rating of VA medical facilities in the Hospital Compare website for the purpose of providing Veterans with information that allows them to compare performance measure information among VA and non-VA health care providers. We take this charge seriously, and will be monitoring performance to ensure we direct resources appropriately. We will develop a consolidated and integrated network of community providers to ensure that all Veteran care furnished by VA, whether delivered in our facilities or purchased in the community, represents the best possible care, every time and everywhere.

As noted earlier, each year, VA will incorporate the collected data, assessments, and remediation plans under sections 1703C and 1706A to inform its resourcing requirements and prioritization of those resources. VA will also consider performance of its facilities against its access standards for appointment wait times when making resource allocation decisions.

There are numerous provisions within the MISSION Act that require the assessment, collection, and monitoring of data about VA performance and improvement, including information on remediation, on a regular annual basis. See, *e.g.,* sections 401(d) and 505(b) of the MISSION Act; see also sections 1703(m)(1), (3); 1703B(d)(3); 1703B(e); and 1706A(d)(1). VA is also required, on a quadrennial basis, to conduct market assessments and develop a strategic plan that specifies a four-year forecast of demand for care and capacity to furnish care in VA and in the community. Through these requirements, VA will provide analyses and assessments on VA's performance in terms of timeliness, quality, and other elements of its health care system collected at the level of the medical service line, and no less than annually, VA will develop and publish a consolidated report detailing a description of care provided both internally and externally. This information will be used to detail resource allocations and the related budget requirements to address quality and access issues, as well as for efforts to improve the VA workforce and

address the problem of underserved facilities.

Effect of Rulemaking

The Code of Federal Regulations, as proposed to be revised by this proposed rulemaking, would represent the exclusive legal authority on this subject. No contrary rules or procedures would be authorized. All VA guidance would be read to conform with this proposed rulemaking if possible or, if not possible, such guidance would be superseded by this rulemaking.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. Under 44 U.S.C. 3507(a), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number. See also 5 CFR 1320.8(b)(2)(vi).

This proposed rule would amend information collection requirements currently approved under control number 2900–0823 and would impose new collections of information requirements and burden. VA will separately notice and take comment on the information collection requirements associated with this proposed rulemaking in the **Federal Register**. As required by 44 U.S.C. 3507(d), VA will submit these information collection amendments to OMB for its review. Notice of OMB approval for this information collection will be published in a future **Federal Register** document.

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Although some eligible entities or providers that would furnish care and services to veterans under this rule might be considered small entities, there would be no significant adverse economic impact. To the extent there is any impact on small entities, it would be a potential increase in business due to proposed expanded eligibility for non-VA care. While this rulemaking defines payment rates and eligible entities and providers, it does so in a way that is consistent with VA's current authorities. We note that a separate and subsequent rulemaking, RIN 2900–AQ45, will authorize VA to enter into agreements with eligible providers, many of whom will likely be small businesses. We will further consider the effects on such entities through that rulemaking. We also do not believe there will be a significant economic impact on insurance companies, as claims would only be submitted for care that would otherwise have been received whether such care was authorized under this Program or not. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866, 13563 and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' which requires review by OMB, 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; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

VA has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action and determined that the action would be an economically significant regulatory action under Executive Order 12866. VA's regulatory impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at *http://www.va.gov/orpm* by following the link for VA Regulations Published from FY 2004 through FYTD. This proposed rule is expected to be an E.O. 13771 regulatory action. Details on the estimated costs of this proposed rule can be found in the rule's economic analysis. Preliminary estimates of the administrative costs that would be tallied for E.O. 13771 purposes appear in the rightmost column of the Regulatory Impact Analysis (RIA) Table 8.

Executive Order 12866 also directs agencies to ''in most cases . . . include a comment period of not less than 60 days.'' This regulation would replace the existing Veterans Choice Program and VA's traditional community care program to be the means for covered veterans to receive VA care in the community from eligible entities or providers. Providing a 30-day comment period would allow the Secretary to ensure a smooth transition from the current Veterans Choice Program that will expire on June 6, 2019, and prevent lapses in regulatory oversight for VA's national community care program. On June 6, 2019, if this rulemaking is not finalized, no one other VA authority would permit expressly the application of the time and geographic standards in determining eligibility for VA community care, which the public and veterans have come to expect. Delays in implementation of the Veterans Community Care Program arising because the regulatory standards and guidelines were not in place by June 6, 2019, would result in inconsistent decision making in VA facilities, which would increase the likelihood that veterans' care would be delayed. Having clear, consistent criteria is essential to ensuring that Veterans receive the right care in the right place at the right time. Moreover, we believe VA community care is now a familiar benefit to the public, and that 30 days would be a sufficient period of time for the public to comment on this rulemaking, which incorporates many of the provisions of the prior Veterans Choice Program. In sum, providing a 60-day public comment period instead of a 30-day public comment period would be against public interest and contrary to the health and safety of eligible veterans. For the above reasons, the Secretary issues this rule with a 30-day public comment period. VA will consider and address comments that are received within 30 days of the date this proposed rule is published in the **Federal Register**.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are as follows: 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical devices, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Veterans.

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Wilkie, Secretary, Department of Veterans Affairs, approved this document on January 2, 2019, for publication.

Dated: January 15, 2019.

Michael P. Shores,

Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set forth in the preamble, we propose to amend 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The general authority citation and specific authority citations for part 17 continue to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

* * * * *

Section 17.46 is also issued under 38 U.S.C. 1710.

* * * * *

Section 17.52 is also issued under 38 U.S.C. 1701, 1703, 1710, 1712, and 3104.

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Section 17.55 is also issued under 38 U.S.C. 513, 1703, and 1728.

Section 17.56 is also issued under 38 U.S.C. 1703 and 1728.

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Section 17.108 is also issued under 38 U.S.C. 501, 1703, 1710, 1725A, and 1730A.

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Section 17.110 is also issued under 38 U.S.C. 501, 1703, 1710, 1720D, 1722A, and 1730A.

Section 17.111 is also issued under 38 U.S.C. 101(28), 501, 1701(7), 1703, 1710, 1710B, 1720B, 1720D, and 1722A.

* * * * *

Section 17.4000 *et seq.* is also issued under 38 U.S.C. 1703, 1703B, and 1703C.

* * * * *

§ 17.46 [Amended]

■ 2. Amend § 17.46 in paragraph (a) introductory text by adding the phrase ''prior to June 6, 2019,'' after the phrase ''In furnishing hospital care''.

■ b. Removing the authority citation at the end of paragraph (a) and paragraph (b).

■ 3. Amend § 17.52 by removing the authority citations following paragraphs (a)(1) through (10) and by adding paragraph (c).

The addition reads as follows:

§ 17.52 Hospital care and medical services in non-VA facilities.

* * * * *

(c) The provisions of this section shall not apply to care furnished by VA after June 6, 2019.

§ 17.54 [Removed and Reserved]

■ 4. Remove and reserve § 17.54.

■ 5. Amend § 17.55 by revising the introductory text and removing the authority citation at the end of the section.

The revision reads as follows:

§ 17.55 Payment for authorized public or private hospital care.

Except as otherwise provided in this section, payment for public or private hospital care furnished prior to June 6, 2019, under 38 U.S.C. 1703 and 38 CFR 17.52, or at any time under 38 U.S.C. 1728 and 38 CFR 17.120 and 17.128 of this part or under 38 U.S.C. 1787 and 38 CFR 17.410 of this part, shall be based on a prospective payment system similar to that used in the Medicare program for paying for similar inpatient hospital services in the community. Payment shall be made using the Centers for Medicare & Medicaid Services (CMS) PRICER for each diagnosis-related group (DRG) applicable to the episode of care.

* * * * *

■ 6. Amend § 17.56 by adding paragraph (e) and removing the authority citation at the end of the section.

The addition reads as follows:

§ 17.56 VA payment for inpatient and outpatient health care professional services at non-departmental facilities and other medical charges associated with non-VA outpatient care.

* * * * *

(e) Except for payments for care furnished under 38 U.S.C. 1725 and section 17.1005 of this part, under 38 U.S.C. 1728 and 38 CFR 17.120 and 17.128 of this part, or under 38 U.S.C. 1787 and 38 CFR 17.410 of this part, the provisions of this section shall not apply to care furnished by VA after June 6, 2019, or care furnished pursuant to an agreement authorized by 38 U.S.C. 1703A.

* * * * *

■ 7. Amend § 17.108:

■ a. In paragraph (b)(4), by adding the phrase '', or the Veterans Community Care Program under § 17.4000 through 17.4040'' after the phrase ''Veterans Choice Program under § 17.1500 through 17.1540'';

■ b. In paragraph (c)(4), by adding the phrase '', or the Veterans Community Care Program under § 17.4000 through 17.4040'' after the phrase ''Veterans Choice Program under § 17.1500 through 17.1540''; and

■ c. Removing the authority citation at the end of the section.

§ 17.110 [Amended]

■ 8. Amend § 17.110 in paragraph (b)(4) by adding the phrase '', or the Veterans Community Care Program under § 17.4000 through 17.4040'' after the phrase ''Veterans Choice Program under § 17.1500 through 17.1540'' and by removing the authority citation at the end of the section.

§ 17.111 [Amended]

■ 9. Amend § 17.111 by in paragraph (b)(3) by adding the phrase '', as well as extended care services furnished through the Veterans Community Care Program under § 17.4000 through 17.4040,'' after the phrase ''hospital care and medical services considered non-

institutional care furnished through the Veterans Choice Program under § 17.1500 through 17.1540'' and by removing the authority citation at the end of the section.

§ 17.1004 [Amended]

■ 10. Amend § 17.1004 in paragraph (b) introductory text by removing the phrase ''HCFA 1500'' and adding in its place ''CMS 1500'' and by removing the authority citation at the end of the section.

■ 11. Add an undesignated center heading and §§ 17.4000 through 17.4040 to read as follows:

Veterans Community Care Program

Sec.
17.4000 Purpose and scope.
17.4005 Definitions.
17.4010 Veteran eligibility.
17.4015 Designated VA medical service lines.
17.4020 Authorized non-VA care.
17.4025 Effect on other provisions.
17.4030 Eligible entities and providers.
17.4035 Payment rates.
17.4040 Designated access standards.

Veterans Community Care Program

§ 17.4000 Purpose and scope.

(a) *Purpose.* Sections 17.4000 through 17.4040 implement the Veterans Community Care Program, authorized by 38 U.S.C. 1703.

(b) *Scope.* The Veterans Community Care Program establishes when a covered veteran may elect to have VA authorize an episode of care for hospital care, medical services, or extended care services from an eligible entity or provider. Sections 17.4000 through 17.4040 do not affect eligibility for non-VA care under sections 1724, 1725, 1725A, or 1728 of title 38, United States Code.

§ 17.4005 Definitions.

For purposes of the Veterans Community Care Program under §§ 17.4000 through 17.4040:

Appointment means an authorized and scheduled encounter with a health care provider for the delivery of hospital care, medical services, or extended care services.

Covered veteran means a veteran enrolled under the system of patient enrollment in § 17.36, or a veteran who otherwise meets the criteria to receive care and services notwithstanding his or her failure to enroll under 38 U.S.C. 1705(c)(2).

Eligible entity or provider means a health care entity or provider that meets the requirements of § 17.4030.

Episode of care means a necessary course of treatment, including follow-up appointments and ancillary and specialty services, which lasts no longer than 1 calendar year.

Extended care services include the same services as described in 38 U.S.C. 1710B(a).

Full-service VA medical facility means a VA medical facility that provides hospital care, emergency medical services, and surgical care and having a surgical complexity designation of at least ''standard.''

Note: VA maintains a website with a list of the facilities that have been designated with at least a surgical complexity of ''standard,'' which can be accessed on VA's website.

Hospital care has the same meaning as defined in 38 U.S.C. 1701(5).

Medical services have the same meaning as defined in 38 U.S.C. 1701(6).

Other health-care plan contract means an insurance policy or contract, medical or hospital service agreement, membership or subscription contract, or similar arrangement not administered by the Secretary of Veterans Affairs, under which health services for individuals are provided or the expenses of such services are paid; and does not include any such policy, contract, agreement, or similar arrangement pursuant to title XVIII or XIX of the Social Security Act (42 U.S.C. 1395 *et seq.*) or chapter 55 of title 10, United States Code.

Residence means a legal residence or personal domicile, even if such residence is seasonal. A covered veteran may maintain more than one residence but may only have one residence at a time. If a covered veteran lives in more than one location during a year, the covered veteran's residence is the residence or domicile where they are staying at the time they want to receive hospital care, medical services, or extended care services through the Veterans Community Care Program. A post office box or other non-residential point of delivery does not constitute a residence.

Schedule means identifying and confirming a date, time, location, and entity or health care provider for an appointment in advance of such appointment.

Note: A VA telehealth encounter and a same-day care encounter are considered to be scheduled even if such an encounter is conducted on an ad hoc basis.

VA facility means a VA facility that offers hospital care, medical services, or extended care services.

VA medical service line means a specific medical service or set of services delivered in a VA facility.

§ 17.4010 Veteran eligibility.

Section 1703(d) of title 38, U.S.C., establishes the conditions under which, at the election of the veteran and subject to the availability of appropriations, VA must furnish care in the community through eligible entities and providers. VA has regulated these conditions under paragraphs (a)(1) through (5) of this section. If VA determines that a covered veteran meets at least one or more of the conditions in paragraph (a) of this section and has provided information required by paragraphs (b) and (c) of this section, the covered veteran may elect to receive authorized non-VA care under § 17.4020.

(a) The covered veteran requires hospital care, medical services, or extended care services and:

(1) No VA facility offers the hospital care, medical services, or extended care services the veteran requires.

(2) VA does not operate a full-service VA medical facility in the State in which the veteran resides.

(3) The veteran was eligible to receive care and services from an eligible entity or provider under section 101(b)(2)(B) of the Veterans Access, Choice, and Accountability Act of 2014 (Pub. L. 113–146, sec. 101, as amended; 38 U.S.C. 1701 note) as of June 5, 2018, and continues to reside in a location that would qualify the veteran under that provision, and:

(i) Resides in Alaska, Montana, North Dakota, South Dakota, or Wyoming; or

(ii) Does not reside in one of the States described in paragraph (a)(3)(i) of this section, but received care or services under title 38 U.S.C. between June 6, 2017, and June 6, 2018, and is seeking care before June 6, 2020.

(4) Has contacted an authorized VA official to request the care or services the veteran requires, but VA has determined it is not able to furnish such care or services in a manner that complies with designated access standards established in § 17.4040.

(5) The veteran and the veteran's referring clinician determine it is in the best medical interest of the veteran, to access the care or services the veteran requires from an eligible entity or provider, based on one or more of the following factors, as applicable:

(i) The distance between the veteran and the facility or facilities that could provide the required care or services;

(ii) The nature of the care or services required by the veteran;

(iii) The frequency the veteran requires the care or services;

(iv) The timeliness of available appointments for the required care or services;

(v) The potential for improved continuity of care;

(vi) The quality of the care provided;

(vii) Whether the veteran faces an unusual or excessive burden in accessing a VA facility based on consideration of the following:

(A) Excessive driving distance; geographical challenges, such as the presence of a body of water (including moving water and still water) or a geologic formation that cannot be crossed by road; or environmental factors, such as roads that are not accessible to the general public, traffic, or hazardous weather.

(B) Whether care and services are available from a VA facility that is reasonably accessible.

(C) Whether a medical condition of the veteran affects the ability to travel.

(D) Whether there is a compelling reason the veteran needs to receive care and services from a non-VA facility.

(E) The need for an attendant, which is defined as a person who provides required aid and/or physical assistance to the veteran, for a veteran to travel to a VA medical facility for hospital care or medical services.

(6) In accordance with § 17.4015, VA has determined that a VA medical service line that would furnish the care or services the veteran requires is not providing such care or services in a manner that complies with VA's standards for quality.

(b) If the covered veteran changes his or her residence, the covered veteran must update VA about the change within 60 days.

(c) A covered veteran must provide to VA information on any other health-care plan contract under which the veteran is covered prior to obtaining authorization for care and services the veteran requires. If the veteran changes such other health-care plan contract, the veteran must update VA about the change within 60 days.

(d) Review of veteran eligibility determinations. The review of any decisions under paragraph (a) of this section are subject to VA's clinical appeals process, and such decisions may not be appealed to the Board of Veterans' Appeals.

(The information collection is pending Office of Management and Budget approval.)

§ 17.4015 Designated VA medical service lines.

(a) VA may identify VA medical service lines that are underperforming based on the timeliness of care when compared with the same medical service line at other VA facilities and based on data related to two or more distinct and appropriate quality measures of VA's standards for quality when compared with non-VA medical service lines.

(b) VA will make determinations regarding VA medical service lines under this section using data described in paragraph (a) of this section, VA standards for quality, and based on factors identified in paragraph (e) of this section.

(c) VA will announce annually any VA medical service lines identified under paragraph (a) of this section by publishing a document in the **Federal Register**. Such document will identify and describe the standards for quality VA used to inform the determination under paragraph (a), as well as how the data described in paragraph (a) and factors identified in paragraph (e) of this section were used to make the determinations. Such document will also identify limitations, if any, concerning when and where covered veterans can receive qualifying care and services at their election in the community based on this section. Such limitations may include a defined timeframe, a defined geographic area, and a defined scope of services. VA will also take reasonable steps to provide direct notice to covered veterans affected under this section.

(d) VA will identify no more than 3 VA medical services lines in a single VA facility under this section, and no more than 36 VA medical service lines nationally under this section.

(e) In determining whether a VA medical service line should be identified under paragraph (a) of this section, and to comply with paragraph (c) of this section, VA will consider:

(1) Whether the differences between performance of individual VA medical service lines, and between performance of VA medical service lines and non-VA medical service lines, is clinically significant.

(2) Likelihood and ease of remediation of the VA medical service line within a short timeframe.

(3) Recent trends concerning the VA medical service line or non-VA medical service line.

(4) The number of covered veterans served by the medical service line or that could be affected by the designation.

(5) The potential impact on patient outcomes.

(6) The effect that designating one VA medical service line would have on other VA medical service lines.

§ 17.4020 Authorized non-VA care.

(a) *Electing non-VA care.* A covered veteran eligible for the Veterans Community Care Program under § 17.4010 may choose to schedule an appointment with a VA health care provider, or have VA authorize the veteran to receive an episode of care for hospital care, medical services, or extended care services from an eligible entity or provider when VA determines such care or services are clinically necessary.

(b) *Selecting an eligible entity or provider.* A covered veteran may specify a particular eligible entity or provider. If a covered veteran does not specify a particular eligible entity or provider, VA will refer the veteran to a specific eligible entity or provider.

(c) *Authorizing emergency treatment.* This paragraph applies only to emergency treatment furnished to a covered veteran by an eligible entity or provider when such treatment was not the subject of an election by a veteran under paragraph (a) of this section. This paragraph does not affect eligibility for, or create any new rules or conditions affecting, reimbursement for emergency treatment under section 1725 or 1728 of title 38, United States Code.

(1) Under the conditions set forth in this paragraph, VA may authorize emergency treatment after it has been furnished to a covered veteran. For purposes of this paragraph, ''emergency treatment'' has the meaning defined in section 1725(f)(1) of title 38, United States Code.

(2) VA may only authorize emergency treatment under this paragraph if the covered veteran, someone acting on the covered veteran's behalf, or the eligible entity or provider notifies VA within 72-hours of such care or services being furnished and VA approves the furnishing of such care or services under paragraph (c)(3) of this section.

(3) VA may approve emergency treatment of a covered veteran under this paragraph only if:

(i) The veteran is receiving emergency treatment from an eligible entity or provider.

(ii) The notice to VA complies with the provisions of paragraph (c)(4) of this section and is submitted within 72 hours of the beginning of such treatment.

(iii) The emergency treatment only includes services covered by VA's medical benefits package in § 17.38 of this part.

(4) Notice to VA must:

(i) Be made to the appropriate VA official at the nearest VA facility;

(ii) Identify the covered veteran; and

(iii) Identify the eligible entity or provider.

§ 17.4025 Effect on other provisions.

(a) *General.* No provision in this section may be construed to alter or modify any other provision of law establishing specific eligibility criteria for certain hospital care, medical services, or extended care services.

(b) *Prescriptions.* Notwithstanding any other provision of this part, VA will:

(1) Pay for prescriptions written by eligible entities or providers for covered veterans, including over-the-counter drugs and medical and surgical supplies, available under the VA national formulary system to cover a course of treatment no longer than 14 days.

(2) Fill prescriptions written by eligible entities or providers for covered veterans, including over-the-counter drugs and medical and surgical supplies, available under the VA national formulary system.

(3) Pay for prescriptions written by eligible entities or providers for covered veterans that have an immediate need for durable medical equipment and medical devices that are required for urgent or emergent conditions (*e.g.,* splints, crutches, manual wheelchairs).

(4) Fill prescriptions written by eligible entities or providers for covered veterans for durable medical equipment and medical devices that are not required for urgent or emergent conditions.

(c) *Copayments.* Covered veterans are liable for a VA copayment for care or services furnished under the Veterans Community Care Program, if required by § 17.108(b)(4), § 17.108(c)(4), § 17.110(b)(4), or § 17.111(b)(3).

§ 17.4030 Eligible entities and providers.

To be eligible to furnish care and services under the Veterans Community Care Program, entities or providers:

(a) Must enter into a contract, agreement, or other arrangement to furnish care and services under the Veterans Community Care Program under §§ 17.4000 through 17.4040.

(b) Must either:

(1) Not be a part of, or an employee of, VA; or

(2) If the provider is an employee of VA, not be acting within the scope of such employment while providing hospital care, medical services, or extended care services through the Veterans Community Care Program under §§ 17.4000 through 17.4040.

(c) Must be accessible to the eligible veteran. VA will determine accessibility by considering the following factors:

(1) The length of time the eligible veteran would have to wait to receive hospital care, medical services, or extended care services from the entity or provider;

(2) The qualifications of the entity or provider to furnish the hospital care, medical services, or extended care services from the entity or provider; and

(3) The distance between the eligible veteran's residence and the entity or provider.

§ 17.4035 Payment rates.

The rates paid by VA for hospital care, medical services, and extended care services (hereafter in this section referred to as ''services'') furnished pursuant to a procurement contract or an agreement authorized by section 1703A of this title will be the rates set forth in the terms of such contract or agreement. Such payment rates will comply with the following parameters:

(a) Except as otherwise provided in this section, payment rates will not exceed the applicable Medicare fee schedule (including but not limited to allowable rates under 42 U.S.C. 1395m) or prospective payment system amount (hereafter ''Medicare rate''), if any, for the period in which the service was provided (without any changes based on the subsequent development of information under Medicare authorities).

(b) With respect to services furnished in a State with an All-Payer Model Agreement under section 1814(b)(3) of the Social Security Act (42 U.S.C. 1395f(b)(3)) that became effective on or after January 1, 2014, the Medicare payment rates under paragraph (a) of this section will be calculated based on the payment rates under such agreement.

(c) Payment rates for services furnished in a highly rural area may exceed the limitations set forth in paragraphs (a) and (b) of this section. The term ''highly rural area'' means an area located in a county that has fewer than seven individuals residing in that county per square mile.

(d) Payment rates may deviate from the parameters set forth in paragraphs (a) through (c) of this section when VA determines, based on patient needs, market analyses, health care provider qualifications, or other factors, that it is not practicable to limit payment for services to the rates available under paragraphs (a) through (c).

(e) Payment rates for services furnished in Alaska are not subject to paragraphs (a) through (d) of this section and will be set forth in the terms of the procurement contract or agreement authorized by section 1703A of this title, pursuant to which such services are furnished. If no payment rate is set forth in the terms of such a contract or agreement pursuant to which such services are furnished, payment rates for services furnished in Alaska will follow the Alaska Fee Schedule of the Department of Veterans Affairs.

§ 17.4040 Designated access standards.

(a) The following access standards have been designated to apply for purposes of eligibility determinations to access care in the community through the Veterans Community Care Program under § 17.4010(a)(4).

(1) Primary care, mental health care, and non-institutional extended care services: VA cannot schedule an appointment for the covered veteran with a VA health care provider for the required care or service:

(i) Within 30 minutes average driving time of the veteran's residence, and

(ii) Within 20 days of the date of request unless a later date has been agreed to by the veteran in consultation with the VA health care provider.

(2) Specialty care: VA cannot schedule an appointment for the covered veteran with a VA health care provider for the required care or service:

(i) Within 60 minutes average driving time of the veteran's residence, and

(ii) Within 28 days of the date of request unless a later date has been agreed to by the veteran in consultation with the VA health care provider.

(b) For purposes of calculating average driving time from the veteran's residence in paragraph (a) of this section, VA will use geographic information system software.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA–R04–RCRA–2019–0768; FRL–9989–92–Region 4]

Florida: Proposed Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Florida has applied to the Environmental Protection Agency (EPA) for final authorization of changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA), as amended. EPA has reviewed Florida's application and has determined, subject to public comment, that these changes satisfy all requirements needed to qualify for final

authorization. Therefore, we are proposing to authorize the State's changes. EPA seeks public comment prior to taking final action.

DATES: Comments must be received on or before March 25, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–RCRA–2019–0768, at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *www.regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Leah Davis, Materials and Waste Management Branch, RCR Division, U.S. Environmental Protection Agency, Atlanta Federal Center, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960; telephone number: (404) 562–8562; fax number: (404) 562–9964; email address: *davis.leah@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. Why are revisions to state programs necessary?

States that have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, states must change their programs and ask EPA to authorize the changes. Changes to state programs may be necessary when Federal or state statutory or regulatory authority is modified or when certain other changes occur. Most commonly, states must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 268, 270, 273, and 279.

New Federal requirements and prohibitions imposed by Federal regulations that EPA promulgates pursuant to the Hazardous and Solid Waste Amendments of 1984 (HSWA) take effect in authorized states at the same time that they take effect in unauthorized states. Thus, EPA will implement those requirements and prohibitions in Florida, including the issuance of new permits implementing those requirements, until the State is granted authorization to do so.

B. What decisions has EPA made in this proposed rule?

Florida submitted a final complete program revision application, dated August 31, 2018, seeking authorization of changes to its hazardous waste program that correspond to certain Federal rules promulgated between July 1, 1991 and June 30, 2017 (including RCRA Clusters [1] II, III, IX, XVIII, XX, XXII, XXIII, XXIV, and XXV). EPA concludes that Florida's application to revise its authorized program meets all of the statutory and regulatory requirements established under RCRA, as set forth in RCRA section 3006(b), 42 U.S.C. 6926(b), and 40 CFR part 271. Therefore, EPA proposes to grant Florida final authorization to operate its hazardous waste program with the changes described in the authorization application, and as outlined below in Section F of this document.

Florida has responsibility for permitting treatment, storage, and disposal facilities within its borders (except in Indian country) and for carrying out the aspects of the RCRA program described in its program revision application, subject to the limitations of HSWA, as discussed above.

C. What is the effect of this proposed authorization decision?

If Florida is authorized for the changes described in Florida's authorization application, these changes will become part of the authorized State hazardous waste program, and will therefore be federally enforceable. Florida will continue to have primary enforcement authority and responsibility for its State hazardous waste program. EPA would maintain its authorities under RCRA sections 3007, 3008, 3013, and 7003, including its authority to:

- Conduct inspections, and require monitoring, tests, analyses and reports;
- Enforce RCRA requirements, including authorized State program requirements, and suspend or revoke permits; and
- Take enforcement actions regardless of whether the State has taken its own actions.

This action will not impose additional requirements on the regulated community because the regulations for which EPA is proposing to authorize Florida are already effective under State law, and are not changed by today's proposed action.

D. What happens if EPA receives comments that oppose this action?

EPA will evaluate any comments received on this proposed action and will make a final decision on approval or disapproval of Florida's proposed authorization. Our decision will be published in the **Federal Register**. You may not have another opportunity to comment. If you want to comment on this authorization, you must do so at this time.

E. What has Florida previously been authorized for?

Florida initially received final authorization on January 29, 1985, effective February 12, 1985 (50 FR 3908), to implement the RCRA hazardous waste management program. EPA granted authorization for changes to Florida's program on the following dates: December 1, 1987, effective March 3, 1988 (52 FR 45634); December 16, 1988, effective January 3, 1989 (53 FR 50529); December 14, 1990, effective February 12, 1991 (55 FR 51416); February 5, 1992, effective April 6, 1992 (57 FR 4371); February 7, 1992, effective April 7, 1992 (57 FR 4738); May 20, 1992, effective July 20, 1992 (57 FR 21351); November 9, 1993, effective January 10, 1994 (58 FR 59367); July 11, 1994, effective September 9, 1994 (59 FR 35266); April 16, 1994, effective October 17, 1994 (59 FR 41979); October 26, 1994, effective December 27, 1994 (59 FR 53753); April 1, 1997, effective June 2, 1997 (62 FR 15407); September 18, 2000, effective November 18, 2000 (65 FR 56256); August 23, 2001, effective October 22, 2001 (66 FR 44307); August 20, 2002, effective October 21, 2002 (67 FR 53886 and 67 FR 53889); October 14, 2004, effective December 13, 2004 (69 FR 60964); August 10, 2007, effective October 9, 2007 (72 FR 44973); February 7, 2011, effective April 8, 2011 (76 FR 6564); and October 8, 2014, effective December 8, 2014 (79 FR 60756). The authorized Florida program, through RCRA Cluster IV, was incorporated by reference into

[1] A "cluster" is a grouping of hazardous waste rules that EPA promulgates from July 1st of one year to June 30th of the following year.

the CFR on January 20, 1998, effective March 23, 1998 (63 FR 2896).

F. What changes are we proposing with today's action?

Florida submitted a final complete program revision application, dated August 31, 2018, seeking authorization of changes to its hazardous waste management program in accordance with 40 CFR 271.21. This application included changes associated with Checklists [2] 104, 107, 178, 218, 222, 223, and 228 through 237. Florida previously submitted program revision applications for Checklists 218, 222, 223, and 228 through 235. It resubmitted these Checklists with its August 31, 2018 application in response to EPA comments. EPA proposes to determine, subject to receipt of written comments that oppose this action, that Florida's hazardous waste program revisions are equivalent to, consistent with, and no less stringent than the Federal program, and therefore satisfy all of the requirements necessary to qualify for final authorization. Therefore, EPA is proposing to authorize Florida for the following program changes:

Description of Federal Requirement	*Federal Register* Date and Page	Analogous State authority [3]
Checklist 104, Used Oil Filter Exclusion	57 FR 21524, 5/20/92	F.A.C. 62–730.030(1).
Checklist 107, Used Oil Filter Exclusion; Technical Correction.	57 FR 29220, 7/1/92	F.A.C. 62–730.030(1).
Checklist 178, Petroleum Refining Process Wastes; Leachate Exemption.	64 FR 6806, 2/11/99	F.A.C. 62–730.030(1).
Checklist 218, F019 Exemption for Wastewater Treatment Sludges from Auto Manufacturing Zinc Phosphating Processes.	73 FR 31756, 6/4/08	F.A.C. 62–730.030(1).
Checklist 222, OECD Requirements; Export Shipments of Spent Lead-Acid Batteries.	75 FR 1236, 1/8/10	F.A.C. 62–730.160(1); 62–730.170(1); 62–730.180(1) and (2); and 62–730.181(1).
Checklist 223, Hazardous Waste Technical Corrections and Clarifications.	75 FR 12989, 3/18/10; 75 FR 31716, 6/4/10.	F.A.C. 62–730.020(1); 62–730.030(1); 62–730.160(1); 62–730.170(1); 62–730.180(1) and (2); 62–730.181(1); 62–730.183; and 62–730.220(1).
Checklist 228, Hazardous Waste Technical Corrections and Clarifications.	77 FR 22229, 4/13/12	F.A.C. 62–730.030(1) and 62–730.181(1).
Checklist 229, Conditional Exclusion for Solvent Contaminated Wipes.	78 FR 46448, 7/31/13	F.A.C. 62–730.020(1) and 62–730.030(1).
Checklist 230, Conditional Exclusion for Carbon Dioxide (CO2) Streams in Geologic Sequestration Activities.	79 FR 350,1/3/14	F.A.C. 62–730.020(1) and 62–730.030(1).
Checklist 231, Hazardous Waste Electronic Manifest Rule.	79 FR 7518, 2/7/14	F.A.C. 62–730.020(1); 62–730.160(1); 62–730.170(1); and 62–730.180(1) and (2).
Checklist 232, Revisions to the Export Provisions of the Cathode Ray Tube Rule.	79 FR 36220, 6/26/14	F.A.C. 62–730.020(1) and 62–730.030(1).
Checklist 233, Revisions to the Definition of Solid Waste		
233A	80 FR 1694, 1/13/15.	F.A.C. 62–730.021.
233B		F.A.C. 62–730.020(1); 62–730.021; and 62–730.030(1).
233C		F.A.C. 62–730.030(1).
233D2		F.A.C. 62–730.020(1); 62–730.021; 62–730.030(1); and 62–730.220.
233E		F.A.C. 62–730.020(1) and 62–730.030(1).
Checklist 234, Response to Vacaturs of the Comparable Fuels Rule and the Gasification Rule.	80 FR 18777, 4/8/15	F.A.C. 62–730.020(1) and 62–730.030(1).
Checklist 235, Disposal of Coal Combustion Residuals from Electric Utilities.	80 FR 21301, 4/17/15	F.A.C. 62–730.030(1).
Checklist 236, Imports and Exports of Hazardous Waste	81 FR 85696, 11/28/16; 82 FR 41015, 8/29/17.	F.A.C. 62–730.020(1); 62–730.021; 62–730.030(1); 62–730.160(1); 62–730.170(1); 62–730.180(1) and (2); 62–730.181(1); and 62–730.185(1).
Checklist 237, Hazardous Waste Generator Improvements Rule.	81 FR 85732, 11/28/16	F.A.C. 62–710.210(2); 62–730.020(1); 62–730.021; 62–730.030(1); 62–730.160(1), (3) and (4); 62–730.170(1); 62–730.180(1) and (2); 62–730.181(1); 62–730.183(1); 62–730.185(1); and 62–730.220(1).

G. Where are the revised State rules different from the Federal rules?

When revised state rules differ from the Federal rules in the RCRA state authorization process, EPA determines whether the state rules are equivalent to, more stringent than, or broader in scope than the Federal program. Pursuant to Section 3009 of RCRA, 42 U.S.C. 6929, state programs may contain requirements that are more stringent than the Federal regulations. Such more stringent requirements can be federally authorized and, once authorized, become federally enforceable. Although the statute does not prevent states from adopting regulations that are broader in scope than the Federal program, states cannot receive federal authorization for such regulations, and they are not federally enforceable.

EPA has determined that certain regulations included in Florida's program revision application are more stringent than the Federal program. All of these more stringent requirements will become part of the federally enforceable RCRA program in Florida when authorized. Florida is more stringent than the Federal program at 40 CFR 262.16 and 40 CFR 262.17 because F.A.C. 62–730.160(3) requires that generators keep written documentation of all inspections required by 40 CFR 262.16 and 40 CFR 262.17 for at least

[2] A ''checklist'' is developed by EPA for each Federal rule amending the RCRA regulations. The checklists document the changes made by each Federal rule and are presented and numbered in chronological order by date of promulgation.

[3] The Florida regulatory citations are from the Florida Administrative Code (F.A.C.), effective June 18, 2018.

three years from the date of the inspection. Documentation of these inspections is not required by the Federal regulations.

Florida is broader in scope than the Federal program in its adoption of 40 CFR 260.43 (2017) at F.A.C. 62–730.021, and 40 CFR 261.4(a)(24) (2017) at F.A.C. 62–730.030(1). Both of these regulations include provisions from the 2015 Revisions to the Definition of Solid Waste (DSW) Rule that have been vacated and replaced with the less stringent requirements of 40 CFR 260.43 (2008) and 40 CFR 261.4(a)(24) and (25) (2008) from the 2008 DSW Rule (*see* 83 FR 24664, May 30, 2018). Broader-in-scope requirements are not part of the authorized program and EPA cannot enforce them. Although regulated entities must comply with these requirements in accordance with State law, they are not RCRA requirements.

States cannot receive authorization for certain Federal regulatory functions included in the regulations associated with the Hazardous Waste Electronic Manifest Rule (Checklist 231). Although Florida has adopted these regulations to maintain its equivalency with the Federal program, it has appropriately maintained the Federal references (*see* F.A.C. 62–730.020(3)(b)(1)).

States also cannot receive authorization for certain Federal regulatory functions included in the regulations involving international shipments (*i.e.,* import and export provisions) associated with the OECD Requirements for Export Shipments of Spent Lead-Acid Batteries (Checklist 222), the Revisions to the Export Provisions of the Cathode Ray Tube Rule (Checklist 232), and the Imports and Exports of Hazardous Waste Rule (Checklist 236). Although Florida has adopted these regulations to maintain its equivalency with the Federal program, it has appropriately maintained the Federal references (*see* F.A.C. 62–730.020(3)(b)(1)).

H. Who handles permits after the final authorization takes effect?

When final authorization takes effect, Florida will issue permits for all the provisions for which it is authorized and will administer the permits it issues. EPA will continue to administer any RCRA hazardous waste permits or portions of permits that EPA issued prior to the effective date of authorization until they expire or are terminated. EPA will not issue any new permits or new portions of permits for the provisions listed in the table above after the effective date of the final authorization. EPA will continue to implement and issue permits for HSWA requirements for which Florida is not yet authorized. EPA has the authority to enforce State-issued permits after the State is authorized.

I. How does today's proposed action affect Indian country (18 U.S.C. 1151) in Florida?

Florida is not authorized to carry out its hazardous waste program in Indian country within the State, which includes the Indian lands associated with the Miccosukee Tribe of Indians of Florida and The Seminole Tribe of Florida. Therefore, this proposed action has no effect on Indian country. EPA retains jurisdiction over Indian country and will continue to implement and administer the RCRA program on these lands.

J. What is codification and will EPA codify Florida's hazardous waste program as proposed in this rule?

Codification is the process of placing citations and references to the State's statutes and regulations that comprise the State's authorized hazardous waste program into the Code of Federal Regulations. EPA does this by adding those citations and references to the authorized State rules in 40 CFR part 272. EPA is not proposing to codify the authorization of Florida's changes at this time. However, EPA reserves the ability to amend 40 CFR part 272, subpart K for the authorization of Florida's program changes at a later date.

K. Statutory and Executive Order Reviews

The Office of Management and Budget (OMB) has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). This action proposes to authorize State requirements for the purpose of RCRA section 3006 and imposes no additional requirements beyond those imposed by State law. Therefore, this action is not subject to review by OMB. This action is not an Executive Order 13771 (82 FR 9339, February 3, 2017) regulatory action because actions such as today's proposed authorization of Florida's revised hazardous waste program under RCRA are exempted under Executive Order 12866. Accordingly, I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action proposes to authorize pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538). For the same reason, this action also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely proposes to authorize State requirements as part of the State RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant and it does not make decisions based on environmental health or safety risks. This action is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

Under RCRA section 3006(b), EPA grants a state's application for authorization as long as the state meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a state authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in proposing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of this action in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive

order. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). ''Burden'' is defined at 5 CFR 1320.3(b). Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. Because this action proposes authorization of pre-existing State rules which are at least equivalent to, and no less stringent than existing Federal requirements, and imposes no additional requirements beyond those imposed by State law, and there are no anticipated significant adverse human health or environmental effects, this proposed rule is not subject to Executive Order 12898.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

Dated: December 21, 2018.

Mary S. Walker,

Acting Regional Administrator, Region 4.

[FR Doc. 2019–03105 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 25

[IB Docket No. 17–95; FCC 18–138]

Use of Earth Stations in Motion Communicating With Geostationary Orbit Space Stations in Frequency Bands Allocated to the Fixed Satellite Service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission seeks comment on additional frequency bands for ESIM communication with GSO satellites. These additional frequencies would promote innovative and flexible use of satellite technology and provide new opportunities for a variety of uses.

DATES: Comments are due April 8, 2019. Reply comments are due May 8, 2019.

ADDRESSES: You may submit comments, identified by IB Docket No. 17–95, by any of the following methods:

- *Federal Communications Commission's Website: http://apps.fcc.gov/ecfs.* Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Cindy Spiers, 202–418–1593, *cindy.spiers@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Further Notice of Proposed Rulemaking (FNPRM), FCC 18–38, adopted September 26, 2018, and released September 27, 2018. The full text of the FNPRM is available at *https://www.fcc.gov/document/fcc-facilitates-use-satellite-earth-stations-motion-0.* The R&O and FNPRM is also available for inspection and copying during business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW, Room CY–A257, Washington, DC 20554. To request materials in accessible formats for people with disabilities, send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Synopsis

In this Further Notice of Proposed Rulemaking, the Commission considers additional frequency bands for ESIM communication with GSO satellites that would promote innovative and flexible use of satellite technology and provide new opportunities for a variety of uses.

Further Notice of Proposed Rulemaking

In this Further Notice of Proposed Rulemaking, in an effort to provide additional flexibility to the growing ESIMs market, the Commission seeks comment on expanding the frequencies available to ESIMs communicating with GSO FSS satellite networks. SES and O3b requested that the Commission consider expanding GSO ESIMs into additional bands. Specifically, SES and O3b suggested that ESIM operations should also be allowed in the FSS downlink frequency bands 10.7–10.95 GHz, 11.2–11.45 GHz, and 17.8–18.3 GHz. AC BidCo support this proposal. SES and O3b also requested that the Commission propose rules for ESIM operations communicating with NGSO FSS systems. The Commission may address the ESIM operation with NGSO FSS systems in a separate NPRM.

The Commission seeks comment on allowing ESIMs to operate in all of the frequency bands in which earth stations at fixed locations operating in GSO FSS satellite networks can be blanket-licensed because in this situation operation of earth stations in motion should not introduce a material change to the interference environment created or to the protection required. Consistent with the revisions to the Table of Frequency Allocations the Commission adopted in the *NGSO FSS Report and Order,* the Commission seeks comment on expanding the Ku-band space-to-Earth frequency ranges in which ESIMs can be authorized to receive transmissions from GSO FSS space stations to also include the ranges 10.7–10.95 GHz and 11.2–11.45 GHz. The Commission seeks comment on whether these operations would be on an unprotected basis with respect to other services. In the Ka-band, the Commission seeks comment on allowing ESIMs to receive signals from GSO FSS satellite space stations on a secondary basis in the 17.8–18.3 GHz band and, on a primary basis, in the 19.3–19.4 and 19.6–19.7 GHz band. Can FSS operators design their systems such that widely deployed ESIMs can avoid interference from widely deployed FS (*e.g.* by switching to other frequencies when interference occurs)? What, if any impact will there be on customers if an ESIMs encounters interference in frequency bands where FSS earth stations are not entitled to protection? The Commission also seeks comment on whether to allow ESIMs to operate in GSO FSS satellite networks in the 18.8–19.3 GHz (space-to-Earth) and 28.6–29.1 GHz (Earth-to-space) frequency bands on an unprotected, non-interference basis with respect to NGSO FSS satellite systems. Finally, the Commission seeks comment on any possible effects expanding the frequencies available to ESIMs communicating with GSO FSS satellite networks may have on existing or future services in these bands or

adjacent frequency bands and on any necessary changes to our rules that may be appropriate to accommodate them.

Procedural Matters

Ex Parte Procedures. The proceeding this Further Notice 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 this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Comment Period and Procedures. Pursuant to sections 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 on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW, Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. 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 overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, 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 (voice), 202–418–0432 (tty).

Regulatory Flexibility Act: Final Regulatory Flexibility Analysis. Pursuant to the Regulatory Flexibility Act of 1980, as amended, 5 U.S.C. 601 *et seq.* (RFA), the Commission's Final Regulatory Flexibility Analysis (FRFA) on the possible significant economic impact on small entities of the policies and rules addressed in this Report and Order, is attached as Appendix D. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of this *Report and Order,* including the FRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

Initial Regulatory Flexibility Analysis. In addition, as required by the RFA, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) regarding the possible significant economic impact on small entities of the policies and rules adopted in the Further Notice of Proposed Rulemaking, which is found in Appendix F. The Commission requests written public comment on the IRFA. Comments must be filed in accordance with the same deadlines as comments filed in response to the FNPRM and must have a separate and distinct heading designating them as responses to the IRFA. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of this FNPRM, including the IRFA, to the Chief Counsel for Advocacy of the SBA.

Paperwork Reduction Act. This document contains modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, other Federal agencies, and the general public are invited to comment on the modified information collection requirements contained in this document. In addition, the Commission notes that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), the Commission previously sought specific comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees.

In this document, the Commission has assessed the effects of reducing the application burdens of GSO FSS ESIM applicants, and find that doing so will serve the public interest and is unlikely to directly affect businesses with fewer than 25 employees.

In addition, this document contains proposed modified 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 to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees.

Congressional Review Act. The Commission will send a copy of this Report and Order to Congress and the

Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act (RFA),[1] the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules that the Commission seeks comment on in this Notice. The Commission requests written public comments on this IRFA. Commenters must identify their comments as responses to the IRFA and must file the comments by the deadlines for comments on the Notice provided above in Section V.B. The Commission will send a copy of the Notice, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.[2] In addition, the Notice and IRFA (or summaries thereof) will be published in the **Federal Register**.[3]

A. Need for, and Objectives of, the Proposed Rules

The Further Notice of Proposed Rulemaking seeks comment on extending the use of other frequency bands in which blanket-licensed FSS earth stations are permitted for ESIMs communicating with GSO FSS space stations.

B. Legal Basis

The action would be authorized under sections 4(i), 7(a), 10, 303, 308(b), and 316 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 157(a), 160, 303,308(b), 316.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules May 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.[4] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.''[5] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[6] 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 Small Business Administration (SBA).[7]

Satellite Telecommunications. This category comprises firms ''primarily engaged in providing telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.''[8] The category has a small business size standard of $32.5 million or less in average annual receipts, under SBA rules.[9] For this category, Census Bureau data for 2012 show that there were a total of 333 firms that operated for the entire year.[10] Of this total, 299 firms had annual receipts of less than $25 million.[11] Consequently, the Commission estimates that the majority of satellite telecommunications providers are small entities.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

The FNPRM seeks comment on extending the use of other frequency bands in which blanket-licensed FSS earth stations are permitted for ESIMs communicating with GSO FSS space stations. This would reduce paperwork costs for such satellite operators who would no longer need to file separate application materials for these systems. Operators will also no longer need to request waivers for operations that would be covered under specific regulations.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): ''(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 rules 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.''[12]

The NPRM seeks comments on extending the use of other frequency bands in which blanket-licensed FSS earth stations are permitted for ESIMs communicating with GSO FSS space stations. This would reduce the economic and other impacts for these service providers by reducing the regulatory burden. Specifically, providers would no longer have to file applications that are outside of the standard rule provisions. However, the Commission invites comment on this change and any alternatives.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

None.

Conclusion and Ordering Clauses

It is ordered, pursuant to sections 4(i), 7(a), 303, 308(b), and 316 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 157(a), 303, 308(b), 316, that this Report and Order is adopted, the policies, rules, and requirements discussed herein are adopted, Parts 2 and 25 of the Commission's rules are amended as set forth in Appendix B, and this Further Notice of Proposed Rulemaking is adopted.

It is further ordered that the rules and requirements adopted in the Report and Order will become effective [30 days from the date of publication in the **Federal Register**], except for those rules and requirements containing new or modified information collection requirements that require review by the OMB under the PRA, which will become effective after OMB review and approval, on the effective date specified in a notice that International Bureau will publish in the **Federal Register**

[1] *See* 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601 *et seq.,* has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 857 (1996).

[2] *See* 5 U.S.C. 603(a).

[3] *Id.*

[4] 5 U.S.C. 603(b)(3).

[5] 5 U.S.C. 601(6).

[6] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small business concern'' in 15 U.S.C. 632). Pursuant to the RFA, the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.'' 5 U.S.C. 601(3).

[7] Small Business Act, 15 U.S.C. 632 (1996).

[8] U.S. Census Bureau, 2012 NAICS Definitions, ''517410 Satellite Telecommunications''; *http://www.census.gov/naics/2007/def/ND517410.HTM.*

[9] 13 CFR 121.201, NAICS code 517410.

[10] U.S. Census Bureau, *2012 Economic Census of the United States,* Table EC1251SSSZ4, Information: Subject Series—Estab and Firm Size: Receipts Size of Firms for the United States: 2012, NAICS code 517410 *http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2012_US_51SSSZ4&prodType=table.*

[11] *Id.*

[12] 5 U.S.C. 603(c)(1)–(c)(4).

announcing such approval and effective date.

It is further ordered that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Report and Order and Further Notice of Proposed Rulemaking, including the Initial and Final Regulatory Flexibility Analyses, to the Chief Counsel for Advocacy of the Small Business Administration.

It is further ordered that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Report and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects

47 CFR Part 2

Radio, Table of Frequency Allocations.

47 CFR Part 25

Administrative practice and procedure, Earth stations, Satellites.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR parts 2 and 25 as follows:

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

■ 2. Section 2.106, the Table of Frequency Allocations, is amended as follows:

■ a. Revise page 52.

■ b. Revise footnote NG527A in the list of non-Federal Government (NG) Footnotes.

The revisions read as follows:

§ 2.106 Table of Frequency Allocations.

* * * * *

	17.8-18.1 FIXED FIXED-SATELLITE (space-to-Earth) 5.484A (Earth-to-space) 5.516 MOBILE 5.519		17.8-18.3 FIXED-SATELLITE (space-to-Earth) US334 G117 US519	17.8-18.3 FIXED Fixed-satellite (space-to-Earth) NG527A US334 US519	Satellite Communications (25) TV Broadcast Auxiliary (74F) Cable TV Relay (78) Fixed Microwave (101)
18.1-18.4 FIXED FIXED-SATELLITE (space-to-Earth) 5.484A 5.516B (Earth-to-space) 5.520 MOBILE 5.519 5.521			18.3-18.6 FIXED-SATELLITE (space-to-Earth) US334 G117 US139	18.3-18.6 FIXED-SATELLITE (space-to-Earth) NG164 NG527A US139 US334	Satellite Communications (25)
18.4-18.6 FIXED FIXED-SATELLITE (space-to-Earth) 5.484A 5.516B MOBILE					
18.6-18.8 EARTH EXPLORATION-SATELLITE (passive) FIXED FIXED-SATELLITE (space-to-Earth) 5.522B MOBILE except aeronautical mobile Space research (passive) 5.522A 5.522C	18.6-18.8 EARTH EXPLORATION-SATELLITE (passive) FIXED FIXED-SATELLITE (space-to-Earth) 5.516B 5.522B MOBILE except aeronautical mobile SPACE RESEARCH (passive) 5.522A	18.6-18.8 EARTH EXPLORATION-SATELLITE (passive) FIXED FIXED-SATELLITE (space-to-Earth) 5.522B MOBILE except aeronautical mobile Space research (passive) 5.522A	18.6-18.8 EARTH EXPLORATION-SATELLITE (passive) FIXED-SATELLITE (space-to-Earth) US255 US334 G117 SPACE RESEARCH (passive) US139 US254	18.6-18.8 EARTH EXPLORATION-SATELLITE (passive) FIXED-SATELLITE (space-to-Earth) US255 NG164 NG527A SPACE RESEARCH (passive) US139 US254 US334	
18.8-19.3 FIXED FIXED-SATELLITE (space-to-Earth) 5.516B 5.523A MOBILE			18.8-20.2 FIXED-SATELLITE (space-to-Earth) US334 G117	18.8-19.3 FIXED-SATELLITE (space-to-Earth) NG165 NG527A US139 US334	
19.3-19.7 FIXED FIXED-SATELLITE (space-to-Earth) (Earth-to-space) 5.523B 5.523C 5.523D 5.523E MOBILE				19.3-19.7 FIXED FIXED-SATELLITE (space-to-Earth) NG166 NG527A US334	Satellite Communications (25) TV Broadcast Auxiliary (74F) Cable TV Relay (78) Fixed Microwave (101)
19.7-20.1 FIXED-SATELLITE (space-to-Earth) 5.484A 5.484B 5.516B 5.527A Mobile-satellite (space-to-Earth) 5.524	19.7-20.1 FIXED-SATELLITE (space-to-Earth) 5.484A 5.484B 5.516B 5.527A MOBILE-SATELLITE (space-to-Earth) 5.524 5.525 5.526 5.527 5.528 5.529 5.524	19.7-20.1 FIXED-SATELLITE (space-to-Earth) 5.484A 5.484B 5.516B 5.527A Mobile-satellite (space-to-Earth)		19.7-20.2 FIXED-SATELLITE (space-to-Earth) NG527A MOBILE-SATELLITE (space-to-Earth)	Satellite Communications (25)
20.1-20.2 FIXED-SATELLITE (space-to-Earth) 5.484A 5.484B 5.516B 5.527A MOBILE-SATELLITE (space-to-Earth) 5.524 5.525 5.526 5.527 5.528				5.525 5.526 5.527 5.528 5.529	
20.2-21.2 FIXED-SATELLITE (space-to-Earth) MOBILE-SATELLITE (space-to-Earth) Standard frequency and time signal-satellite (space-to-Earth) 5.524			US139 20.2-21.2 FIXED-SATELLITE (space-to-Earth) MOBILE-SATELLITE (space-to-Earth) Standard frequency and time signal-satellite (space-to-Earth) G117	US334 20.2-21.2 Standard frequency and time signal-satellite (space-to-Earth)	

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Non-Federal Government (NG) Footnotes

* * * * *

NG527A Earth Stations in Motion (ESIMs), as regulated under 47 CFR part 25, are an application of the fixed-satellite service and the following provisions shall apply:

(a) In the band 10.7–11.7 GHz (space-to-Earth), ESIMs may be authorized to communicate with geostationary satellites, subject to the condition that these earth stations may not claim protection from transmissions of non-Federal stations in the fixed service.

(b) In the bands 11.7–12.2 GHz (space-to-Earth), 14.0–14.5 GHz (Earth-to-space), 18.3–18.8 GHz (space-to-Earth), 19.3–19.4 GHz (space-to-Earth, 19.6–20.2 GHz (space-to-Earth), 28.35–28.6 GHz (Earth-to-space), and 29.25–30.0 GHz (Earth-to-space), ESIMs may be authorized to communicate with geostationary satellites on a primary basis.

(c) In the band 17.8–18.3 GHz (space-to-Earth), ESIMs may be authorized to communicate with geostationary satellites on a secondary basis.

(d) In the bands 18.8–19.3 GHz (space-to-Earth) and 28.6–29.1 GHz (Earth-to-space), ESIMs may be authorized to communicate with geostationary satellites, subject to the condition that these earth stations may not cause harmful interference to, or claim protection from, non-geostationary-satellite systems in the fixed-satellite service.

* * * * *

PART 25—SATELLITE COMMUNICATIONS

■ 3. The authority citation for part 25 continues to read as follows:

Authority: 47 U.S.C. 154, 301, 302, 303, 307, 309, 310, 319, 332, 605, and 721, unless otherwise noted.

■ 4. Section 25.202 is amended by revising paragraphs (a)(8) and (10) and removing and reserving paragraph (a)(11) to read as follows:

§ 25.202 Frequencies, frequency tolerance, and emission limits.

(a) * * *

(8) The following frequencies are available for use by Earth Stations on Vessels (ESVs) communicating with GSO FSS space stations, subject to the provisions in § 2.106 of this chapter:

3700–4200 MHz (space-to-Earth)
5925–6425 MHz (Earth-to-space)

* * * * *

(10) The following frequencies are available for use by Earth Stations in Motion (ESIMs) communicating with GSO FSS space stations, subject to the provisions in § 2.106 of this chapter:

10.7–11.7 GHz (space-to-Earth)
11.7–12.2 GHz (space-to-Earth)
14.0–14.5 GHz (Earth-to-space)
17.8–18.3 GHz (space-to-Earth)
18.3–18.8 GHz (space-to-Earth)
18.8–19.3 GHz (space-to-Earth)
19.3–19.4 GHz (space-to-Earth)
19.6–19.7 GHz (space-to-Earth)
19.7–20.2 GHz (space-to-Earth)
28.35–28.6 GHz (Earth-to-space)
28.6–29.1 GHz (Earth-to-space)
29.25–30.0 GHz (Earth-to-space)

[FR Doc. 2019–01487 Filed 2–21–19; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 84, No. 36

Friday, February 22, 2019

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

[DOC. NO. AMS–FGIS–18–0087]

Grain Export Registration Renewal Information

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: With this publication, the Agricultural Marketing Service (AMS) notifies persons about annual requirements for renewing the Application for Registration as required by the United States Grain Standards Act. All persons engaged in the business of buying grain for sale in foreign commerce and in the business of handling, weighing, or transporting grain for sale in foreign commerce in excess of 15,000 metric tons during the preceding or current calendar year must register annually. The realignment of offices within the U.S. Department of Agriculture authorized by the Secretary's Memorandum dated November 14, 2017, eliminates the Grain Inspection, Packers and Stockyards Administration (GIPSA) as a standalone agency. The grain inspection activities formerly part of GIPSA are now organized under AMS.

DATES: Export Registration is for the calendar year with 2019 registrations expiring on December 31, 2019.

ADDRESSES: Prospective registrants may submit an Application for Registration (FORM FGIS–945) online through FGISONLINE, Delegations, Designations, and Export Registration (DDR) and make payments through *Pay.gov*.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Candace A. Hildreth by telephone at 202–720–0203 or by email to *FGISQACD@usda.gov* with ''2019 Application for Registration Renewal'' as the subject line.

SUPPLEMENTARY INFORMATION: Instruction on how to submit an Application for Registration through DDR can be found at *https://www.ams.usda.gov/services/fgis/ddr-export-registration-instructions.*

Below are the applicable export registration regulatory provisions:

(1) 7 U.S.C. 87f–1 requires registration for all persons who are engaged in the business of buying grain for sale in foreign commerce and in the business of handling, weighing, or transporting grain for sale in foreign commerce in excess of 15,000 metric tons during the preceding or current calendar year.

(2) 7 CFR 800.30–39 defines foreign commerce grain business as persons who regularly engage in buying for sale, handling, weighing, or transporting grain totaling 15,000 metric tons or more during the preceding or current calendar year.

(3) 7 U.S.C. 87b(a)(11), Prohibited Acts, states that no person shall violate Section 87f–1, and if a person does violate Section 87f–1, Section 87c (a) states that any person who commits any offense prohibited by section 87b shall be guilty of a felony and shall, on conviction thereof, be subject to imprisonment for not more than five years, or a fine of not more than $20,000, or both imprisonment and fine.

Authority: 7 U.S.C. 87f–1.

Dated: February 15, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–03076 Filed 2–21–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket No. AMS–SC–19–0013; SC19–981–2]

Almonds Grown in California; Notice of Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Agricultural Marketing Service's (AMS) intention to request an extension for and revision to a currently approved information collection for Almonds Grown in California, Marketing Order No. 981.

DATES: Comments on this notice must be received by April 23, 2019.

ADDRESSES: Interested persons are invited to submit written comments concerning this notice. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or internet: *www.regulations.gov.* Comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *www.regulations.gov.* All comments submitted in response to this notice will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made available to the public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Andrew Hatch, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Room 1406–S, Washington, DC 20250–0237; Telephone:(202) 720–6862, Fax:(202) 720–8938, or Email: *andrew.hatch@usda.gov.*

Small businesses may request information on this notice by contacting Richard Lower, Assistant to the Director, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Room 1406–S, Washington, DC 20250–0237; Telephone (202) 720–2491, Fax: (202) 720–8938; or Email: *Richard.lower@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Almonds Grown in California, Marketing Order No. 981.

OMB Number: 0581–0242.

Expiration Date of Approval: July 31, 2019.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: The information collection requirements in this request are

essential to carry out the intent of the Agricultural Marketing Agreement Act of 1937 (Act), as amended (7 U.S.C. 601–674), to provide the respondents the type of service they request, and to administer the California almond marketing order (7 CFR part 981), which has been operating since 1950.

The marketing order and its rules and regulations authorize the Almond Board of California (Board), the agency responsible for local administration of the marketing order, to require handlers and other certain entities to submit information.

Since September 2007, the Board has been operating a mandatory program under the marketing order to help reduce the potential for Salmonella in almonds. The Board had developed forms as a means for handlers to file required information with the Board relating to the treatment of almonds. Almond handlers are required to submit annual treatment plans to the Board and inspection agency regarding how they plan to treat their almonds in compliance with the program.

Entities interested in being almond process authorities that validate technologies are required to submit an application to the Board on ABC Form No. 51, ''Application for Process Authority for Almonds.'' Manufacturers in the United States, Canada, and Mexico interested in being approved to accept untreated almonds, provided they agree to treat the almonds themselves under the Board's Direct Verifiable (DV) program, are required to submit an application to the Board on ABC Form No. 52, ''Application for Direct Verifiable (DV) Program for Further Processing of Untreated Almonds.'' Entities interested in being approved DV user auditors are required to apply to the Board on ABC Form No. 53, ''Application for Direct Verifiable (DV) Program Auditors.'' To ensure compliance with the mandatory program, entities are required to use either an on-site or audit-based verification program and annually submit a treatment plan to the Board on ABC Form No. 54, ''Handler Treatment Plan.''

The information collected is used only by authorized representatives of USDA, including AMS, Specialty Crops Program's regional and headquarters' staff, and authorized employees and agents of the Board. Authorized Board employees, agents, and the industry are the primary users of the information, and AMS is the secondary user.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 1.5 hours per response.

Respondents: Almond handlers; persons or organizations that would like to qualify to be Board-approved process authorities that validate treatments and technologies; manufacturers who would like to qualify to participate in the Board's DV program; and entities that would like to qualify as auditors under the DV program.

Estimated Number of Respondents: 175.

Estimated Number of Responses per Respondent: 1.00.

Estimated Total Annual Burden on Respondents: 4,200 hours.

Comments are invited on: (1) Whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (2) the accuracy of the agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on those who respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Dated: February 15, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–03075 Filed 2–21–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Information Collection Activity; Comment Request

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the U.S. Department of Agriculture (USDA) Rural Utilities Service (RUS) invites comments on this information collection for the Distance Learning and Telemedicine Loan and Grant Program, which it intends to request approval from the Office of Management and Budget (OMB).

DATES: Comments on this notice must be received by April 23, 2019.

FOR FURTHER INFORMATION CONTACT: Thomas P. Dickson, Rural Development Innovation Center—Regulatory Team 2, USDA, 1400 Independence Avenue SW, STOP 1522, Room 5164, South Building, Washington, DC 20250–1522. Telephone: (202) 690–4492. Email *Thomas.dickson@usda.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that RUS is submitting to OMB for extension.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent by any of the following methods:

- *Mail:* Thomas P. Dickson, Rural Development Innovation Center, 1400 Independence Avenue SW, STOP 1522, Room 5164, South Building, Washington, DC 20250–1522. Telephone: (202) 690–4492. Email: *Thomas.Dickson@wdc.usda.gov.*

Federal eRulemaking Portal: Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.

Title: Distance Learning and Telemedicine Loan and Grant Program.

OMB Control Number: 0572–0096.

Type of Request: Extension of a currently approved information collection package.

Abstract: The Rural Utilities Service's (RUS) Distance Learning and Telemedicine (DLT) Loan and Grant program provides loans and grants for advanced telecommunications services to improve rural areas' access to educational and medical services. The various forms and narrative statements required are collected from the

applicants (rural community facilities, such as schools, libraries, hospitals, and medical facilities, for example). The purpose of collecting the information is to determine such factors as eligibility of the applicant; the specific nature of the proposed project; the purposes for which loan and grant funds will be used; project financial and technical feasibility; and, compliance with applicable laws and regulations. In addition, for grants funded pursuant to the competitive evaluation process, information collected facilitates RUS' selection of those applications most consistent with DLT goals and objectives in accordance with the authorizing legislation and implementing regulation.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 2.45 hours per response.

Respondents: Business or other for-profit; Not-for-profit institutions; and State, Local or Tribal Government.

Estimated Number of Respondents: 200.

Estimated Number of Responses per Respondent: 23.3.

Estimated Total Annual Burden on Respondents: 11,031 hours.

Copies of this information collection can be obtained from Robin M. Jones, Innovation Center, at (202) 772–1172, Email: *robin.m.jones@wdc.usda.gov.*

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: February 14, 2019.

Bette B. Brand,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2019–03077 Filed 2–21–19; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Rhode Island Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a meeting of the Rhode Island Advisory Committee to the Commission will convene at 1:30 p.m. (EST) on Tuesday, March 5, 2019, at 40 South Main Street, Woonsocket, RI 02895. The purpose of the meeting is to discuss next steps in the distribution of the payday lending report.

DATES: Tuesday, March 5, 2019 (EST) at 1:30 p.m.

ADDRESSES: 40 South Main Street, Woonsocket, RI 02895.

FOR FURTHER INFORMATION CONTACT: Evelyn Bohor at *ero@usccr.gov,* or 202–376–7533.

SUPPLEMENTARY INFORMATION: Persons who plan to attend the meeting and who require other accommodations, please contact Evelyn Bohor at *ebohor@usccr.gov* at least ten (10) working days before the scheduled date of the meeting.

Members of the public are invited to submit written comments; the comments must be received in the regional office by Friday, April 5, 2019. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376–7548, or emailed to Evelyn Bohor at *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

The activities of this advisory committee, including records and documents discussed during the meeting, will be available for public viewing, as they become available at: *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzm4AAA.* Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone number, email or street address.

Agenda

Tuesday, March 5, 2019; 1:30 p.m. (EST)

Welcome and Roll Call

Discussion of Potential Civil Rights topics

Discussion of Potential Topics of Study

Open Comment

Adjourn

Dated: February 18, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019–03047 Filed 2–21–19; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the District of Columbia Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a meeting of the District of Columbia Advisory Committee to the Commission will convene by conference call, at 12:00 p.m. (EST) Thursday, March 7, 2019. The purpose of the planning meeting is to continue project planning for a future briefing meeting on the Committee's civil rights project that examines the intersection of homelessness, mental health and the criminal justice system, including a review of the DC Mental Health Court.

Date/Time: Thursday, March 7, 2019 at 12:00 p.m. (EST).

Public Call-In Information: Conference call number: 1–855–719–5012 and conference call ID number: 3606878.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis, at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call number: 1–855–719–5012 and conference call ID number: 3606878. Please be advised that before placing them into the conference call, the conference call operator may ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number herein.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–800–877–8339 and providing the operator with the toll-free conference call number: 1–855–719–5012 and conference call ID number: 3606878.

Members of the public are invited to make statements during the Public Comments section of the meeting or to submit written comments. The comments must be received in the regional office by Monday, April 8, 2019. Comments may be mailed to the Eastern Regional Office, U.S.

Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425 or emailed to Evelyn Bohor at *ero@usccr.gov*. Persons who desire additional information may contact the Eastern Regional Office at 202–376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at: *https://gsageo.force.com/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzlKAAQ*. Please click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone numbers, email or street address.

Agenda

Thursday, March 7, 2019, at 12:00 p.m. (EST)

I. Welcome and Rollcall
II. Discuss Project Planning
III. Other Business
IV. Next Planning Meeting
V. Public Comments
VI. Adjourn

Dated: February 19, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019–03103 Filed 2–21–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration.

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: International Trade Administration.

Title: Foreign-Trade Zone Applications.

OMB Control Number: 0625–0139.

Form Number(s): NA.

Type of Request: Regular Submission.

Number of Respondents: 288.

Average Hours per Response: New Zone Application, 131 hours; Subzone Application, 4.5 hours; Reorganization/Expansion Application, 99 hours; Production Notification, 5.5 hours; Production Application, 34 hours; Minor Boundary Modifications, 3.5 hours; Waivers, 9 hours.

Burden Hours: 2,532.

Needs and Uses: The Foreign-Trade Zone Application is the vehicle by which individual firms or organizations apply for foreign-trade zone (FTZ) status, for subzone status, production authority, or for expansion/reorganization of an existing zone. The FTZ Act and Regulations require that an application with a description of the proposed project be made to the FTZ Board (19 U.S.C. 81b and 81f; 15 CFR 400.24–26) before a license can be issued or a zone can be expanded. The Act and Regulations require that applications contain detailed information on facilities, financing, operational plans, proposed production operations, need, and economic impact. Production activity in zones or subzones, can involve issues related to domestic industry and trade policy impact. Such applications must include specific information on the customs tariff-related savings that result from zone procedures and the economic consequences of permitting such savings. The FTZ Board needs complete and accurate information on the proposed operation and its economic effects because the Act and Regulations authorize the Board to restrict or prohibit operations that are detrimental to the public interest.

Affected Public: State, local, or tribal governments or not-for-profit institutions which are FTZ grantees, as well as private companies.

Frequency: As necessary to receive FTZ benefits.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–03104 Filed 2–21–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Minority Business Development Agency

Proposed Information Collection; Comment Request; Online Customer Relationship Management (CRM)/Performance Databases

AGENCY: Minority Business Development Agency (MBDA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before April 23, 2019.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at (*docpra@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Nakita Chambers, Program Manager, Minority Business Development Agency, U.S. Department of Commerce, Office of Business Development, 1401 Constitution Avenue NW, Washington, DC 20230, (202) 482–0065, and email: *nchambers@mbda.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

As part of its national service delivery system, MBDA awards cooperative agreements and grant awards through broad agency announcements each year to fund the provision of business development services to eligible minority business enterprises (MBEs). The recipient of each grant award is competitively selected to participate in one of the MBDA's programs. In accordance with the Government Performance Results Act (GPRA), MBDA requires all grant participants to report basic client information, service activities and progress on attainment of program goals via the Online CRM/Performance database. The data inputs into the CRM/Performance database originate from client intake forms used by each participant to collect information about each minority

business enterprise that receives technical business assistance from the servicing grant participants. This data provides the baseline from which the CRM/Performance database is populated. The Online CRM/Performance Database is used to regularly monitor and evaluate the progress of the MBDA programs, to provide the Department and OMB with a summary of the quantitative information required to be submitted about government supported programs, and to implement the GPRA. This information is also summarized and included in the MBDA Annual Performance Report, which is made available to the public.

In 2012, the overall estimate of burden hours decreased for users under the newly adopted program structure as a result of the streamlining of certain administrative and reporting requirements. The MBDA grant programs will continue to use the Customer Relationship Management/Performance database until the new program is redesigned during Fiscal Year 2019.

Revision: In Fiscal Year 2018, MBDA has included broad agency announcement grants into the service delivery model for the agency. The client transaction and verification forms in use for the business center program will also be used to collect information about the effectiveness of other grant programs funded by the agency. The forms include a statement regarding MBDA's intended use by MBDA and transfer of the information collected to other federal agencies for the purpose of conducting research and studies on minority businesses.

II. Method of Collection

Information will be collected manually and electronically.

III. Data

OMB Control Number: 0640–0002.

Form Number(s): 0640–002.

Type of Review: Regular (Reinstatement) submission.

Affected Public: Individuals or households; Business or other for-profit organizations; Not-for-profit institutions; State, Local, or Tribal government; Federal government.

Estimated Number of Respondents: 2,633.

Estimated Time per Response: 1 minute to 210 minutes, depending upon function.

Estimated Total Annual Burden Hours: 4,516.

Estimated Total Annual Cost to Public: 0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection. All comments received are part of the public record and will be posted to *http://www.regulations.gov* for public viewing. 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.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–03117 Filed 2–21–19; 8:45 am]

BILLING CODE 3510–21–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG775

Fisheries of the Exclusive Economic Zone Off Alaska; Alaska Groundfish and Halibut Seabird Working Group; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: NMFS Alaska Groundfish and Halibut Seabird Working Group will meet to discuss use of leading indicators as tool to assess inseason seabird bycatch risk, vessel-specific seabird bycatch mortality, and an update on studies examining seabird bycatch in the trawl fisheries.

DATES: The meeting will be held on March 27, 2019, from 1 p.m. to 5 p.m., and on March 28, 2019, from 9 a.m. to 4 p.m., Alaska Daylight Time.

ADDRESSES: The meeting will be held at the NMFS Alaska Regional Office located at 709 W 9th St., Room 445C, Juneau, AK. Photo identification is required to enter this facility.

FOR FURTHER INFORMATION CONTACT: Anne Marie Eich, 907–586–7172.

SUPPLEMENTARY INFORMATION: The Alaska Groundfish and Halibut Seabird Working Group formed as a result of the 2015 biological opinion on effects of the Gulf of Alaska and Bering Sea/Aleutian Islands groundfish fisheries on short-tailed albatross. The working group is tasked with reviewing information for mitigating effects of the groundfish fisheries on short-tailed albatross and other seabirds. The workgroup will hold an in-person meeting in Juneau, Alaska on March 27 and 28, 2019. Meeting topics include the use of leading indicators as tool to assess inseason seabird bycatch risk, vessel-specific seabird bycatch mortality, and an update on studies examining seabird bycatch in the trawl fisheries. NMFS will keep the North Pacific Fishery Management Council (Council) apprised of the working group's activities and any resulting recommendations for methods to reduce seabird bycatch. Any changes to seabird avoidance regulations are expected to follow the standard Council process.

Special Accommodations

This workshop will be physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Anne Marie Eich, 907–586–7172, at least 5 working days prior to the meeting date.

Dated: February 15, 2019.

Karen H. Abrams,

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

[FR Doc. 2019–03013 Filed 2–21–19; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Addition and Deletions

AGENCY: Committee for Purchase From People who are Blind or Severely Disabled.

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

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

DATES: *Comments must be received on or before:* March 24, 2019.

ADDRESSES: Committee for Purchase From People who are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

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

Addition

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

The following service is proposed for addition to the Procurement List for production by the nonprofit agency listed:

Service

Service Type: Janitorial Service
Mandatory for: U.S. Navy, NEX Food Court, Norfolk Naval Air Station,1560 Mall Drive, Norfolk, VA
Mandatory Source of Supply: Sara's Mentoring Center, Inc., Virginia Beach, VA
Contracting Activity: DEPT OF THE NAVY, Navy Exchange Service Command

Deletions

The following products and services are proposed for deletion from the Procurement List:

Products

NSN—Product Name: 6510–00–935–5823—Bandage, Elastic, 6″ x 4.5 Yards
NSN—Product Name: 8340–00–223–7849—Pole Section, Tent
Mandatory Source of Supply: Development Workshop, Inc., Idaho Falls, ID
Contracting Activity: Defense Logistics Agency Troop Support

Services

Service Type: JWOD Staffing Services
Mandatory for: GSA, Nationwide, Washington, DC
Mandatory Sources of Supply: Arizona Industries for the Blind, Phoenix, AZ, Columbia Lighthouse for the Blind, Washington, DC, The Lighthouse for the Blind, Inc., Seattle, WA, Alabama Industries for the Blind, Talladega, AL, Blind Industries & Services of Maryland, Baltimore, MD
Service Type: Furniture Rehabilitation
Mandatory for: GSA, National Furniture Center, Arlington, VA
Mandatory Source of Supply: J.M. Murray Center, Inc., Cortland, NY
Contracting Activity: General Services Administration, FPDS Agency Coordinator

Service Type: Computer Facilities Management Services
Mandatory for: Federal Center, Defense Reutilization & Marketing Service—POB: 74, North Washington—ADP Op, Battle Creek, MI
Mandatory Source of Supply: Peckham Vocational Industries, Inc., Lansing, MI
Contracting Activity: Defense Logistics Agency, DLA DISPOSITION SERVICES

Service Type: Sewing
Mandatory for: Redstone Arsenal, Huntsville, AL
Mandatory Source of Supply: Huntsville Rehabilitation Foundation, Huntsville, AL
Contracting Activity: Dept of the Army, W40M NORTHEREGION Contract OFC

Service Type: Shelf Stocking, Custodial & Warehousing
Mandatory for: Dahlgren Naval Surface Warfare Center, Dahlgren, VA
Mandatory Source of Supply: Rappahannock Goodwill Industries, Inc., Fredericksburg, VA
Contracting Activity: Defense Commissary Agency

Patricia Briscoe,

Deputy Director, Business Operations, Pricing and Information Management.

[FR Doc. 2019–03070 Filed 2–21–19; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0016]

Agency Information Collection Activities; Comment Request; Fiscal Operations Report for 2018–2019 and Application to Participate 2020–2021 (FISAP) and Reallocation Form

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before April 23, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0016. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Fiscal Operations Report for 2018–2019 and Application to Participate 2020–2021 (FISAP) and Reallocation Form.

OMB Control Number: 1845–0030.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 3,962.

Total Estimated Number of Annual Burden Hours: 91,348.

Abstract: The Higher Education Opportunity Act (HEOA) (Pub. L. 110–315) was enacted on August 14, 2008 and reauthorized the Higher Education Act of 1965, as amended, (HEA). It requires participating Title IV institutions to apply for funds and report expenditures for the Federal Perkins Loan (Perkins), the Federal Supplemental Educational Opportunity Grant (FSEOG) and the Federal Work-Study (FWS) Programs on an annual basis.

The data submitted electronically in the Fiscal Operations Report and Application to Participate (FISAP) is used by the Department of Education to determine the institution's funding need for the award year and monitor program effectiveness and accountability of fund expenditures. The data is used in conjunction with institutional program reviews to assess the administrative capability and compliance of the applicant. There are no other resources for collecting this data.

The HEA requires that if an institution anticipates not using all of its allocated funds for the FWS, and FSEOG programs by the end of an award year, it must specify the anticipated remaining unused amount to the Secretary, who reduces the institution's allocation accordingly. The changes to the version of the FISAP update the deadline and award year references, incorporate 2 new questions on the FSEOG and FWS programs. Additionally, this version of the FISAP provides clarification of the information that must be reported for the Perkins loan program now that there are no new loans being made due to the expiration of the program.

Dated: February 19, 2019.

Kate Mullan,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–03069 Filed 2–21–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, March 13, 2019; 1:00 p.m.–5:15 p.m.

ADDRESSES: University of New Mexico, Los Alamos Campus, 4000 University Drive, Los Alamos, New Mexico 87544.

FOR FURTHER INFORMATION CONTACT: Menice Santistevan, Northern New Mexico Citizens' Advisory Board (NNMCAB), 94 Cities of Gold Road, Santa Fe, NM 87506. Phone (505) 995–0393; Fax (505) 989–1752 or Email: *Menice.Santistevan@em.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

- Call to Order
- Welcome and Introductions
- Approval of Agenda and Meeting Minutes of November 7, 2018 and January 30, 2019
- Old Business
  - Report from Chair
  - Other Items
- New Business
- Presentation on Site-Specific Cleanup Standards and Agreements Between the Los Alamos Field Offices of EM and the National Nuclear Security Administration
- Break
- Public Comment Period
- Update on Natural Resource Damage Assessment (NRDA)
- Update From New Mexico Environment Department
- Update from EM-Los Alamos Field Office
- Update from NNMCAB Deputy Designated Federal Officer and Executive Director
- Wrap-Up Comments From NNMCAB Members
- Adjourn

Public Participation: The EM SSAB, Northern New Mexico, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Menice Santistevan at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Menice Santistevan at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Menice Santistevan at the address or phone number listed above. Minutes and other Board documents are on the internet at: *https://energy.gov/em/nnmcab/meeting-materials.*

Signed in Washington, DC, on January 31, 2019.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2019–03094 Filed 2–21–19; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2004–0015; FRL–9989–54–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Part 70 State Operating Permit Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Part 70 State Operating Permit Program (EPA ICR Number 1587.14, OMB Control Number 2060.0243) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently

approved through March 31, 2019. Public comments were previously requested via the **Federal Register** on September 11, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before March 25, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2004–0015, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Dylan C. Mataway-Novak, Air Quality Policy Division, Office of Air Quality Planning and Standards, C504–05, U.S. Environmental Protection Agency, Research Triangle Park, NC; telephone number: (919) 541–5795; fax number: (919) 541–5509; email address: *mataway-novak.dylan@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: Title V of the CAA requires states to develop and implement a program for issuing operating permits to all sources that fall under any Act definition of ''major'' and certain other non-major sources that are subject to Federal air quality regulations. The Act further requires the EPA to develop regulations that establish the minimum requirements for those state operating permits programs and to oversee implementation of the state programs. The EPA regulations setting forth requirements for the state operating permit program are found at 40 CFR part 70. The part 70 program is designed to be implemented primarily by state, local and tribal permitting authorities in all areas where they have jurisdiction.

In order to receive an operating permit for a major or other source subject to the permitting program, the applicant must conduct the necessary research, perform the appropriate analyses and prepare the permit application with documentation to demonstrate that its facility meets all applicable statutory and regulatory requirements. Specific activities and requirements are listed and described in the Supporting Statement for the 40 CFR part 70 ICR.

Under 40 CFR part 70, state, local and tribal permitting authorities review permit applications, provide for public review of proposed permits, issue permits based on consideration of all technical factors and public input and review information submittals required of sources during the term of the permit. Also, under 40 CFR part 70, the EPA reviews certain actions of the permitting authorities and provides oversight of the programs to ensure that they are being adequately implemented and enforced. Consequently, information prepared and submitted by sources is essential for sources to receive permits, and for federal, state, local and tribal permitting authorities to adequately review the permit applications and thereby properly administer and manage the program.

Information that is collected is handled according to the EPA's policies set forth in title 40, chapter 1, part 2, subpart B—Confidentiality of Business Information (*see* 40 CFR part 2). *See* also section 114(c) of the Act.

Form Numbers: None.

Respondents/affected entities: Industrial plants (sources); state, local and tribal permitting authorities.

Respondent's obligation to respond: Mandatory (*see* 40 CFR part 70).

Estimated number of respondents: 13,712 sources and 117 state, local and tribal permitting authorities.

Frequency of response: On occasion.

Total estimated burden: 4,738,925 hours (per year). Burden is defined at 5 CFR 1320.03(b).

T*otal estimated cost:* $321,878,589 (per year). There are no annualized capital or operation & maintenance costs.

Changes in Estimates: There is a decrease of 429,890 hours per year for the estimated respondent burden compared with the ICR currently approved by OMB. This decrease is due to updated estimates of the number of sources and permits subject to the part 70 program, rather than any change in federal mandates.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–03059 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2013–0298; FRL–9988–36–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Industrial, Commercial, and Institutional Boilers Area Sources (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Industrial, Commercial, and Institutional Boilers Area Sources (EPA ICR No. 2253.04, OMB Control No. 2060–0668), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which was previously approved through October 31, 2018. Public comments were previously requested, via the **Federal Register**, on October 1, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before March 25, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2013–0298, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov,* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The NESHAP for Industrial, Commercial, and Institutional Boilers Area Sources (40 CFR part 63, subpart JJJJJJ) affects new and existing industrial, commercial, and institutional boilers that are located at or part of area sources of hazardous air pollutants (HAP). The standard contains six subcategories: Existing boilers designed to burn biomass, coal, or liquid fuels and new boilers designed to burn biomass, coal, or liquid fuels. The information collection activities include initial and annual stack tests, fuel analyses, operating parameter monitoring, biennial tune-ups, one-time energy audits, one-time and periodic reports, and maintenance of records. Varying levels of requirements apply to each subcategory. The information collection activities will enable EPA to determine initial and continuous compliance with emission standards for regulated pollutants, and ensure that facilities conduct proper planning, operation, and unit maintenance. The provisions of Section 114(a)(1) of the Clean Air Act, 42 U.S.C. 7414(a)(1) provide the broad authority for the reporting of compliance monitoring and enforcement information, along with Subpart Q—Reports in 40 CFR 51: Sections 51.324(a) and (b), and 51.327.

Form Numbers: None.

Respondents/affected entities: Owners and operators of industrial, commercial, or institutional boilers.

Respondent's obligation to respond: Mandatory (40 CFR 63, subpart JJJJJJ).

Estimated number of respondents: 100,374 (total).

Frequency of response: Initially, biennially, semiannually and annually.

Total estimated burden: 1,830,000 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: Total annual labor costs are $208,000,000 (per year), and annualized capital or operation & maintenance costs are $132,000,000.

Changes in the Estimates: There is an increase in the total estimated burden previously identified in the OMB Inventory of Approved Burdens. This increase is not due to any program changes. The change in burden and cost estimates occurred because the number of respondents has increased, resulting in an increase in the number of responses and the total respondent labor hours. This ICR reflects the on-going burden and costs for existing facilities and the costs to new facilities and includes new estimates of 'burden' for existing sources to refamiliarize themselves with the rule provisions each year, which is estimated at one hour per source per year. The overall result is an increase in burden hours and costs.

There is also an increase in total annual capital/startup and O&M costs as compared to the previous ICR. This increase is attributed to the fact that new facilities complying with the rules have initial compliance costs. All existing facilities will have on-going O&M costs.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–03071 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2012–0103; FRL–9988–32–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Diesel Emissions Reduction Act (DERA) Rebate Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Diesel Emissions Reduction Act (DERA) Rebate Program (EPA ICR Number 2461.03, OMB Control Number 2060–0686) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through March 31, 2019. Public comments were previously requested via the **Federal Register** on September 11, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before March 25, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number HQ–OAR–2012–0103, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *a-and-r-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Jason Wilcox, Office of Transportation and Air Quality, (Mail Code: 6406A), Environmental Protection Agency, 1200

Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–343–9571; fax number: 202–343–2803; email address: *wilcox.jason@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: This is an extension of the current Information Collection Request (ICR) for the Diesel Emissions Reduction Act program (DERA) authorized by Title VII, Subtitle G (Sections 791 to 797) of the Energy Policy Act of 2005 (Pub. L. 109–58), as amended by the Diesel Emissions Reduction Act of 2010 (Pub. L. 111–364), codified at 42 U.S.C. 16131 *et seq.* DERA provides the Environmental Protection Agency (EPA) with the authority to award grants, rebates or low-cost revolving loans on a competitive basis to eligible entities to fund the costs of projects that significantly reduce diesel emissions from mobile sources through implementation of a certified engine configuration, verified technology, or emerging technology. Eligible mobile sources include buses (including school buses), medium heavy-duty or heavy heavy-duty diesel trucks, marine engines, locomotives, or nonroad engines or diesel vehicles or equipment used in construction, handling of cargo (including at ports or airports), agriculture, mining, or energy production. In addition, eligible entities may also use funds awarded for programs or projects to reduce long-duration idling using verified technology involving a vehicle or equipment described above. The objective of the assistance under this program is to achieve significant reductions in diesel emissions in terms of tons of pollution produced and reductions in diesel emissions exposure, particularly from fleets operating in areas designated by the Administrator as poor air quality areas.

EPA collects information from applicants to the DERA rebate program. Information collected is used to ensure eligibility of applicants and engines to receive funds under DERA, and to calculate estimated and actual emissions benefits that result from activities funded with rebates as required in DERA's authorizing legislation.

Respondents/affected entities: Entities potentially affected by this action are those interested in applying for a rebate under EPA's Diesel Emission Reduction Act (DERA) Rebate Program and include but are not limited to the following NAICS (North American Industry Classification System) codes: 23 Construction; 482 Rail Transportation; 483 Water Transportation; 484 Truck Transportation; 485 Transit and Ground Passenger Transportation; 4854 School and Employee Bus Transportation; 48831 Port and Harbor Operations; 61111 Elementary and Secondary Schools; 61131 Colleges, Universities, and Professional Schools; 9211 Executive, Legislative, and Other Government Support; and 9221 Justice, Public Order, and Safety Activities.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 500–1000 (total).

Frequency of response: On occasion.

Total estimated burden: 2945 hours (per year). Burden is defined at 5 CFR 1320.03(b)

Total estimated cost: $103,197.33 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is an increase of 136 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to a higher reported burden by the two responses to consultation outreach. The higher burden reported by these past respondents was weighted against previous estimates for the latest burden estimate.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–03063 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2002–0091: FRL–9988–30–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Ambient Air Quality Surveillance (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Ambient Air Quality Surveillance (EPA ICR Number 0940.29, OMB Control Number 2060–0084) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through March 31, 2019. Public comments were previously requested via the **Federal Register** on September 4, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before March 25, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2002–0091, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *A-and-R-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Laurie Trinca, Air Quality Assessment Division, Office of Air Quality Planning and Standards, C304–06, Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: 919–541–0520; fax number: 919–541–1903: email address: *trinca.laurie@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The data collected through this information collection consist of ambient air concentration measurements for the seven air pollutants with national ambient air quality standards (*i.e.,* ozone, sulfur dioxide, nitrogen dioxide, lead, carbon monoxide, $PM_{2.5}$ and PM_{10}), ozone precursors, meteorological variables at a select number of sites and other supporting measurements. Accompanying the pollutant concentration data are quality assurance/quality control data and air monitoring network design information.

The U.S. EPA and others (*e.g.,* state and local air quality management agencies, tribal entities, environmental groups, academic institutions, industrial groups) use the ambient air quality data for many purposes. Some of the more prominent uses include informing the public and other interested parties of an area's air quality, judging an area's (*e.g.,* county, city, neighborhood) air quality in comparison with the established health or welfare standards (including both national and local standards), evaluating an air quality management agency's progress in achieving or maintaining air pollutant levels below the national and local standards, developing and revising State Implementation Plans (SIPs) in accordance with 40 CFR 51, evaluating air pollutant control strategies, developing or revising national control policies, providing data for air quality model development and validation, supporting enforcement actions, documenting episodes and initiating episode controls, air quality trends assessment, and air pollution research.

The state and local agencies and tribal entities with responsibility for reporting ambient air quality data and information as requested in this ICR submit these data electronically to the U.S. EPA's Air Quality System (AQS) database. Quality assurance/quality control records and monitoring network documentation are also maintained by each state and local agency, in AQS electronic format where possible.

Although the state and local air pollution control agencies and tribal entities are responsible for the operation of the air monitoring networks, the EPA funds a portion of the total costs through federal grants. These grants generally require an appropriate level of contribution, or ''match,'' from the state/local agencies or tribal entities. The costs shown in this renewal are the total costs incurred for the monitoring program regardless of the source of the funding. This practice of using the total cost is consistent with prior ICR submittals and renewals.

Form Numbers: None.

Respondents/affected entities: State, local and Tribal Air Pollution Control Agencies.

Respondent's obligation to respond: Mandatory (40 CFR part 58).

Estimated number of respondents: 168 (total).

Frequency of response: Quarterly.

Total estimated burden: 1,771,662 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $215,352,864 (per year), includes $81,263,356 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is a decrease of 18,359 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is due to a change in program requirements as well as adjustments to the estimates (*e.g.* to account for inflation, network growth/shrinkage, etc.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–03062 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9043–5]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa/*.

Weekly receipt of Environmental Impact Statements
Filed 02/11/2019 Through 02/14/2019
Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search*.

EIS No. 20190014, Draft, FERC, CA, Don Pedro Hydroelectric Project and La Grange Hydroelectric Project, Comment Period Ends: 04/08/2019, Contact: Office of External Affairs 866–208–3372

EIS No. 20190015, Draft, TVA, TN, 2019 Draft Integrated Resource Plan, Comment Period Ends: 04/08/2019, Contact: Ashley Pilakowski 865–632–2256

EIS No. 20190016, Final, NSF, WV, Green Bank Observatory, Green Bank, West Virginia, Review Period Ends: 03/25/2019, Contact: Elizabeth Pentecost 703–292–4907

Dated: February 15, 2019.

Robert Tomiak,

Director, Office of Federal Activities.

[FR Doc. 2019–02913 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0069; FRL—9989–69–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Source Categories: Generic Maximum Achievable Control Technology Standards for Acetal Resin; Acrylic and Modacrylic Fiber; Hydrogen Fluoride and Polycarbonate Production (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Source Categories: Generic Maximum Achievable Control Technology Standards for Acetal Resin; Acrylic and Modacrylic Fiber; Hydrogen Fluoride and Polycarbonate Production (EPA ICR No. 1871.10, OMB Control No. 2060–0420), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through March 31, 2019. Public comments were previously requested, via the **Federal Register**, on May 30, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before March 25, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0069, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW,

Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The New Source Performance Standards (NSPS) for Generic Maximum Achievable Control Technology Standards for Acetal Resin; Acrylic and Modacrylic Fiber; Hydrogen Fluoride and Polycarbonate Production apply to new and existing facilities of the following four categories: Polycarbonates (PC) Production, Acrylic and Modacrylic Fibers (AMF) Production, Acetal Resins (AR) Production, and Hydrogen Fluoride (HF) Production. In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance with 40 CFR part 63, subpart YY.

Form Numbers: None.

Respondents/affected entities: Respondents are existing facilities and new of the following four categories: Polycarbonates (PC) Production, Acrylic and Modacrylic Fibers (AMF) Production, Acetal Resins (AR) Production, and Hydrogen Fluoride (HF) Production. The PC industry consists of facilities that produce polycarbonates, a process that involves a polymerization reaction using either a solution or suspension process in either a batch or continuous mode. All production of polycarbonates in the United States is currently based on the polymerization reaction of bisphenols with phosgene in the presence of catalysts, solvents (mainly methylene chloride) and other additives. The AMF industry consists of facilities that produce acrylic and modacrylic fibers, which are manufactured synthetic fibers in which the fiber-forming substance is any long-chain synthetic polymer containing acrylonitrile units. The AR industry consists of facilities that produce homopolymers and/or copolymers of alternating oxymethylene units. Acetal resins are also known as polyoxymethylenes, polyacetals, and aldehyde resins. The HF industry consists of facilities that produce and recover hydrogen fluoride by reacting calcium fluoride with sulfuric acid. In this subpart, hydrogen fluoride production is not a process that produces gaseous hydrogen fluoride for direct reaction with hydrated aluminum to form aluminum fluoride (*i.e.,* the hydrogen fluoride is not recovered as an intermediate or final product prior to reacting with the hydrated aluminum).

Respondent's obligation to respond: Mandatory (40 CFR 63, Subpart YY).

Estimated number of respondents: 7 (total).

Frequency of response: Initially, occasionally, and semiannually.

Total estimated burden: 2,910 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $361,000 (per year), which includes $43,100 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: The decrease in burden from the most-recently approved ICR is due to an adjustment. The change in the burden and cost estimates occurred because the most-recent amendments to these standards have been in effect for more than three years and the requirements are different during initial compliance (new facilities) as compared to on-going compliance (existing facilities). The previous ICR reflected those burdens and costs associated with the initial activities for subject facilities from the October 8, 2014 final rule. This included purchasing monitoring equipment, conducting performance tests, and establishing recordkeeping systems. This ICR, by in large, reflects the on-going burden and costs for existing facilities. Activities for existing sources include continuous monitoring of pollutants and the submission of semiannual reports. There is a decrease in capital/startup vs. operation and maintenance (O&M) costs as calculated in section 6(b)(iii) compared with the ICR currently approved by OMB due there being no new respondents.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–03057 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0531; FRL–9989–62–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Surface Coating of Large Appliances (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for Surface Coating of Large Appliances (EPA ICR Number 0659.14, OMB Control Number 2060–0108), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through March 31, 2019. Public comments were previously requested, via the **Federal Register**, on June 29, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before March 25, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2012–0531, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via

email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

The EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The New Source Performance Standards (NSPS) for Surface Coating of Large Appliances apply to large appliance coating facilities. In general, all NSPS standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance with 40 CFR part 60, subpart SS.

Form Numbers: None.

Respondents/affected entities: Large appliance surface coating facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart SS).

Estimated number of respondents: 72 (total).

Frequency of response: Initially, quarterly, and semiannually.

Total estimated burden: 7,220 (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $830,000 (per year), includes $8,400 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment decrease in the total estimated burden as compared to the previous ICR due to an adjustment to the number of respondents expected to submit excess emissions and monitoring systems performance reports from 100 percent of respondents to 20 percent of respondents. The prior ICR included an assumption that all respondents would experience an exceedance; based on Agency knowledge and experience with the NSPS, 20 percent is more likely representative of the actual number of respondents submitting these reports. These changes resulted in an overall decrease in the labor costs.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–03058 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2018–0818; FRL–9989–74–OGC]

Proposed Partial Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed partial consent decree; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (''CAA'' or the ''Act''), notice is given of a proposed partial consent decree in *Sierra Club* v. *Pruitt,* No. 1:17–cv–02174–APM (D.D.C.). On October 19, 2017, Sierra Club filed a complaint in the United States District Court for the District of Columbia, alleging that the Administrator of the United States Environmental Protection Agency (''EPA'') failed to perform a non-discretionary duty to assess and report to Congress on the environmental and resource conservation impacts of the Energy Independence and Security Act's (EISA) Renewable Fuel Standard (RFS) program, failed to complete the required anti-backsliding study to determine whether the vehicle and engine air pollutant emissions changes resulting from the RFS program's renewable fuel volumes adversely impact air quality, and failed to promulgate fuel regulations to implement appropriate measures to mitigate any such adverse impacts or make a determination that such regulations were unnecessary. The proposed partial consent decree would establish a deadline for EPA to take action on the anti-backsliding study.

DATES: Written comments on the proposed partial consent decree must be received by March 25, 2019.

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2018–0818, online at *www.regulations.gov* (EPA's preferred method). For comments submitted at *www.regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *www.regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Seth Buchsbaum, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone: (202) 564–2484; email address: *buchsbaum.seth@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Partial Consent Decree

The proposed partial consent decree would partially resolve a lawsuit filed by Sierra Club seeking to compel the Administrator to take action under the Clean Air Act to complete a study to determine whether the vehicle and engine air pollutant emissions changes resulting from the RFS program's renewable fuel volumes adversely impact air quality (Anti-backsliding Study), and either promulgate fuel regulations to implement appropriate measures to mitigate any such adverse impacts or make a determination that such regulations are unnecessary (Follow-up Action).

Under the terms of the proposed partial consent decree, EPA shall

complete the Anti-backsliding Study on or before March 30, 2020. In addition, within three months of completing the Anti-backsliding Study, if the parties cannot reach an agreement on a deadline for the Follow-up Action, they will promptly submit a joint motion (or, if the Parties are unable to agree, separate motions) to govern further proceedings.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed partial consent decree from persons who are not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed partial consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act.

II. Additional Information About Commenting on the Proposed Partial Consent Decree

A. How can I get a copy of the partial consent decree?

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2018–0818) contains a copy of the proposed partial consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *www.regulations.gov.* You may use *www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at *www.regulations.gov* without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to whom do I submit comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment and with any disk or CD–ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *www.regulations.gov* website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (email) system is not an ''anonymous access'' system. If you send an email comment directly to the Docket without going through *www.regulations.gov,* your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: January 30, 2019.

Gautam Srinivasan,

Acting Associate General Counsel.

[FR Doc. 2019–03108 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

Privacy Act of 1974; System of Records

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of a modified system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act, EPA's Office of Pollution Prevention and Toxics (OPPT) is providing notice of its proposal to modify an existing system of records (SOR) by updating the category of uses to add lead-based paint and renovator professionals' photographs, to add names of training program managers and principal course instructors as well as their education or experience or training qualifications, to discuss EPA's Central Data Exchange (CDX) interconnection for online applications and notifications submissions and other administrative updates to the ''Federal Lead-Based Paint Program System of Records'' (FLPPSOR). FLPPSOR stores information in both electronic and hard-copy formats and contains information about individuals who have applied for certification to conduct lead-based paint and renovation, repair and painting (RRP) activities and students taking classes in lead-based paint and RRP activities. FLPPSOR contains information about individuals who have been trained or applied for certification to perform lead-based paint and RRP activities. FLPPSOR contains information about individuals who are trained or certified in the following disciplines: abatement workers, inspectors, supervisors, risk assessors, project designers, renovators and dust sampling technicians. The EPA Federal Lead-Based Paint Program system of records does not duplicate any existing system of records. The system handles Privacy Act protected information in the same manner regardless of whether the information is contained in electronic or hard-copy form.

DATES: Persons wishing to comment on this system of records notice amendment must do so by March 25, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OEI–2017–0588, by one of the following methods:

Regulations.gov: www.regulations.gov. Follow the online instructions for submitting comments.

Email: oei.docket@epa.gov.

Fax: 202–566–1752.

Mail: OEI Docket, Environmental Protection Agency, Mail code: 2822T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

Hand Delivery: OEI Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OEI–2017–0588. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov.* The *www.regulations.gov* website is an ''anonymous access'' system for EPA, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. Each agency determines submission requirements within their own internal processes and standards. EPA has no requirement of personal information. If you send an email comment directly to the EPA without going through *www.regulations.gov* 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. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the OEI Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: Robert Wright, National Program Chemicals Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1975; email address: *wright.robert@epa.gov.*

SUPPLEMENTARY INFORMATION:

1. General Information

On August 29, 1996, EPA published the requirements for Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities in the **Federal Register** with an effective date of October 28, 1996. These regulations established requirements for firms to be certified, an accreditation program for training providers, and training, certification and work practice requirements for individuals in the following abatement disciplines: Inspectors, supervisors, risk assessors, project designers and workers. On April 8, 2004, EPA published the notification requirements for Lead-Based Paint Abatement Activities and Training in the **Federal Register** with an effective date of May 10, 2004. These regulations established notification procedures for certified lead abatement firms to notify EPA prior to commencement of lead-based paint abatement activities and accredited training providers to notify EPA prior to teaching an abatement training course and submit a post-training notification following completion of the training course to provide EPA information about the individuals that were trained. On April 22, 2008, EPA published the RRP rule in the **Federal Register** with an effective date of June 23, 2008. The RRP rule established requirements for training renovators and dust-sampling technicians; certifying renovators, dust sampling technicians and renovation firms; and accrediting providers of renovator and dust sampling technician training. FLPPSOR contains information about individuals who are certified inspectors, supervisors, risk assessors, project designers, abatement workers, renovators and dust sampling technicians. Also, FLPPSOR contains the names of training program managers and principal course instructors as well as their education or experience or training qualifications. EPA administers the certification and accreditation programs in States, Tribal areas, and territories that do not have EPA's authorization to independently administer such programs. Access to the system is restricted to authorized users and will be maintained in a secure, password-protected computer system, in secure areas and buildings with physical access controls and environmental controls.

The system is maintained by EPA's Office of Chemical Safety and Pollution Prevention, Office of Pollution Prevention and Toxics.

SYSTEM NAME AND NUMBER

Federal Lead-Based Paint Program System of Records (FLPPSOR) and EPA–54.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records maintained in FLPPSOR are stored in electronic and hard-copy formats at Research Triangle Park (RTP), NC, EPA regional offices and the Federal program contractor's office.

SYSTEM MANAGER(S):

Tanya Mottley, Director, National Program Chemicals Division, USEPA, Office of Pollution Prevention and Toxics, (7404T), 1200 Pennsylvania Ave. NW, Washington, DC 20460, (202) 566–1652; and Michelle Price, Chief, Lead, Heavy Metals and Inorganics Branch, National Program Chemicals Division, USEPA, Office of Pollution Prevention and Toxics, (7404T), 1200 Pennsylvania Ave. NW, Washington, DC 20460, (202) 566–0744.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

40 CFR part 745 Lead—Requirements for Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities and 40 CFR part 745 Lead—Renovation, Repair, and Painting Program.

PURPOSE(S) OF THE SYSTEM:

The purpose of FLPPSOR is to maintain information submitted

electronically via EPA's CDX system to the Agency and through various documents under the Federal Lead-Based Paint and RRP Programs. These records include application forms, notification forms, and various support documents. FLPPSOR supports activities integral to the program (*i.e.,* issuing certificates, analyzing information, generating letters and reports, and providing information to allow for executing various enforcement actions). EPA's CDX Customer Registration Subsystem's System of Records Notice is EPA–52 [(**Federal Register**: December 8, 2003 (Volume 68, Number 234)]. The CDX system has an interconnection to the FLPP Database system. On January 15, 2015, the CDX Memorandum of Understanding (MOU) and CDX Interconnection Security Agreement (ISA) documents were signed. The MOU defines the responsibilities of the participating organizations of the interconnection and the ISA specifies the technical and security requirements of the interconnection.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by the system include those who have been trained or have applied for certification to perform lead-based paint and RRP activities in the following disciplines: inspectors, supervisors, risk assessors, project designers, abatement workers, renovators, and dust sampling technicians. In addition, individuals covered by the system include training program managers and principal course instructors who have been accredited to teach lead-based paint and RRP activities in the following disciplines: inspectors, supervisors, risk assessors, project designers, abatement workers, renovators, and dust sampling technicians.

CATEGORIES OF RECORDS IN THE SYSTEM:

FLPPSOR contains individuals' names, addresses, telephone numbers, dates of birth, photographs of lead-based paint and RRP professionals, signatures, course test scores, submitted fees, and certificate numbers as well as the names of training program managers and principal course instructors as well as their education or experience or training qualifications.

RECORD SOURCE CATEGORIES:

Information is obtained from individuals who have submitted a certification application and have been trained by an accredited training provider. FLPPSOR maintains records on individuals derived from a variety of sources relating to the undertaking of individuals applying for certification and being trained to perform lead-based paint and RRP activities. Also, FLPPSOR maintains records of the names of training program managers and principal course instructors as well as their education or experience or training qualifications.

These record sources include the following forms submitted to EPA: EPA Form 8500–28, ''Application and Instructions for Individuals Applying for Certification to Conduct Lead-Based Paint Activities'' and EPA Form 8500–25, ''Application and Instructions for Training Providers Applying for Accreditation of Lead-Based Paint Activity and Renovator Training Programs.'' The information derived from these forms concerns individuals who have applied for certification or accreditation in lead-based paint or renovation, repair and painting activities. Two record sources include information derived from required notifications submitted to EPA pursuant to 40 CFR part 745. The first record source requires firms certified under 40 CFR 745.227 to provide notification to the Agency prior to conducting lead-based paint abatement activities. The second record source requires training programs accredited under 40 CFR 745.225 to provide notification to the Agency prior to (pre-training notice) and then following conducting lead-based paint and RRP activities training courses (post-training notice). The data derived from the post-training notifications includes information on inspectors, supervisors, risk assessors, project designers, abatement workers, renovators and dust sampling technicians who have been trained. Finally, other record sources of information stored in the system may include supplementary documents obtained by headquarters and regional offices in the application approval process.

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

General routine uses are as follows: A, B, C, E, F, G, H, I, K(73 FR 2245). (*https://www.federalregister.gov/documents/2008/01/14/E8-445/amendment-to-general-routine-uses*)

In addition, the Agency may disclose information from FLPPSOR to Federal, State, or local agencies, present and former employers and business and personal associates, and hearing officials, as a given situation might require for purposes including the following:

(1) To verify the identity of the individual;

(2) To enforce the conditions or terms of the Agency's Lead-Based Paint Program and RRP Program regulations;

(3) To investigate possible fraud by, for example, applicants and users, and verify compliance with the Agency's Lead-Based Paint Program and RRP Program regulations;

(4) To prepare for litigation or to litigate fee collections and reporting enforcement matters;

(5) To initiate a limitation, suspension, and termination (LS&T) or debarment action;

(6) To investigate complaints, update files, and correct errors;

(7) To prepare for alternative dispute resolutions (ADR) in any of the cases described in paragraphs (2), (3), and (4);

(8) To engage in audits or other internal matters within EPA;

(9) To contact certified individuals and applicants in the event of a system modification that changes their application or certification information; or

(10) To respond to a change to FLPPSOR, as in the case of a modification, revocation, or termination of a user's access privileges.

(11) Disclosure to Persons or Entities in Response to an Actual or Suspected Compromise or Breach of Personally Identifiable Information

To appropriate agencies, entities, and persons when (1) the Agency suspects or has confirmed that there has been a breach of the system of records,· (2) the Agency has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Agency (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Agency's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(12) Disclosure to assist another agency in its efforts to respond to a breach.

To another Federal agency or Federal entity, when the Agency determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national

security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Storage: Records maintained under the FLPPSOR are stored in different formats and in several locations. Each of these record collections, which together comprise the FLPPSOR, must adhere to the requirements of the Privacy Act and are subject to the rules and restrictions for disclosure of information specified under the Freedom of Information Act.

(1) The main system is located at EPA's National Computer Center (NCC) in Research Triangle Park (RTP), North Carolina. This database contains information entered from some of the primary sources listed above under ''Categories of Records in the System'' (submitted form and notifications).

(2) Hard-copy files are located in EPA regional offices and the facility operated by EPA's Federal program contractor's office. These records include the original or photocopied paper submissions (including supplementary information) provided to the Agency.

(3) EPA regional offices have developed electronic systems for their local uses. These electronic records are maintained separate from the main central server at RTP and are used solely by the regional offices.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Retrievability: Records are retrieved by an individual's name, application ID number, applicant ID number, or program activity.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Retention and Disposal: EPA will retain and dispose of these records in accordance with the EPA Records Schedule 089 and the National Archives and Records Administration General Records Schedule 23/8. Application records maintained in the system are deleted/destroyed two years after the date of the last entry.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Safeguards: Physical access to the system housed in the facility at RTP is controlled by a computerized badge-reading system, with security patrols during non-business hours. All interactions between the system and the authorized individual users are recorded through use of a card reader and tracking database. Paper records stored at EPA's Federal program contractor and storage facility are protected by computerized badge-reading security systems, with files maintained in locked file drawers. Records stored at EPA offices are secured through building security protocols and computerized badge-reading systems. FLPP's Security Manager gives access and assigns the different access roles to FLPP users. The FLPP database uses an authentication system to valid FLPP users to have access to use the database.

RECORD ACCESS PROCEDURES:

Requesters seeking access to this system of records must follow the ''Notification Procedure'' listed below and will be required to provide adequate identification (*e.g.,* driver's license, military identification card, employee badge or identification card). Additional identity verification procedures may be required as warranted. Requests must meet the requirements of EPA regulations at 40 CFR part 16.

CONTESTING RECORD PROCEDURES:

If you wish to contest a record in the system of records, contact the Agency's National Privacy Program as described under ''Notification Procedure'' listed below. Your written inquiry should identify the record(s) to be corrected, the corrective action sought, including any requested amendment to the records, and any supporting documentation you consider relevant to EPA's consideration of your request.

NOTIFICATION PROCEDURE:

Requests to determine whether this system of records contains a record pertaining to you must be sent to the Agency's National Privacy Program. The address is: U.S. Environmental Protection Agency; 1200 Pennsylvania Ave. NW, Room 2335 West; Washington, DC 20460; (202) 566–1668; *Email:* (*privacy@epa.gov*); *Attn:* Agency Privacy Officer.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

70 FR 35251—Established a new System of Records (SOR) under the Federal Lead-Based Paint Program (June 17, 2005).

74 FR 42298—Amended an existing system of records (SOR) by changing the title of ''Lead-Based Paint System of Records'' (LPSOR) to the ''Federal Lead-Based Paint Program System of Records'' (FLPPSOR).

Dated: September 11, 2018.

Vaughn Noga,

Principal Deputy Assistant Administrator.

[FR Doc. 2019–03107 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2004–0082; FRL–9988–73–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; EPA's Natural Gas STAR Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), EPA's Natural Gas STAR Program (EPA ICR No. 1736.08, OMB Control No. 2060–0328) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a renewal with modification of the existing ICR which expires on March 31, 2019. Public comments were previously requested via the **Federal Register** on September 5, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before March 25, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2004–0082 to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *a-and-r-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Jerome Blackman, Office of Atmospheric Programs, Climate Change Division, (6207A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460;

telephone number: 202–343–9630; email address: *Blackman.Jerome@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: Natural Gas STAR is a voluntary program sponsored by the U.S. Environmental Protection Agency (EPA) that encourages oil and natural gas companies to adopt cost effective technologies and practices that improve operational efficiency and reduce methane emissions. Methane is the primary component of natural gas and a potent greenhouse gas. The Program works with oil and natural gas companies in the production, gathering & processing, transmission, and distribution sectors to remove barriers that inhibit the implementation of technologies and practices that reduce methane emissions. The Program effectively promotes the adoption of emission reduction technologies and practices by helping Natural Gas Star partners evaluate Best Management Practices (BMPs) in the context of their current operations and implement them where cost effective. Implementation of the Program's BMPs saves participants money, improves operational efficiency, and enhances the protection of the environment.

The current Memorandum of Understanding used to join the partnership has not been updated in 25 years. EPA proposes to replace it with a streamlined and more flexible Partnership Agreement which will more realistically reflect options companies have to engage with the Program. This change, in addition to updates to the annual report forms and increased flexibility regarding partner Implementation Plans, will reduce the total burden estimate for companies participating in Natural Gas STAR.

Form Numbers:

- Partnership Agreement: EPA Form No. 5900–105.
- Production Partners: EPA Form No. 5900–103.
- Transmission Partners: EPA Form No. 5900–109.
- Distribution Partners: EPA Form No. 5900–97.
- Gathering and Processing Partners: EPA Form No. 5900–100.
- Production Partners: EPA Form No. 5900–104.
- Transmission Partners: EPA Form No. 5900–95.
- Distribution Partners: EPA Form No. 5900–99.
- Gathering and Processing Partners: EPA Form No. 5900–102.

Respondents/affected entities: The gathering and processing, production, transmission, and distribution sectors of the oil and natural gas industry.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 147 total (97 partners; 50 vendors).

Frequency of response: Annual for partners and semi-annual for vendor service directory.

Total estimated burden: 2,846 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $268,577 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is decrease of burden for Partner respondents from 6,995 hours in the ICR currently approved by OMB to 2,834 under this renewal request. This decrease is attributed to the Program's maturity and the fact that partner burden decreases over time as internal processes are established, a decrease in the number of companies joining Gas STAR, a decrease in the estimated number of partners submitting reports annually, and the streamlining of the Partnership Agreement and annual report forms. EPA estimates that approximately 50 companies will complete the Service Provider Directory form with a total burden of 13 hours annually.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–03060 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0044; FRL—9987–99–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Coke Oven Batteries (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Coke Oven Batteries (EPA ICR Number 1362.11, OMB Control Number 2060–0253) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved. Public comments were previously requested via the **Federal Register** on June 29, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before March 25, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0044, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for the regulations published at 40 CFR part 63, subpart L apply to all coke oven batteries, whether existing, new, reconstructed, rebuilt, or restarted. It also applies to all batteries using conventional by-product recovery processes, non-recovery processes, or any new recovery processes. In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance with 40 CFR part 63, subpart L.

Form Numbers: None.

Respondents/affected entities: Coke oven batteries.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart L).

Estimated number of respondents: 19 (total).

Frequency of response: Initially, occasionally, and semiannually.

Total estimated burden: 79,800 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $8,730,000 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is an adjustment decrease in labor hours from the most recently approved ICR. This decrease reflects revisions to the number of existing respondents that are anticipated to reconstruct or close batteries subject to this standard; the burden reflected in this ICR assumes that reconstruction for one existing facility has been completed. This decrease is not due to any program changes.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–03054 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (''Act'') (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than March 11, 2019.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *William Nathan Salin Family Irrevocable Trust #1, Carmel, Indiana, and Margaret Jane Salin, Carmel, Indiana, as Trustee, individually, and together as a group acting in concert, with the Margaret Jane Salin Irrevocable Grandchildren's Trust No. 1 dated December 11, 2012, Trustee William N. Salin II, Syracuse, Indiana, the William N. Salin, II, Irrevocable Children's Trust dated December 11, 2012, Trustee, William N. Salin II, Syracuse, Indiana, the Margaret Jane Salin Irrevocable Grandchildren's Trust No. 2 dated December 11, 2012, Trustee Sherri S. Fritsch, Carmel, Indiana, the Sherri Fritsch Irrevocable Children's Trust dated December 11, 2012, Trustee Sherri S. Fritsch, Carmel, Indiana, the Margaret Jane Salin Irrevocable Grandchildren's Trust No. 3 dated December 11, 2012, Trustee Susan S. McClain, Carmel, Indiana, the Susan McClain Irrevocable Children's Trust dated December 11, 2012, Trustee Susan S. McClain, William N. Salin II, Syracuse, Indiana, Sherri S. Fritsch, Carmel, Indiana, and Susan S. McClain, Carmel, Indiana;* to acquire voting shares of Horizon Bancorp, and thereby indirectly acquire shares of Horizon Bank, both of Michigan City, Indiana.

Board of Governors of the Federal Reserve System, February 19, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–03092 Filed 2–21–19; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission (''FTC'' or ''Commission'').

ACTION: Notice; request for comments.

SUMMARY: The FTC requests that the Office of Management and Budget (''OMB'') extend for an additional three years the current Paperwork Reduction Act (''PRA'') clearance for the information collection requirements in its Alternative Fuels Rule (''Rule''). That clearance expires on May 31, 2019.

DATES: Comments must be submitted on or before March 25, 2019.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Paperwork Comment: FTC File No. P134200'' on your comment, and file your comment online at *https://www.regulations.gov/searchResults?rpp=25&so=DESC&sb=postedDate&po=0&cp=O&a=FTC* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information requirements for the Alternative Fuels Rule should be directed to Hampton Newsome, Attorney, (202) 326–2889, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

Title: Alternative Fuels Rule, 16 CFR part 309.

OMB Control Number: 3084–0094.

Type of Review: Extension of currently approved collection.

Abstract: Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing a second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rule. The Rule, which implements the Energy Policy Act of 1992, Public Law 102–486, requires disclosure of specific information on labels posted on fuel dispensers for non-liquid alternative fuels. To ensure the accuracy of these disclosures, the Rule also requires that sellers maintain records substantiating product-specific disclosures they include on these labels.

It is common practice for alternative fuel industry members to determine and monitor fuel ratings in the normal course of their business activities. This is because industry members must determine the fuel ratings of their products in order to monitor quality and to decide how to market them. ''Burden'' for PRA purposes is defined to exclude effort that would be expended regardless of any regulatory requirement. 5 CFR 1320.2(b)(2). Moreover, as originally anticipated when the Rule was promulgated in 1995, many of the information collection requirements and the originally estimated hours were associated with one-time start up tasks of implementing standard systems and processes.

Other factors also limit the burden associated with the Rule. Certification may be a one-time event or require only infrequent revision. Disclosures on electric vehicle fuel dispensing systems may be useable for several years. Nonetheless, there is still some burden associated with posting labels. There also will be some minimal burden associated with new or revised certification of fuel ratings and recordkeeping. The burden on vehicle manufacturers is limited because only newly manufactured vehicles will require label posting and manufacturers produce very few new models each year.

On November 29, 2018, the Commission sought comment on the Rule's information collection requirements and staff's associated PRA burden estimates (''November 29, 2018 Notice''). One comment was received. The comment opined favorably on the Rule as a whole and, in particular, on the Rule's required disclosure of specific information on fuel dispenser labels, which the comment stated leads to more informed consumers. Further, it advocated for the FTC receiving renewed OMB clearance to enable the FTC ''to properly consider [the Rule] and how it will affect the public'' and to ''allow the FTC more feedback and to create a more refined and effective rule when they enter the final rule phase.''

To clarify, neither the November 29, 2018 Notice or the instant publication concern a rulemaking. Rather, pursuant to the PRA, the Commission seeks OMB's continued clearance to impose and enforce the Rule's recordkeeping and disclosure requirements described above and detailed further in the November 29, 2018 Notice. Nonetheless, pursuant to Section 3506(c)(2)(A) of the PRA, the Commission sought in its preceding Notice public comments on (1) whether the recordkeeping and disclosure requirements are necessary, including whether the information will be practically useful; (2) the accuracy of our burden estimates, including whether the methodology and assumptions used are valid; (3) how to improve the quality, utility, and clarity of the disclosure requirements; and (4) how to minimize the burden of providing the required information to consumers. No further comment than that noted above was received. The Commission invites again further public comments pursuant to the above-stated criteria.

Estimated Annual Burden [1]

Hours: Recordkeeping (2,000) + certification (400) + labeling (3,600) = 6,000 hours.

Labor Costs: Recordkeeping ($31,037) + certification ($13,112) and labeling ($118,008) = $162,157.

Non-Labor Cost: $3,040 (estimated annual fuel labeling costs).

Request for Comment

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before March 25, 2019. Write ''Paperwork Comment: FTC File No. P134200'' on your comment. Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or to send them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it through the *https://www.regulations.gov* website by following the instructions on the web-based form provided. Your comment—including your name and your state—will be placed on the public record of this proceeding, including the *https://www.regulations.gov* website. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on *www.regulations.gov.*

If you file your comment on paper, write ''Paperwork Comment: FTC File No. P134200'' on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *www.regulations.gov,* we cannot redact or remove your comment unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 25, 2019. For information

[1] The calculations underlying these estimates are detailed in the related November 29, 2018 Notice. See 83 FR at 61381.

on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.* For supporting documentation and other information underlying the PRA discussion in this Notice, see *http://www.reginfo.gov/public/jsp/PRA/praDashboard.jsp.*

Comments on the information collection requirements subject to review under the PRA also should be submitted to OMB. If sent by U.S. mail, they should be addressed to: Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503. Comments sent to OMB by U.S. postal mail are subject to delays due to heightened security precautions and also can be sent by email to *wliberante@omb.eop.gov.*

Heather Hippsley,

Deputy General Counsel.

[FR Doc. 2019–03020 Filed 2–21–19; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–19–18UC]

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 Costs of Implementing Community-based Sodium Reduction Strategies 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 June 1, 2018 to obtain comments from the public and affected agencies. The 60-day FRN was published under the title ''Evaluation of the Sodium Reduction in Communities Program.'' Since then, the project title has been modified for better alignment with study aims. CDC received two non-substantive comments 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 or send an email to *omb@cdc.gov.* 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

Costs of Implementing Community-based Sodium Reduction Strategies—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) is the primary Federal agency for protecting health and promoting quality of life through the prevention and control of disease, injury, and disability. CDC is committed to programs that reduce the health and economic consequences of the leading causes of death and disability, thereby ensuring a long, productive, healthy life for all people.

Sodium reduction is a public health imperative. Although the *2015–2020 Dietary Guidelines for Americans* recommends no more than 2,300 mg/day of sodium for adults, U.S. adults consume an average of more than 3,500 mg/day. The significant gap between recommended intake and average intake poses a serious public health risk; high sodium intake leads to hypertension, a common and costly health risk in the United States. The increasing prevalence of hypertension is especially troubling because high blood pressure leads to serious health issues, including cardiovascular disease (CVD), stroke, and kidney disease. One study projected that the real direct medical costs of CVD will triple between 2010 and 2030, from $273 billion to $818 billion. Recent studies have shown that even modest population-level sodium reductions can lead to significant decreases in blood pressure and to potentially enormous savings—in lives and in dollars.

Reducing sodium levels presents a special set of challenges for public health programs because high sodium intake is largely the result of sodium found in processed foods and foods prepared in restaurants. As such, multiple reports by the Institute of Medicine (IOM) and the Food and Drug Administration (FDA) have asserted the need for large-scale, population-based efforts to decrease sodium consumption.

Recognizing the importance of population-based approaches, CDC launched the first round of the Sodium Reduction in Communities Program (SRCP) in 2010 to reduce sodium intake by helping to create healthier food environments and a second round in 2013 to reduce sodium intake in food environments through population-based sodium reduction strategies. SRCP's project goals include increasing access to and availability of lower-sodium food options. The long-term goal of the initiative is to reduce sodium intake to within the recommended levels in the *2010 Dietary Guidelines for Americans.* CDC funded eight SRCP grantees in 2016 to continue improving community and environmental supports for sodium reduction and to build practice-based evidence around effective population-based strategies to reduce sodium consumption. Grantees included state and local health departments and one university medical center. These communities are partnering with organizations to implement sodium reduction strategies in their food service venues. By creating a healthier environment, CDC seeks to decrease the population-wide burden of sodium intake.

CDC and RTI International propose to collect information from all partners of SRCP recipients that are willing to participate in order to estimate the costs to SRCP partners of implementing sodium reduction strategies. Partner organizations are those that work to implement the sodium reduction strategies in their food services and can

include worksites, schools, universities, hospitals, senior meal programs, food banks, and restaurants. The information collection will occur via the SRCP Partner Cost Survey, in which respondents will be asked about a key set of sodium reduction activities that were developed based on a pilot study with eight partners as part of the evaluation of SRCP Round 2. Activities include: Establishing nutrition guidelines, developing lower sodium products or recipes, preparing lower-sodium food, promoting lower-sodium foods, and attending additional meetings. We will request participation from all SRCP partners via email and offer a $50 gift card as an incentive. Complete surveys will be returned to CDC's data collection contractor by email. The estimated burden per response is one hour.

The insights to be gained from this data collection will be critical to understanding the full costs of implementing community-based sodium reduction strategies. Estimates will be considered preliminary and not externally generalizable but can provide a basis for future planning and evaluation. Understanding the costs to partners is important for program planning to support program longevity and sustainability. For example, CDC can use findings to provide guidance or technical assistance to entities that are interested in population-based strategies for reducing sodium consumption. Results will also be disseminated to other state and local organizations to inform planning and sustainability of other community-based public health initiatives.

OMB approval is requested for one year. CDC estimates that information will be collected from 44 of the SRCP's community partners (50% response rate). Participation is voluntary and there are no costs to respondents other than their time. The estimated annualized burden hours are 44.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Partner Program Manager	SRCP Partner Cost Survey	44	1	1

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–03100 Filed 2–21–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2014–0012]

Information for Providers To Share With Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and Other Health Outcomes

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

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces the availability of ''Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes.''

FOR FURTHER INFORMATION CONTACT: Division of HIV/AIDS, National Centers for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS D–21, Atlanta, Georgia 30329; phone: 404–639–5200; email: *circumcision@cdc.gov.*

SUPPLEMENTARY INFORMATION: On December 2, 2014, CDC published a notice in the **Federal Register** (79 FR 71433) requesting public comment on a draft document titled *Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, STIs, and Other Health Outcomes* (referred to as The Initial Draft Document). On August 30, 2018, the title was changed to *Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes* to better align with the content in the final version of the document.

The intent of this document is to assist health care providers in the United States who share information with men and parents of male infants, children and adolescents for their use in decision making about male circumcision as it relates to the prevention of human immunodeficiency virus (HIV) infection, sexually transmitted infections (STIs), and other health outcomes. Such decision making is made in the context of not only health considerations, but also other social, cultural, ethical, and religious factors. Although observational and ecologic data have been accumulating about infant male circumcision for many years, clinical trials conducted between 2005–2010 have demonstrated safety and significant efficacy of voluntary adult male circumcision performed by clinicians for reducing the risk of acquisition of human immunodeficiency virus (HIV) by a male during penile-vaginal sex (''heterosexual sex''). Three randomized clinical trials conducted in Kenya, Uganda, and South Africa [1 2 3] showed that adult male circumcision reduced HIV infection risk by 50–60%. These trials also found that adult circumcision reduced the risk of men acquiring two common sexually transmitted infections (STIs), herpes simplex virus type-2 (HSV–2) and types of human papilloma virus (HPV) that can cause penile and other anogenital cancers. Since the release of these trial data, various medical professional organizations have updated their information about adult male and infant male circumcision.

Initial comment period. The initial comment period was open for public and peer review during December 2, 2014—January 16, 2015.

Public comments (initial comment period). CDC received 3,234 comments on the *Initial Draft Document* from the public, including but not limited to

[1] Bailey RC, Moses S, Parker CB, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial. Lancet. 2007; 369 (9562):643–656.

[2] Auvert B, Taljaard D, Lagarde E, Sobngwi-Tambekou J, Sitta R, Puren A. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 Trial. PLoS Med. 2005;2(11):e298.

[3] Gray RH, Kigozi G, Serwadda D, et al. Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial. Lancet. 2007; 369 (9562): 657–666.

individuals (*e.g.,* parents and physicians) and representatives of professional medical and community-based organizations. A summary of public comments and responses to comments, including changes are noted in the *Summary of Public Comments and CDC Responses to Public Comments for Information for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes.* This document is in the docket at: *www.regulations.gov* and at *https://www.cdc.gov/hiv/pdf/risk/MC-HISA-Public-Comments-and-Responses.pdf.*

Peer Review comments (initial comment period). Peer reviewers were asked to review the *Initial Draft Document* and its companion document, *Background, Methods, and Synthesis of Scientific Information Used to Inform the 'Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, STIs, and other Health Outcomes.'* On August 30, 2018, the title of this companion document was changed to *Background, Methods, and Synthesis of Scientific Information Used to Inform 'Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes'* to better align with the content in the final document.

CDC considers these documents to be highly influential scientific assessments (HISA) as defined by the Office of Management and Budget's (OMB) directive, Final Information Quality Bulletin for Peer Review, dated December 15, 2004. HISA documents are subject to peer review.

Peer reviewers evaluated the appropriateness of the methods and of the interpretation of findings, including generalizability of the evidence to the United States. Peer review comments were received from three physician peer reviewers. A copy of peer review comments, CDC responses, and changes are noted in the documents titled: *Peer Review Comments and CDC Responses for Peer Review Comments and CDC Responses for ''Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes''* and *''Background, Methods, and Synthesis of Scientific Information Used to Inform 'Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes.'* These documents are in the public docket at *www.regulations.gov* and at *https://www.cdc.gov/hiv/pdf/risk/MC-HISA-Round-1-Peer-Review-Comments-and-Responses.pdf.*

Second comment period. The second comment period was opened during September 15–30, 2016, for peer review only.

Peer Review comments (second comment period). Peer Reviewers reviewed and commented on a revised copy of the *Initial Draft Document.* Peer Reviewers were asked to limit their comments only to changes that were made as a result of the initial comment period.

Comments were received from two peer reviewers. A summary of peer review comments, CDC responses, and changes made are noted in the *Summary of Peer Review Comments and CDC Responses to Second Round of Peer Review Comments for Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes* are in the public docket at *www.regulations.gov* and at *https://www.cdc.gov/hiv/pdf/risk/MC-HISA-Round-2-Peer-Review-Comments-and-Responses.pdf.*

All comments were carefully reviewed and considered in the development of the final version of the document found in the public docket at *www.regulations.gov* and at *https://www.cdc.gov/hiv/risk/male-c*ircumcision.html.

Dated: February 14, 2019.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2019–02907 Filed 2–21–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Institute for Occupational Safety and Health: Notice of Charter Renewal

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

ACTION: Notice of charter renewal.

SUMMARY: This gives notice under the Federal Advisory Committee Act of October 6, 1972, that the Board of Scientific Counselors, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through February 3, 2021.

FOR FURTHER INFORMATION CONTACT: Alberto Garcia, M.S., Executive Secretary, BSC, NIOSH, CDC, 555 Ridge Avenue, MS–R5, Cincinnati, OH 45213, telephone (513) 841–4596, fax (513) 841–4506.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–03008 Filed 2–21–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–18–18AQQ]

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 ''HIV prevention among Latina transgender women: Evaluation of a Locally Developed Intervention (ChiCAS)'' 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 August 23, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments 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 or send an email to *omb@cdc.gov.* 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

HIV prevention among Latina Transgender Women: Evaluation of a Locally Developed Intervention (ChiCAS)''—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention is requesting approval for 20-months of data collection entitled, ''HIV prevention among Latina transgender women: Evaluation of a locally developed intervention.'' The goal of this study is to evaluate the efficacy of ChiCAS (Chicas Creando Acceso a la Salud [Chicas: Girls Creating Access to Health]), a locally developed and culturally congruent two-session Spanish-language small-group combination intervention designed to promote consistent condom use, and access to and participation in pre-exposure prophylaxis (PrEP) and medically supervised hormone therapy by HIV seronegative Hispanic/Latina transgender women who have sex with men.

The information collected through this study will be used to evaluate whether the ChiCAS intervention is an effective HIV-prevention strategy by assessing whether exposure to the intervention results in improvements in participants' health and HIV prevention behaviors. The study will compare pre-(baseline) and post-intervention (6-month) levels of HIV risk among participants who have received the intervention and participants who have not yet received the intervention (delayed-intervention group).

This study will be carried out in five metropolitan areas in North Carolina: Ashville, NC; Charlotte, NC; Research Triangle (metropolitan area of Greensboro, Winston-Salem and High Point NC); Raleigh, NC; and Wilmington, NC. The study population will include 140 HIV-negative Spanish-speaking transgender women. Participants will be adults, at least 18 years of age, self-identify as male-to-female transgender or report having been born male and identifying as female, and report having sex with at least one man in the past six months. We anticipate participants will be comprised mainly of racial/ethnic minority participants under 35 years of age, consistent with the epidemiology of HIV infection among transgender women.

Intervention participants will be recruited to the study through a combination of approaches, including traditional print advertisement, referral, in-person outreach, and through word of mouth. A quantitative assessment will be used to collect information for this study, which will be delivered at the time of study enrollment and again at 6-month follow up. The assessment will be used to measure differences in sexual risk knowledge, perceptions and behaviors including condom use, PrEP use and use of medically supervised hormone therapy. Intervention mediators, including healthcare provider trust and communication skills, self-reported health status and healthcare access, community attachment and social support will also be measured. All participants will complete the assessment at baseline and again at 6-month follow-up after enrolling in the study. The intervention group will participate in ChiCAS after completing the baseline assessment and the delayed intervention group will participate in ChiCAS after completing the 6-month follow up assessment.

We will also examine intervention experiences through in-depth interviews with 30 intervention group participants. The interviews will capture participants' general experiences with the ChiCAS intervention, as well as their experiences and perceptions specific to the main study outcomes: PrEP knowledge, awareness, interest and use; condom skills and use; and hormone therapy knowledge, awareness, interest and use.

It is expected that 50% of transgender women screened will meet study eligibility. We expect the initial screening to take approximately four minutes to complete. The assessment will take 60 minutes (one hour) to complete and will be administered to 140 participants a total of two times. The interview will take 90 minutes (one and one-half hours) to complete and will be administered to 30 participants from the intervention group one time. There are no costs to the respondents other than their time. The total number of burden hours is 344 across 23-months of data collection. The total estimated annualized burden hours is 172.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General Public—Adults	Eligibility Screener	140	1	3/60
General Public—Adults	Contact Information	70	1	1/60
General Public—Adults	Assessment	70	2	60/60
General Public—Adults	Interview	15	1	90/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–03099 Filed 2–21–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIAC)

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

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Clinical Laboratory Improvement Advisory Committee (CLIAC). This meeting is open to the public, limited only by the space available. The meeting room accommodates approximately 100 people. The public is also welcome to view the meeting by webcast. Check the CLIAC website on the day of the meeting for the webcast link *www.cdc.gov/cliac.*

DATES: The meeting will be held on April 10, 2019, 8:30 a.m. to 6:00 p.m., EDT and April 11, 2019, 8:30 a.m. to 1:00 p.m., EDT.

ADDRESSES: The Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244 and via webcast at *www.cdc.gov/cliac.*

FOR FURTHER INFORMATION CONTACT: Nancy Anderson, MMSc, MT(ASCP), Senior Advisor for Clinical Laboratories, Division of Laboratory Systems, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24–3, Atlanta, Georgia 30329–4018, telephone (404) 498–2741; *NAnderson@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: This Committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services (HHS); the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare and Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the Clinical Laboratory Improvement Amendment (CLIA) standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods, the electronic transmission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

All people attending the CLIAC meeting in-person are required to register for the meeting online at least five business days in advance for U.S. citizens and at least 15 business days in advance for international registrants. Register at *www.cdc.gov/cliac.* Register by scrolling down and clicking the ''Register for this Meeting'' button and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than April 2, 2019 for U.S. registrants and March 19, 2019 for international registrants.

It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments on agenda items. Public comment periods for each agenda item are scheduled immediately prior to the Committee discussion period for that item. In general, each individual or group requesting to make oral comments will be limited to a total time of five minutes (unless otherwise indicated). To assure adequate time is scheduled for public comments, speakers should notify the contact person below at least five business days prior to the meeting date. For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least five business days prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments, one hard copy with original signature, should be provided to the contact person at the mailing or email address below, and will be included in the meeting's Summary Report.

The CLIAC meeting materials will be made available to the Committee and the public in electronic format (PDF) on the internet instead of by printed copy. Check the CLIAC website on the day of the meeting for materials: *www.cdc.gov/cliac.*

Matters to be Considered: The agenda will include agency updates from CDC, CMS, and FDA. Presentations and discussions will focus on an update from the CDC's Office of Infectious Diseases Board of Scientific Counselors meeting and reports from three CLIAC workgroups: the CLIA Personnel Regulations Workgroup, the Nontraditional Testing Workflow Model Workgroup, and the Next Generation Sequencing Workgroup. Agenda items are subject to change as priorities dictate.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–03009 Filed 2–21–19; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control, NCIPC; Correction

Notice is hereby given of a change in the meeting of the Board of Scientific Counselors, National Center for Injury Prevention and Control; March 14, 2019, 02:00 p.m. to 05:00 p.m. EDT which was published in the **Federal Register** on January 30, 2019 Volume 84, Number 20, page 473.

The meeting is being changed to a partially open and partially closed meeting. This meeting will be open to the public from 02:00 p.m.–02:40 p.m. to update the public on the Opioid Prescribing Estimate project. The dial in number for the open portion of the meeting is as follows: 1–866–880–0098; Conference ID: 31769267. The meeting will be closed to the public from 02:45 p.m.–05:00 p.m.

FOR FURTHER INFORMATION CONTACT: Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Deputy Associate Director for Science, National Center for Injury Prevention and Control, CDC, 4770

Buford Highway NE, MS F–63, Atlanta, GA 30341, telephone (770) 488–3953; *NCIPCBSC@cdc.gov.*

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–03007 Filed 2–21–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–19–0978]

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 Emerging Infections Program 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 November 15, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments 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 or send an email to *omb@cdc.gov.* 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

Emerging Infections Program (OMB Control No. 0920–0978, Expiration Date 5/31/2021)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Emerging Infections Programs (EIPs) are population-based centers of excellence established through a network of state health departments collaborating with academic institutions; local health departments; public health and clinical laboratories; infection control professionals; and healthcare providers. EIPs assist in local, state, and national efforts to prevent, control, and monitor the public health impact of infectious diseases.

Activities of the EIPs fall into the following general categories: (1) Active surveillance; (2) applied public health epidemiologic and laboratory activities; (3) implementation and evaluation of pilot prevention/intervention projects; and (4) flexible response to public health emergencies. Activities of the EIPs are designed to: (1) Address issues that the EIP network is particularly suited to investigate; (2) maintain sufficient flexibility for emergency response and new problems as they arise; (3) develop and evaluate public health interventions to inform public health policy and treatment guidelines; (4) incorporate training as a key function; and (5) prioritize projects that lead directly to the prevention of disease.

A revision is being submitted to make existing collection instruments clearer and to add several new forms specifically surveying laboratory practices. These forms will allow the EIP to better detect, identify, track changes in laboratory testing methodology, gather information about laboratory utilization in the EIP catchment area to ensure that all cases are being captured, and survey EIP staff to evaluate program quality.

The total estimated burden is 40,601 hours per year, an increase of 612 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of responders	Number of responses per respondent	Average burden per response (in hours)
State Health Department	ABCs Case Report Form	10	809	20/60
	ABCs Invasive Pneumococcal Disease in Children Case Report Form.	10	22	10/60
	ABCs *H. influenzae* Neonatal Sepsis Expanded Surveillance Form.	10	6	10/60
	ABCs Severe GAS Infection Supplemental Form.	10	136	20/60
	ABCs Neonatal Infection Expanded Tracking Form.	10	37	20/60
	FoodNet Campylobacter	10	942	21/60
	FoodNet Cyclospora	10	163	10/60
	FoodNet Listeria monocytogenes	10	15	20/60
	FoodNet Salmonella	10	789	21/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of responders	Number of responses per respondent	Average burden per response (in hours)
	FoodNet Shiga toxin producing E. coli	10	205	20/60
	FoodNet Shigella	10	213	10/60
	FoodNet Vibrio	10	34	10/60
	FoodNet Yersinia	10	48	10/60
	FoodNet Hemolytic Uremic Syndrome Case Report Form.	10	10	1
	FoodNet Clinical Laboratory Practices and Testing Volume—NEW.	10	70	20/60
	Influenza Hospitalization Surveillance Network Case Report Form.	10	1000	25/60
	Influenza Hospitalization Surveillance Project Vaccination Phone Script Consent Form (English/Spanish).	10	333	5/60
	Influenza Hospitalization Surveillance Project Vaccination Phone Script (English/Spanish).	10	333	5/60
	Influenza Hospitalization Surveillance Project Provider Vaccination History Fax Form (Children/Adults).	10	333	5/60
	FluSurv-NET Laboratory Survey—NEW	10	23	10/60
	HAIC CDI Case Report Form	10	1650	35/60
	HAIC CDI Annual Laboratory Survey—NEW	10	16	10/60
	HAIC CDI Annual Surveillance Officers Survey—NEW.	10	1	15/60
	HAIC CDI LTCF Survey—NEW	10	45	5/60
	HAIC Multi-site Gram-Negative Bacilli Case Report Form *(MuGSI–CRE/CRAB)*.	10	500	25/60
	HAIC Multi-site Gram-Negative Surveillance Initiative—Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (MuGSI–ESBL).	10	1200	25/60
	HAIC Invasive Methicillin-resistant *Staphylococcus aureus* (MRSA).	10	474	25/60
	HAIC Invasive Methicillin-sensitive *Staphylococcus aureus* (MSSA).	10	754	25/60
	HAIC Invasive *Staphylococcus aureus* Annual Laboratory Survey—NEW.	10	11	8/60
	HAIC Invasive *Staphylococcus aureus* Annual Surveillance Officers Survey—NEW.	10	1	10/60
	HAIC Candidemia Case Report Form	9	800	20/60
	HAIC Candidemia Periodic Laboratory Survey—NEW.	9	15	20/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–03101 Filed 2–21–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19–1092]

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 ''Sudden Death in the Young (SDY) Case Registry'' 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 November 6, 2018 to obtain comments from the public and affected agencies. CDC received no comments 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 or send an email to *omb@cdc.gov.* 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

Sudden Death in the Young Registry—Reinstatement with Change—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Sudden Death in the Young (SDY) is defined as a sudden and unexpected death in an infant, child, or young adults (up to age 20), which is not explained by homicide, suicide, overdose, or the result of an external cause that was the only and obvious reason for the fatal injury, or terminal illnesses. Injury deaths where there may have been an initiating natural cause (*e.g.,* drowning or death of the driver in a motor vehicle accident, which may have been triggered by an underlying cardiac or neurological condition) are also included in the definition.

SDY deaths are not systematically monitored and estimates of the annual incidence of SDY vary due to differences in definitions, inconsistencies in classifying cause, variable age and study populations, and differing case ascertainment methodologies. Because standardized information has not been collected on the incidence, causes, and risk factors, developing evidence-based prevention measures has been challenging.

To address these gaps, CDC, in collaboration with the National Heart, Lung, and Blood Institute and the National Institute of Neurological Disorders and Stroke at the National Institutes of Health implemented the SDY Case Registry in 2015 (OMB #0920–1092, Expiration 12/31/2018). Standardized data collected through the SDY Case Registry has been used by the NIH and CDC awardees to generate estimates of the incidence of SDY; to elucidate risk factors; and to develop evidence-based prevention strategies for SDY. The SDY Registry also creates infrastructure for future research about previously unknown or unrecognized risk factors for, and causes of, these deaths.

This information collection request is to reinstate OMB approval for the SDY Registry. By continuing the prior work of the SDY Registry, the information collected under this request will allow CDC to provide technical assistance to awardees so they can improve their jurisdiction's information on SDY. This includes two additions to their routine Child Death Review (CDR) program: (1) Entering SDY information from existing data sources (*e.g.,* medical records, autopsy reports) used during CDR review into the established web-based NCFRP Case Reporting System; and (2) convening clinicians with three different types of expertise (pediatric cardiology; pediatric neurology or epileptology; and forensic pathology) to conduct advanced clinical reviews of a subset of SDY cases to allow for a more thorough review of information compiled and to generate additional data about the classification of the death. The intended result will be data that can establish incidence and guide program and policy decisions at the state/jurisdiction and local levels.

CDC estimates that the participating states/jurisdictions will collect data on approximately 739 SDY cases per year. For participating states/jurisdictions, burden is estimated for reporting required case information. Based on historical program information, it is estimated that approximately half (370) of the 739 estimated SDY cases each year will undergo an advanced clinical review and classification of cause by a team of three medical experts.

This reinstatement request differs from the previously approved information collection in reducing the number of burden hours. While CDC is not proposing changes to any of the data collection tools, the SDY module, or the advanced review process, CDC has, with experience, been able to: (1) Obtain better estimates of the actual numbers of respondents anticipated on average per jurisdiction; (2) obtain more accurate estimates of the amount of time needed to complete the SDY modules; (3) better determine the number of cases that will need to continue to advance review and the types of medical experts that are needed. Because of these changes, despite the increase in participating jurisdiction, the net estimated burden is lower. OMB approval is requested for three years. The total estimated annual burden is 521 hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State Health Personnel	SDY Module I	14	53	10/60
Medical Experts	Advanced Review	42	26	15/60
State Health Personnel	SDY Module N	14	53	10/60

Jeffrey Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–03102 Filed 2–21–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2018–0050; Docket Number NIOSH–314]

Final National Occupational Research Agenda for Healthcare and Social Assistance

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: NIOSH announces the availability of the final *National Occupational Research Agenda for Healthcare and Social Assistance.*

DATES: The final document was published on February 15, 2019 on the CDC website.

ADDRESSES: The document may be obtained at the following link: *https://www.cdc.gov/nora/councils/hcsa/agenda.html.*

FOR FURTHER INFORMATION CONTACT: Emily Novicki, M.A., M.P.H, (*NORACoordinator@cdc.gov*), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498–2581 (not a toll free number).

SUPPLEMENTARY INFORMATION: On June 21, 2018, NIOSH published a request for public review in the **Federal Register** [83 FR 28849] of the draft version of the *National Occupational Research Agenda for Healthcare and Social Assistance.* All comments received were reviewed and addressed where appropriate.

Frank J Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2019–03072 Filed 2–21–19; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3373–N]

Medicare Program; Announcement of the Re-Approval of COLA Under the Clinical Laboratory Improvement Amendments of 1988

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the application of COLA for re-approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for the specialty and subspecialty areas listed in this notice under CLIA. We have determined that COLA meets or exceeds the applicable CLIA requirements. We are announcing the re-approval and grant COLA deeming authority for a period of 6 years.

DATES: Re-approval is effective February 22, 2019 and COLA deeming authority is granted from February 22, 2019 to February 22, 2025.

FOR FURTHER INFORMATION CONTACT: Raelene Perfetto, (410) 786–6876.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (Pub. L. 100–578) (CLIA). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Re-Approval of COLA as an Accreditation Organization

In this notice, we approve COLA as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for the following specialty and subspecialty areas under CLIA:

- Microbiology, including Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology.
- Diagnostic Immunology, including Syphilis Serology, General Immunology.
- Chemistry, including Routine Chemistry, Urinalysis, Endocrinology, Toxicology.
- Hematology.
- Immunohematology, including ABO Group and Rh Group, Antibody Detection, Antibody Identification, Compatibility Testing.

We have examined the initial COLA application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for re-approval of an accreditation organization under subpart E of part 493. We have determined that COLA meets or exceeds the applicable CLIA requirements. We have also determined that COLA will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R. Therefore, we grant COLA re-approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for the submitted specialty and subspecialty areas under CLIA. As a result of this determination, any laboratory that is accredited by COLA during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements for the listed subspecialties and specialties, and therefore, will generally not be subject to routine inspections by a state survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of COLA's Request for Re-Approval as an Accreditation Organization Under CLIA

The following describes the process we used to determine that COLA's accreditation program meets the necessary requirements to be approved by CMS and that, as such, we may approve COLA as an accreditation program with deeming authority under the CLIA program. COLA formally applied to CMS for re-approval as an accreditation organization under CLIA for the following specialties and subspecialties.

• Microbiology, including Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology.

• Diagnostic Immunology, including Syphilis Serology, General Immunology.

• Chemistry, including Routine Chemistry, Urinalysis, Endocrinology, Toxicology.

• Hematology.

• Immunohematology, including ABO Group and Rh Group, Antibody Detection, Antibody Identification, Compatibility Testing.

In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

A. Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

COLA submitted a description of its mechanisms for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of COLA's individual accreditation requirements with the comparable condition-level requirements. We determined COLA's policies and procedures for oversight of laboratories performing laboratory testing for the submitted CLIA specialties and subspecialties with respect to inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available, are equivalent to those of CLIA. COLA also submitted descriptions of its infrastructure and procedures for monitoring and inspecting laboratories in the areas of data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. We have determined that the requirements of COLA's accreditation program are equal to or more stringent than our requirements of the CLIA regulations.

Our evaluation determined that COLA requirements regarding waived testing are more stringent than the CLIA requirements at 42 CFR 493.15(e) that require eligible laboratories to follow the manufacturer's instructions for performing tests and obtain a certificate of waiver as outlined in part 493, subpart B. COLA requires the laboratory director to review quality control results for waived tests monthly and also requires that competency be assessed and documented for personnel performing waived testing.

B. Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

COLA's requirements are equal to the CLIA requirements at §§ 493.801 through 493.865. Like CLIA, all of COLA's accredited laboratories are required to participate in an HHS-approved PT program for tests listed in Subpart I. COLA also encourages its accredited laboratories to participate in PT for tests that are waived under CLIA.

C. Subpart J—Facility Administration for Nonwaived Testing

COLA's requirements are equal to the CLIA requirements at §§ 493.1100 through 493.1105.

D. Subpart K—Quality System for Nonwaived Testing

COLA's requirements are equal to the CLIA requirements at §§ 493.1200 through 493.1299.

E. Subpart M—Personnel for Nonwaived Testing

We have determined that COLA's requirements are equal to the CLIA requirements at §§ 493.1403 through 493.1495 for laboratories that perform moderate and high complexity testing.

F. Subpart Q—Inspection

We have determined that COLA's requirements are equal to the CLIA requirements at §§ 493.1771 through 493.1780. COLA will continue to conduct biennial onsite inspections. An unannounced inspection would be performed when a complaint, lodged against a laboratory accredited by COLA, indicates that problems may exist within the laboratory that may have a serious or immediate impact on patient care.

G. Subpart R—Enforcement Procedures

COLA meets the requirements of subpart R to the extent that such requirements apply to accreditation organizations. COLA policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, COLA will deny, suspend, or revoke accreditation in a laboratory accredited by COLA and report that action to us within 30 days. COLA also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that COLA laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The federal validation inspections of laboratories accredited by COLA may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the state survey agencies, will be our principal means for verifying that the laboratories accredited by COLA remain in compliance with CLIA requirements. This federal monitoring is an ongoing process.

V. Denial of Re-Approval as an Accrediting Organization

Our regulations provide that we may deny the re-approval of an accreditation organization, such as that of COLA, for cause at any time. If we determine that COLA has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which COLA would be allowed to address any identified issues, under our rules at § 493.575(b). Should COLA be unable to address the identified issues within that timeframe, CMS may, in accordance with the applicable regulations, revoke COLA's deeming authority under CLIA.

Should circumstances result in our withdrawal of COLA's re-approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

The information collection requirements associated with the accreditation process for clinical laboratories under the CLIA program are currently OMB-approved under OMB control number 0938–0686 and expire July 31, 2021. Additionally, this notice does not impose any new or revised information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Dated: February 6, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–03169 Filed 2–21–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–855R, CMS–2746, CMS–2728, and CMS–10065/10066]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by April 23, 2019.

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, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–855R Reassignment of Medicare Benefits

CMS–2746 End Stage Renal Disease Death Notification

CMS–2728 End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration

CMS–10065/10066 Hospital Notices: IM/DND

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension; *Title of Information Collection:* Reassignment of Medicare Benefits; *Use:* The reassignment application is submitted at the time the provider/supplier first reassigns of his/her Medicare benefits to a group practice, as well as any subsequent reassignments, changes to current reassignment information or terminations of established reassignments as requested by the provider/supplier or group. The application is used by the Medicare Administrative Contractor (MAC) to collect data to assure the applicant has the necessary information that allows the MAC to correctly establish, change, or terminate the reassignment.

The collection and verification of reassignment information defends and protects our beneficiaries from illegitimate providers/suppliers. These procedures also protect the Medicare Trust Fund against fraud. It gathers information that allow Medicare contractors to ensure that the provider/supplier is not sanctioned from the Medicare and/or Medicaid program(s), or debarred, or excluded from any other Federal agency or program. The data (*e.g.,* Social Security Numbers, Employer Identification Numbers) collected also ensures that the applicant has the necessary credentials to provide the health care services for which they intend to bill Medicare through the reassignment. This is sole instrument implemented for this purpose. *Form Number:* CMS–855R (OMB control number: 0938–1179); *Frequency:* Occasionally; *Affected Public:* Private Sector (Businesses or other for-profits, Not-for-profit institutions); *Number of Respondents:* 357,628; *Number of Responses:* 357,628; *Total Annual Hours:* 89,407. For policy questions regarding this collection, contact Kimberly McPhillips at 410–786–5374.

2. *Type of Information Collection Request:* Reinstatement of previously approved collection; *Title of Information Collection:* End Stage Renal Disease Death Notification; *Use:* The ESRD Death Notification form (CMS–2746) is completed by all Medicare-approved ESRD facilities upon death of an ESRD patient. Its primary purpose is to collect fact of death and cause of death of ESRD patients. The ESRD Program Management and Medical Information System (PMMIS) has the responsibility of collecting, maintaining and disseminating, on a national basis, uniform data pertaining to ESRD patients and their treatment of care. All renal facilities approved to participate

in the ESRD program are required by Pub. L. 95–292 to supply data to this system. *Form Number:* CMS–2746 (OMB control number: 0938 –0448); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 7,311; *Total Annual Responses:* 92,023; *Total Annual Hours:* 46,011.50. (For policy questions regarding this collection contact Gequinicia Polk at 410–786–2305.)

3. *Type of Information Collection Request:* Reinstatement of previously approved collection; *Title of Information Collection:* End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration; *Use:* The primary purpose of this form is to have a physician medically determine that a patient has end stage renal disease for purposes of filing for Medicare benefits. The End Stage Renal Disease (ESRD) Medical Evidence (CMS–2728) is completed for all ESRD patients either by the first treatment facility or by a Medicare-approved ESRD facility when it is determined by a physician that the patient's condition has reached that stage of renal impairment that a regular course of kidney dialysis or a kidney transplant is necessary to maintain life. The data reported on the CMS–2728 is to monitor and assess the quality and type of care provided to end stage renal disease beneficiaries. Collection of these data are also necessary for the maintenance of a single, nationwide kidney disease registry for dialysis, transplant, and prospective transplant patients. *Form Number:* CMS–2728 (OMB control number: 0938–0046); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 7,311; *Total Annual Responses:* 138,000; *Total Annual Hours:* 103,500. (For policy questions regarding this collection contact Gequinicia Polk at 410–786–2305.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Hospital Notices: IM/DND; *Use* The purpose of the IM is to inform beneficiaries and enrollees of their rights as hospital inpatients and how to request a discharge appeal by a Quality Improvement Organization (QIO) and how to file a request. For all Medicare beneficiaries, hospitals must deliver valid, written notice of a beneficiary's rights as a hospital inpatient, including discharge appeal rights. The hospital must use a standardized notice, as specified by CMS. This is satisfied by IM delivery.

Consistent with 42 CFR 405.1205 for Original Medicare and 422.620 for Medicare health plans, hospitals must provide the initial IM within 2 calendar days of admission. A follow-up copy of the signed IM is given no more than 2 calendar days before discharge. The follow-up copy is not required if the first IM is provided within 2 calendar days of discharge. In accordance with 42 CFR 405.1206 for Original Medicare and 422.622 for Medicare health plans, if a beneficiary/enrollee appeals the discharge decision, the beneficiary/enrollee and the QIO must receive a detailed explanation of the reasons services should end. This detailed explanation is provided to the beneficiary/enrollee using the DND, the second notice included in this renewal package. *Form Number:* CMS–10065/10066 (OMB control number: 0938–1019); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 6,123; *Total Annual Responses:* 17,742,803; *Total Annual Hours:* 2,990,720. (For policy questions regarding this collection contact Janet Miller at 410–786–1799.)

Dated: February 15, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–03015 Filed 2–21–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–643]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by April 23, 2019.

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, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–643 Hospice Survey and Deficiencies Report Form and Supporting Regulations

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Hospice Survey and Deficiencies Report Form and Supporting Regulations; *Use:* We use the information collected as the basis for certification decisions for hospices that wish to obtain or retain participation in the Medicare and Medicaid programs. The information is used by CMS regional offices, which have the delegated authority to certify Medicare facilities for participation, and by State Medicaid agencies, which have comparable authority under Medicaid. The information on the Hospice Survey and Deficiencies Report Form is coded for entry into the OSCAR system. The data is analyzed by the CMS regional offices and by the CMS central office components for program evaluation and monitoring purposes. The information is also available to the public upon request. *Form Number:* CMS–643 (OMB control number: 0938–0379); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 4,811; *Total Annual Responses:* 1,603; *Total Annual Hours:* 1,603. (For policy questions regarding this collection contact Thomas Pryor at 410–786–1132.)

Dated: February 19, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–03079 Filed 2–21–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; ACF's Generic Clearance for Grant Reviewer Recruitment Forms (OMB #0970–0477)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Office of Planning, Research, and Evaluation (OPRE) is proposing an extension of a currently approved generic clearance (OMB No. 0970–0477) for Grant Reviewer Recruitment (GRR) forms. The GRR forms will be used to select reviewers who will participate in the grant review process for the purpose of selecting successful applications.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Description: Under this generic approval, ACF conducts and proposes to continue to conduct more than one information collection that is very similar, voluntary, low-burden and uncontroversial. The purpose is to select qualified reviewers for the grant peer review process based on professional qualifications using data entered by candidates and the uploaded writing sample and/or curriculum vitae and/or resume. The grant review process is in accordance with the U.S. Department of Health and Human Services' (DHHS) Grants Policy Directive (GPD) 2.04 ''Awarding Grants'', the DHHS Awarding Agency Grants Administration Manual (AAGAM), Chapter 2.04.104C ''Objective Review of Grant Applications'', and the Public Health Service (PHS) Act, Sections 799(f) and 806(e).

Respondents: Individuals who may apply to review ACF grant applications.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Grant Reviewer Recruitment Form	3000	1	.5	1500

Estimated Total Annual Burden Hours: 1500.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–03068 Filed 2–21–19; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0297]

Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products.'' The document provides guidance to assist sponsors in the clinical development of nicotine replacement therapy (NRT) drug products, including but not limited to those intended for smoking cessation and related chronic indications.

DATES: Submit either electronic or written comments on the draft guidance by April 23, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

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

Instructions: All submissions received must include the Docket No. FDA–2019–D–0297 for ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

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

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Alina Salvatore, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5418, Silver Spring, MD 20993–0002, 240–402–0379.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products.'' This draft guidance reflects the FDA's current recommendations regarding overall development programs to support the approval of NRT drug products for smoking cessation and related chronic indications. There are several FDA-approved prescription and nonprescription NRT drug products for cessation of smoking cigarettes, but the Agency encourages the development of additional NRT drug products, which could help more smokers quit. In November 2017, FDA published a notice in the **Federal Register** requesting comments on the Agency's approach to evaluating the safety and efficacy of NRT drug products, including how they should be used and labeled (82 FR 56759; Docket No. FDA–2017–N–6529). The Agency hosted a public hearing in January 2018 to obtain input from stakeholders on these issues. This draft

guidance takes into consideration the feedback received and is intended to serve as a focus for continued discussions among the Agency, pharmaceutical sponsors, the academic community, and the public on this topic.

The draft guidance focuses on drug development and trial design issues that are specific to the study of NRT drug products. NRT drug products are typically studied and labeled for use as adjuncts to behavioral self-help materials and to date have involved single treatment regimens that begin on the patient's quit day. Alternate treatment regimens (*e.g.,* pretreatment before quit day, quitting by gradual reduction (reduce to quit), using multiple NRT drug products together) are discussed in the guidance.

As outlined in the guidance, NRT drug products can be developed for smoking cessation and/or reduction in risk of relapse. NRT drug products that first have demonstrated efficacy for at least one of these indications can also include additional information in labeling by demonstrating efficacy in certain secondary endpoints. Sponsors can evaluate reduction in the urge to smoke or relief of cue-induced craving in former smokers, as secondary endpoints. Additionally, sponsors that can demonstrate, via a secondary endpoint, that the drug product provides relief of withdrawal symptoms in smokers *who are not trying to quit smoking,* may be able to include labeling instructions to address situations when such individuals are required to abstain and therefore experience withdrawal symptoms (*e.g.,* while traveling on an airplane).

FDA is aware of the serious risks associated with smoking and is committed to facilitating the development of therapies to support smoking cessation efforts. Both the regulatory pathway for an NRT drug product and the amount of nonclinical or clinical data needed to support approval will depend on the characteristics of the proposed NRT drug product relative to an approved NRT drug product. This guidance outlines general considerations for NRT drug development and trial design, and FDA encourages sponsors to contact FDA for feedback on their proposed development plans. Sponsors developing an over-the-counter drug product should bear in mind that it is often not possible to answer all regulatory questions in a single trial, and additional sequential steps may be needed.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

The collection of information in 21 CFR part 314 for the submission of new drug applications (NDAs), including the submission of labeling under §§ 314.50(e)(2)(ii) and 314.50(l)(1)(i), as well as the submission of 505(b)(2) applications and abbreviated new drug applications, has been approved under OMB control number 0910–0001. The submission of biologics license applications (BLAs) has been approved under OMB control number 0910–0338. The collection of information in 21 CFR part 312 has been approved under OMB control number 0910–0014.

The submission of prescription drug labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572. The collections of information in 21 CFR parts 50 and 56 (*Protection of Human Subjects: Informed Consent; Institutional Review Boards*) have been approved under OMB control number 0910–0755.

The collection of information in the draft guidance for industry entitled ''Formal Meetings Between FDA and Sponsors and Applicants for PDUFA Products,'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm590547.pdf*) including requests for pre-NDA and pre-BLA meetings, has been approved under OMB control number 0910–0429.

The submission of special protocol assessments has been approved under OMB control number 0910–0470.

In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: February 15, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03064 Filed 2–21–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Cancellation of Meeting

Notice is hereby given of the cancellation of the Center for Scientific Review Special Emphasis Panel, March 1, 2019, 11:00 a.m. to March 1, 2019, 5:00 p.m., St. Gregory Hotel, 2033 M Street NW, Washington, DC 20036 which was published in the **Federal Register** on February 5, 2019, 84 FR 1766.

The meeting is cancelled.

Dated: February 15, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–03027 Filed 2–21–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cellular Signaling and Regulatory Systems.

Date: March 6, 2019.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301–435–1022, *balasundaramd@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 15, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–03028 Filed 2–21–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Role of Mitochondria or Insulin Sensitivity in Aging.

Date: March 5, 2019.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Samuel C. Edwards, Ph.D., Chief, BDCN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Interdisciplinary Molecular Sciences and Training.

Date: March 27, 2019.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Allen Richon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, 301–379–9351, *allen.richon@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Comparative and Training in Veterinary Medicine.

Date: April 2, 2019.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Vonda K. Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6188, MSC 7892, Bethesda, MD 20892, 301–435–1789, *smithvo@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Synthetic Psychoactive Drugs and Strategic Approaches to Counteract.

Date: April 12, 2019.

Time: 12:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Richard D. Crosland, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, 301–694–7084, *crosland@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 19, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–03066 Filed 2–21–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Biological Chemistry and Macromolecular Biophysics.

Date: March 21–22, 2019.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301–435–1180, *ruvinser@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 15, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–03026 Filed 2–21–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2010–0164]

National Boating Safety Advisory Council

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The National Boating Safety Advisory Council and its Subcommittees will meet to discuss issues relating to recreational boating safety. These meetings will be open to the public.

DATES: *Meetings.* The National Boating Safety Advisory Council will meet on Tuesday, April 9, 2019, from 9:00 a.m. to 5:00 p.m., on Wednesday April 10, from 9:00 a.m. to 5:00 p.m., and on Thursday, April 11, 2019 from 8:30 a.m. to 11:30 a.m. The Boats and Associated Equipment Subcommittee will meet on Wednesday, April 10, 2019, from 8:00 a.m. to 10:00 a.m. The Prevention through People Subcommittee will meet on Wednesday, April 10, 2019, from 10:15 a.m. to 2:15 p.m. The Recreational Boating Safety Strategic Planning Subcommittee will meet on Wednesday, April 10, from 2:30 p.m. to 5:00 p.m. Please note that these meetings may conclude early if the National Boating Safety Advisory Council completed all business.

Comments and supporting documentation. To ensure your comments are reviewed by Council members before the meetings, submit your written comments no later than March 29, 2019.

ADDRESSES: All meetings will be held at the Royal Sonesta Hotel, 300 Bourbon Street, New Orleans, LA 70130. *https://www.sonesta.com/us/louisiana/new-orleans/royal-sonesta-new-orleans.*

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section below as soon as possible.

Instructions: You are free to submit comments at any times, including orally at the meetings, but if you want Council members to review your comment before the meetings, please submit your comments no later than March 22, 2019. We are particularly interested in the comments in the ''Agenda'' section below. You must include ''Department of Homeland Security'' and the docket number USCG–2010–0164. Written comments may also be submitted using the Federal eRulemaking Portal at *http://www.regulations.gov.*

If you encounter technical difficulties with comments submission, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section below. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided. For more information about privacy and the docket, review the Privacy and Security Notice for the Federal Docket Management System at *https://www.regulations.gov/privacyNotice.*

Docket Search: For access to the docket to read documents or comments related to this notice, go to *http://www.regulations.gov* insert USCG–2010–0164 in the ''Search'' box, press Enter, then click the item you wish to view.

FOR FURTHER INFORMATION CONTACT: Mr. Jeff Decker, Alternate Designated Federal Officer of the National Boating Safety Advisory Council, telephone (202) 372–1507, or at *NBSAC@uscg.mil.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given pursuant to the *Federal Advisory Committee Act,* (Title 5, U.S.C, Appendix). Congress established the National Boating Safety Advisory Council in the *Federal Boat Safety Act of 1971* (Pub. L. 92–75). The National Boating Safety Advisory Council currently operates under the authority of 46 U.S.C. 13110 and 46 U.S.C. 4302(c). The latter requires the Secretary of Homeland Security and the Commandant of the U.S. Coast Guard by delegation to consult with the National Boating Safety Advisory Council in prescribing regulations for recreational vessels and associated equipment and on other major safety matters.

Agenda

Day 1

The agenda for the National Boating Safety Advisory Council meeting is as follows:

Tuesday, April 9, 2019

(1) Opening remarks.

(2) Presentation of Awards to Outgoing National Boating Safety Advisory Committee Members.

(3) Receipt and discussion of the following reports:

(a) Chief, Office of Auxiliary and Boating Safety, update on the U.S. Coast Guard's implementation of National boating Safety Advisory Council Recommendations and Recreational Boating Safety Program Report.

(b) Alternate Designated Federal Officer's report concerning Council administrative and logistical matters including update on key elements contained in the Frank LoBiondo Coast Guard Authorization Act of 2018 affecting the Council.

(c) Update on the implementation of the National Recreational Boating Survey.

(d) Update on the National Recreational Boating Grant Program.

(4) Presentation on regulatory changes contained in the Frank LoBiondo Coast Guard Authorization Act of 2018.

(5) Presentation on voluntary life jacket wear efforts.

(6) Presentation on driverless boats research.

(7) Presentation on high yield interventions for accident reduction.

(8) Presentation on the Sport Fish Restoration and Boating Safety Trust Fund.

(9) Public comment period.

(10) Meeting Recess.

Day 2

Wednesday, April 10, 2019

The day will be dedicated to Subcommittee sessions:

(1) *Boats and Associated Equipment Subcommittee.*

Issues to be discussed include alternatives to pyrotechnic visual distress signals; grant projects related to boats and associated equipment; and updates to 33 CFR 181 ''Manufacturer Requirements'' and 33 CFR 183 ''Boats and Associated Equipment.''

(2) *Prevention Through People Subcommittee.*

Issues to be discussed include paddle sports participation, overview of State boating Safety programs, and licensing requirements for on-water boating safety instruction providers.

(3) *Recreational Boating Safety Strategic Planning Subcommittee.*

Issues to be discussed include progress on implementation of the 2017–2021 Strategic Plan.

Day 3

Thursday, April 11, 2019

The full Council will resume meeting.

(1) Receipt and Discussion of the Boats and Associated Equipment, Prevention through People and Recreational Boating Safety Strategic Planning Subcommittee reports.

(2) Discussion of any recommendations to be made to the U.S. Coast Guard.

(3) Public comment period.

(4) Voting on any recommendations to be made to the U.S. Coast Guard.

(5) Closing remarks.

(6) Adjournment of meeting.

There will be a comment period for the National Boating Safety Advisory Council members and a comment period for the public after each report presentation, but before each is voted on by the Council. The Council members will review the information presented on each issue, deliberate on any recommendations presented in the Subcommittees' reports, and formulate recommendations for the Department's consideration.

The meeting agenda and all meeting documentation can be found at: *https://homeport.uscg.mil/missions/ports-and-waterways/safety-advisory-committees/*

nbsac/announcements. Alternatively, you may contact Mr. Jeff Decker as noted in the **FOR FURTHER INFORMATION CONTACT** section above.

Public comments or questions will be taken throughout the meeting as the Council discusses the issues and prior to deliberations and voting. There will also be a public comment period at the end of the meeting. Speakers are requested to limit their comments to 3 minutes. Please note that the public comment period may end before the period allotted, following the call for comments. Contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section above to register as a speaker.

Dated: February 15, 2019.

Jennifer F. Williams,

Captain, U.S. Coast Guard, Director of Inspections and Compliance.

[FR Doc. 2019–03052 Filed 2–21–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation of Altol Chemical and Environmental Laboratory, Inc. (Ponce, PR), as a Commercial Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation of Altol Chemical and Environmental Laboratory, Inc., as a commercial laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Altol Chemical and Environmental Laboratory, Inc. (Ponce, PR), has been accredited to test petroleum and petroleum products for customs purposes for the next three years as of September 27, 2018.

DATES: *Effective*—Altol Chemical and Environmental Laboratory, Inc., was accredited as a commercial laboratory as of September 27, 2018. The next triennial inspection date will be scheduled for September 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Cassata, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12, that Altol Chemical and Environmental Laboratory, Inc., Sabanetas Industrial Park Building M–1380, Ponce, PR 00715, has been accredited to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12. Altol Chemical and Environmental Laboratory, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM method	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–02	D1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–58	D5191	Standard Test Method For Vapor Pressure of Petroleum Products (Mini Method).

Anyone wishing to employ this entity to conduct laboratory analyses services should request and receive written assurances from the entity that it is accredited by the U.S. Customs and Border Protection to conduct the specific test requested. Alternatively, inquiries regarding the specific test this entity is accredited to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories: *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: February 13, 2019.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2019–03126 Filed 2–21–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Approval of Altol Petroleum Products Services, Inc. (Ponce, PR), as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of Altol Petroleum Products Services, Inc., as a commercial gauger.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Altol Petroleum Products Services, Inc. (Ponce, PR), has been approved to gauge petroleum and petroleum products for customs purposes for the next three years as of September 28, 2018.

DATES: Effective—Altol Petroleum Products Services, Inc., was approved as a commercial gauger as of September 28, 2018. The next triennial inspection date will be scheduled for September 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Cassata, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.13, that Altol Petroleum Products Services, Inc., Parque Industrial Sabanetas, Edificio M–1380–01–02, Ponce, PR 00731, has been approved to gauge petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.13. Altol Petroleum Products Services, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API chapters	Title
1	Vocabulary.
3	Tank gauging.

API chapters	Title
7	Temperature Determination.
8	Sampling.
11	Physical Properties Data.
12	Calculations.
17	Maritime Measurements.

Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories: *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: February 13, 2019.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2019–03111 Filed 2–21–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of AmSpec LLC (Concord, CA) as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of AmSpec LLC (Concord, CA), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that AmSpec LLC (Concord, CA), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of October 17, 2018.

DATES: AmSpec LLC (Concord, CA) was approved and accredited as a commercial gauger and laboratory as of October 17, 2018. The next triennial inspection date will be scheduled for October 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Justin Shey, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that AmSpec LLC, 4075 Sprig Drive, Suite A, Concord, CA 94520, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13.

AmSpec LLC (Concord, CA) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
1	Vocabulary.
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
11	Physical Properties Data.
12	Calculations.
17	Maritime Measurement.

AmSpec LLC (Concord, CA) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–02	D1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–50	D93	Standard Test Methods for Flash-Point by Pensky-Martens Closed Cup Tester.
27–53	D2709	Standard Test Method for Water and Sediment in Middle Distillate Fuels by Centrifuge.
27–54	D1796	Standard Test Method for Water and Sediment in Fuel Oils by the Centrifuge Method.
27–58	D5191	Standard Test Method for Vapor Pressure of Petroleum Products (Mini Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov.* Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories: *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: February 12, 2019.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services.

[FR Doc. 2019–03124 Filed 2–21–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of SGS North America, Inc. (St. Rose, LA), as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of SGS North America, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that SGS North America, Inc. (St. Rose, LA), has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes for the next three years as of May 9, 2018.

DATES: Effective—SGS North America, Inc., was accredited and approved as a commercial gauger and laboratory as of May 9, 2018. The next triennial inspection date will be scheduled for May 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Cassata, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that SGS North America, Inc., 151 James Drive West, St Rose, LA 70087, has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. SGS North America, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API chapters	Title
3	Tank gauging
5	Metering
7	Temperature Determination
8	Sampling
12	Calculations
17	Maritime Measurements

SGS North America, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM method	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–14	D2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–46	D5002	Standard Test Method for density and relative density of crude oils by digital densitometer.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–53	D2709	Standard test method for water and sediment in middle distillate by the centrifuge method.
27–58	D5191	Standard Test Method for Vapor Pressure of Petroleum Products (Mini Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories: *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: February 13, 2019.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2019–03112 Filed 2–21–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc. (Richmond, CA), as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Camin Cargo Control, Inc. (Richmond, CA), has been approved to gauge and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of March 15, 2018.

DATES: Effective—Camin Cargo Control, Inc., was accredited and approved as a commercial gauger and laboratory as of March 15, 2018. The next triennial inspection date will be scheduled for March 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Cassata, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Camin Cargo Control, Inc., 845 Marina Bay Parkway, STE 8, Richmond, CA 94804, has been approved to gauge and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Camin Cargo Control, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API Chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
11	Physical Properties Data.
12	Calculations.
17	Maritime Measurements.

Camin Cargo Control, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM method	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–02	D1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–07	D4807	Standard Test Method for Sediment in Crude Oil by Membrane Filtration.
27–08	D86	Standard Test Method for Distillation of Petroleum Products.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–20	D4057	Standard Practice for Manual Sampling of Petroleum and Petroleum Products.
27–21	D4177	Standard Practice for the Automatic Sampling of Petroleum and Petroleum Products.
27–46	D5002	Standard Test Method for Density and Relative Density of Crude Oils by Digital Density Analyzer.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–50	D93	Standard Test Methods for Flash-Point by Pensky-Martens Closed Cup Tester.
27–54	D1796	Standard Test Method for Water and Sediment in Crude Oil by Centrifuge Method (Laboratory Procedure).
27–58	D5191	Standard Test Method For Vapor Pressure of Petroleum Products (Mini Method).
N/A	D664	Standard Test Method for Acid Number of Petroleum Products by Potentiometric Titration.
N/A	D4530	Standard Test Method for Determination of Carbon Residue (Micro Method).
N/A	D5705	Standard Test Method for Measurement of Hydrogen Sulfide in the Vapor Phase Above Residual Fuel Oils.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the website listed below for the current CBP Approved Gaugers and Accredited Laboratories List: *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories*.

Dated: February 13, 2019.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2019–03114 Filed 2–21–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of AmSpec LLC (Sulphur, LA) as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of AmSpec LLC (Sulphur, LA), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that AmSpec LLC (Sulphur, LA), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of August 24, 2018.

DATES: AmSpec LLC (Sulphur, LA) was approved and accredited as a commercial gauger and laboratory as of August 24, 2018. The next triennial inspection date will be scheduled for August 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Justin Shey, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that AmSpec LLC, 2308 East Burton St., Sulphur, LA 70663, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13.

AmSpec LLC (Sulphur, LA) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
11	Physical Properties Data.
12	Calculations.
17	Maritime Measurement.

AmSpec LLC (Sulphur, LA) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory

Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–50	D93	Standard Test Methods for Flash-Point by Pensky-Martens Closed Cup Tester.
27–54	D1796	Standard Test Method for Water and Sediment in Fuel Oils by the Centrifuge Method.
27–58	D5191	Standard Test Method for Vapor Pressure of Petroleum Products (Mini Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: February 12, 2019.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services.

[FR Doc. 2019–03123 Filed 2–21–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of AmSpec LLC (Signal Hill, CA) as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of AmSpec LLC (Signal Hill, CA), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that AmSpec LLC (Signal Hill, CA), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of October 11, 2018.

DATES: AmSpec LLC (Signal Hill, CA) was approved and accredited as a commercial gauger and laboratory as of October 11, 2018. The next triennial inspection date will be scheduled for October 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Justin Shey, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that AmSpec LLC, 1980 Orizaba Ave., Signal Hill, CA 90755, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13.

AmSpec LLC (Signal Hill, CA) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
11	Physical Properties Data.
12	Calculations.
17	Maritime Measurement.

AmSpec LLC (Signal Hill, CA) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–46	D5002	Standard Test Method for Density and Relative Density of Crude Oils by Digital Density Analyzer.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border

Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories: *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories*.

Dated: February 12, 2019.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services.

[FR Doc. 2019–03121 Filed 2–21–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation of Oil Technologies Services, Inc. DBA Seahawk Services (West Deptford, NJ) as a Commercial Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation of Oil Technologies Services, Inc. DBA Seahawk Services (West Deptford, NJ), as a commercial laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Oil Technologies Services, Inc. DBA Seahawk Services (West Deptford, NJ), has been accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of September 26, 2018.

DATES: Oil Technologies Services, Inc. DBA Seahawk Services (West Deptford, NJ) was accredited as a commercial laboratory as of September 26, 2018. The next triennial inspection date will be scheduled for September 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Justin Shey, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12, that Seahawk Services, 1501 Grandview Ave., West Deptford, NJ 08066, has been approved to accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12.

Seahawk Services (West Deptford, NJ) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–02	D1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories: *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories*.

Dated: February 12, 2019.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services.

[FR Doc. 2019–03128 Filed 2–21–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc. (Linden, NJ), as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Camin Cargo Control, Inc. (Linden, NJ), has been approved to gauge and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of August 21, 2018.

DATES: Effective—Camin Cargo Control, Inc., was accredited and approved as a commercial gauger and laboratory as of August 21, 2018. The next triennial inspection date will be scheduled for August 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Cassata, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Camin Cargo Control, Inc., 230 Marion Ave., Linden, NJ 07036, has been approved to gauge and accredited to test petroleum and

certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Camin Cargo Control, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
12	Calculations.
17	Maritime Measurements.

Camin Cargo Control, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM method	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–02	D1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–14	D2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–58	D5191	Standard Test Method For Vapor Pressure of Petroleum Products (Mini Method).
N/A	D1319	Standard Test Method for Hydrocarbon Types in Liquid Petroleum Products by Fluorescent Indicator Adsorption.
N/A	D2699	Standard Test Method for Research Octane Number of Spark-Ignition Engine Fuel.
N/A	D2700	Standard Test Method for Motor Octane Number of Spark-Ignition Engine Fuel.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the website listed below for the current CBP Approved Gaugers and Accredited Laboratories List: *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Date: February 13, 2019.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2019–03118 Filed 2–21–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of SGS North America, Inc. (Corpus, Christi, TX), as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of SGS North America, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that SGS North America, Inc. (Corpus Christi, TX), has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes for the next three years as of August 8, 2018.

DATES: *Effective Dates:* SGS North America, Inc., was accredited and approved as a commercial gauger and laboratory as of August 8, 2018. The next triennial inspection date will be scheduled for August 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Cassata, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that SGS North America, Inc., 925 Corn Products Road, Corpus Christi, TX 78409, has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. SGS North America, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API chapters	Title
3	Tank gauging.
7	Temperature Determination.
8	Sampling.
12	Calculations.
17	Maritime Measurements.

SGS North America, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM method	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–02	D1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.

CBPL No.	ASTM method	Title
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–14	D2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–46	D5002	Standard Test Method for density and relative density of crude oils by digital densitometer.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
N/A	D4007	Standard Test Method for water and sediment in crude oils by the Centrifuge Method.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories: *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: February 13, 2019.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2019–03113 Filed 2–21–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc. (Corpus Christi, TX), as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Camin Cargo Control, Inc. (Corpus Christi, TX), has been approved to gauge and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of August 8, 2018.

DATES: Effective—Camin Cargo Control, Inc., was accredited and approved as a commercial gauger and laboratory as of August 8, 2018. The next triennial inspection date will be scheduled for August 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Cassata, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Camin Cargo Control, Inc., 218 Centaurus St., Corpus Christi, TX 78405, has been approved to gauge and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Camin Cargo Control, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
12	Calculations.
17	Maritime Measurements.

Camin Cargo Control, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM method	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–02	D1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–14	D2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–54	D1796	Standard Test Method for Water and Sediment in Crude Oil by Centrifuge Method (Laboratory Procedure).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the website listed below for the current CBP Approved Gaugers and Accredited Laboratories List: *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Date: February 13, 2019.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2019–03119 Filed 2–21–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2019–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *https://msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov*; or visit the FEMA Map Information eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Alabama:					
Madison (FEMA Docket No.: B–1848).	City of Madison (17–04–4981P).	The Honorable Paul Finley, Mayor, City of Madison, 100 Hughes Road, Madison, AL 35758.	Engineering Department, 100 Hughes Road, Madison, AL 35758.	Nov. 8, 2018	010308
Morgan (FEMA Docket No.: B–1852).	City of Decatur (18–04–5607P).	The Honorable Tab Bowling, Mayor, City of Decatur, P.O. Box 488, Decatur, AL 35602.	Building Department, 402 Lee Street Northeast, 4th Floor, Decatur, AL 35601.	Dec. 7, 2018	010176
Morgan (FEMA Docket No.: B–1852).	City of Decatur (18–04–5608P).	The Honorable Tab Bowling, Mayor, City of Decatur, P.O. Box 488, Decatur, AL 35602.	Building Department, 402 Lee Street Northeast, 4th Floor, Decatur, AL 35601.	Dec. 7, 2018	010176
Morgan (FEMA Docket No.: B–1852).	Unincorporated areas of Morgan County (18–04–5608P).	The Honorable Ray Long, Chairman, Morgan County Commission, P.O. Box 668, Decatur, AL 35602.	Morgan County Engineering Department, 580 Shull Road Northeast, Hartselle, AL 35640.	Dec. 7, 2018	010175
Shelby (FEMA Docket No.: B–1855).	City of Helena (18–04–3885P).	The Honorable Mark R. Hall, Mayor, City of Helena, 816 Highway 52 East, Helena, AL 35080.	City Hall, 816 Highway 52 East, Helena, AL 35080.	Dec. 10, 2018	010294

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Shelby (FEMA Docket No.: B–1855).	City of Pelham (18–04–3885P).	The Honorable Gary W. Waters, Mayor, City of Pelham, 3162 Pelham Parkway, Pelham, AL 35124.	City Hall, 3162 Pelham Parkway, Pelham, AL 35124.	Dec. 10, 2018	010193
Colorado:					
Adams (FEMA Docket No.: B–1855).	City of Commerce City (18–08–0619P).	The Honorable Sean Ford, Mayor, City of Commerce City, 7887 East 60th Avenue, Commerce City, CO 80022.	City Hall, 5291 East 60th Avenue, Commerce City, CO 80022.	Dec. 5, 2018	080006
Adams (FEMA Docket No.: B–1855).	Unincorporated areas of Adams County (18–08–0619P).	The Honorable Mary Hodge, Chair, Adams County Board of Commissioners, 4430 South Adams County Parkway, 5th Floor, Suite C5000A, Brighton, CO 80601.	Adams County Community and Economic Development Department, 4430 South Adams County Parkway, Brighton, CO 80601.	Nov. 2, 2018	080024
Douglas (FEMA Docket No.: B–1852).	Unincorporated areas of Douglas County (17–08–1424P).	The Honorable Lora Thomas, Chair, Douglas County Board of Commissioners, 100 3rd Street, Castle Rock, CO 80104.	Douglas County Public Works Engineering Division, 100 3rd Street, Castle Rock, CO 80104.	Dec. 14, 2018	080049
Garfield (FEMA Docket No.: B–1852).	City of Rifle (18–08–0106P).	Mr. Davis Farrar, Interim City Manager, City of Rifle, 202 Railroad Avenue, Rifle, CO 81650.	City Hall, 202 Railroad Avenue, Rifle, CO 81650.	Nov. 23, 2018	085078
Garfield (FEMA Docket No.: B–1852).	Unincorporated areas of Garfield County (18–08–0106P).	The Honorable John Martin, Chairman, Garfield County Board of Commissioners, 108 8th Street, Suite 101, Glenwood Springs, CO 81601.	Garfield County Courthouse, 109 8th Street, Glenwood Springs, CO 81601.	Nov. 23, 2018	080205
Connecticut:					
New Haven (FEMA Docket No.: B–1852).	Town of Cheshire (17–01–2563P).	The Honorable Rob Oris, Jr., Chairman, Town of Cheshire Council, 84 South Main Street, Cheshire, CT 06410.	Town Hall, 84 South Main Street, Cheshire, CT 06410.	Dec. 7, 2018	090074
Florida:					
Collier (FEMA Docket No.: B–1855).	City of Naples (18–04–4573P).	The Honorable Bill Barnett, Mayor, City of Naples, 735 8th Street South, Naples, FL 34102.	Building Department, 295 Riverside Circle, Naples, FL 34102.	Dec. 7, 2018	125130
Lee (FEMA Docket No.: B–1855).	City of Sanibel (18–04–4404P).	The Honorable Kevin Ruane, Mayor, City of Sanibel, 800 Dunlop Road, Sanibel, FL 33957.	Planning Department, 800 Dunlop Road, Sanibel, FL 33957.	Dec. 7, 2018	120402
Lee (FEMA Docket No.: B–1852).	City of Sanibel (18–04–5183P).	The Honorable Kevin Ruane, Mayor, City of Sanibel, 800 Dunlop Road, Sanibel, FL 33957.	Planning Department, 800 Dunlop Road, Sanibel, FL 33957.	Dec. 17, 2018	120402
Monroe (FEMA Docket No.: B–1852).	Unincorporated areas of Monroe County (18–04–4626P).	The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 9400 Overseas Highway, Suite 210, Marathon, FL 33050.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	Dec. 12, 2018	125129
Monroe (FEMA Docket No.: B–1852).	Unincorporated areas of Monroe County (18–04–4628P).	The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 9400 Overseas Highway, Suite 210, Marathon, FL 33050.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	Dec. 14, 2018	125129
Massachusetts:					
Barnstable (FEMA Docket No.: B–1852).	Town of Mashpee (18–01–1102P).	The Honorable Thomas F. O'Hara, Chairman, Town of Mashpee Board of Selectmen, 16 Great Neck Road North, Mashpee, MA 02649.	Building Department, 16 Great Neck Road North, Mashpee, MA 02649.	Dec. 10, 2018	250009
Barnstable (FEMA Docket No.: B–1855).	Town of Truro (18–01–0789P).	The Honorable Robert Weinstein, Chairman, Town of Truro Board of Selectmen, 24 Town Hall Road, Truro, MA 02666.	Building Department, 24 Town Hall Road, Truro, MA 02666.	Dec. 17, 2018	255222
Barnstable (FEMA Docket No.: B–1855).	Town of Wellfleet (18–01–0789P).	The Honorable Janet Reinhart, Chair, Town of Wellfleet Board of Selectmen, 300 Main Street, Wellfleet, MA 02667.	Building Department, 220 West Main Street, Wellfleet, MA 02667.	Dec. 17, 2018	250014
New Mexico:					
Bernalillo (FEMA Docket No.: B–1855).	City of Albuquerque (18–06–0625P).	The Honorable Tim Keller, Mayor, City of Albuquerque, P.O. Box 1293, Albuquerque, NM 87103.	Development Review Services Division, 600 2nd Street Northwest, Albuquerque, NM 87102.	Dec. 17, 2018	350002
Bernalillo (FEMA Docket, No.: B–1855).	Unincorporated areas of Bernalillo County (18–06–0625P).	Ms. Julie Morgas Baca, Bernalillo County Manager, 1 Civic Plaza Northwest, 10th Floor, Albuquerque, NM 87102.	Bernalillo County Public Works Division, 2400 Broadway Boulevard Southeast, Albuquerque, NM 87102.	Dec. 17, 2018	350001
North Carolina:					
Montgomery (FEMA Docket No.: B–1871).	Unincorporated areas of Montgomery County (18–04–1965P.	The Honorable Jackie Morris, Chairman, Montgomery County Board of Commissioners, 102 East Spring Street, Troy, NC 27371.	Montgomery County Inspections and Zoning Department, 219 South Main Street, Troy, NC 27371.	Nov. 23, 2018	370336
Warren (FEMA Docket, No.: B–1863).	Unincorporated areas of Warren County (18–04–2099P).	The Honorable Victor Hunt, Chairman, Warren County Board of Commissioners, 602 West Ridgeway Street, Warrenton, NC 27589.	Warren County Planning, Zoning & Code Enforcement Department, 542 West Ridgeway Street, Warrenton, NC 27589.	Dec. 27, 2018	370396
North Dakota: Oliver (FEMA Docket No.: B–1852).	City of Center (17–08–1350P).	The Honorable Harold Wilkens, Mayor, City of Center, P.O. Box 76, Center, ND 58530.	City Hall, 312 Lincoln Avenue, Center, ND 58530.	Dec. 7, 2018	380078

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Oklahoma: Canadian (FEMA Docket No.: B–1852).	City of Oklahoma City (18–06–1144P).	The Honorable David Holt, Mayor, City of Oklahoma City, 200 North Walker Avenue, 3rd Floor, Oklahoma City, OK 73102.	Department of Public Works, 420 West Main Street, Suite 700, Oklahoma City, OK 73102.	Dec. 6, 2018	405378
South Carolina:					
Berkeley (FEMA Docket No.: B–1848).	Unincorporated areas of Berkeley County (17–04–6038P).	The Honorable William W. Peagler, III, Supervisor, Berkeley County, P.O. Box 6122, Moncks Corner, SC 29461.	Berkeley County Planning and Zoning Department, 1003 Highway 52, Moncks Corner, SC 29461.	Dec. 10, 2018	450029
Berkeley (FEMA Docket No.: B–1852).	Unincorporated areas of Berkeley County (18–04–3970P).	The Honorable William W. Peagler, III, Chairman, Berkeley County Council, 1003 Highway 52, Moncks Corner, SC 29461.	Berkeley County Planning and Zoning Department, 1003 Highway 52, Moncks Corner, SC 29461.	Dec. 10, 2018	450029
Berkeley (FEMA Docket No.: B–1848.	Unincorporated areas of Berkeley County (18–04–3971P).	The Honorable William W. Peagler, III, Supervisor, Berkeley County, P.O. Box 6122, Moncks Corner, SC 29461.	Berkeley County Planning and Zoning Department, 1003 Highway 52, Moncks Corner, SC 29461.	Dec. 10, 2018	450029
Texas:					
Bexar (FEMA Docket No.: B–1852).	Unincorporated areas of Bexar County (18–06–1810P).	The Honorable Nelson W. Wolff, Bexar County Judge, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 233 North Pecos-La Trinidad Street, Suite 420, San Antonio, TX 78207.	Dec. 17, 2018	480035
Bexar (FEMA Docket No.: B–1852).	Unincorporated areas of Bexar County (18–06–2765X).	The Honorable Nelson W. Wolff, Bexar County Judge, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 233 North Pecos-La Trinidad Street, Suite 420, San Antonio, TX 78207.	Dec. 10, 2018	480035
Dallas (FEMA Docket No.: B–1855).	Town of Sunnyvale (18–06–1127P).	The Honorable Saji George, Mayor, Town of Sunnyvale, 127 North Collins Road, Sunnyvale, TX 75182.	Development Services Department, 127 North Collins Road, Sunnyvale, TX 75182.	Dec. 7, 2018	480188
Rockwall (FEMA Docket No.: B–1855).	City of Heath (18–06–0869P).	The Honorable Kelson Elam, Mayor, City of Heath, 200 Laurence Drive, Heath, TX 75032.	City Hall, 200 Laurence Drive, Heath, TX 75032.	Dec. 10, 2018	480545
Virginia: Fairfax (FEMA Docket No.: B–1852).	Unincorporated areas of Fairfax County (18–03–1757X).	Mr. Bryan Hill, Fairfax County Executive, 12000 Government Center Parkway, Fairfax, VA 22035.	Fairfax County Stormwater Planning Division, 12000 Government Center Parkway, Suite 449, Fairfax, VA 22035.	Dec. 10, 2018	515525

[FR Doc. 2019–03021 Filed 2–21–19; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2019–0002; Internal Agency Docket No. FEMA–B–1900]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in

this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Arkansas:						
Benton	City of Rogers (18–06–2232P).	The Honorable Greg Hines, Mayor, City of Rogers, 301 West Chestnut Street, Rogers, AR 72756.	Community Development Department, 301 West Chestnut Street, Rogers, AR 72756.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 8, 2019	050013
Lonoke	City of Cabot (18–06–0979P).	The Honorable Bill Cypert, Mayor, City of Cabot, 101 North 2nd Street, Cabot, AR 72023.	City Hall, 101 North 2nd Street, Cabot, AR 72023.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 8, 2019	050309
Lonoke	Unincorporated areas of Lonoke County (18–06–0979P).	The Honorable Doug Erwin, Lonoke County Judge, 301 North Center Street, Lonoke, AR 72086.	Lonoke County Annex Building, 301 North Center Street, Lonoke, AR 72086.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 8, 2019	050448
Colorado:						
Adams and Jefferson.	City of Westminster (18–08–0906P).	The Honorable Herb Atchison, Mayor, City of Westminster, 4800 West 92nd Avenue, Westminster, CO 80031.	City Hall, 4800 West 92nd Avenue, Westminster, CO 80031.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 15, 2019	080008
Adams	Unincorporated areas of Adams County (18–08–0906P).	The Honorable Mary Hodge, Chair, Adams County Board of Commissioners, 4430 South Adams County Parkway, 5th Floor, Suite C5000A, Brighton, CO 80601.	Adams County Community and Economic Development Department, 4430 South Adams County Parkway, Brighton, CO 80601.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 15, 2019	080001
Arapahoe	City of Aurora (18–08–0713P).	The Honorable Bob LeGare, Mayor, City of Aurora, 15151 East Alameda Parkway, Aurora, CO 80012.	Public Works Department, 15151 East Alameda Parkway, Aurora, CO 80012.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 12, 2019	080002
Arapahoe	City of Greenwood Village (18–08–0275P).	The Honorable Ron Rakowsky, Mayor, City of Greenwood Village, 6060 South Quebec Street, Greenwood Village, CO 80111.	Public Works Department, 10001 East Costilla Avenue, Greenwood Village, CO 80112.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 15, 2019	080195
Boulder	City of Boulder (18–08–0892P).	The Honorable Suzanne Jones, Mayor, City of Boulder, 1777 Broadway Street, Boulder, CO 80306.	Central Records Department, 1777 Broadway Street, Boulder, CO 80306.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 26, 2019	080024
Broomfield	City and County of Broomfield (18–08–0246P).	The Honorable Randy Ahrens, Mayor, City and County of Broomfield, 1 DesCombes Drive, Broomfield, CO 80020.	City and County of Broomfield Engineering Department, 1 DesCombes Drive, Broomfield, CO 80020.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 15, 2019	085073
Eagle	Unincorporated areas of Eagle County (18–08–0593P).	Mr. Jeff Shroll, Eagle County Manager, P.O. Box 850, Eagle, CO 81631.	Eagle County Engineering Department, 500 Broadway Street, Eagle, CO 81631.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 15, 2019	080051

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
El Paso	Unincorporated areas of El Paso County (18–08–0702P).	The Honorable Darryl Glenn, President, El Paso County Board of Commissioners, 200 South Cascade Avenue, Suite 100, Colorado Springs, CO 80903.	Pikes Peak Regional Building Department, 2880 International Circle, Colorado Springs, CO 80910.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 4, 2019	080059
Summit	Town of Silverthorne (18–08–0559P).	The Honorable Ann-Marie Sandquist, Mayor, Town of Silverthorne, P.O. Box 1309, Silverthorne, CO 80498.	Public Works Department, 264 Brian Avenue, Silverthorne, CO 80498.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 25, 2019	080201
Connecticut: Fairfield.	Town of Darien (18–01–1839P).	The Honorable Jayme J. Stevenson, First Selectwoman, Town of Darien Board of Selectmen, 2 Renshaw Road, Darien, CT 06820.	Planning and Zoning Department, 2 Renshaw Road, Darien, CT 06820.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 25, 2019	090005
Florida:						
Broward	City of Deerfield Beach (18–04–4897P).	The Honorable Bill Ganz, Mayor, City of Deerfield Beach, 150 Northeast 2nd Avenue, Deerfield Beach, FL 33441.	Environmental Services Department, 200 Goolsby Boulevard, Deerfield Beach, FL 33442.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 19, 2019	125101
Collier	City of Marco Island (18–04–5452P).	The Honorable Jared Grifoni, Chairman, City of Marco Island Council, 50 Bald Eagle Drive, Marco Island, FL 34145.	Building Department, 50 Bald Eagle Drive, Marco Island, FL 34145.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 15, 2019	120426
Collier	Unincorporated areas of Collier County (18–04–5751P).	The Honorable Andy Solis, Chairman, Collier County Board of Commissioners, 3299 Tamiami Trail East, Suite 303, Naples, FL 34112.	Collier County Growth Management Department, 2800 North Horseshoe Drive, Naples, FL 34104.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 29, 2019	120067
Lee	City of Sanibel (18–04–6446P).	The Honorable Kevin Ruane, Mayor, City of Sanibel, 800 Dunlop Road, Sanibel, FL 33957.	Planning Department, 800 Dunlop Road, Sanibel, FL 33957.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 21, 2019	120402
Lee	City of Sanibel (18–04–6717P).	The Honorable Kevin Ruane, Mayor, City of Sanibel, 800 Dunlop Road, Sanibel, FL 33957.	Planning and Code Enforcement Department, 800 Dunlop Road, Sanibel, FL 33957.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 12, 2019	120402
Manatee	Unincorporated areas of Manatee County (18–04–1654P).	The Honorable Priscilla Trace, Chair, Manatee County Board of Commissioners, P.O. Box 1000, Bradenton, FL 34206.	Manatee County Building and Development Services Department, 1112 Manatee Avenue West, Bradenton, FL 34205.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 8, 2019	120153
Monroe	Unincorporated areas of Monroe County (18–04–6657P).	The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 9400 Overseas Highway, Suite 210, Marathon, FL 33050.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 18, 2019	125129
Monroe	Unincorporated areas of Monroe County (18–04–6765P).	The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 9400 Overseas Highway, Suite 210, Marathon, FL 33050.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 19, 2019	125129
Pinellas	City of Treasure Island (18–04–5348P).	The Honorable Lawrence Lunn, Mayor, City of Treasure Island, 120 108th Avenue, Treasure Island, FL 33707.	Community Improvement Department, 120 108th Avenue, Treasure Island, FL 33707.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 22, 2019	125153
Georgia: Chatham	City of Savannah (18–04–7121P).	The Honorable Eddie DeLoach, Mayor, City of Savannah, 2 East Bay Street, Savannah, GA 31402.	Development Services Department, 5515 Abercorn Street, Savannah, GA 31405.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 9, 2019	135163
Louisiana:						

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Ascension	City of Gonzales (18–06–0401P).	The Honorable Barney Arceneaux, Mayor, City of Gonzales, 120 South Irma Boulevard, Gonzales, LA 70737.	City Hall, 120 South Irma Boulevard, Gonzales, LA 70737.	*https://msc.fema.gov/portal/advanceSearch.*	May. 15, 2019	220015
Ascension	Town of Sorrento (18–06–0401P).	The Honorable Michael Lambert, Mayor, Town of Sorrento, P.O. Box 65, Sorrento, LA 70778.	Town Hall, 8173 Main Street, Sorrento, LA 70778.	*https://msc.fema.gov/portal/advanceSearch.*	May. 15, 2019	220016
Ascension	Unincorporated areas of Ascension Parish (18–06–0401P).	The Honorable Kenny Matassa, Ascension Parish President, 615 East Worthy Road, Gonzales, LA 70737.	Ascension Parish Government Complex, 615 East Worthy Road, Gonzales, LA 70737.	*https://msc.fema.gov/portal/advanceSearch.*	May. 15, 2019	220013
Massachusetts:						
Plymouth.	Town of East Bridgewater (18–01–1360P).	The Honorable David J. Sheedy, Chairman, Town of East Bridgewater Board of Selectmen, 175 Central Street, East Bridgewater, MA 02333.	Department of Emergency Management, 268 Bedford Street, East Bridgewater, MA 02333.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 21, 2019	250264
Montana:						
Gallatin	City of Bozeman (18–08–1068P).	Ms. Andrea Surratt, Manager, City of Bozeman, P.O. Box 1230, Bozeman, MT 59771.	Engineering Department, 20 East Olive Street, Bozeman, MT 59715.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 18, 2019	300028
Gallatin	City of Bozeman (18–08–1069P).	Ms. Andrea Surratt, Manager, City of Bozeman, P.O. Box 1230, Bozeman, MT 59771.	Engineering Department, 20 East Olive Street, Bozeman, MT 59715.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 14, 2019	300028
Gallatin	City of Bozeman (18–08–1070P).	Ms. Andrea Surratt, Manager, City of Bozeman, P.O. Box 1230, Bozeman, MT 59771.	Engineering Department, 20 East Olive Street, Bozeman, MT 59715.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 18, 2019	300028
Gallatin	Unincorporated areas of Gallatin County (18–08–1068P).	The Honorable R. Stephen White, Chairman, Gallatin County Board of Commissioners, 311 West Main Street, Room 306, Bozeman, MT 59715.	Gallatin County Planning Department, 311 West Main Street, Room 108, Bozeman, MT 59715.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 18, 2019	300027
North Carolina:						
Avery	Unincorporated areas of Avery County (18–04–5170P).	The Honorable Martha J. Hicks, Chair, Avery County Board of Commissioners, P.O. Box 640, Newland, NC 28657.	Avery County Inspections and Planning Department, 200 Montezuma Street, Newland, NC 28657.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 11, 2019	370010
Durham	City of Durham (18–04–5360P).	The Honorable Steve Schewel, Mayor, City of Durham, 101 City Hall Plaza, Durham, NC 27701.	Development Services Department, 101 City Hall Plaza, Durham, NC 27701.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 10, 2019	370086
Henderson	City of Hendersonville (18–04–7062P).	The Honorable Barbara Volk, Mayor, City of Hendersonville, 145 5th Avenue East, Hendersonville, NC 28792.	Development Assistance Department, 100 North King Street, Hendersonville, NC 28792.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 25, 2019	370128
Union	Unincorporated areas of Union County (17–04–7709P).	The Honorable Jerry Simpson, Chairman, Union County Board of Commissioners, 500 North Main Street, Room 921, Monroe, NC 28112.	Union County Growth Management, Planning Division, 500 North Main Street, Monroe, NC 28112.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 21, 2019	370234
North Dakota:						
Stark.	City of Dickinson (18–08–0453P).	The Honorable Scott Decker, Mayor, City of Dickinson, 99 2nd Street East, Dickinson, ND 58601.	City Hall, 99 2nd Street East, Dickinson, ND 58601.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 13, 2019	380117
Oklahoma:						
Tulsa	City of Jenks (18–06–0767P).	The Honorable Josh Wedman, Mayor, City of Jenks, P.O. Box 2007, Jenks, OK 74037.	Engineering Department, 211 North Elm Street, Jenks, OK 74037.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 25, 2019	400209
Woodward	City of Woodward (18–06–1551P).	The Honorable John Meinders, Mayor, City of Woodward, 722 Main Street, Woodward, OK 73801.	Department of Community Development, 722 Main Street, Woodward, OK 73801.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 15, 2019	400209
Pennsylvania:						

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Allegheny	City of Pittsburgh (18–03–0982P).	The Honorable William Peduto, Mayor, City of Pittsburgh, 414 Grant Street, 5th Floor, Pittsburgh, PA 15219.	Planning Department, 200 Ross Street, Suite 309, Pittsburgh, PA 15219.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 14, 2019	420063
Chester	Township of Sadsbury (18–03–1405P).	The Honorable Dave Reynolds, Chairman, Township of Sadsbury Board of Supervisors, 2920 Lincoln Highway, Sadsburyville, PA 19369.	Township Hall, 2920 Lincoln Highway, Sadsburyville, PA 19369.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 22, 2019	421488
Dauphin	Township of Lower Paxton (18–03–1580P).	The Honorable Lowman S. Henry, Chairman, Township of Lower Paxton Board of Supervisors, 425 Prince Street, Harrisburg, PA 17109.	Community Development Department, 425 Prince Street, Harrisburg, PA 17109.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 13, 2019	420384
Potter	Borough of Galeton (18–03–2057P).	The Honorable Joseph Petrencsik, President, Borough of Galeton Council, 21 East Main Street, Galeton, PA 16922.	Building Code Department, 972 Boom Station Road, Lawrenceville, PA 16929.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 25, 2019	420762
Potter	Township of Pike (18–03–2057P).	The Honorable Paul Pitchard, Chairman, Township of Pike Board of Supervisors, 68 Meeker Road, Galeton, PA 16922.	Township Hall, 76 Route 6 West, Galeton, PA 16922.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 25, 2019	421983
Potter	Township of West Branch (18–03–2057P).	The Honorable Stephen J. Piaquadio, Chairman, Township of West Branch Board of Supervisors, 187 Gross Road, Galeton, PA 16922.	Township Hall, 533 Germania Road, Galeton, PA 16922.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 25, 2019	421992
South Carolina: Charleston.	Town of Sullivan's Island (18–04–6935P).	The Honorable Patrick O'Neil, Mayor, Town of Sullivan's Island, P.O. Box 427, Sullivan's Island, SC 29482.	Town Hall, 2056 Middle Street, Sullivan's Island, SC 29482.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 8, 2019	455418
Texas:						
Collin	City of Celina (18–06–3631P).	The Honorable Sean Terry, Mayor, City of Celina, 142 North Ohio Street, Celina, TX 75009.	City Hall, 142 North Ohio Street, Celina, TX 75009.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 1, 2019	480133
Collin	Unincorporated areas of Collin County (18–06–1253P).	The Honorable Keith Self, Collin County Judge, 2300 Bloomdale Road, Suite 4192, McKinney, TX 75071.	Collin County Emergency Management Department, 4690 Community Avenue, Suite 200, McKinney, TX 75071.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 8, 2019	480130
Collin	Unincorporated areas of Collin County (18–06–3631P).	The Honorable Keith Self, Collin County Judge, 2300 Bloomdale Road, Suite 4192, McKinney, TX 75071.	Collin County Emergency Management Department, 4690 Community Avenue, Suite 200, McKinney, TX 75071.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 1, 2019	480130
Ellis	City of Waxahachie (18–06–0880P).	The Honorable Kevin Strength, Mayor, City of Waxahachie, P.O. Box 757, Waxahachie, TX 75168.	Engineering Department, 401 South Rogers Street, Waxahachie, TX 75165.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 28, 2019	480211
Hays	City of Kyle (18–06–2155P).	The Honorable Travis Mitchell, Mayor, City of Kyle, 100 West Center Street, Kyle, TX 78640.	Building Department, 100 West Center Street, Kyle, TX 78640.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 7, 2019	481108
Kendall	Unincorporated areas of Kendall County (18–06–2515P).	The Honorable Darrel L. Lux, Kendall County Judge, 201 East San Antonio Avenue, Suite 122, Boerne, TX 78006.	Kendall County Engineering Department, 201 East San Antonio Avenue, Suite 101, Boerne, TX 78006.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 8, 2019	480417
Liberty	City of Dayton (18–06–1877P).	The Honorable Jeff Lambright, Mayor, City of Dayton, 117 Cook Street, Dayton, TX 77535.	City Hall, 117 Cook Street, Dayton, TX 77535.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 22, 2019	480440

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Liberty	Unincorporated areas of Liberty County (18–06–1877P).	The Honorable Jay Knight, Liberty County Judge, 1923 Sam Houston Street, Room 201, Liberty, TX 77575.	Liberty County Courthouse, 1923 Sam Houston Street, Liberty, TX 77575.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 22, 2019	480438
Midland	City of Midland (18–06–1530P).	Mr. Courtney Sharp, Manager, City of Midland, 300 North Loraine Street, Midland, TX 79701.	City Hall, 300 North Loraine Street, Midland, TX 79701.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 28, 2019	480477
Tarrant	City of Fort Worth (18–06–2376P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	City Hall, 200 Texas Street, Fort Worth, TX 76102.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 22, 2019	480596
Tarrant	City of Fort Worth (18–06–3483P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	City Hall, 200 Texas Street, Fort Worth, TX 76102.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 21, 2019	480596
Tarrant	City of Haslet (18–06–2110P).	The Honorable Bob Golden, Mayor, City of Haslet, 101 Main Street, Haslet, TX 76052.	City Hall, 101 Main Street, Haslet, TX 76052.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 11, 2019	480600
Tarrant	Unincorporated areas of Tarrant County (18–06–2376P).	The Honorable B. Glen Whitley, Tarrant County Judge, 100 East Weatherford Street, Fort Worth, TX 76196.	Tarrant County Administration Building, 100 East Weatherford Street, Fort Worth, TX 76196.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 22, 2019	480582
Webb	Unincorporated areas of Webb County (18–06–2395P).	The Honorable Tano E. Tijerina, Webb County Judge, 1000 Houston Street, 3rd Floor, Laredo, TX 78040.	Webb County Planning Department, 1110 Washington Street, Suite 302, Laredo, TX 78040.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 12, 2019	481059
Wise	City of Bridgeport (18–06–2510P).	The Honorable Randy Singleton, Mayor, City of Bridgeport, 900 Thompson Street, Bridgeport, TX 76426.	Infrastructure Services Department, 901 Cates Street, Bridgeport, TX 76426.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 8, 2019	480677
Wise	Unincorporated areas of Wise County (18–06–2510P).	The Honorable J.D. Clark, Wise County Judge, P.O. Box 393, Decatur, TX 76234.	Wise County Engineering Department, 2901 South FM 51, Building 200, Decatur, TX 76234.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 8, 2019	481051
Utah: Davis	City of Kaysville (18–08–1167X).	The Honorable Katie Witt, Mayor, City of Kaysville, 23 East Center Street, Kaysville, UT 84037.	Public Works Department, 721 West Old Mill Lane, Kaysville, UT 84037.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 5, 2019	490046
Virginia: Fauquier	Unincorporated areas of Fauquier County (18–03–1561P).	The Honorable Christopher T. Butler, Chairman, Fauquier County Board of Supervisors, 10 Hotel Street, Suite 208, Warrenton, VA 20186.	Fauquier County Planning Division, 10 Hotel Street, 3rd Floor, Warrenton, VA 20186.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 14, 2019	510055
Wyoming: Natrona	City of Casper (18–08–0739P).	The Honorable Ray Pacheco, Mayor, City of Casper, 200 North David Street, Casper, WY 82601.	City Hall, 200 North David Street, Casper, WY 82601.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 13, 2019	560037

[FR Doc. 2019–03024 Filed 2–21–19; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Internal Agency Docket No. FEMA–4412–DR; Docket ID FEMA–2019–0001]

North Carolina; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of North Carolina (FEMA–4412–DR), dated January 31, 2019, and related determinations.

DATES: The declaration was issued January 31, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated January 19, 2019, the President issued a

major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of North Carolina resulting from Tropical Storm Michael during the period of October 10–12, 2018, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of North Carolina.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Albert Lewis, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of North Carolina have been designated as adversely affected by this major disaster:

Alamance, Brunswick, Caswell, Chatham, Dare, Davidson, Davie, Forsyth, Granville, Hyde, Iredell, McDowell, Montgomery, Orange, Person, Randolph, Rockingham, Stokes, Surry, Vance, and Yadkin Counties for Public Assistance.

All areas within the State of North Carolina are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–03022 Filed 2–21–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4414–DR; Docket ID FEMA–2019–0001]

Minnesota; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Minnesota (FEMA–4414–DR), dated February 1, 2019, and related determinations.

DATES: The declaration was issued February 1, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated February 1, 2019, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Minnesota resulting from severe storms and flooding during the period of October 9 to October 11, 2018, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Minnesota.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Steven W. Johnson, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Minnesota have been designated as adversely affected by this major disaster:

St. Louis County for Public Assistance.

All areas within the State of Minnesota are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–03023 Filed 2–21–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R6–ES–2018–N142; FXES11140600000–190–FF06E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments by March 25, 2019.

ADDRESSES: *Document availability and comment submission:* Use one of the following methods to request documents or submit comments. Requests and comments should specify the applicant name(s) and application number(s) (*e.g.,* TE123456):

- *Email: permitsR6ES@fws.gov.*
- *U.S. Mail:* Marjorie Nelson, Chief, Division of Ecological Services, U.S. Fish and Wildlife Service, 134 Union Blvd., Suite 670, Lakewood, CO 80228.

FOR FURTHER INFORMATION CONTACT: Kathy Konishi, Recovery Permits Coordinator, Ecological Services, 303–236–4224 (phone), or *permitsR6ES@fws.gov* (email). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Background

The Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.;* ESA), prohibits certain activities with endangered and threatened species unless authorized by a Federal permit. The ESA and our implementing regulations in part 17 of title 50 of the Code of Federal Regulations (CFR) provide for the issuance of such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

We invite local, State, and Federal agencies; Tribes; and the public to comment on the following applications.

Application No.	Applicant, city, state	Species	Location	Activity	Type of take	Permit action
TE12174D–0	Joshua M. Allen, Easton, KS.	Gray bat (*Myotis grisescens*), Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*).	Alabama, Arkansas, Connecticut, Delaware, District of Columbia, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.	Presence/absence surveys, population monitoring, whitenose syndrome surveillance, and studies to document habitat use.	Capture, handle, mark, biosampling, release.	New.
TE12893D–0	Alisa Halpin	Interior least tern (*Sternula antillarum athalassos*).	Nebraska	Presence/absence surveys, nest monitoring.	Harassment	New.
TE070027–7	University of Nebraska.	Interior least tern (*Sternula antillarum athalassos*).	Nebraska	Presence/absence surveys, nest monitoring, banding.	Capture, handle, harassment.	Renew.
TE13508D–0	Turner Endangered Species Fund.	American burying beetle (*Nicrophorus americanus*).	Nebraska, South Dakota	Presence/absence surveys.	Capture, handle, harassment.	New.
TE61451C–1	Amy Hammesfahr.	Indiana bat (*Myotis sodalis*).	Minnesota	Presence/absence surveys.	Capture, handle, mark, biosampling, release.	Amend.
TE96435A–3	Laura Steger	Southwestern willow flycatcher (*Empidonax traillii extimus*).	Colorado	Presence/absence surveys.	Harassment	Renew.

Public Availability of Comments

Written comments we receive become part of the administrative record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we

will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Nicole Alt,

Acting Assistant Regional Director, Mountain-Prairie Region.

[FR Doc. 2019–03074 Filed 2–21–19; 8:45 am]

BILLING CODE 4333–15–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. TA–204–013]

Large Residential Washers: Monitoring Developments in the Domestic Industry

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission has instituted investigation No. TA–204–013, Large Residential Washers: Report on Monitoring of Developments in the Domestic Industry, for the purpose of preparing the report to the President and the Congress required by section 204(a)(2) of the Trade Act of 1974 on its monitoring of developments in the domestic industry following the President's decision to impose a safeguard measure on imports of large residential washers and certain washer parts as described in Proclamation 9694 of January 23, 2018.

DATES: February 15, 2019.

FOR FURTHER INFORMATION CONTACT: Nathanael Comly (202–205–3174), 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 investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On January 23, 2018, the President, pursuant to section 203 of the Trade Act of 1974 (19 U.S.C. 2253) (Trade Act), issued Proclamation 9694, imposing a safeguard measure on imports of certain large residential washers and parts thereof in the form of tariff-rate quotas. The proclamation was published in the **Federal Register** on January 25, 2018 (83 FR 3553). The measure took effect on February 7, 2018, for a period of three years and one day, or through February 7, 2021. The President imposed the measure following receipt of a report from the Commission in December 2017 under section 202 of the Trade Act (19 U.S.C. 2252) that contained an affirmative determination, remedy recommendations, and certain additional findings (see Large Residential Washers, investigation No. TA–201–076, USITC Publication 4745, December 2017).

Section 204(a)(1) of the Trade Act (19 U.S.C. 2254(a)(1)) requires the Commission to monitor developments with respect to the domestic industry, including the progress and specific efforts made by workers and firms in the domestic industry to make a positive adjustment to import competition, as long as any action under section 203 of the Trade Act remains in effect. Whenever the initial period of such an action exceeds 3 years, section 204(a)(2) requires the Commission to submit a report on the results of the monitoring to the President and the Congress no later than the mid-point of the initial period of the relief—in this case by August 7, 2019. Section 204(a)(3) requires the Commission to hold a hearing in the course of preparing each such report.

For further information concerning the conduct of this investigation, hearing procedures, 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 206, subparts A and F (19 CFR part 206).

Participation in the investigation and service list.—Persons wishing to participate in the investigation 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, not later than 21 days after publication of this notice in the **Federal Register**. The Secretary will prepare a service list containing the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance.

Limited disclosure of confidential business information (CBI).—Pursuant to section 206.17 of the Commission's rules, the Secretary will make CBI gathered in this investigation available to authorized applicants representing interested parties (as defined in 19 CFR 206.17(a)(3)(iii)) under an administrative protective order (APO) issued in the investigation, provided that the application is made not later than 21 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 CBI under the APO.

The Commission may include CBI in the report it sends to the President and to the U.S. Trade Representative. Additionally, all information, including CBI, submitted in this investigation may be disclosed to and used by (i) the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel for cybersecurity purposes.

The Commission will not release information which the Commission considers to be confidential business information unless the party submitting the confidential business information had notice, at the time of submission, that such information would be released by the Commission, or such party subsequently consents to the release of the information. The Commission will not otherwise disclose any CBI in a manner that would reveal the operations of the firm supplying the information.

Public hearing.—As required by statute, the Commission has scheduled a hearing in connection with this investigation. The hearing will be held beginning at 9:30 a.m. on June 25, 2019, at the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before June 14, 2019. All persons desiring to appear at the hearing and make an oral presentation should participate in a prehearing conference to be held on June 21, 2019 at the U.S.

International Trade Commission Building, if deemed necessary. Oral testimony and written materials to be submitted at the hearing are governed by sections 201.6(b)(2), and 201.13(f) of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 days prior to the date of the hearing.

Written submissions.—Each party is encouraged to submit a prehearing brief to the Commission. The deadline for filing prehearing briefs is June 14, 2019. Parties may also file posthearing briefs. The deadline for filing posthearing briefs is July 2, 2019. In addition, any person who has not entered an appearance as a party to the investigation may submit, on or before July 2, 2019, a written statement concerning the matters to be addressed in the Commission's report to the President. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain CBI must also conform with the requirements of section 201.6 of the Commission's rules. Any CBI that is provided will be subject to limited disclosure under the APO (see above) and may be included in the report that the Commission sends to the President and the U.S. Trade Representative. The Commission's *Handbook on E-Filing,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's rules with respect to electronic filing

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, will 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 section 201.16(c) of the Commission's rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by the 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.

Authority: This investigation is being conducted under the authority of section 204(a) of the Trade Act of 1974; this notice is published pursuant to section 206.3 of the Commission's rules.

By order of the Commission.

Issued: February 19, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019–03073 Filed 2–21–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Semiconductor Devices, Integrated Circuits, and Consumer Products Containing the Same, DN 3363;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Innovative Foundry Technologies LLC (''IFT'') on February 15, 2019. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain semiconductor devices, integrated circuits, and consumer products containing same. The complaint names as respondents: BBK Communication Technology Co., Ltd. of China; Vivo Mobile Communication Co., Ltd. of China; OnePlus Technology (Shenzhen) Co., Ltd. of China; Guangdong OPPO Mobile Telecommunications Co., Ltd. of China; Hisense Electric Co., Ltd. of China; Hisense USA Corporation of Suwanee, GA; Hisense USA Multimedia R & D Center Inc. of Suwanee, GA; TCL Corporation of China; TCL Communication, Inc. of Irvine, CA; TTE Technology, Inc. (d/b/a TCL America) of Corona, CA; TCT Mobile (US) Inc. of Irvine, CA; VIZIO, Inc. of Irvine, CA; MediaTek Inc. of Taiwan; MediaTek USA Inc. of San Jose, CA; Mstar Semiconductor, Inc. of Taiwan; Qualcomm Incorporated of San Diego, CA; Qualcomm Technologies, Inc. of San Diego, CA; Taiwan Semiconductor Manufacturing Company Limited of Taiwan; TSMC North America of San Jose, CA; and TSMC Technology, Inc. of San Jose, CA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders and impose a bond during the 60-day review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the

subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues should be filed no later than by close of business nine calendar days after the date of publication of this notice in the **Federal Register**. Complainant may file a reply to any written submission no later than the date on which complainant's reply would be due under § 210.8(c)(2) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(c)(2)).

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3363'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures.[1]) 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. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: February 15, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–03029 Filed 2–21–19; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

[OMB Number 1105–0030]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of and Renewal of Previously Approved Collection; Comments Requested: Electronic Applications for the Attorney General's Honors Program and the Summer Law Intern Program

AGENCY: Office of Attorney Recruitment and Management, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Justice Management Division, Office of Attorney Recruitment and Management (OARM), is submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until March 25, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Deana Willis, Assistant Director, Office of Attorney Recruitment and Management, 450 5th Street NW, Suite 10200, Washington, DC 20530; *Deana.Willis@usdoj.gov*; (202) 514–8902.

Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Office of Attorney Recruitment and Management, including whether the information will have practical utility;

(2) 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;

(3) Evaluate whether, and if so, how, the quality, utility, and clarity of the information to be collected can be enhanced; 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: Revision and Renewal of a Currently Approved Collection.

2. The title of the form/collection: Electronic Applications for the Attorney General's Honors Program and Summer Law Intern Program.

3. The agency form number, if any, and the applicable component of the department sponsoring the collection: There is no agency form number for this collection. The applicable component within the Department of Justice is the Office of Attorney Recruitment and Management, Justice Management Division, U.S. Department of Justice.

4. Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or households. Other: None. The application form is submitted voluntarily, once a year, by law students and recent law school graduates (*e.g.,* judicial law clerks) who will be in this applicant pool only once.

5. An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: It is estimated that 3500 respondents will complete the application in approximately 1 hour per application. It is further estimated that it takes an average of an additional 45 minutes to review the instructions, search existing data sources, gather the data needed, and complete and review the application. In addition, an estimated 600 respondents (Honors Program candidates selected for interviews) will complete a Travel Survey used to schedule interviews and prepare official travel authorizations prior to the interviewees' performing pre-employment interview travel (as defined by 41 CFR Sec. 301–1.3), as needed, in approximately 10 minutes per form, plus an estimated 400 respondents who will complete a Reimbursement Form (if applicable) in order for the Department to prepare the travel vouchers required to reimburse candidates for authorized costs they incurred during pre-employment interview travel at approximately 10 minutes per form.

6. An estimate of the total public burden (in hours) associated with the collection: The estimated revised total annual public burden associated with this application is 6292 hours.

If additional information is required, please contact: Melody Braswell, Department Clearance Officer, U.S. Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Room 3E.405B, Washington, DC 20530.

Dated: February 19, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–03090 Filed 2–21–19; 8:45 am]

BILLING CODE 4410–PB–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On February 19, 2019, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Western District of Washington in the lawsuit entitled *United States* v. *Trident Seafoods Corp., Royal Viking Inc., Golden Dawn, LLC,* Civil Action No. 2:19–cv–00231.

The United States, on behalf of the United States Environmental Protection Agency (''EPA''), filed a complaint against Trident Seafoods Corp., Royal Viking Inc., and Golden Dawn, LLC (collectively, ''Trident''), seeking injunctive relief and the imposition of civil penalties for violations of the Clean Air Act in connection with the Companies' use of ozone-depleting refrigerants on board vessels and at seafood processing facilities in Alaska and the Pacific Northwest. The Consent Decree requires Trident to retrofit or retire a number of refrigeration appliances, implement comprehensive refrigerant management practices, cap refrigerant losses, and employ a third-party auditor, as well as pay a civil penalty of $900,000 and perform a Supplemental Environmental Project.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Trident Seafoods Corp., Royal Viking Inc., Golden Dawn, LLC,* Civil Action No. 2:19–cv–00231. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *http://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $38.00 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $19.00.

Susan M. Akers,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2019–03110 Filed 2–21–19; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0029]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection; Annual Reporting Requirement for Manufacturers of Listed Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Drug Enforcement Administration (DEA), is submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register**, on December 14, 2018, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until March 25, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Kathy L. Federico, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812. Written comments and/or suggestions may also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503, or sent to *OIRA_submission@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary

for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.
2. *Title of the Form/Collection:* Annual Reporting Requirement for Manufacturers of Listed Chemicals.
3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number: N/A. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.
4. *Affected public who will be asked or required to respond, as well as a brief abstract:*
Affected public (Primary): Business or other for-profit.
Affected public (Other): None.
Abstract: Pursuant to 21 U.S.C. 830(b)(2) and 21 CFR 1310.05(d), manufacturers of listed chemicals must file annual reports of manufacturing, inventory, and use data for the listed chemicals they manufacture. These reports allow the DEA to monitor the volume and availability of domestically manufactured listed chemicals, which may be subject to diversion for the illicit production of controlled substances.
5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Each respondent for this information collection completes one response per year. The DEA estimates there are 50 respondents, and that each response takes 0.25 hours to complete.
6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates this collection takes a total of 12.5 annual burden hours.

If additional information is required, please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: February 15, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–03004 Filed 2–21–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0031]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Revision of a Currently Approved Collection; Application for Registration Under Domestic Chemical Diversion Control Act of 1993, Renewal Application for Registration Under Domestic Chemical Diversion Control Act of 1993; DEA Forms 510, 510A

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register** on December 14, 2018, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until March 25, 2019.

FOR FURTHER INFORMATION CONTACT: If you have comments on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Kathy L. Federico, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503, or sent to *OIRA_submission@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:
—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a currently approved collection.
2. *Title of the Form/Collection:* Application for Registration under Domestic Chemical Diversion Control Act of 1993; Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993.
3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* DEA Forms: 510, 510A. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.
4. *Affected public who will be asked or required to respond, as well as a brief abstract:*
Affected public (Primary): Business or other for-profit.
Affected public (Other): None.
Abstract: The DEA implements the Controlled Substances Act (CSA) which requires that every person who manufactures or distributes a list I chemical shall annually obtain a registration for that purpose. The DEA will be revising the proposed information collection instruments concerning the liability questions on the Application for Registration under Domestic Chemical Diversion Control Act of 1993; and Renewal Application

for Registration under Domestic Chemical Diversion Control Act of 1993. Over the years, many applicants have answered some of the liability questions incorrectly. These changes will avoid confusion to the applicant by separating compound questions into multiple parts that will require the applicant to answer them individually.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

	Number of annual respondents	Average time per response	Total annual burden hours
DEA–510 (paper)	6	0.20 hours (12 minutes)	1.20
DEA–510 (electronic)	88	0.17 hours (8 minutes)	11.73
DEA–510A (paper)	28	0.2 hours (10 minutes)	4.67
DEA–510A (electronic)	874	0.07 hours (4 minutes)	58.27
Total	996		76.87

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates that this collection takes 76.87 annual burden hours.

If additional information is required please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: February 15, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–03005 Filed 2–21–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0038]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection; Reporting and Recordkeeping for Digital Certificates

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until April 23, 2019.

FOR FURTHER INFORMATION CONTACT: If you have comments on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Kathy L. Federico, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Reporting and Recordkeeping for Digital Certificates.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form Number:

DEA Form 251: CSOS DEA Registrant Certificate Application.

DEA Form 252: CSOS Principal Coordinator/Alternate Coordinator Certificate Application.

DEA Form 253: CSOS Power of Attorney Certificate Application.

DEA Form 254: CSOS Certificate Application Registrant List Addendum.

The Department of Justice component is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public (Primary): Business or other for-profit.

Affected public (Other): None.

Abstract: The DEA collects information in regards to reporting and recordkeeping for digital certificates. The application for a digital certificate is required to ensure that the person applying for the certificate is either a DEA registrant or someone who has power of attorney from a DEA registrant to sign orders for Schedule I and II substances. The DEA Certification Authority uses the information to verify the person's identity and eligibility to hold a DEA-issued digital certificate.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates a total of 10,064 respondents. The average time to respond: 1.5 hours.

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates that this collection takes 40,439 annual burden hours.

If additional information is required please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: February 15, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–03010 Filed 2–21–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0014]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Revision of a Currently Approved Collection; Application for Registration and Applicaton for Registration Renewal; DEA Forms 224, 224A

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register** on December 14, 2018, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until March 25, 2019.

FOR FURTHER INFORMATION CONTACT: If you have comments on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Kathy L. Federico, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503, or sent to *OIRA_submission@omb.eop.gov.*

SUPPLEMENTARY INFORMATION:

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a currently approved collection.

2. *Title of the Form/Collection:* Application for Registration and Application for Registration Renewal.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* DEA Forms: 224, 224A. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public (Primary): Business or other for-profit.

Affected public (Other): Not-for-profit institutions; Federal, State, local, and tribal governments.

Abstract: The Controlled Substances Act (CSA) (21 U.S.C. 801–971) requires all persons that manufacture, distribute, dispense, conduct research with, import, or export any controlled substance to obtain a registration issued by the Attorney General. The DEA will be revising the proposed information collection instruments concerning the liability questions on the Application for Registration and Application for Registration Renewal. Over the years, many applicants have answered some of the liability questions incorrectly. These changes will avoid confusion to the applicant by separating compound questions into multiple parts that will require the applicant to answer them individually.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

	Number of annual respondents *	Average time per response **	Total annual hours **
DEA–224 (paper)	3,838	0.22 hours (13 minutes)	832
DEA–224 (electronic)	125,848	0.15 hours (9 minutes)	18,877
DEA–224A (paper)	6,193	0.22 hours (13 minutes)	1,342
DEA–224A (electronic)	482,100	0.08 hours (5 minutes)	40,175
Total	617,979		61,226

* Although practitioners are registered for a three-year cycle and the number of registrants is not equally distributed between years of the cycle, October 1, 2017 to September 30, 2018 is a reasonable approximation of the average annual burden as it is very close to the average of the three years. Additionally, the growth rate in the number of practitioners is low enough where the actual numbers for this period would not be materially different from the number expected for the next several years.

** An extra minute has been added to each average time per response to reflect the proposal for the first liability question in the application to now be broken down into two parts.

*** Figures are rounded.

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates that this collection takes 61,226 annual burden hours.

If additional information is required please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution

Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: February 15, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–03014 Filed 2–21–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0006]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection; Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine; DEA Form 189

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Drug Enforcement Administration (DEA), is submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register** on December 14, 2018, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until March 25, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Kathy L. Federico, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503, or sent to *OIRA_submission@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* DEA Form 189. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public (Primary): Business or other for-profit.

Affected public (Other): None.

Abstract: Pursuant to 21 U.S.C. 826(c) and 21 CFR 1303.22 and 1315.22, any person who is registered to manufacture any basic class of controlled substances listed in Schedule I or II, or the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine, and who desires to manufacture a quantity of such class or such List I chemical, must apply on DEA Form 189 for a manufacturing quota for such quantity of such class or List I chemical.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates 33 respondents complete 859 DEA Form 189 applications annually, and that each form takes 0.5 hours to complete.

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates this collection takes a total of 430 annual burden hours.

If additional information is required, please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: February 15, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–03006 Filed 2–21–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OJP) Docket No. 1756]

Meeting of the Global Justice Information Sharing Initiative Federal Advisory Committee

AGENCY: Office of Justice Programs (OJP), Justice.

ACTION: Notice of meeting.

SUMMARY: This is an announcement of a meeting of the Global Justice Information Sharing Initiative (Global) Federal Advisory Committee (GAC) to discuss the Global Initiative, as described at *www.it.ojp.gov/global.* This meeting will provide an update on existing projects as well as a preview of priorities for the FY19 Fiscal Year.

DATES: The meeting will take place on Thursday, March 28, 2019, from 9:00 a.m. ET to 4:30 p.m. ET.

ADDRESSES: The meeting will take place at the Office of Justice Programs offices (in the Main Conference Room), 810 7th Street, Washington, DC 20531; Phone: (202) 514–2000 [note: this is not a toll-free number].

FOR FURTHER INFORMATION CONTACT: Tracey Trautman, Global Designated Federal Official (DFO), Bureau of Justice Assistance, Office of Justice Programs, 810 7th Street, Washington, DC 20531; Phone (202) 305–1491 [note: this is not a toll-free number]; Email: *tracey.trautman@ojp.usdoj.gov.*

SUPPLEMENTARY INFORMATION: This meeting is open to the public. Due to security measures, however, members of the public who wish to attend this meeting must register with Ms. Tracey Trautman at the above address at least

(7) days in advance of the meeting. Registrations will be accepted on a space available basis. Access to the meeting will not be allowed without registration. All attendees will be required to sign in at the meeting registration desk. Please bring photo identification and allow extra time prior to the meeting.

Anyone requiring special accommodations should notify Ms. Trautman at least seven (7) days in advance of the meeting.

Purpose: The GAC will act as the focal point for justice information systems integration activities in order to facilitate the coordination of technical, funding, and legislative strategies in support of the Administration's justice priorities.

The GAC will guide and monitor the development of the Global information sharing concept. It will advise the Director of the Bureau of Justice Assistance; the Principal Deputy Assistant Attorney General, OJP; the Attorney General; the President (through the Attorney General); and local, state, tribal, and federal policymakers in the executive, legislative, and judicial branches. The GAC will also advocate for strategies for accomplishing a Global information sharing capability.

Interested persons whose registrations have been accepted may be permitted to participate in the discussions at the discretion of the meeting chairman and with approval of the DFO.

Tracey Trautman,

Global DFO, Deputy Director, Bureau of Justice Assistance, Office of Justice Programs, U.S. Department of Justice.

[FR Doc. 2019–03046 Filed 2–21–19; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Benefit Accuracy Measurement (BAM) Program

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL's) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Benefit Accuracy Measurement (BAM) Program.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by April 23, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Dennis Austin by telephone at 202–693–3056, TTY 1–877–889–5627 (these are not toll-free numbers), or by email at *Austin.Dennis@dol.gov.*

Submit written comments about or requests for a copy of this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance, Room S–4520, 200 Constitution Avenue NW, Washington, DC 20210, by email at *Austin.Dennis@dol.gov,* or by Fax at 202–693–3975.

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: As part of continuing efforts to reduce paperwork and respondent burden, DOL conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data is provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

Since 1987, all State Workforce Agencies (SWAs), except the U.S. Virgin Islands, have been required by regulation at 20 CFR part 602 to operate BAM programs to assess the accuracy of their unemployment insurance (UI) benefit payments in three programs: State UI, Unemployment Compensation for Federal Employees (UCFE), and Unemployment Compensation for Ex-servicemembers (UCX). Beginning in 2001, BAM was modified to include the sampling and investigation of UI claims denied for monetary, separation, or nonseparation issues.

BAM is one of the tools DOL uses to measure and reduce waste, fraud, and abuse in the UI program. By investigating small representative weekly samples of both paid and denied UI claims, each SWA is able to estimate reliably the number and dollar value of proper and improper payments; the number of proper and improper denials of claims for UI benefits; the rates of occurrence of these proper and improper payments and denials; and the error types, error causes, and the parties that are responsible for the errors.

Paid Claims Accuracy. Each week, SWAs select random samples of both intrastate and interstate original payments (including combined wage claims) made for a week of UI benefits under the State UI, UCX, and UCFE programs. A sample of 360 cases per year are pulled in the 10 SWAs with the smallest UI program workloads (defined as the average annual UI weeks paid during the last five years) and 480 cases per year in the other SWA. SWA BAM staff audit each selected claim, examining all aspects of a claimant's eligibility to receive UI benefits during the sampled week. The findings are entered into an automated database that is maintained on a computer located in each SWA.

Denied Claims Accuracy (DCA). Each week, SWAs select random samples from three separate sampling frames constructed from the universes of UI claims for which eligibility was denied for monetary, separation, and nonseparation reasons. All SWAs sample a minimum of 150 cases of each denial type in each calendar year. SWAs' BAM staff members review agency records and contact claimants, employers, and all other relevant parties to verify information in agency records or obtain additional information pertinent to the determination that denied eligibility for UI benefits. Unlike the investigation of paid claims, in which all prior determinations affecting claimant eligibility for the compensated week selected for the sample are evaluated, the investigation of denied claims is limited to the issue upon which the denial determination is based. The findings are entered into an automated database that is maintained on a computer located in each SWA.

DOL maintains a database of each SWA's BAM paid and denied claims cases, minus any personally identifying information. DOL uses BAM data to measure SWA performance with respect to UI payment integrity and to meet the DOL's reporting requirements of the Improper Payments Information Act of 2002 (IPIA), the Improper Payments Elimination and Recovery Act of 2010, and the Government Performance and Results Act. DOL also relies heavily on BAM data for information on UI operations, such as claims filing method, UI wage replacement rates, and claimant characteristics. The results of the BAM survey are reported annually on the ETA website at the following

link: *https://oui.doleta.gov/unemploy/bqc.asp.* The Improper Payments Elimination and Recovery Act of 2010 (31 U.S.C. 3321) authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB control number 1205–0245.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- 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 submission of responses.

Agency: DOL–ETA.

Type of Review: Extension without changes.

Title of Collection: Unemployment Insurance Benefit Accuracy Measurement.

Form: BAM State Operations Handbook (ET Handbook 395, 5th edition).

OMB Control Number: 1205–0245.

Affected Public: State Workforce Agencies (Primary), individuals, businesses, and not-for-profit institutions.

Estimated Number of Respondents: 117,962.

Frequency: Varies.

Total Estimated Annual Responses: 165,074.

Estimated Average Time per Response: Varies.

Estimated Total Annual Burden Hours: 535,312.

Total Estimated Annual Other Cost Burden: $0.

Molly E. Conway,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2019–03003 Filed 2–21–19; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0065]

Proposed Extension of Information Collection; Petitions for Modification of Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, 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 collections of information in accordance with the Paperwork Reduction Act of 1995. 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. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection for Petitions for Modification of Mandatory Safety Standards.

DATES: All comments must be received on or before April 23, 2019.

ADDRESSES: Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below.

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments for docket number MSHA–2018–0043.
- *Regular Mail:* Send comments to USDOL–MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452.
- *Hand Delivery:* USDOL-Mine Safety and Health Administration, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.

FOR FURTHER INFORMATION CONTACT: Sheila McConnell, Director, Office of Standards, Regulations, and Variances, MSHA, at *MSHA.information.collections@dol.gov* (email); (202) 693–9440 (voice); or (202) 693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Section 101(c), of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. Section 811(c), provides that a mine operator or a representative of miners may petition the Secretary of Labor (Secretary) to modify the application of a mandatory safety standard. A petition for modification may be granted if the Secretary determines (1) that an alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard, or (2) that the application of such standard to such mine will result in a diminution of safety to the miners in such mine.

Under 30 CFR 44.9, mine operators must post a copy of each petition for modification concerning the mine on the mine's bulletin board and maintain the posting until a ruling on the petition becomes final. This applies only to mines for which there is no representative of miners.

Under 30 CFR 44.10, detailed guidance for filing a petition for modification is provided for the operator of the affected mine or any representative of the miners at that mine. The petition must be in writing, filed with the Director, Office of Standards, Regulations and Variances, and a copy of the petition served by the filing party (the mine operator or representative of miners) on the other party.

Under 30 CFR 44.11(a), the petition for modification must contain the

petitioner's name and address; the mailing address and mine identification number of the mine or mines affected; the mandatory safety standard to which the petition is directed; a concise statement of the modification requested and whether the petitioner (1) proposes to establish an alternate method in lieu of the mandatory safety standard, or (2) alleges that application of the standard will result in diminution of safety to the miners affected, or (3) requests relief based on both grounds; a detailed statement of the facts that show the grounds upon which a modification is claimed or warranted; and, if the petitioner is a mine operator, the identity of any representative of miners at the affected mine.

II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to Petitions for Modification of Mandatory Safety Standards. MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

The information collection request will be available on *http://www.regulations.gov.* MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on *www.regulations.gov* and *www.reginfo.gov.*

The public may also examine publicly available documents at USDOL-Mine Safety and Health Administration, 201 12th South, Suite 4E401, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION** section of this notice.

III. Current Actions

This request for collection of information contains provisions for Petitions for Modification of Mandatory Safety Standards. MSHA has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0065.

Affected Public: Business or other for-profit.

Number of Respondents: 56.

Frequency: On occasion.

Number of Responses: 56.

Annual Burden Hours: 2,240 hours.

Annual Respondent or Recordkeeper Cost: $35,017.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Sheila McConnell,

Certifying Officer.

[FR Doc. 2019–03089 Filed 2–21–19; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Physics; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Mid-Term Site Visit to BaPSF for the Division of Physics (1208)—University of California—Los Angeles.

Date and Time: March 25, 2019; 8:00 a.m.–6:30 p.m.

Place: University of California, 1000 Veteran Ave, Los Angeles, CA 90024.

Type of Meeting: Part-Open.

Contact Person: Lukin Vyacheslav, Program Director for Plasma, Division of Physics, National Science Foundation, 2415 Eisenhower Avenue, Room W9218, Alexandria, VA 22314; Telephone: (703) 292–7382.

Purpose of Meeting: Site visit to provide an evaluation of the progress of the projects at the host site for the Division of Physics at the National Science Foundation.

Agenda

March 25, 2019; 8:00 a.m.–6:30 p.m.

8:00 a.m.–8:30 a.m. Executive Session—(CLOSED)
8:30 a.m.–9:00 a.m. Overview
9:00 a.m.–9:45 a.m. Physics Topic 1
9:45 a.m.–10:15 a.m. Lab Tour
10:15 a.m.–10:30 a.m. Break
10:30 a.m.–11:15 a.m. Physics Topic 2
11:15 a.m.–11:45 a.m. Physics Topic 3
12:00 p.m.–12:30 p.m. Executive Session—(CLOSED)
12:30 p.m.–1:15 p.m. Lunch with Students
1:15 p.m.–2:00 p.m. Physics Topic 4 (Co-PIs)
2:00 p.m.–2:45 p.m. Education Broader Impacts (PI and Co-PIs)
2:45 p.m.–3:15 p.m. Operations and Structure of Group (PI)
3:15 p.m.–3:45 p.m. Personnel Information (PI)
3:45 p.m.–4:15 p.m. Executive Session—(CLOSED)
4:15 p.m.–4:45 p.m. Coffee with Collaborating Groups
4:45 p.m.–5:05 p.m. Executive Session with Dean and V.P. for Research
5:05 p.m.–6:05 p.m. Questions for PI's
6:05 p.m.–6:30 p.m. Site Visitors and NSF Staff Dinner—(CLOSED)

Reason for Closing: Topics to be discussed and evaluated during closed portions of the site review will include information of a proprietary or confidential nature, including technical information and information on personnel. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: February 19, 2019.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2019–03053 Filed 2–21–19; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Final Environmental Impact Statement (FEIS) for the Green Bank Observatory, Green Bank, West Virginia

AGENCY: National Science Foundation.

ACTION: Notice of Availability.

SUMMARY: The National Science Foundation (NSF) announces the availability of the Final Environmental Impact Statement (FEIS) for Green Bank Observatory, Green Bank, WV. This Final EIS identifies and analyzes the potential environmental consequences of the following alternatives: *Alternative A,* Collaboration with interested parties for continued science- and education-focused operations with reduced NSF funding *(Agency-preferred Alternative);*

Alternative B, Collaboration with interested parties for operation as a technology and education park; *Alternative C,* Mothballing of Facilities; *Alternative D,* Demolition and Site Restoration; and the *No Action Alternative,* Continued NSF Investment for Science-focused Operations. It also proposes mitigation measures to minimize the adverse impacts from alternatives that include demolition where such impacts may occur.

DATES: The National Science Foundation will execute a Record of Decision no sooner than 30 days after the date of publication of the Notice of Availability published in the **Federal Register** by the Environmental Protection Agency.

ADDRESSES: The Final EIS is made available for public inspection on-line at *www.nsf.gov/AST.* A copy of the FEIS will be available for review at the following libraries:

Green Bank Public Library, 5683 Potomac Highlands Trail, Green Bank, WV 24944

Durbin Community Library, 4361 Staunton Parkersburg Turnpike, Durbin, WV 26264

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth Pentecost, Re: Green Bank Observatory, 2415 Eisenhower Avenue, Room W9152, Alexandria, VA 22314, *envcomp-AST-greenbank@nsf.gov;* 703–292–4907.

SUPPLEMENTARY INFORMATION: Green Bank Observatory (GBO) is located in Pocahontas County, West Virginia, adjacent to the Monongahela National Forest. NSF owns the GBO land, which consists of numerous parcels acquired by the U.S. Army Corps of Engineers in the 1950s, when GBO was formed as the first (and then, only) site of the National Radio Astronomy Observatory (NRAO). The GBO facilities include the Robert C. Byrd Green Bank Telescope, the largest fully steerable radio telescope in the world; the 43-meter Telescope; the Green Bank Solar Radio Burst Spectrometer; the 20-meter Geodetic Telescope; the 40-foot Telescope; the Interferometer Range; and previously operational telescopes.

Through a series of academic community-based and portfolio reviews, NSF identified the need to divest several facilities from its portfolio in order to retain the balance of capabilities needed to deliver the best performance on the key science of the present decade and beyond. In 2016, NSF completed a feasibility study to inform and define options for the site's future disposition that would involve significantly decreasing or eliminating NSF funding of the Green Bank Observatory. NSF issued a Notice of Intent to prepare an EIS on October 19, 2016, held scoping meetings on November 9, 2016, and held a 30-day public comment period that closed on November 25, 2016.

The Draft EIS was made available for public review and comment from November 8, 2017 through January 8, 2018. The full Draft EIS was also posted on the NSF, Division of Astronomical Sciences website (*www.nsf.gov/AST*) and hard copies were delivered to local libraries. A public meeting on the draft EIS was held in Green Bank, WV on November 30, 2017. During the review period, the NSF received over 340 comments. After considering all comments received, the NSF prepared the Final EIS. There are no substantive changes to the range of alternatives considered. *Alternative A,* Collaboration with interested parties for continued science- and education-focused operations with reduced NSF funding, is identified as the ''*Agency-preferred Alternative.*''

Dated: February 15, 2019.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2019–03017 Filed 2–21–19; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–263; NRC–2019–0059]

Northern States Power Company; Monticello Nuclear Generating Plant

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued an exemption in response to a April 6, 2017, request from Norther States Power Company to allow the use of structural steel columns and beams supporting the floor of the Cable Spreading Room that are not coated with fireproofing material to provide a fire resistance equivalent to that of the fire barrier.

DATES: The exemption was issued on February 14, 2019.

ADDRESSES: Please refer to Docket ID NRC–2019–0059 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 *http://www.regulations.gov* and search for Docket ID NRC–2019–0059. Address questions about Docket IDs in *Regulations.gov* to Krupskaya Castellon; telephone: 301–287–9221; email: *Krupskaya.Castellon@nrc.gov.* For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The 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. For the convenience of the reader, the ADAMS accession numbers are provided in a table in the ''Availability of Documents'' section of this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Robert F. Kuntz, Office or Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3733, email: *robert.kuntz@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated at Rockville, Maryland, this 19th day of February, 2019.

For the Nuclear Regulatory Commission.

Robert F. Kuntz,

Senior Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

Attachment—Exemption

NUCLEAR REGULATORY COMMISSION

Docket No. 50–263;

Northern States Power Company

Monticello Nuclear Generating Plant

Exemption

I. Background

Northern States Power Company, doing business as Xcel Energy (the licensee), is the holder of Renewed Facility Operating License Number 50–263 which authorizes operation of the

Monticello Nuclear Generating Plant (MNGP). The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC, the Commission) now or hereafter in effect.

The facility consists of a boiling water reactor located in Wright County, Minnesota.

II. Request/Action

Section III.G.2. of Appendix R to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 states in part:

Except as provided for in paragraph G.3 of this section, where cables or equipment, including associated non-safety circuits that could prevent operation or cause maloperation due to hot shorts, open circuits, or shorts to ground, of redundant trains of systems necessary to achieve and maintain hot shutdown conditions are located within the same fire area outside of primary containment, one of the following means of ensuring that one of the redundant trains is free of fire damage shall be provided:

a. Separation of cables and equipment and associated non-safety circuits of redundant trains by a fire barrier having a 3-hour rating. Structural steel forming a part of or supporting such fire barriers shall be protected to provide fire resistance equivalent to that required of the barrier[.]

The licensee determined that certain structural steel columns and beams supporting the floor of the Cable Spreading Room are not coated with fireproofing material that provides a fire resistance equivalent to that of the fire barrier. To address this finding, by letter dated March 21, 2018 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18080A161), as supplemented by letter dated July 20, 2018 (ADAMS Accession No. ML18201A558), the licensee requested an exemption from the portion of paragraph III.G.2.a. of Appendix R that requires structural steel to be protected by an equivalent 3-hour fire barrier. The licensee indicated that the scope of its exemption request is limited to the unprotected structural steel in the floor of Fire Zone 8 (Cable Spreading Room) forming the barrier with all or parts of Fire Zones 7A, 7B, and 10 (125V Division I Battery Room, 250V Division I Battery Room, and Plant Administration Building (PAB), respectively).

III. Discussion

Pursuant to 10 CFR 50.12(a)(1), the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 which are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security. However, 10 CFR 50.12(a)(2) states that the Commission will not consider granting an exemption unless special circumstances are present. Further, per 10 CFR 50.12(a)(2), special circumstances are present whenever:

(i) Application of the regulation in the particular circumstances conflicts with other rules or requirements of the Commission; or

(ii) Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule; or

(iii) Compliance would result in undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted, or that are significantly in excess of those incurred by others similarly situated; or

(iv) The exemption would result in benefit to the public health and safety that compensates for any decrease in safety that may result from the grant of the exemption; or

(v) The exemption would provide only temporary relief from the applicable regulation and the licensee or applicant has made good faith efforts to comply with the regulation; or

(vi) There is present any other material circumstance not considered when the regulation was adopted for which it would be in the public interest to grant an exemption. If such condition is relied on exclusively for satisfying paragraph (a)(2) of this section, the exemption may not be granted until the Executive Director for Operations has consulted with the Commission.

The licensee stated that special circumstances as described in 10 CFR 50.12(a)(2)(ii) are present in that the application of the regulation in this particular circumstance is not necessary to achieve the underlying purpose of the rule (i.e., the underlying purpose of paragraph III.G.2.a. of Appendix R (stating in part that structural steel forming a part of, or supporting, a fire barrier shall be protected to provide fire resistance equivalent to a 3-hour fire barrier)).

A. Underlying Purpose of Protecting Structural Steel with 3-Hour Barrier

The Commission proposed its fire protection rules in 1980 via Proposed Rule, Fire Protection Program for Nuclear Power Plants Operating Prior to January 1, 1979, 45 Fed. Reg. 36082 (May 29, 1980) (proposing, among other things, a new Appendix R to 10 CFR part 50). Proposed section III.M ''Fire Barriers'' of Appendix R (45 Fed. Reg. at 36089) stated in part:

M. *Fire Barriers.* Fire barriers (floors, walls, ceilings, or other enclosures) separating fire areas, or equipment or components of redundant systems important to safe shutdown within an area shall have a fire rating of 3 hours unless a lower rating is justified by the fire hazard analysis.

Structural steel forming a part of or supporting such fire barriers shall have fire resistance equivalent to that required of the barrier. Such fire resistance shall be provided by protection equivalent to metal lath and plaster covering.

Penetrations in these fire barriers, including conduits, cable trays, and piping shall be sealed or closed to provide fire resistance rating equivalent to that required of the barrier. Door openings shall be protected with doors, frames, and hardware that have been tested and approved by a nationally recognized testing laboratory to have a fire resistance rating equivalent to that required of the barrier. Penetrations for ventilation systems shall be protected by a standard ''fire door damper.''

The Commission subsequently finalized its fire protection rule in 1980 (Final Rule, Fire Protection Program for Operating Nuclear Power Plants, 45 Fed. Reg. 76602 (Nov. 19, 1980)). The Commission explained (45 Fed. Reg. at 76608) that it ''has selected 3 hours as an acceptable minimum fire resistance rating for fire barriers separating redundant trains for safe shutdown systems. This will give ample time for automatic and manual fire suppression activities to control any potential fire and for safe shutdown activities to properly control the reactor.'' The Commission addressed several comments related to the proposed (45 Fed. Reg. at 36089) fire barrier and structural steel requirements, writing (45 Fed. Reg. at 76608):

Several commenters made a number of suggestions of an editorial nature. One suggestion was to add ''or unless other fire protection features have been provided to ensure equivalent protection'' in the first paragraph, where three-hour rated fire barriers were stipulated unless a lower rating was justified by the fire hazards analysis. The Commission feels that this adds nothing in the way of clarification and the suggestion was not adopted. The second paragraph requires that structural steel forming a part of or supporting any fire barrier have a fire resistance equivalent to that required of

the barrier. An example was given of metal lath and plaster covering as being one means of providing equivalent protection. Several commenters stated that they thought this was too narrow and would be interpreted by some people as the only acceptable method permitted. Since the example seemed to be confusing, a decision has been made to eliminate it. Other comments to the effect that the requirement was excessively restrictive with regard to fire barrier penetrations, including fire doors and their associated frames and hardware, and ventilation systems have been acted upon by the staff and the requirement, as it had affected these items, was deleted.

The final rule moved the structural steel fire barrier requirement to paragraph III.G.2.a. of Appendix R (45 Fed. Reg. 76613) (saying ''Separation of cables and equipment and associated non-safety circuits of redundant trains by a fire barrier having a 3-hour rating. Structural steel forming a part of or supporting such fire barriers shall be protected to provide fire resistance equivalent to that required of the barrier.'').

Therefore, the underlying purpose of paragraph III.G.2.a. is to ensure that the protection of structural steel provides (i.e., does not undermine) the 3-hour minimum fire resistance rating for fire barriers separating redundant trains for safe shutdown systems. Three hours will give ample time for automatic and manual fire suppression activities to control any potential fire and for safe shutdown activities to properly control the reactor.

Licensee's application for exemption

The licensee stated that for Fire Zones 7A, 7B, 8, and 10, MNGP is required to comply with 10 CFR 50, Appendix R, and that the deterministic requirements of section III.G.2 mandate that, using one of the options given, the redundant trains should be adequately separated and protected, such that in the event of a fire in that fire area, at least one train will remain free of fire damage. The licensee further stated that contrary to the requirement, the structural steel in a portion of the floor of the Cable Spreading Room is not protected with fireproofing material to provide fire resistance equivalent to that of the barrier.

The licensee stated that the intent of section III.G.2 has been met by means other than the deterministic physical separation requirements, and that instead, based on a detailed fire modeling analysis, it has determined that the structural steel will not fail in the event of a fire. The licensee stated that the approach used in the detailed fire modeling analysis was similar in nature to a previously approved structural steel survivability analysis known as the ''Limerick Methodology'' and described in NUREG-0991, Supplement 2, ''Safety Evaluation Report Related to the Operation of Limerick Generating Station, Units 1 and 2,'' dated October 1984 (Legacy ADAMS Accession No. 8411090445).

The licensee stated that this conclusion is further supported by instructions provided in the American Society of Mechanical Engineers/American Nuclear Society (ASME/ANS) Probabilistic Risk Assessment (PRA) Standard (ASME/ANS RA–Sa–2009, ''Addenda to ASME/ANS RA–S–2008 Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Application,'' dated February 2, 2009), which recommends the screening of such structural steel when high hazard fire sources are not present.

The licensee stated that because the structural steel will not fail, a fire that originates in Fire Zones 7A, 7B, or 10 will not propagate into Fire Zone 8 and that the existing barriers between Fire Zones 8 and 7A, 7B, and 10 provide protection commensurate with the fire hazards therein and ensure the safe shutdown strategy will be preserved. The licensee concluded that MNGP retains the ability to reach and maintain safe shutdown in the event of a fire in any plant area and protecting the exposed steel members would have no demonstrable safety benefit over current conditions.

The licensee further stated that the underlying purpose of the rule, which is to provide reasonable assurance that safe shutdown of the reactor can be achieved and maintained in the event of a single postulated fire in any plant area, is satisfied and the application of the deterministic requirements of section III.G.2 in these particular circumstances is not necessary to achieve the underlying purpose of the rule.

The licensee stated that a fire area approach is employed at MNGP to demonstrate compliance with 10 CFR 50, Appendix R, and that fire zones are combined into fire areas based on the redundant trains of safe shutdown equipment therein and the feasibility of providing adequate fire boundary barriers to separate them from other fire areas. The licensee further stated that the Cable Spreading Room (Fire Zone 8) is a part of Fire Area VI with the remainder of the fire area being comprised of Fire Zones 7A, 7B, 10, and 11, and that the alternate shutdown system is the credited safe shutdown strategy for Fire Zone 8 and that Division II equipment is the credited safe shutdown strategy for Fire Zones 7A, 7B, 10, and 11. The licensee further stated that because the shutdown strategy is different for the Cable Spreading Room than the rest of Fire Area VI, it is not appropriate for the Cable Spreading Room to be a part of Fire Area VI and, therefore, the barriers between the Cable Spreading Room and adjacent fire zones must meet the requirements of 10 CFR, Part 50, Appendix R.

The licensee stated that the MNGP Fire Protection Program (FPP), which is consistent with Branch Technical Position (BTP) APCSB 9.5–1, 10 CFR 50.48, Appendix R of 10 CFR 50, and supporting generic communications, is designed and implemented based on a foundation of defense-in-depth that consists of:

Fire Prevention—Preventing fires from starting through control of fuel and ignition sources and conditions.

Fire Detection and Suppression—Providing the capability to promptly detect any fires that may occur and the capability to promptly and effectively control and extinguish any such fire.

Protection of Safe Shutdown Capability—Providing protection for systems, structures, and components important to safety such that any fire that is not promptly detected and extinguished will not prevent the safe shutdown of the plant.

The licensee stated that the Cable Spreading Room is located on the 939-foot elevation of the PAB and is bordered by the Turbine Building to the north, other PAB areas to the east and south, and the Reactor Building to the west. The licensee further stated that the Cable Spreading Room is directly above the 125V Division I and II Battery Rooms, 250V Division I Battery Room, and other portions of the basement of the PAB and that the Cable Spreading Room is directly below the Control Room.

The licensee stated that because the Cable Spreading Room north and west walls, the entirety of the ceiling, and the portion of the floor over the 125V Division II Battery Room were previously classified as fire barriers between adjacent fire areas, they have already been demonstrated to meet the requirements of 10 CFR 50, Appendix R. The licensee further stated that the east and south walls separating the Cable Spreading Room from other rooms on the 939-foot elevation of the PAB are comprised of poured concrete and provide a 3-hour fire barrier. Therefore, the only boundary of the Cable

Spreading Room which will not meet 10 CFR, Part 50, Appendix R, is the portion of floor that is not directly above the Division II Battery Room. The licensee indicated that the scope of its exemption request is limited to the unprotected structural steel in the floor of Fire Zone 8 (Cable Spreading Room) forming the barrier with all or parts of Fire Zones 7A, 7B, and 10 (125V Division I Battery Room, 250V Division I Battery Room, and PAB, respectively).

The licensee provided the details of combustible loading/fire severity and active fire protection features for the specific fire zones of concern in Table 1 of its request. The licensee stated that the localization of the hazards and combustibles by fire zone, combined with the separation between fire zones by spatial and barrier separation, provide reasonable assurance that fires that occur within a given zone will be confined to the fire zone of origination.

The licensee provided summary descriptions of each of the fire zones that included the types of combustibles, available detection and suppression, and smoke/hot gas ejection methods.

Fire Zone 7A—928 foot elevation, PAB (125V Division I Battery Room). The combustible loading in this zone primarily consists of battery cases and cable insulation. Combustible loading is administratively controlled by procedures. Ignition sources within the fire zone include batteries, battery chargers, and electrical cabinets. There is no fixed fire suppression system installed in this zone, but hose stations and portable extinguishers are available in an adjacent fire zone. The ionization detection system alarms in the control room thereby providing an early warning of a fire and, subsequently, an early response of the fire brigade to extinguish the fire. Smoke and hot gases can be evacuated using normal air handling systems or opening the access door. Portable smoke ejectors can be used as a backup. The zone contains Division I safe shutdown equipment. In the event of a fire in this zone, Division II safe shutdown equipment would be available for shutdown.

Fire Zone 7B—928 foot elevation, PAB (250V Division I Battery Room). The combustible loading in this zone primarily consists of battery cases and cable insulation. Combustible loading is administratively controlled by procedures. Ignition sources within the zone include batteries, battery chargers, and electrical cabinets. There is no fixed fire suppression system installed in this zone, but hose stations and portable extinguishers are available in an adjacent fire zone. The ionization detection system alarms in the control room thereby providing an early warning of a fire and, subsequently, an early response of the fire brigade to extinguish the fire. Smoke and hot gases can be evacuated using normal air handling systems or opening the access door. Portable smoke ejectors can be used as a backup. The zone contains Division I safe shutdown equipment. In the event of a fire in this zone, Division II safe shutdown equipment would be available for shutdown.

Fire Zone 8—939 foot elevation, PAB (Cable Spreading Room). The combustible loading in this zone primarily consists of cable insulation. Combustible loading is administratively controlled by NSPM [Northern States Power Company – Minnesota) procedures. Ignition sources within the zone include electrical cabinets. The fire zone is equipped with an automatic halon suppression system as well as portable extinguishers. Hose stations are located in adjacent fire zones. The ionization and thermal detection systems alarm in the control room thereby providing an early warning of a fire and, subsequently, an early response of the fire brigade to extinguish the fire. Smoke and hot gases can be evacuated using normal air handling systems with portable smoke ejectors available as a backup, if necessary. The zone contains both Division I and Division II safe shutdown equipment. In the event of a fire in this zone, the alternate shutdown system would be available for safe shutdown.

Fire Zone 10—multiple elevations, PAB (Plant Administration Building excluding the Battery, Cable Spreading, Control, and heating, ventilation and air conditioning (HVAC) Rooms). The scope of this exemption request is limited to a portion of this fire zone on the 928 foot elevation, however, the discussion below includes features of the fire zone in its entirety. The combustible loading in this zone primarily consists of those combustibles typical of office occupancy. As Fire Zone 10 is comprised mostly of office space, the introduction of combustible material is not controlled in the same manner as fire zones in the power block. Ignition sources include an electric motor, a power transformer, ventilation systems, and electrical cabinets. However, electrical cabinets and one dry power transformer are the only ignition sources present in the portion of the fire zone below the Cable Spreading Room. Portions of the fire zone (Records Storage Vault and Computer Room) are equipped with automatic halon suppression systems. There is no fixed fire suppression system installed in the remainder of the fire zone, but hose stations and portable extinguishers are available throughout. Ionization detectors are available in portions of the fire zone and will alarm in the control room thereby providing an early warning of a fire and, subsequently, an early response of the fire brigade to extinguish the fire. However, none of the ionization detectors are installed in the portions of Fire Zone 10 pertinent to this request. Smoke and hot gases can be evacuated using normal air handling systems with portable smoke ejectors available as a backup, if necessary. The zone contains Division I safe shutdown equipment. In the event of a fire in this zone, Division II safe shutdown equipment would be available for shutdown.

The licensee provided a discussion of its detailed fire modeling analysis regarding the survivability of the structural steel for the postulated fire hazards present in the fire zones in question. Similar to the referenced Limerick Methodology, the licensee used a mathematical model to calculate the time-temperature profile for potential fires in each fire area and that if any of the calculations show that the time-temperature profile in an area will exceed 1100 degree Fahrenheit (°F) within 3 hours, an evaluation is performed to calculate the corresponding temperature response of the supporting structural steel and that if the steel temperature does not exceed 1100 °F within 3 hours, the steel need not be protected.

The licensee stated that the Limerick Methodology is based on the availability and quantity of two specific types of fixed combustibles found in a nuclear power plant: cable insulation and lubricating oil. The licensee further stated that lube oil is not present and there are no significant concentrations of exposed cable insulation in the applicable fire zones and, therefore, the areas beneath the Cable Spreading Room would screen out of the Limerick Methodology and the structural steel would not need to be protected with no further analysis required. The licensee further stated that while the results of this analysis appropriately reflect the low significance of the exposed structural steel, it determined it was prudent to perform additional analysis to demonstrate the acceptability of the exposed structural steel.

The licensee stated that it performed fire modeling using the Fire Dynamics Simulator (FDS) code which is a computational fluid dynamics model of fire-driven fluid flow that numerically solves the governing equations of fluid dynamics with a particular emphasis on fire and smoke transport. The licensee

further stated that FDS is known to provide better predictions for heat flux and surface temperatures than comparable tools (e.g., CFAST and MAGIC) and that it has been shown to predict heat flux and wall temperature within 20 percent with a bias towards over-prediction. The licensee further stated that two distinct analyses were performed using FDS, the first examined the plant access control area, while the second examined the battery rooms.

The licensee stated that an acceptance criterion of 1100 °F was established to determine the acceptability of the exposed structural steel and that Generic Letter (GL) 83–33, ''NRC Positions on Certain Requirements of Appendix R to 10 CFR 50,'' (ADAMS Accession No. ML031080522) states that this temperature is typically considered the critical temperature of steel because at this temperature the yield stress in the steel has decreased to about 60 percent of the value at room temperature. The licensee further stated that it reviewed the structural design for the as-built configuration of the PAB and determined that the acceptance criterion in GL 83–33 is applicable to the exposed structural steel supporting the MNGP Cable Spreading Room floor.

The licensee stated that for the plant access control area, a transient fire was assumed to occur directly below a structural beam and immediately adjacent to a structural steel column and that the assumed fire was the 98th percentile transient fire with a heat release rate (HRR) of 317 kW, consistent with the guidance in NUREG/CR–6850, ''EPRI/RES Fire PRA Methodology for Nuclear Power Facilities,'' Table G–1 (ADAMS Accession Nos. ML15167A401, and ML15167A411). The licensee further stated that this fire was determined to be the most limiting postulated fire based on a walkdown of the applicable plant areas and review of all potential ignition sources and that the duration of the fire was assumed to be 1 hour. The licensee further stated that sensitivity studies were performed to verify the adequacy of the results of the final FDS model and that these studies were performed to verify the numerical grid size, the use of a simplified small-scale model, and the effects on structural steel temperature based on the location of the fire.

The licensee stated that the ignition sources in the area consist of batteries, battery chargers, a dry transformer, or electrical cabinets so it is unclear to the NRC staff why the licensee stated that a 317 kW transient fire was assumed to represent the most limiting postulated fire because the identified ignition sources all represent larger fires. The NRC staff requested that the licensee provide technical justification for why the smaller transient fire was selected as more limiting than a battery, battery charger, dry transformer, or electrical cabinet fire. In its letter dated July 20, 2018 (ADAMS Accession No. ML18201A558), the licensee responded to the NRC staff's request and stated that the licensee used information contained in NUREG–2178, ''Refining and Characterizing Heat Release Rates from Electrical Enclosures During Fire (RACHELLE-FIRE),'' Volume 1 (ADAMS Accession No. ML16110A140), to support its assumption that electrical cabinets in the areas containing low fuel loading would exhibit a shorter fire duration and smaller peak HRR than the 317 kW transient fire selected for their analysis. The licensee stated that the heat rates and shorter durations demonstrated by other potential ignition sources (i.e. batteries, battery chargers, a dry transformer, or electrical cabinets) are subsumed by the transient fire that continues for 60 minutes which is used in the analysis. The licensee also stated that they performed a sensitivity study using the default HRR value for the cabinets and determined that the transient fire resulted in higher calculated peak steel temperatures, thereby representing a conservative approach. The staff found the licensee's response acceptable because it represents a conservative analysis that was based on plant walk down information and accepted methods or guidance.

The licensee provided a figure that displayed the manner in which the structural steel columns and beams were modeled in the plant access control area which showed a 2 foot by 2 foot fire located immediately adjacent to a structural steel column as it was found to be the most limiting configuration (i.e., highest resultant temperatures). The licensee also provided a figure that showed the temperature response of an exposed structural steel beam located directly above the transient fire in the plant access control area. This figure identified that the temperature of the structural steel beam is beginning to level off at approximately 350 °F after 1 hour and the licensee concluded that the critical temperature of 1100 °F will not be reached and the structural steel will continue to support the Cable Spreading Room floor despite the lack of fireproofing material.

The licensee stated that for the battery rooms, FDS runs were completed only for the Division I 125 V Battery Room (Fire Zone 7A). The licensee stated that citing the significantly smaller air volume in Fire Zone 7A, it determined the air temperature and resulting structural steel temperature would bound that of a similar analysis for Fire Zone 7B. The licensee further stated that a 98th percentile transient fire with a HRR of 317 kW was assumed to occur directly below the structural steel, immediately adjacent to a concrete wall and that the duration was assumed to be 1 hour. The licensee further stated that sensitivity studies were performed to verify the adequacy of the results of the final FDS model and that these studies were performed to verify the numerical grid size, the effects of different fire soot yields, and the effects on structural steel temperature based on the location and size of the fire.

The licensee provided a figure that displayed the manner in which the structural steel beams were modeled in the Division I 125 V Battery Room. The figure showed a 1ft by 1ft fire located adjacent to a wall and directly below a structural steel beam as it was found to be the most limiting configuration (i.e., highest resultant temperatures). The licensee provided a figure that showed the temperature response of the exposed structural steel beam for a variety of modeled conditions (e.g., different fire position, mesh size, soot yields, room door open and closed) that showed the temperature of the structural steel beam in the most limiting case levels off at approximately 800 °F during the 1-hour duration of the fire. The licensee concluded that the critical temperature of 1100 °F will not be reached and the structural steel will continue to support the Cable Spreading Room floor despite the lack of fireproofing material.

The licensee stated that physical fire dimensions of the assumed 317 kW fire were 2 foot by 2 foot for the plant access control area and 1 foot by 1 foot for the battery rooms but did not provide any technical justification for the use of different fire dimensions. The NRC staff requested that the licensee provide technical justification for using different fire sizes. In its letter dated July 20, 2018, the licensee responded to the NRC staff's request and stated that the physical dimensions, i.e., 1 foot by 1 foot and 2 foot by 2 foot, of the transient fires used in their analysis were based on scenarios that represented bounding cases for the steel beams and columns, respectively. The staff found the licensee's response acceptable because it represents a conservative analysis that was based on plant walk down information that reflects the physical design of the plant and sound engineering judgement.

The licensee stated that the following conservatisms were built into the FDS runs:

FDS only simulates one-dimensional heat conduction; therefore, conduction of heat away from the fire plume is not included in the calculations.

Transient fires were assumed to burn continuously for 1 hour at the 98th percentile HRR. This is especially conservative when reviewing the HRR over time for the various fires studied in Table G–7 of NUREG/CR–6850 that show transient fires have a growth and decay period on either side of the peak HRR and do not last longer than 15 minutes. These fire studies also show that the higher HRR fires (such as the 98th percentile fire) have durations much shorter than 15 minutes since they quickly burn away the available fuel.

Ventilation was assumed to be failed for all fire simulations. This conservatively overpredicts the air temperatures in the room since the HVAC would likely run for at least some portion of a real fire.

No manual or automatic suppression of the fire was assumed to occur for 1 hour. There is no automatic suppression in the areas, but there is a continuously staffed room (Secondary Alarm Station (SAS)) in the vicinity with open ventilation paths between the SAS and the plant access control area. The personnel in the SAS are likely to identify a fire in any of the areas quickly and alert the fire brigade. Furthermore, the plant access control area is the main entrance and exit for all personnel into and out of the Turbine and Reactor Buildings. If there is a fire in the area, there is a high likelihood of it being discovered and suppressed rapidly.

For the battery room analysis, the door to the room is assumed to be open for all scenarios to ensure the fire does not become oxygen-limited. This is conservative as these doors are typically kept closed and a postulated fire was determined to burn out within 3 minutes of ignition.

The licensee stated that for the battery room analysis, the door to the room was assumed to be open, but does not state whether the same assumption was made for the plant access control area. The NRC staff requested that the licensee discuss whether the same assumption was made for the plant access control area or provide the technical justification for not doing so. In its letter dated July 20, 2018, the licensee responded to the NRC staff's request and stated that the ventilation and enclosure characteristics used in their analysis were based on conditions present in the plant, i.e., open to adjacent spaces where walls or doors are not present and enclosed where walls or doors are present. The licensee stated that the approach taken yielded conservative results because the enclosed scenarios provided less air entrainment and higher room and steel temperatures. The staff found the licensee's response acceptable because it represents a conservative analysis that was based on plant walk down information that reflects the physical design of the plant and sound engineering judgement.

The licensee stated that it has determined that, based on fire modeling, the critical temperature of 1100 °F for the structural steel will not be reached during a postulated fire, and therefore, the exposed structural steel will not fail despite the lack of fireproofing and need not be protected.

B. Authorized by Law

This exemption would allow MNGP to rely on the results of a structural steel survivability analysis and fire modeling that demonstrated that unprotected steel columns and beams supporting the floor of the Cable Spreading Room will not fail in the event of a fire, to ensure that at least one means of achieving and maintaining hot shutdown remains available during and following a postulated fire event as part of its fire protection program, in lieu of meeting the requirements specified in 10 CFR part 50, appendix R, section III.G.2.a, for a fire in the analyzed fire areas. As stated above, 10 CFR 50.12 allows the NRC to grant exemptions from the requirements of 10 CFR part 50. The NRC staff has determined that granting of this exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

C. No Undue Risk to Public Health and Safety

The underlying purpose of 10 CFR part 50, appendix R, section III.G, is to ensure that at least one means of achieving and maintaining hot shutdown remains available during and following a postulated fire event. Based on the licensee's analysis, the staff has determined that lack of fire proofing in the subject locations does not represent any additional risk to public health and safety because the licensee demonstrated that for the postulated, credible fire scenarios, the structural steel would not be exposed to conditions that would result in a structural failure.

D. Consistent With the Common Defense and Security

This exemption would allow MNGP to rely on the results of a structural steel survivability analysis and fire modeling to demonstrated that unprotected steel columns and beams supporting the floor of the Cable Spreading Room will not fail in the event of a fire, in lieu of meeting the requirements specified in 10 CFR part 50, appendix R, section III.G.2.a. Because the lack of protection on the structural steel does not lead to a failure of the associated 3-hour fire barriers, there is no change to any site security matters. Therefore, the exemption is consistent with common defense and security.

E. Special Circumstances

One of the special circumstances described in 10 CFR 50.12(a)(2)(ii) is that the application of the regulation is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR part 50, appendix R, section III.G, is to ensure that at least one means of achieving and maintaining hot shutdown remains available during and following a postulated fire event. While the licensee does not comply with the explicit requirements of 10 CFR part 50, appendix R, section III.G.2.a, specifically, it does meet the underlying purpose of section III.G as a whole by ensuring that safe shutdown capability remains available. Therefore, special circumstances exist that warrant the issuance of this exemption as required by 10 CFR 50.12(a)(2)(ii).

IV. Environmental Considerations

The NRC staff determined that the issuance of the requested exemption meets the provisions of categorical exclusion 10 CFR 51.22(c)(9) because the exemption is from a requirement, with respect to the installation or use of a facility component located within the restricted area, as defined in 10 CFR part 20 and the issuance of the exemption involves: (i) No significant hazards consideration; (ii) no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; and (iii) no significant increase in individual or cumulative occupational radiation exposure. Therefore, in accordance with 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the NRC's issuance of this exemption. The basis for the NRC staff's determination is provided in the following evaluation of the requirements in 10 CFR 51.22(c)(9)(i)–(iii).

Requirements in 10 CFR 51.22(c)(9)(i)

The NRC staff evaluated whether the exemption involves no significant hazards consideration by using the standards in 10 CFR 50.92(c), as presented below:

1. Does the requested exemption involve a significant increase in the probability or consequences of an accident previously evaluated?

No. This exemption would allow MNGP to rely on the results of a structural steel survivability analysis and fire modeling that demonstrated that unprotected steel columns and beams supporting the floor of the Cable Spreading Room will not fail in the event of a fire, to ensure that at least one means of achieving and maintaining hot shutdown remains available during and following a postulated fire event as part of its fire protection program, in lieu of meeting the requirements specified in 10 CFR part 50, appendix R, section III.G.2.a, for a fire in the analyzed fire areas. Coating of the structural steel is to maintain the integrity of the fire barrier during a postulated fire and therefore, no new accident precursors are created by the use of the unprotected steel. Therefore, the probability of postulated accidents is not increased. Also, the critical temperature of 1100°F for the structural steel will not be reached during a postulated fire, and therefore, the exposed structural steel will not fail despite the lack of fireproofing and need not be protected. Therefore, granting of the exemption does not increase the consequences of an accident previously evaluated.

Therefore, the exemption does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the requested exemption create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The underlying purposes of 10 CFR part 50, Appendix R, III.G.2 is to provide reasonable assurance of fire protection safe shutdown capability. No new accident precursors are created by the use of the unprotected steel in response to a fire in the analyzed fire areas.

Therefore, the exemption does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the requested exemption involve a significant reduction in a margin of safety?

No. The use of unprotected steel in response to a fire in the analyzed fire areas does not alter plant operation and does not impact any safety margins because codes and standards or their alternatives approved by the NRC are met, and the safety analysis acceptance criteria described in the licensing basis are met.

Therefore, the exemption does not involve a significant reduction in a margin of safety.

Based on the evaluation above, the NRC staff has determined that the proposed exemption involves no significant hazards consideration. Therefore, the requirements of 10 CFR 51.22(c)(9)(i) are met.

Requirements in 10 CFR 51.22(c)(9)(ii) and (iii)

The proposed exemption would for structural steel columns and beams supporting the floor of the Cable Spreading Room that are not coated with fireproofing material to provide a fire resistance equivalent to that of the fire barrier as required by 10 CFR part 50, Appendix R, Section III.G.2.a for MNGP. The exemption does not modify plant operation because fire protection for structures, systems, and components important to safe shutdown continue to be provided. Thus, the exemption does not result in a significant change in the types or amount of effluents that may be released and does not result in any additional occupational exposure. Therefore, the requirements of 10 CFR51.22(c)(9)(ii) and (iii) are met.

V. Conclusions

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances are present in that application of the regulation is not necessary to achieve the underlying purpose of the rule. Therefore, the Commission hereby grants Northern States Power Company, doing business as Xcel Energy, an exemption from the requirements of 10 CFR 50, Appendix R, Section III.G.2.a, for MNGP, for structural steel columns and beams supporting the floor of the Cable Spreading Room that are not coated with fireproofing material to provide a fire resistance equivalent to that of the fire barrier.

VI. Availability of Documents

The documents identified in the following table are available in ADAMS.

Document	ADAMS accession No.
Request for Permanent Exemption from 10 CFR 50 Appendix R III.G.2.a Requirements for Exposed Structural Steel.	ML18080A161.
Response to Request for Additional Information regarding Request for Permanent Exemption from 10 CFR 50 Appendix R III.G.2.a Requirements for Exposed Structural Steel (EPID L–2018–LLE–0001).	ML18201A558.
NUREG–0991, Supplement 2, ''Safety Evaluation Report Related to the Operation of Limerick Generating Station, Units 1 and 2,'' dated October 1984.	Legacy Library: 8411090445.
Generic Letter (GL) 83–33, ''NRC Positions on Certain Requirements of Appendix R to 10 CFR 50''	ML031080522.
NUREG/CR–6850, ''EPRI/RES Fire PRA Methodology for Nuclear Power Facilities'' Volume 1: Summary and Overview.	ML15167A401.
NUREG/CR–6850, ''EPRI/RES Fire PRA Methodology for Nuclear Power Facilities'' Volume 2: Detailed Methodology.	ML15167A411.
NUREG–2178, ''Refining and Characterizing Heat Release Rates from Electrical Enclosures During Fire (RACHELLE-FIRE),'' Volume 1.	ML16110A140.

Dated at Rockville, Maryland, 14th day of February, 2019.

For the Nuclear Regulatory Commission.

/RA/

Craig G. Erlanger,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2019–03055 Filed 2–21–19; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Revision of a Previously Approved Information Collection: Declaration for Federal Employment, Optional Form (OF) 306

AGENCY: Office of Personnel Management.

ACTION: 60-day notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the National Background Investigations Bureau (NBIB), Office of Personnel Management (OPM) offers the opportunity to comment on its proposed revision of a previously-approved information collection, Declaration for Federal Employment, Optional Form (OF) 306.

DATES: Comments are encouraged and will be accepted until April 23, 2019. This process is conducted in accordance with 5 CFR 1320.8(d)(1).

ADDRESSES: You may submit comments, identified by docket number and title, by the following method:

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

All submissions received must include the agency name and docket number for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the National Background Investigations Bureau, Office of Personnel Management, 1900 E Street NW, Washington, DC 20415, Attention: Donna McLeod or sent by email to *FISFormsComments@opm.gov.*

SUPPLEMENTARY INFORMATION: OPM is soliciting comments for this collection as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

The Declaration for Federal Employment Optional Form (OF) 306 is completed by applicants who are under consideration for Federal or Federal contract employment. It collects information about an applicant's selective service registration, military service, and general background. The information collected on this form is mainly used to determine a person's acceptability for Federal and Federal contract employment, and his or her retirement status and life insurance enrollment. However, if necessary, and usually in conjunction with another form or forms, the information on this form may be used in conducting an investigation to determine a person's suitability or ability to hold a security clearance, and it may be disclosed to authorized officials making similar, subsequent determinations.

The OF 306 requests that the applicant provide personal identifying data, including past convictions, imprisonments, probations, paroles or military court martial, delinquency on a Federal debt, Selective Service Registration, United States military service, Federal civilian or military retirement benefits received or applied for, and life insurance enrollment.

OPM proposes the following modifications to the OF 306.

• The Instructions include an explanation that the questions and answers are not optional and must be answered.

• In the Privacy Act Statement, section headings (Authorities, Purpose, Information Regarding Disclosure of Your Social Security Number (SSN)) are added for clarity; additional authority is cited for collecting the respondent's SSN; and a website link is added for the System Notice OPM/GOVT–1, General Personnel Records, *https://www.opm.gov/information-management/privacy-policy/sorn/opm-sorn-govt-1-general-personnel-records.pdf.*

• The Public Burden Statement includes an updated address for the submission of comments regarding the burden estimate.

• Additional examples added to Question 5, Other Names Ever Used.

• Military Service, Question 8 was amended to list the specific branch (Army, Army National Guard, Navy, Air Force, Air National Guard, Marine Corps, and/or Coast Guard).

• The Background Information instructions were amended to reflect a higher traffic fines reporting threshold and reads 'traffic fines of $1,000 or less' from 'traffic fines of $300 or less.'

• Question 9 currently reads, ''During the last 7 years, have you been convicted, been imprisoned, been on probation, or been on parole? (Includes felonies, firearms or explosives violations, misdemeanors, and all other offenses.) If 'YES,' use item 16 to provide the date, an explanation of the violation, place of occurrence, and the name and address of the police department or court involved.'' Question 9 is amended to read, ''During the last 7 years, have you: Been convicted of any crime (Include misdemeanors, felonies, firearms or explosives violations, domestic violence, alcohol, drugs, and all other crimes or offenses); Been subject to judge or court specified conditions requiring satisfactory completion before a criminal charge has been or will be dismissed; Served time in jail or prison as a result of being convicted of a crime; or Been on probation or parole? If ''YES,'' use item 16 to provide the date, explanation of the violation/charge, place of occurrence, and the name and address of the police and court involved.''

The verbiage change from asking if one has been ''imprisoned'' to ask if one has ''served time in jail or prison'' as the result of a conviction is also for clarity. OPM is proposing to add a requirement to admit charges for which one has been placed into a pretrial intervention or diversionary program or the like. These programs allow individuals to agree to comply with specific conditions in lieu of criminal prosecution and upon compliance, to have the charge(s) dismissed. They are generally available to those accused of committing a wide range of offenses. The offender is not commonly placed into traditional

community supervision and participants or those who successfully complete the program, are not considered to have been convicted. The proposed change closes a gap for those who participate in or successfully complete this type of alternative disposition and may not have to answer affirmatively to the current question and report the details of the offense.

- Question 11, ''Are you currently under charges for any violation of law?'' was amended to ''Are you currently under charges for any violation of law, on trial or awaiting a trail on criminal charges?''
- Question 12, related to reasons for leaving employment, was organized into bullet points to improve readability.
- Question 13, related to financial delinquency, was amended to clarify that its coverage includes co-signers and guarantors as well as sole debtors.
- Continuation Space/Agency Optional Questions, item 16, was reorganized for greater clarity.
- Certifications/Additional Questions, APPLICANT instructions were amended to instruct the applicant to read and complete the form's certification paragraph, and a separate new consent statement.
- The ''I consent'' paragraph was separated from the ''I certify'' paragraph, and each paragraph must be signed and dated. Also added was an explanation that ''This consent is valid for two (2) years from the date signed below, or expires when my affiliation with the Federal Government ends, whichever is sooner.''

Analysis

Agency: NBIB, U.S. Office of Personnel Management.

Title: Declaration for Federal Employment, Optional Form (OF) 306.

OMB Number: 3206–0182.

Affected Public: Individuals.

Number of Respondents: 315,478.

Estimated Time Per Respondent: 15 minutes.

Total Burden Hours: 78,870.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2019–03056 Filed 2–21–19; 8:45 am]

BILLING CODE 6325–53–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

Summary: In accordance with the requirement of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and Purpose of Information Collection: Request for Medicare Payment; OMB 3220–0131

Under Section 7(d) of the Railroad Retirement Act, the RRB administers the Medicare program for persons covered by the railroad retirement system. The collection obtains the information needed by Palmetto GBA, the Medicare carrier for railroad retirement beneficiaries, to pay claims for payments under Part B of the Medicare program. Authority for collecting the information is prescribed in 42 CFR 424.32.

The RRB currently utilizes Forms G–740S, Patient's Request for Medicare Payment, along with Centers for Medicare & Medicaid Services Form CMS–1500, to secure the information necessary to pay Part B Medicare Claims. One response is completed for each claim. Completion is required to obtain a benefit. The RRB proposes the following changes to Form G–740S:

- Changed Item 2a from ''Medicare Claim'' to ''Medicare Number''
- Replaced the 12-digit Claim Number field with an 11-digit Medicare Number field

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–740S	1	0	1

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Brian Foster at (312) 751–4826 or *Brian.Foster@rrb.gov.* Comments regarding the information collection should be addressed to Brian Foster, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–1275 or emailed to *Brian.Foster@rrb.gov.* Written comments should be received within 60 days of this notice.

Brian Foster,

Clearance Officer.

[FR Doc. 2019–03048 Filed 2–21–19; 8:45 am]

BILLING CODE 7905–01–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

In accordance with the requirement of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

1. Title and purpose of information collection: Employer Reporting; 3220–0005.

Under Section 9 of the Railroad Retirement Act (RRA), and Section 6 of the Railroad Unemployment Insurance Act (RUIA), railroad employers are required to submit reports of employee service and compensation to the RRB as needed for administering the RRA and RUIA. To pay benefits due on a deceased employee's earnings records or determine entitlement to, and amount of

annuity applied for, it is necessary at times to obtain from railroad employers current (lag) service and compensation not yet reported to the RRB through the annual reporting process. The reporting requirements are specified in 20 CFR 209.6 and 209.7. The RRB currently utilizes the following forms to collect information to obtain the required lag service and related information from railroad employers: Form AA–12, *Notice of Death and Request for Service Needed for Eligibility,* Form G–88A.1 (or its internet equivalent, Form G–88A.1 (internet)), *Request for Verification of Date Last Worked,* and Form G–88A.2 (or its internet equivalent, Form G–88A.2 (internet)), *Notice of Retirement and Request for Service Needed for Eligibility.* Form AA–12 obtains a report of lag service and compensation from the last railroad employer of a deceased employee. This report covers the lag period between the date of the latest record of employment processed by the RRB and the date an employee last worked, the date of death or the date the employee may have been entitled to benefits under the Social Security Act. The information is used by the RRB to determine benefits due on the deceased employee's earnings record. Form G–88A.1 is sent by the RRB via a computer-generated listing or transmitted electronically via the RRB's Employer Reporting System (ERS) to employers. ERS consists of a series of screens with completion instructions and collects essentially the same information as the approved manual version. Form G–88A.1 is used for the specific purpose of verifying information previously provided to the RRB regarding the date last worked by an employee. If the information is correct, the employer need not reply. If the information is incorrect, the employer is asked to provide corrected information. Form G–88A.2 is used by the RRB to secure lag service and compensation information when it is needed to determine benefit eligibility. The RRB proposes minor non-burden impacting changes to Forms AA–12, G–88A.1 (internet), G–88A.2 (internet). The RRB proposes no changes to Forms G–88A.1 and G–88A.2.

In addition, 20 CFR 209.12(b) requires all railroad employers to furnish the RRB with the home addresses of all employees hired within the last year (new-hires). Form BA–6a, *Form BA–6 Address Report* (or its internet equivalent, Form BA–6a (internet)) is used by the RRB to obtain home address information of employees from railroad employers who do not have the home address information computerized and who submit the information in a paper format. The form also serves as an instruction sheet to railroad employers who submit the information electronically by CD–ROM. Completion of the forms is mandatory. Multiple responses may be filed by respondent. The RRB proposes minor non-burden impacting editorial changes to Form BA–6a (internet). The RRB proposes no changes to Form BA–6a.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
AA–12	60	5	5
G–88A.1	100	5	8
G–88A.1 Internet	260	4	17
G–88A.1 Internet (Class I railroads)	144	16	38
G–88A.2	100	5	8
G–88A.2 (Internet)	1,200	2.5	50
BA–6a (CD–ROM)	14	15	4
BA–6a (E-mail)	30	15	8
BA–6a (File Transfer Protocol)	10	15	3
BA–6a Internet (RR initiated)	250	17	71
BA–6a Internet (RRB initiated)	250	12	50
BA–6a Paper (RR initiated)	80	32	43
BA–6a Paper (RRB initiated)	250	32	133
Total	2,748	.....	438

2. Title and purpose of information collection: Employee Representative's Status and Compensation Reports; OMB 3220–0014.

Under Section 1(b)(1) of the Railroad Retirement Act (RRA), the term ''employee'' includes an individual who is an employee representative. As defined in Section 1(c) of the RRA, an employee representative is an officer or official representative of a railway labor organization other than a labor organization included in the term ''employer,'' as defined in the RRA, who before or after August 29, 1935, was in the service of an employer under the RRA and who is duly authorized and designated to represent employees in accordance with the Railway Labor Act, or, any individual who is regularly assigned to or regularly employed by such officer or official representative in connection with the duties of his or her office. The requirements relating to the application for employee representative status and the periodic reporting of the compensation resulting from such status is contained in 20 CFR 209.10.

The RRB utilizes Form DC–2, *Employee Representative's Report of Compensation,* to obtain the information needed to determine employee representative status and to maintain a record of creditable service and compensation resulting from such status. Completion is required to obtain or retain a benefit. One response is requested of each respondent. The RRB proposes minor non-burden impacting editorial changes to Form DC–2.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
DC–2	82	30	41
Total	82		41

3. Title and purpose of information collection: Survivor Questionnaire; OMB 3220–0032.

Under Section 6 of the Railroad Retirement Act (RRA), benefits that may be due on the death of a railroad employee *or* a survivor annuitant include (1) a lump-sum death benefit (2) a residual lump-sum payment (3) accrued annuities due but unpaid at death, and (4) monthly survivor insurance payments. The requirements for determining the entitlement of possible beneficiaries to these benefits are prescribed in 20 CFR 234.

When the RRB receives notification of the death of a railroad employee or survivor annuitant, an RRB field office utilizes Form RL–94–F, *Survivor Questionnaire,* to secure additional information from surviving relatives needed to determine if any further benefits are payable under the RRA. Completion is voluntary. One response is requested of each respondent. The RRB proposes minor non-burden impacting editorial changes to Form RL–94–F.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
RL–94–F Items 5–10, and 18	50	9	8
RL–94–F, Items 5–18	5,000	11	917
RL–94–F, Item 18 only	400	5	34
Total	5,450		959

4. Title and purpose of information collection: Employer's Deemed Service Month Questionnaire; OMB 3220–0156

Section 3 (i) of the Railroad Retirement Act (RRA), as amended by Public Law 98–76, provides that the Railroad Retirement Board (RRB), under certain circumstances, may deem additional months of service in cases where an employee does not actually work in every month of the year, provided the employee satisfies certain eligibility requirements, including the existence of an employment relation between the employee and his or her employer. The procedures pertaining to the deeming of additional months of service are found in the RRB's regulations at 20 CFR 210, Creditable Railroad Service.

The RRB utilizes Form GL–99, *Employer's Deemed Service Months Questionnaire,* to obtain service and compensation information from railroad employers to determine if an employee can be credited with additional deemed months of railroad service. Completion is mandatory. One response is required for each RRB inquiry. The RRB proposes non-burden impacting editorial changes to Form GL–99.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
GL–99	2,000	2	67

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Brian Foster at (312) 751–4826 or *Brian.Foster@RRB.GOV.* Comments regarding the information collection should be addressed to Brian Foster, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–1275 or emailed to *Brian.Foster@rrb.gov.* Written comments should be received within 60 days of this notice.

Brian Foster,

Clearance Officer.

[FR Doc. 2019–03036 Filed 2–21–19; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85152; File Nos. SR–BX–2018–066 and SR–Phlx–2018–83]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Nasdaq PHLX LLC; Suspension of and Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Changes To Amend the Exchanges' Port Fee Schedules

February 15, 2019.

I. Introduction

On December 20, 2018, Nasdaq BX, Inc. (''BX'') and Nasdaq PHLX LLC (''Phlx'') (each an ''Exchange,'' and collectively the ''Exchanges'') each filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend its port fee schedule. Each proposed rule change was immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.[3] Each proposed rule change was published for comment in the **Federal Register** on January 31, 2019.[4] The Commission has received no comment letters on the proposed rule changes. Under Section 19(b)(3)(C) of the Act,[5] the Commission is hereby: (i) Temporarily suspending the proposed rule changes; and (ii) instituting proceedings to determine whether to approve or disapprove the proposed rule changes.

II. Description of the Proposed Rule Changes

Equity 7, Section 115 of BX's rules and Equity 7, Section 3 of Phlx's rules set forth the Exchanges' port fee schedules. These port fee schedules provided that the fees for specified ports are assessed on a per port per month basis.

In their proposals, each Exchange states that it currently assesses ports fees in two ways. First, for certain port types (*i.e.,* Multicast TotalView-ITCH, TCP ITCH data feed, DROP, and their corresponding disaster recovery ports), the Exchange assigns a port only to the MPID of the customer that requested it.[6] Even if, as a practical matter, others also utilize the port, the Exchange only bills the MPID of the customer that requested the port.[7] According to the Exchanges, the requesting customer may then, at its discretion, subsequently bill any other users for their shared usage of the port.[8] Second, for other port types (*i.e.,* OUCH, FIX trading ports (FIX and FIX Lite), RASH, and their corresponding disaster recovery ports), the Exchange assigns the port to the MPID of the customer that requested it, as well as to any other MPIDs that the requester had specified.[9] In these instances, the Exchange does not only bill the port-requesting MPID. Instead, the Exchange assesses a separate monthly fee to each of the MPIDs it assigned to the port.[10]

Each Exchange proposes to reorganize its port fee schedule into two sections. The first section would provide that, for OUCH, FIX trading ports (FIX and FIX Lite), RASH, and their corresponding disaster recovery ports, where a customer has requested that the Exchange assign more than one MPID to a particular port, the Exchange will assess a separate monthly fee to each MPID assigned to the port. Each Exchange also proposes to revise its price formula for these port types from ''$X/port/month'' to ''$X/each MPID assigned to port/month.'' The second section would provide that, for Multicast TotalView-ITCH (software-based), TCP ITCH data feed, DROP, DROP disaster recovery, and trading ports used in test mode, the Exchange will assess the monthly fee to the single MPID that requested that particular port. For these ports, each Exchange would maintain its existing price formula of ''$X/port/month.''[11]

Each Exchange represents that its proposal would merely codify the existing practices of the Exchange with respect to port fees and would not make any substantive changes to the port fees that the Exchange's customers have been paying to date.[12]

III. Suspension of the Proposed Rule Changes

Pursuant to Section 19(b)(3)(C) of the Act,[13] at any time within 60 days of the date of filing of a proposed rule change pursuant to Section 19(b)(1) of the Act,[14] the Commission summarily may temporarily suspend the change in the rules of a self-regulatory organization (''SRO'') 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. As discussed below, the Commission believes a temporary suspension of the proposed rule changes is necessary and appropriate to allow for additional analysis of the proposed rule changes' consistency with the Act and the rules thereunder.

The Commission notes that, in connection with the proposals, each Exchange states its belief that the existing per port per month language is accurate, but the language should be more descriptive so as to avoid confusion as to the circumstances in which a customer will incur port fees.[15] Moreover, in describing why its proposal is consistent with Sections 6(b)(4) and 6(b)(5) of the Act,[16] each Exchange relies on the argument that its proposal would clarify and more fully describe the port fees, codify the Exchange's existing practices for assessing port fees, avoid potential

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] *See* Securities Exchange Act Release Nos. 84965 (December 26, 2018), 84 FR 842 (''BX Notice''); 84967 (December 26, 2018), 84 FR 861 (''Phlx Notice'').

[5] 15 U.S.C. 78s(b)(3)(C).

[6] *See* BX Notice, *supra* note 4, at 842; Phlx Notice, *supra* note 4, at 861.

[7] *See* BX Notice, *supra* note 4, at 842; Phlx Notice, *supra* note 4, at 861.

[8] *See* BX Notice, *supra* note 4, at 842; Phlx Notice, *supra* note 4, at 861.

[9] *See* BX Notice, *supra* note 4, at 842; Phlx Notice, *supra* note 4, at 861.

[10] *See* BX Notice, *supra* note 4, at 842; Phlx Notice, *supra* note 4, at 861.

[11] The second section of each Exchange's amended port fee schedule would also include the ports for which the Exchange charges no fee: Data retransmission ports (production and disaster recovery), disaster recovery ports for Multicast TotalView-ITCH (software-based), and disaster recovery ports for TCP ITCH data feed. Moreover, each Exchange proposes to add a parenthetical with the word ''Glimpse'' next to data retransmission ports to provide that such ports include access to the ''Glimpse'' product, which allows a subscriber to replay market data from the current trading day.

[12] *See* BX Notice, *supra* note 4, at 842–43; Phlx Notice, *supra* note 4, at 862. BX also proposes to correct a typographical error in the port fee schedule. Phlx also proposes to remove an expired fee waiver from the port fee schedule.

[13] 15 U.S.C. 78s(b)(3)(C).

[14] 15 U.S.C. 78s(b)(1).

[15] *See* BX Notice, *supra* note 4, at 842; Phlx Notice, *supra* note 4, at 861.

[16] *See* 15 U.S.C. 78f(b)(4), (5).

confusion among customers, and would not change the fees that port users currently pay.[17] Similarly, in discussing why its proposal would not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, each Exchange relies on the argument that its proposal would merely codify existing practice and would not change the fees that the Exchange currently charges.[18]

The Commission notes that the Exchanges do not provide other explanations for why the proposals are consistent with the Act, such as why it is consistent with the Act to charge a fee for each MPID assigned to certain port types offered by the Exchange (*i.e.,* OUCH, FIX trading port, RASH, and corresponding disaster recovery ports), rather than simply charging one fee per port for all port types. As noted above, the proposals would amend the Exchanges' price formulas for these port types from ''$X/port/month'' to ''$X/each MPID assigned to port/month,'' which reflects that if there are multiple MPIDs assigned to one of these ports, rather than charging one ''$X/port/month'' fee for the port, the Exchanges charge a multiple of the ''$X/port/month'' fee for the port (*i.e.,* a separate fee for each MPID assigned).[19] The Commission also notes that, while the Exchanges state that the proposals would reflect their existing practices for assessing port fees, the Exchanges do not reference previous Exchange rule filings that explained why their existing practices (*i.e.,* for a subset of the port types offered, charging a fee for each MPID assigned to the port) are consistent with the Act.

When exchanges file proposed rule changes with the Commission, they are required to provide a statement supporting the proposal's basis under the Act and the rules and regulations thereunder applicable to the exchange.[20] The instructions to Form 19b–4, on which exchanges file their proposed rule changes, specify that such statement ''should be sufficiently detailed and specific to support a finding that the proposed rule change is consistent with [those] requirements.'' [21]

Among other things, exchange proposed rule changes are subject to Section 6 of the Act, including Sections 6(b)(4), (5), and (8), which require the rules of an exchange to: (1) Provide for the equitable allocation of reasonable fees among members, issuers, and other persons using the exchange's facilities; [22] (2) perfect the mechanism of a free and open market and a national market system, protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers; [23] and (3) not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[24]

In temporarily suspending the changes to the Exchanges' fee schedules, the Commission intends to further consider whether the proposed changes to the Exchanges' port fee schedules are consistent with the statutory requirements applicable to a national securities exchange under the Act. In particular, the Commission will consider whether the proposed rule changes satisfy the standards under the Act and the rules thereunder requiring, among other things, that an exchange's rules provide for the equitable allocation of reasonable fees among members, issuers, and other persons using its facilities; not permit unfair discrimination between customers, issuers, brokers or dealers; and do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[25]

Therefore, the Commission finds that it is appropriate in the public interest, for the protection of investors, and otherwise in furtherance of the purposes of the Act, to temporarily suspend the proposed rule changes.[26]

IV. Proceedings To Determine Whether To Approve or Disapprove the Proposed Rule Changes

The Commission is instituting proceedings pursuant to Sections 19(b)(3)(C) [27] and 19(b)(2)(B) of the Act [28] to determine whether the proposed rule changes should be approved or disapproved. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to provide additional comment on the proposed rule changes to inform the Commission's analysis of whether to approve or disapprove the proposed rule changes.

Pursuant to Section 19(b)(2)(B) of the Act,[29] the Commission is providing notice of the grounds for possible disapproval under consideration:

- Section 6(b)(4) of the Act, which requires that the rules of a national securities exchange ''provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities,'' [30]
- Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be designed to ''perfect the mechanism of a free and open market and a national market system'' and ''protect investors and the public interest,'' and not be ''designed to permit unfair discrimination between customers, issuers, brokers, or dealers,'' [31] and
- Section 6(b)(8) of the Act, which requires that the rules of a national securities exchange ''not impose any burden on competition not necessary or appropriate in furtherance of the purposes of [the Act].'' [32]

As noted above, the proposals would, among other things, amend the Exchanges' port fee schedules to provide that certain port fees are charged on a ''$X/each MPID assigned to port/month'' basis rather than a ''$X/port/month'' basis.[33] Also as discussed above, in connection with the proposals, each Exchange states that its proposal would clarify and more fully describe the port fees, codify the Exchange's existing practices for assessing port fees, avoid potential confusion among customers, and would not change the fees that port users currently pay.[34] The Exchanges do not provide other explanations for why the proposals are consistent with the Act, and do not reference previous Exchange rule filings that provided such explanations.

Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the [Act] and the rules and regulations issued thereunder . . .

[17] *See* BX Notice, *supra* note 4, at 842–43; Phlx Notice, *supra* note 4, at 862.

[18] *See* BX Notice, *supra* note 4, at 843; Phlx Notice, *supra* note 4, at 862.

[19] *See supra* Section II.

[20] *See* Form 19b–4 (Item 3 entitled ''Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change'').

[21] *Id.*

[22] 15 U.S.C. 78f(b)(4).

[23] 15 U.S.C. 78f(b)(5).

[24] 15 U.S.C. 78f(b)(8).

[25] *See* 15 U.S.C. 78f(b)(4), (5), and (8), respectively.

[26] For purposes of temporarily suspending the proposed rule changes, the Commission has considered the proposed rules' impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[27] 15 U.S.C. 78s(b)(3)(C). Once the Commission temporarily suspends a proposed rule change, Section 19(b)(3)(C) of the Act requires that the Commission institute proceedings under Section 19(b)(2)(B) to determine whether a proposed rule change should be approved or disapproved.

[28] 15 U.S.C. 78s(b)(2)(B).

[29] 15 U.S.C. 78s(b)(2)(B).

[30] 15 U.S.C. 78f(b)(4).

[31] 15 U.S.C. 78f(b)(5).

[32] 15 U.S.C. 78f(b)(8).

[33] *See supra* Section II.

[34] *See supra* Section III.

is on the [SRO] that proposed the rule change.'' [35] The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding,[36] and any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Act and the applicable rules and regulations thereunder.[37]

The Commission is instituting proceedings to allow for additional consideration and comment on the issues raised herein, including as to whether the proposed rule changes are consistent with the Act, and specifically, with its requirements that exchange fees be reasonable and equitably allocated; be designed to perfect the mechanism of a free and open market and the national market system, protect investors and the public interest, and not be unfairly discriminatory; and not impose an unnecessary or inappropriate burden on competition.[38]

V. Commission's Solicitation of Comments

The Commission requests written views, data, and arguments with respect to the concerns identified above as well as any other relevant concerns. Such comments should be submitted by March 15, 2019. Rebuttal comments should be submitted by March 29, 2019. Although there do not appear to be any issues relevant to approval or disapproval which would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[39]

The Commission asks that commenters address the sufficiency and merit of the Exchanges' statements in support of the proposals, in addition to any other comments they may wish to submit about the proposed rule changes. Interested persons are invited to submit written data, views, and arguments concerning the proposed rule changes, including whether the proposed rule changes are consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2018–066, SR–Phlx–2018–83, or both on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2018–066, SR–Phlx–2018–83, or both. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submissions, all subsequent amendments, all written statements with respect to the proposed rule changes that are filed with the Commission, and all written communications relating to the proposed rule changes between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filings also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2018–066, SR–Phlx–2018–83, or both and should be submitted on or before March 15, 2019. Rebuttal comments should be submitted by March 29, 2019.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(3)(C) of the Act,[40] that File Numbers SR–BX–2018–066 and SR–Phlx–2018–83 be and hereby are, temporarily suspended. In addition, the Commission is instituting proceedings to determine whether the proposed rule changes should be approved or disapproved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[41]

Eduardo A. Aleman,

Deputy Secretary.

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[35] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[36] *See id.*

[37] *See id.*

[38] *See* 15 U.S.C. 78f(b)(4), (5), and (8).

[39] 15 U.S.C. 78s(b)(2). Section 19(b)(2) of the Act grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by an SRO. *See* Securities Acts Amendments of 1975, Report of the Senate Committee on Banking, Housing and Urban Affairs to Accompany S. 249, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[40] 15 U.S.C. 78s(b)(3)(C).

[41] 17 CFR 200.30–3(a)(57), (58).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85155; File No. SR–MIAX–2018–36]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend MIAX Rule 518, Complex Orders

February 15, 2019.

I. Introduction

On November 9, 2018, Miami International Securities Exchange, LLC (''Exchange'' or ''MIAX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to make several changes to MIAX Rule 518, ''Complex Orders.'' The proposed rule change was published for comment in the **Federal Register** on November 23, 2018.[3] On December 21, 2018, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change.[5]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 84613 (Nov. 16, 2018), 83 FR 59435 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 84950, 83 FR 67758 (December 31, 2018). The Commission designated February 21, 2019, as the date by which the Commission shall approve or disapprove, or

Continued

On February 13, 2019, the Exchange filed Amendment No. 1 to the proposed rule change.[6] The Commission has received no comments regarding the proposal. The Commission is publishing this notice to solicit comment on Amendment No. 1 to the proposed rule change from interested persons and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1

As described more fully in the Notice,[7] the proposal amends MIAX Rule 518 to (1) establish a new Complex Liquidity Exposure Process (''cLEP Auction'') for Complex Orders and make corresponding changes to the Complex MIAX Price Collar (''MPC'') price protection feature; (2) eliminate the Defined Time Period and revise the Response Time Interval for the Complex Auction; (3) provide that the Calendar Spread Variance (''CSV'') Price Protection applies only to American-style option classes; and (4) add the Liquidity Exposure Process as a Simple Market Auction or Timer (''SMAT'') Event.[8]

cLEP Auction

Under the proposal, MIAX's System[9] will initiate a cLEP Auction whenever a complex order or eQuote would execute or post at a price that would violate its MPC Price.[10] The System will post the complex order or eQuote to the Strategy Book at its MPC Price and begin the cLEP Auction by broadcasting a liquidity exposure message to all subscribers of the Exchange's data feeds.[11] The liquidity exposure message will include the symbol, side of the market, auction start price (the MPC Price of the complex order or eQuote), and the imbalance quantity.[12] Members may respond to the liquidity exposure message during the Response Time Interval.[13] Responses, which may be in $0.01 increments, must be a cAOC order or a cAOC eQuote, and may be submitted on either side of the market.[14] Responses represent non-firm interest that can be withdrawn at any time prior to the end of the Response Time Interval.[15] At the end of the Response Time Interval, responses are firm (*i.e.,* guaranteed at the response price and size).[16] Any responses not executed in full will expire at the end of the cLEP Auction.[17]

At the conclusion of the cLEP Auction the resulting trade price will be determined, and interest will execute, as described in MIAX Rule 518(d)(6).[18] The resulting trade price will never be more aggressive than the MPC Price.[19] Liquidity remaining at the conclusion of the cLEP Auction with an original limit price that is (i) less aggressive (lower for a buy order or eQuote, or higher for a sell order or eQuote) than or equal to the MPC Price will be handled in accordance with MIAX Rule 518(c)(2)(ii)–(v), or (ii) more aggressive than the MPC Price will be subject to the reevaluation process.[20] Orders and eQuotes executed in a cLEP Auction will be allocated first in price priority based upon their original limit price, and thereafter in accordance with the Complex Auction allocation procedures described in MIAX Rule (d)(7)(i)–(vi).[21]

At the start of the Reevaluation process, the System will calculate the next potential MPC Price for remaining auction liquidity with an original limit price more aggressive than the existing MPC Price.[22] The next MPC Price will be calculated as the MPC Price plus (minus) the next MPC increment for buy (sell) orders (the ''New MPC Price'').[23] The System will initiate a cLEP Auction for liquidity that would execute or post at a price that would violate its New MPC Price.[24] Liquidity with an original limit price less aggressive (lower for a buy order or eQuote, or higher for a sell order or eQuote) than or equal to the New MPC Price will be posted to the Strategy Book at its original limit price or handled in accordance with MIAX Rule (c)(2)(ii)–(v).[25] The cLEP process will continue until no liquidity remains with an original limit price that is more aggressive than its MPC Price.[26] At the

institute proceedings to determine whether to approve or disapprove, the proposed rule change.

[6] Amendment No. 1 revises the proposal to (1) clarify the rule describing the operation of the proposed Complex Liquidity Exposure Period (''cLEP'') Auction and provide an additional example demonstrating the operation of the proposed cLEP Auction; (2) provide additional rationale for eliminating the Defined Time Period for the Complex Auction and make representations regarding system capability and surveillance with respect to the Complex Auction, as modified by the proposal; (3) indicate that the Auction Timer for MIAX's cPRIME Auction will remain at 100 milliseconds; and (4) clarify the discussion of the proposed change to the Calendar Spread Variance Price Protection. Amendment No. 1 is available at *https://www.sec.gov/comments/sr-miax-2018-36/srmiax201836-4932160-178431.pdf.*

[7] *See* note 3, *supra.*

[8] The Liquidity Exposure Process was approved in a separate proposal. *See* Securities Exchange Release No. 85147 (February 15, 2019) (order approving File No. SR–MIAX–2018–35) (''LEP Filing'').

[9] The System is the automated trading system used by the Exchange for the trading of securities. *See* MIAX Rule 100.

[10] *See* Amendment No. 1. The MPC price protection feature is an Exchange-wide price protection mechanism under which a complex order or eQuote to sell will not be displayed or executed at a price that is lower than the opposite side cNBBO bid at the time the MPC is assigned by the System (*i.e.,* upon receipt or upon opening) by more than a specific dollar amount expressed in $0.01 increments (the ''MPC Setting''), and under which a complex order or eQuote to buy will not be displayed or executed at a price that is higher than the opposite side cNBBO offer at the time the MPC is assigned by the System by more than the MPC Setting (each the ''MPC Price''). *See* MIAX Rule 518, Interpretation and Policy .05(f). *See* Notice, 83 FR at 59437, and Amendment No. 1 for examples of the operation of the proposed cLEP Auction.

[11] *See* proposed MIAX Rule 518(e).

[12] *See id.*

[13] The duration of the Response Time Interval will be no less than 100 milliseconds and no more than 5,000 milliseconds, as determined by the Exchange and announced through a Regulatory Circular. *See id.*

[14] *See id.* A Complex Auction-or-Cancel or ''cAOC'' order is a complex limit order used to provide liquidity during a specific Complex Auction with a time in force that corresponds with that event. cAOC orders are not displayed to any market participant, and are not eligible for trading outside of the event. A cAOC order with a size greater than the aggregate auctioned size (as defined in MIAX Rule 518(d)(4)) will be capped for allocation purposes at the aggregate auctioned size. *See* MIAX Rule 518(b)(3). A ''Complex Auction or Cancel eQuote'' or ''cAOC eQuote,'' is an eQuote submitted by a Market Maker that is used to provide liquidity during a specific Complex Auction with a time in force that corresponds with the duration of the Complex Auction. A cAOC eQuote with a size greater than the aggregate auctioned size (as defined in MIAX Rule 518(d)(4)) will be capped for allocation purposes at the aggregate auctioned size. cAOC eQuotes will not: (i) Be executed against individual orders and quotes resting on the Simple Order Book; (ii) be eligible to initiate a Complex Auction, but may join a Complex Auction in progress; (iii) rest on the Strategy Book; or (iv) be displayed. *See* MIAX Rule 518, Interpretation and Policy .02(c)(1).

[15] *See id.*

[16] *See id.*

[17] *See id.* A response on the opposite side of the initiating order with a size greater than the aggregate size of interest at the same price on the same side of the market as the initiating order (the ''aggregate auctioned size'') will be capped for allocation purposes at the aggregate auctioned size. *See id.* and Amendment No. 1.

[18] *See* proposed MIAX Rule 518(e) and Amendment No. 1.

[19] *See* proposed MIAX Rule 518(e) and Amendment No. 1.

[20] *See id.*

[21] *See* proposed MIAX Rule 518(e).

[22] *See* proposed MIAX Rule 518(e) and Amendment No. 1.

[23] *See id.*

[24] *See id.*

[25] *See id.*

[26] *See id.* The proposal makes technical corrections to the MPC Price protection provisions in MIAX Rule 518, Interpretation and Policy .05(f) to incorporate changes associated with the proposed cLEP Auction process. Because the MPC Price of certain complex orders and eQuotes may change as a result of the cLEP Reevaluation process, the proposal deletes Interpretation and Policy .05(f)(4), which states that the MPC Price of a complex order or eQuote will not change during the life of the complex order or eQuote. The proposal renumbers the remaining subparagraphs in paragraph (f) to reflect the elimination of subparagraph (4). The proposal also revises Interpretation and Policy .05(f)(6)(A) to provide that any unexecuted portion of a market order or a

conclusion of the cLEP process, any liquidity that has not been executed will be posted to the Strategy Book at its original limit price.[27]

MIAX notes that the proposed cLEP Auction process provides an additional price discovery opportunity for orders and eQuotes that would trade through their MPC Price.[28] MIAX believes that it is in the best interest of a Member to seek liquidity for the unexecuted portion of an order that exceeds its MPC Price rather than cancelling any unexecuted portion of the order back to the Member.[29]

Complex Auction

Currently, MIAX provides a single-sided Complex Auction functionality, as described in MIAX Rule 518, and a cPRIME Auction for paired complex orders, as described in MIAX Rule 515A, Interpretation and Policy .12.[30] The proposal makes related changes to the Defined Time Period and the Response Time Interval of the Complex Auction. MIAX Rule 518(d)(2) states that the System will not commence a Complex Auction within a defined time period prior to the end of the trading session (the ''Defined Time Period'') established by the Exchange.[31] MIAX Rule 518(d)(3) defines the Response Time Interval as the period of time during which Complex Auction responses (*i.e.,* responses to the Request for Responses message) may be entered.[32] The proposal removes references to the Defined Time Period from MIAX Rules 518(b)(2)(i) and (d)(2).[33] The proposal amends MIAX Rule 518(d)(3) to state that the end of the trading session will also serve as the end of the Response Time Interval for a Complex Auction still in progress. The proposal makes no changes to the cPRIME Auction, and the cPRIME Timer will remain at 100 milliseconds.[34]

MIAX notes that under its current rules there is no opportunity for price improvement via a Complex Auction when there is less than two seconds left in the trading session.[35] MIAX believes that removing the Defined Time Period and allowing the end of the trading session to serve as the end of the Response Time Interval when a Complex Auction is initiated with less than 200 milliseconds left in the trading session will allow for more opportunities for price improvement via the auction process.[36] In this regard, MIAX notes that Members responding to Complex Auctions are able to do so in less than 10 milliseconds.[37] In addition, MIAX states that if a Member initiates a Complex Auction and no Members respond, the initiating Member is no worse off under the proposed rule than the Member would have been under MIAX's current rule, which prevents the Member from even attempting to initiate a Complex Auction with less than two seconds left in the trading session.[38] MIAX notes that a Member who initiates a Complex Auction will not forego the opportunity to trade with unrelated interest received during the Complex Auction because unrelated interest is included in the Complex Auction.[39]

MIAX represents that is has the System capacity and capability to conduct auctions and execute transactions in a timely fashion at any time during the trading session, including the last two seconds of the trading session.[40] MIAX further represents that it has surveillances in place to surveil for conduct that violates the Exchange's rules, specifically as they pertain to Complex Auctions as described in the proposal.[41]

CSV Price Protection

The proposal amends MIAX Rule 518, Interpretation and Policy .05(b) to indicate that the CSV Price Protection applies only to strategies in American-style option classes.[42] MIAX notes that the CSV establishes a minimum trading price limit for Calendar Spreads of zero minus the preset value of $.10, thereby ensuring that a Calendar Spread does not trade more than $.10 away from its intrinsic value.[43] MIAX states that an American-style option must be worth at least as much as its intrinsic value because the holder of the option can realize the intrinsic value by immediately exercising the option.[44] In a Calendar Spread strategy comprised of American-style options, other things being equal, the far month should be worth more than the near month due to its having a longer time to expiration and therefore a greater time value.[45] MIAX states that because European-style options may be exercised only on their expiration date, the relationship between the stock price, option price, and option strike price that exists for American-style options does not exist for European-style options.[46] Accordingly, MIAX states that the CSV Price Protection would be ineffective for strategies comprised of European-style options.[47]

SMAT Event

As described more fully in the Notice, MIAX Rule 518(a)(16) currently defines a SMAT Event as any one of the following: A MIAX Price Improvement Mechanism (''PRIME'') Auction (pursuant to Exchange Rule 515A), a Route Timer (pursuant to Exchange Rule 529), or a liquidity refresh pause (pursuant to Exchange Rule 515(c)(2).[48] If a SMAT Event exists during free trading for an option component of a complex strategy, trading in the complex strategy will be suspended.[49] MIAX notes that the temporary suspension of trading in complex orders during a SMAT Event is intended to enhance continuity, trade-through protection, and orderliness in the simple market and to protect complex order components from being executed at prices that could improve following a SMAT Event.[50] The proposal amends MIAX Rule 518(a)(16) to add the Liquidity Exposure Process, as described in MIAX Rule 515(c)(2), as a

complex order or eQuote priced more aggressively than its MPC Price will be subject to the cLEP Auction process, rather than cancelled if it would otherwise be displayed or executed at a price outside its MPC Price. *See* Notice, 83 FR at 59437–8.

[27] *See id.* MIAX notes that a Member who believes that an execution has occurred at an erroneous price may avail itself of the protections provided in MIAX Rule 521, ''Nullification and Adjustment of Options Transactions Including Obvious Errors.'' *See id.* at n. 29.

[28] *See id.* at 59438.

[29] *See id.*

[30] *See id.* at 59436 and Amendment No. 1.

[31] MIAX notes that the Defined Time Period currently is 2,000 milliseconds, while the duration of a Complex Auction is 200 milliseconds. *See* Notice, 83 FR at 59436.

[32] MIAX notes that the Response Time Interval currently is set to 200 milliseconds. *See id.* at n. 10. *See also* MIAX Regulatory Circular 2016–46.

[33] MIAX Rule 518(b)(2)(i) states, in part, that a Complex Auction-on-Arrival (''cAOA'') Order received during the Defined Time Period will not initiate a new Complex Auction.

[34] *See* Amendment No. 1.

[35] *See* Notice, 83 FR at 59436.

[36] *See id.*

[37] *See* Amendment No. 1.

[38] *See* Notice, 83 FR at 59438, and Amendment No. 1.

[39] *See* Amendment No. 1 and MIAX Rule 518(d)(8).

[40] *See id.*

[41] *See id.* MIAX notes that MIAX Rule 518, Interpretation and Policy .04, ''Dissemination of Information,'' remains in effect for any Complex Auction-eligible order submitted to MIAX at any time. *See* Amendment No. 1. MIAX Rule 518, Interpretation and Policy .04 provides that dissemination of information related to Complex Auction-eligible orders by the submitting Member to third parties will be deemed conduct inconsistent with just and equitable principles of trade as described in Rule 301.

[42] *See* proposed MIAX Rule 518, Interpretation and Policy .05(b)(3).

[43] *See* Notice, 83 FR at 59438.

[44] *See id.*

[45] *See* Amendment No. 1.

[46] *See* Notice, 83 FR at 59438.

[47] *See id.*

[48] *See id.*

[49] *See* MIAX Rule 518, Interpretations and Policies .05(e)(2)(i) and Notice, 83 FR at 59436.

[50] *See id.*

SMAT Event.[51] The Liquidity Exposure Process will apply to an order in a Proprietary Product that would be posted, managed, or would trade at a price more aggressive than the order's protected price.[52]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, with Section 6(b) of the Act.[53] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[54] which requires, among other things, that the rules of a national securities 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.

The Commission believes that the cLEP Auction is designed to potentially benefit market participants by providing price improvement opportunities for complex orders and eQuotes that are priced more aggressively than their MPC Price. In addition, the Commission believes that Members' ability to submit cLEP Auction responses on either side of the market potentially could enhance liquidity in the cLEP Auction and provide execution opportunities for trading interest on both sides of the market.

The Commission believes that eliminating the Defined Time Period and allowing Members to initiate a single-sided Complex Auction at any time prior to the close could potentially provide price improvement opportunities for complex orders submitted within two seconds of the close. As noted above, MIAX represents that it has the system capacity and capability to conduct Complex Auctions and execute transactions that occur within two seconds of the close, and that it has surveillance in place to monitor conduct that violates MIAX's rules, including MIAX Rule 518, Interpretation and Policy .04, which prohibits a submitting Member from disseminating information with respect to Complex Auction-eligible orders to third parties.[55] MIAX states that a Member who initiates a Complex Auction will not forego the opportunity to trade with unrelated interest received during the Complex Auction because this interest is included in the Complex Auction.[56] The Commission notes that proposal does not modify the Auction Timer for MIAX's paired order cPRIME Auction, which will remain at 100 milliseconds.[57]

As noted above, MIAX states that the CSV Price Protection would be ineffective for Calendar Spreads comprised of European-style options because the relationship between the stock price, the option price, and the option strike price that exists for American-style options does not exist for European-style options.[58] Accordingly, the proposal limits the CSV Price Protection to strategies in American-style option classes. The Commission believes that applying the CSV Price Protection solely to Calendar Spreads comprised of American-style options is reasonable in that this price protection will be applied to orders for which it is meaningful to do so.

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2018–36 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–MIAX–2018–36. 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 (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2018–36, and should be submitted on or before March 15, 2019.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of publication of notice of the filing of Amendment No. 1 in the **Federal Register**. As noted above, Amendment No. 1 revises the proposal to (1) clarify the rule describing the operation of the proposed cLEP Auction and provide an additional example demonstrating the operation of the proposed cLEP Auction; (2) provide additional rationale for eliminating the Defined Time Period for the Complex Auction and make representations regarding system capability and surveillance with respect to the Complex Auction, as modified by

[51] *See id.* at 59435–6. In addition to adding the Liquidity Exposure Process to MIAX Rule 518(a)(16), MIAX proposes to correct an internal cross reference in MIAX Rule 518(a)(16)(iii) to reflect changes included in the LEP Filing. *See* Notice, 83 FR at 59436.

[52] The term ''Proprietary Product'' means a class of options that is listed exclusively on the Exchange. *See* Notice, 83 FR at 59436. *See also* LEP Filing, *supra* note 8.

[53] 15 U.S.C. 78f(b). In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[54] 15 U.S.C. 78f(b)(5).

[55] *See* notes 39–40, *supra,* and accompanying text.

[56] *See* note 38, *supra,* and accompanying text.

[57] *See* note 33, *supra,* and accompanying text.

[58] *See* notes 45–46, *supra,* and accompanying text.

the proposal; (3) indicate that the Auction Timer for MIAX's cPRIME Auction will remain at 100 milliseconds; and (4) clarify the discussion of the proposed change to the Calendar Spread Variance Price Protection. The Commission believes that Amendment No. 1 does not raise any novel regulatory issues. The Commission also believes that Amendment No. 1 provides additional clarity to the rule text and additional analysis and representations concerning several aspects of the proposal, thereby facilitating the Commission's ability to make the findings set forth above to approve the proposal. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[59] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[60] that the proposed rule change (SR–MIAX–2018–36), as modified by Amendment No. 1, is approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[61]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03039 Filed 2–21–19; 8:45 am]

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[59] 15 U.S.C. 78s(b)(2).

[60] 15 U.S.C. 78s(b)(2).

[61] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85147; File No. SR–MIAX–2018–35]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1, To Amend Exchange Rule 100 (Definitions); Rule 515 (Execution of Orders and Quotes); and Rule 503 (Openings on the Exchange)

February 15, 2019.

I. Introduction

On November 9, 2018, Miami International Securities Exchange, LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Exchange Rules 100 (Definitions), 515 (Execution of Orders and Quotes), and 503 (Openings on the Exchange). The proposed rule change was published for comment in the **Federal Register** on November 20, 2018.[3] On December 20, 2018, the Commission extended the time period for Commission action on the proposed rule change from January 4, 2019, to February 18, 2019.[4] The Commission received no comments on the proposal.

On February 13, 2019, the Exchange filed Amendment No. 1 to make a clarifying change to the proposal.[5] The Commission is publishing this notice to solicit comment on Amendment No. 1, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposal, as Modified by Amendment No. 1

As more fully set forth in the Notice and Amendment No. 1, the Exchange proposes to amend its rules to address how price protection will apply to non-multi listed option products that are proprietary to the Exchange. More specifically, the Exchange proposes to amend (i) Exchange Rule 100 (Definitions), to adopt definitions for the terms ''Proprietary Product'' and ''Non-Proprietary Product;'' (ii) Exchange Rule 515 (Execution of Orders and Quotes), to specify how the Exchange will provide price protection to eligible non-Market Orders for Proprietary Products; and (iii) Exchange Rule 503 (Openings on the Exchange), to specify how certain orders for Proprietary Products will be handled at the conclusion of the Opening Process.

The Exchange proposes to amend Exchange Rule 100 (Definitions), to adopt definitions for the terms ''Proprietary Product'' and ''Non-Proprietary Product,'' to provide clarity and ease of reference in Exchange rules.[6] The proposed definition of a Proprietary Product is ''a class of options that is listed exclusively on the Exchange,'' and the proposed definition of a Non-Proprietary Product is ''a class of options that is not a Proprietary Product.''[7]

The Exchange further proposes to amend Exchange Rule 515 (Execution of Orders and Quotes). Currently, Rule 515(c)(1) describes a price protection process for certain non-Market Maker orders received during a trading session.[8] This price protection process prevents certain orders from being executed beyond the price designated in the order's price protection instructions (the ''price protection limit''). When triggered, this price protection process will cancel an order or the remaining contracts of an order. The Exchange proposes to amend the heading of Rule 515(c)(1) to read ''Price Protection on Non-Market Maker Orders in Non-Proprietary Products,''[9] and add new subsection (c)(2) to Exchange Rule 515 to address and distinguish how price protection would apply to Proprietary Products.

Proposed Exchange Rule 515(c)(2) would establish a price protection process for eligible non-Market Maker orders in Proprietary Products received during a regular trading session that are larger than, and priced through, the opposite side NBBO.[10] The proposed price protection process provides for exposure of such orders and a limited time (*i.e.,* a liquidity exposure period or ''LEP'') during which market participants may respond to provide liquidity, subject to certain parameters, in lieu of the Exchange canceling the order back to the Member. The price protection limit for applicable orders in Proprietary Products will be calculated by the System[11] as follows: By adding (subtracting) a set number of MPVs[12] if the order is a buy (sell) to: (i) The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 84589 (Nov. 14, 2018), 83 FR 58633 (''Notice'').

[4] *See* Securities Exchange Act Release No. 84900 (December 20, 2018), 83 FR 67394 (December 28, 2018).

[5] In Amendment No. 1, the Exchange modified its proposal to clarify that the term ''Proprietary Product'' refers to an options product that is listed exclusively on the Exchange, and is not multiply listed. The full text of Amendment No. 1 has been placed in the public comment file for SR–MIAX–2018–35 and is available at: *https://www.sec.gov/rules/sro/miax.htm#SR-MIAX-2018-35.*

[6] *See* Notice, *supra* note 3, at 58634.

[7] *See* proposed Exchange Rule 100 and *supra* note 5.

[8] *See* Exchange Rule 515(c)(1). This price protection process does not apply to Intermarket Sweep Orders (''ISO''), Immediate or Cancel (''IOC'') orders, or Fill-or-Kill (''FOK'') orders.

[9] *See* Notice, *supra* note 3, at 58634.

[10] The term ''NBBO'' means the national best bid or offer as calculated by the Exchange based on market information received by the Exchange from OPRA. *See* Exchange Rule 100. The proposed new price protection process would apply to non-Market Maker orders in Proprietary Products, excluding ISOs and Auction or Cancel orders. *See* Notice, *supra* note 3, at 58634.

[11] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[12] The term ''MPV'' means Minimum Price Variation. *See* Exchange Rule 510. The number of MPVs will be determined by the Exchange and announced to Members through a Regulatory Circular, provided that the minimum shall be no less than two MPVs and the maximum shall be no more than twenty MPVs. *See* proposed Exchange Rule 515(c)(2).

opposite side NBBO, or (ii) the previous price protection limit,[13] or (iii) in certain circumstances, the limit price of same side joining interest after the expiration of the liquidity exposure process timer.[14]

The proposed LEP applies to oversized non-Market Maker eligible orders in Proprietary Products. More specifically, interest that would be posted or managed, or that would trade at a price more aggressive than the order's protected price (also referred to as the ''Book price'') will be subject to the LEP. To begin the LEP, the System will broadcast a liquidity exposure message to all subscribers of the Exchange's data feeds which will include the symbol, side of the market, quantity of matched contracts, the imbalance quantity, ''must fill'' quantity, and price. Additionally, the System will start an LEP timer, not to exceed three seconds, as determined by the Exchange and announced via Regulatory Circular. All market participants may respond to the liquidity exposure broadcast message. The System will evaluate interest received during the LEP based on price and the side of the market relative to the side of the market of the initiating order.

During the LEP, if the Exchange receives interest on the opposite side of the market from the initiating order that locks or crosses the Book price of the interest subject to the LEP, the interest will trade, with resting liquidity executed prior to joining liquidity. During the LEP, if the Exchange receives interest on the same side of the market as the initiating order that is priced more aggressively than the Book price of the interest subject to the LEP that also locks or crosses the opposite side NBBO, the System will immediately terminate the timer and treat the new interest as joining liquidity for allocation purposes.

Proposed Exchange Rule 515(c)(2)(i)(B) provides that at the end of the timer, the initiating order, resting liquidity, and any same side joining interest will (i) be handled in accordance to Exchange Rule 515, Execution of Orders and Quotes, or (ii) trade against opposite side interest in the following sequence: resting interest will be filled first, followed by joining interest in the order it was received; and opposite side interest will be allocated in accordance with the Exchange's standard allocation, as described in Exchange Rule 514, Priority of Quotes and Orders.

The Exchange also proposes to amend subsection (f)(2)(vii)(B)(5) of Exchange Rule 503 (Openings on the Exchange), which currently provides that if there is an opening transaction, any unexecuted contracts from the imbalance not traded or routed will be cancelled back to the entering Member if the price for those contracts crosses the opening price, unless the Member that submitted the original order has instructed the Exchange in writing to re-enter the remaining size, in which case the remaining size will be automatically submitted as a new order. The Exchange proposes to amend the rule to adopt a new provision to state that unexecuted contracts that are from a non-Market Maker order in a Proprietary Product will be placed on the Book with a protected price equal to the opening price, and the LEP will begin immediately after the Opening Process is complete.

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, with Section 6(b) of the Act.[15] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[16] which requires, among other things, that the rules of a national securities 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.

The Commission believes that adopting definitions for the terms Proprietary Product and Non-Proprietary Product on the Exchange adds additional detail and promotes transparency and clarity in the Exchange's rules. The proposed definitions allow the Exchange to distinguish between two separate and distinct classes of options listed on the Exchange and to describe rules that may be applicable to one class and not the other.

As described above, the Exchange proposes a new price protection and order handling mechanism for Proprietary Products that is similar to drill-through protection currently offered by other exchanges, and offers an opportunity for an investor's order in a Proprietary Product to be filled rather than cancelled.[17] The Commission believes that the proposed price protection and liquidity exposure process for eligible non-Market Maker orders in Proprietary Products is reasonably designed to facilitate the execution of orders larger than and priced-through the opposite side NBBO, as it offers a mechanism to seek and potentially provide liquidity to a Member, subject to specified parameters, in lieu of canceling back an order for which there are no other venues to seek an execution.

In addition, the Exchange proposes that if there are unexecuted contracts from an eligible non-Market Maker order in a Proprietary Product at the conclusion of the Opening Process, the remaining contracts will be placed on the Book with a protected price equal to the opening price, and the LEP will begin immediately after the Opening Process is complete. The Commission believes that this aspect of the proposal similarly provides an additional opportunity for price discovery and a mechanism by which an investor's order in a Proprietary Product may ultimately be filled.

For the foregoing reasons, the Commission finds the proposal, as modified by Amendment No. 1, to be consistent with the Act.

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MIAX–2018–35 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

[13] *See* proposed Exchange Rule 515(c)(2)(i)(iv).

[14] *See* proposed Exchange Rule 515(c)(2)(i)(v).

[15] 15 U.S.C. 78f(b). In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 15 U.S.C. 78f(b)(5).

[17] *See* Notice, *supra* note 3, at 58636.

Commission, 100 F Street NE, Washington, DC 20549–1090.
All submissions should refer to File Number SR–MIAX–2018–35. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2018–35, and should be submitted on or before March 15, 2019.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of publication of notice of the filing of Amendment No. 1 in the **Federal Register**. In Amendment No. 1, the Exchange modified its proposal to specify that the term ''Proprietary Product'' refers to an options product that is listed exclusively on the Exchange. The Commission notes that Amendment No. 1 does not otherwise modify the proposed rule change, which was subject to a full notice-and-comment period during which no comments were received. Amendment No. 1 narrows the scope of the original proposal by limiting the extent of products that may meet the Exchange's proposed definition of ''Proprietary Product,'' and harmonizes the definition with the rationale for the proposal, which is to provide price protection for products that do not trade on other execution venues. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[18] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[19] that the proposed rule change (SR–MIAX–2018–35), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03034 Filed 2–21–19; 8:45 am]

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[18] 15 U.S.C. 78s(b)(2).

[19] 15 U.S.C. 78s(b)(2).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85148; File No. SR–MIAX–2018–34]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Exchange Rule 519, MIAX Order Monitor; Exchange Rule 519A, Risk Protection Monitor; and Exchange Rule 517, Quote Types Defined

February 15, 2019.

I. Introduction

On November 9, 2018, Miami International Securities Exchange, LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Exchange Rules 519 (MIAX Order Monitor), 519A (Risk Protection Monitor), and 517 (Quote Types Defined). The proposed rule change was published for comment in the **Federal Register** on November 20, 2018.[3] On December 20, 2018, the Commission extended the time period for Commission action on the proposed rule change from January 4, 2019, to February 18, 2019.[4] The Commission has received no comments on the proposal. On February 12, 2019, the Exchange filed Amendment No. 1 to the proposed rule change to modify one provision of its proposal.[5] The Commission is publishing this notice to solicit comment on Amendment No. 1, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1[6]

The Exchange recently received Commission approval to list and trade options on the SPIKES™ Index (''Index''), a new index that measures expected 30-day volatility of the SPDR S&P 500 ETF Trust.[7] To establish the settlement value for the Index, the Exchange conducts a settlement auction (the ''SPIKES Special Settlement Auction''), during which the Exchange will accept settlement auction only orders (''SAO Orders'') and settlement auction only eQuotes (''SAO eQuotes'' and, collectively with SAO Orders, ''SAOs''), in addition to any other order types that may regularly be accepted by the Exchange.[8] Market participants entering interest for participation in the SPIKES Special Settlement Auction that is related to positions in, or a trading strategy involving, Index options, and that are ''SPIKES strategy orders'' may be tagged as SAOs.[9]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 84594 (November 14, 2018), 83 FR 58642 (''Notice'').

[4] *See* Securities Exchange Act Release No. 84888 (December 20, 2018), 83 FR 67390 (December 28, 2018).

[5] In Amendment No. 1, the Exchange modified its proposal by removing a provision that would deem an SAO eQuote a ''priority quote'' for trade allocation purposes in accordance with Exchange Rule 514(e), a provision that was contained in proposed Interpretations and Policies .02 to Exchange Rule 517. The full text of Amendment No. 1 has been placed in the public comment file for SR–MIAX–2018–34 and is available at: *https://www.sec.gov/rules/sro/miax.htm#SR-MIAX-2018-34.*

[6] For a full description of the proposal, *see* Notice, *supra* note 3 and Amendment No. 1, *supra* note 5.

[7] *See* Securities Exchange Act Release No. 84417 (October 12, 2018), 83 FR 52865 (October 18, 2018) (SR–MIAX–2018–14) (Order Granting Approval of a Proposed Rule Change by Miami International Securities Exchange, LLC to List and Trade Options on the SPIKES™ Index).

[8] *Id.*

[9] *See id.* at 52866. *See also* Exchange Rule 503.03(c) (defining ''SPIKES strategy orders,'' and stating that the Exchange will generally consider orders to be SPIKES Strategy Orders if the orders possess the following characteristics: (i) They are for options with the expiration that will be used to calculate the exercise or final settlement value of the applicable volatility index option contract; (ii) they are for options spanning the full range of strike

Continued

The Exchange anticipates that market participants that actively trade SPIKES options may hedge their positions with SPY option series that will also be used to calculate the SPIKES exercise settlement/final settlement value.[10] The Exchange believes that in order to seek convergence with the SPIKES exercise/final settlement value, these market participants may liquidate their hedges by submitting SPIKES strategy orders in the appropriate SPY option series during the SPIKES Special Settlement Auction on the SPIKES expiration/final settlement date.[11] The Exchange proposes to amend its rules to exclude SAOs from certain risk protection features offered by the Exchange. According to the Exchange, given that SAOs are designed for the special purpose of closing a hedged position and are available for use only during the SPIKES Special Settlement Auction, the application of certain risk protection features could diminish the utility of SAO Orders and SAO eQuotes.

Specifically, the Exchange proposes to amend Exchange Rule 519, Interpretations and Policies, to adopt new subsection .03, to provide that the order protections of the MIAX Order Monitor pursuant to sections (b), (c), and (d) of that rule will not apply to SAO Orders, as defined in Interpretations and Policies .03 of Exchange Rule 503. The MIAX Order Monitor is a risk management feature of the Exchange's System. Pursuant to paragraph (a) of Exchange Rule 519, the MIAX Order Monitor prevents certain orders from executing or being placed on the Book [12] at prices outside pre-set standard limits.[13] Paragraph (b) prevents certain orders from executing or being placed on the Book if the size of the order exceeds the order size protection designated by the Member; [14] paragraph (c) specifies that the System will reject any orders that exceed the maximum number of open orders held in the System on behalf of a particular Member, as designated by the Member; [15] and paragraph (d) specifies that the System will reject any orders that exceed the maximum number of open contracts represented by orders held in the System on behalf of a particular Member, as designated by the Member.[16] According to the Exchange, the application of the order size protection described in Exchange Rule 519(b) may prevent an SAO order from being placed on the Book and may prevent the Member from effectively hedging or closing a hedged position in SPIKES options.[17] Similarly, the Exchange does not believe that an SAO Order should be subject to the open order protection described in Exchange Rule 519(c) as this protection aggregates open orders held in the System and may inadvertently prevent the Member from hedging or closing a hedged position in SPIKES options by preventing the submission of an SAO Order.[18] Likewise, the Exchange does not believe that an SAO Order should be subject to the open contract protection described in Exchange Rule 519(d), as this protection aggregates the number of open contracts represented by orders held in the System, and including SAO Orders in this protection may inadvertently prevent the Member from hedging or closing a hedged position in SPIKES options by preventing the submission of an SAO Order.[19]

The Exchange similarly proposes to amend Exchange Rule 519A, Interpretations and Policies, to adopt new subsection .02 to state that SAO Orders, as defined in Interpretations and Policies .03 of Exchange Rule 503, are not eligible to participate in the Risk Protection Monitor (''RPM'').[20] The RPM is a feature of the MIAX System, which maintains a counting program for each participating Member that will count the number of orders entered and the number of contracts traded via an order entered by a Member on the Exchange within a specified time period that has been established by the Member. The RPM maintains one or more Member-configurable Allowable Order Rate settings and Allowable Contract Execution Rate settings. The Risk Protection Monitor shall remain engaged until the Member communicates with the Help Desk to enable the acceptance of new orders.[21] According to the Exchange, excepting SAO Orders from participating in the RPM ensures that these orders may be freely submitted to the Exchange and will remain active in the System once accepted.[22] As noted, SAO Orders are SPIKES strategy orders used for hedging or closing a hedged position in SPIKES options during the SPIKES Special Settlement Auction which is conducted only once per month. If engaged, the RPM may prevent the Member from submitting SAO Orders to the Exchange until the Member communicates with the Help Desk to enable the acceptance of new orders. The Exchange does not believe it is in the best interest of the Member to introduce this type of delay for SAO Orders, as they are time sensitive and are designed to participate in the SPIKES Special Settlement Auction.[23]

Additionally, the Exchange proposes to amend Exchange Rule 517, Quote Types Defined. Exchange Rule 517(d) currently provides that bids and offers in certain limited time-in-force eQuote types (Auction-or-Cancel, Opening Only, Immediate-or-Cancel, Fill-or-Kill, and Immediate-or-Cancel Intermarket Sweep) will not be disseminated by the Exchange in accordance with Rule 602 of Regulation NMS, and that executions resulting from these eQuote types will not be used by the Exchange's Aggregate Risk Manager (''ARM'') to determine whether the Market Maker has exceeded the Allowable Engagement Percentage. As more fully described in Exchange Rule 612, the MIAX System will engage the ARM in a particular option class when the counting program has determined that a Market Maker has traded during the specified time period a number of contracts equal to or above their Allowable Engagement Percentage. The ARM will then automatically remove the Market Maker's Standard Quotations and Day eQuotes from the Exchange's disseminated quotation in all series of that particular option class until the Market Maker sends a notification to the System of the intent to reengage quoting and submits a new revised quotation.[24] The Exchange proposes to add SAO eQuote, as defined in Interpretations and Policies .03 of Exchange Rule 503, to the list of eQuotes that are not disseminated by the Exchange in accordance with Rule 602 of Regulation NMS and not subject to the ARM. An SAO eQuote is a special purpose eQuote available only during

prices for the appropriate expiration for options that will be used to calculate the exercise or final settlement value of the applicable volatility index option contract, but not necessarily every available strike price; and (iii) they are for put options with strike prices less than the at-the-money strike price, for call options with strike prices greater than the at-the-money strike price, or for put and call options with at-the-money strike prices). The Exchange notes that it may also deem order types other than those provided above as SPIKES Strategy Orders if the Exchange determines that to be the case based on the applicable facts and circumstances. *See id.*

[10] *See* Notice, *supra* note 3, at 56842.

[11] *See id.*

[12] The term ''Book'' means the electronic book of buy and sell orders and quotes maintained by the System. *See* Exchange Rule 100.

[13] *See* Exchange Rule 519(a).

[14] *See* Exchange Rule 519(b).

[15] *See* Exchange Rule 519(c).

[16] *See* Exchange Rule 519(d).

[17] *See Notice, supra* note 3, at 58642–43.

[18] *See Notice, supra* note 3, at 58643.

[19] *See id.*

[20] For a more complete description of the Risk Protection Monitor, see *id.*

[21] *See* Exchange Rule 519A(a).

[22] *See Notice, supra* note 3, at 58643.

[23] *See id.*

[24] *See* Exchange Rule 612(b)(1).

the SPIKES Special Settlement Auction and as such, the Exchange believes it should be treated similarly to other limited time-in-force eQuote types.[25]

III. Discussion and Commission Findings

After careful consideration of the proposal, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange,[26] and, in particular, the requirements of Section 6 of the Act.[27] Specifically, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[28] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Commission believes that the proposal to remove SAO Orders, which are designed specifically for closing a hedged position and are available for use only during the SPIKES Special Settlement Auction,[29] from certain risk protection features offered by the Exchange, as described above, is reasonably designed to mitigate the potential risks associated with preventing market participants from effectively hedging or closing a hedged position in SPIKES options. Specifically, the proposal to exclude SAO Orders from the order size protection, open order protection, and open contract protection of the MIAX Order Monitor is reasonably designed to prevent a market participant from being unable to effectively hedge or close a hedged position in SPIKES options in the event those order protections may inadvertently prevent the submission or posting of an SAO Order.[30] The Commission further believes that the proposal to exclude SAO Orders from the RPM is reasonably designed to prevent any unintended delay in the submission of SAO Orders, which MIAX states are time sensitive and designed to participate in the SPIKES Special Settlement Auction.[31]

The Commission also believes that the proposal to add SAO eQuotes to the list of eQuotes that are not disseminated by the Exchange in accordance with Rule 602 of Regulation NMS or counted as executions for purposes of the ARM is reasonably designed to promote fair and orderly markets by ensuring that SAO eQuotes, which are only available during the SPIKES Special Settlement Auction, are treated similarly to other limited time-in-force eQuotes.[32]

Accordingly, for the reasons discussed above, the Commission believes that the proposed rule change, as modified by Amendment No. 1, is consistent with the Act.

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2018–34 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2018–34. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2018–34, and should be submitted on or before March 15, 2019.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of publication of notice of the filing of Amendment No. 1 in the **Federal Register**. As discussed above, in Amendment No. 1, the Exchange is removing from its proposal a provision that would deem an SAO eQuote a ''priority quote'' for trade allocation purposes in accordance with Exchange Rule 514(e), a provision that was contained in proposed Interpretations and Policies .02 of Exchange Rule 517. The Commission notes that Amendment No. 1 does not otherwise modify the proposed rule change, which was subject to a full notice-and-comment period during which no comments were received. Amendment No. 1 eliminates one discrete aspect of the original proposal that does not impact the remaining portions of the proposed rule change. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[33] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[34] that the proposed rule change (SR–MIAX–2018–34), as modified by Amendment No. 1 be, and hereby is, approved on an accelerated basis.

[25] *See Notice, supra* note 3, at 58643.

[26] In approving this proposed rule change, as modified by Amendment No. 1, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[27] 15 U.S.C. 78f.

[28] 15 U.S.C. 78f(b)(5).

[29] *See* Notice, *supra* note 3, at 58642.

[30] *See id.* at 58643.

[31] *See id.*

[32] *See id.*

[33] 15 U.S.C. 78s(b)(2).

[34] 15 U.S.C. 78s(b)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[35]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03042 Filed 2–21–19; 8:45 am]

BILLING CODE 8011–01–P

[35] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–54, OMB Control No. 3235–0056]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Form 8–A

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Form 8–A (17 CFR 249.208a) is a registration statement used to register a class of securities under Section 12(b) or Section 12(g) of the Securities Exchange Act of 1934 (15 U.S.C. 78*l*(b) and 78*l*(g)) (''Exchange Act''). Section 12(a) (15 U.S.C. 78*l*(a)) of the Exchange Act makes it unlawful for any member, broker, or dealer to effect any transaction in any security (other than an exempted security) on a national securities exchange unless such security has been registered under the Exchange Act (15 U.S.C. 78a *et seq.*). Exchange Act Section 12(b) establishes the registration procedures. Exchange Act Section 12(g) requires an issuer that is not a bank or bank holding company to register a class of equity securities (other than exempted securities) within 120 days after its fiscal year end if, on the last day of its fiscal year, the issuer has total assets of more than $10 million and the class of equity securities is ''held of record'' by either (i) 2,000 persons, or (ii) 500 persons who are not accredited investors. An issuer that is a bank or a bank holding company, must register a class of equity securities (other than exempted securities) within 120 days after the last day of its first fiscal year ended after the effective date of the JOBS Act if, on the last day of its fiscal year, the issuer has total assets of more than $10 million and the class of equity securities is ''held of record'' by 2,000 or more persons. The information must be filed with the Commission on occasion. Form 8–A is a public document. Form 8–A takes approximately 3 hours to prepare and is filed by approximately 871 respondents for a total annual reporting burden of 2,613 hours (3 hours per response × 871 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following website, *www.reginfo.gov*. Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Lindsay.M.Abate@omb.eop.gov;* and (ii) Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: February 19, 2019.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03083 Filed 2–21–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85157; File No. SR–ICC–2019–002]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change Relating to ICC's Risk Parameter Setting and Review Policy

February 15, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] and Rule 19b–4,[2] notice is hereby given that on February 6, 2019, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by ICC. 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. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to revise the ICC Risk Parameter Setting and Review Policy (''Risk Parameter Policy''). These revisions do not require any changes to the ICC Clearing Rules (''Rules'').

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICC proposes to formalize the Risk Parameter Policy that describes the process of setting and reviewing the risk management model (''model'') core parameters and the performance of sensitivity analyses related to certain parameter settings. ICC proposes to formalize the Risk Parameter Policy following Commission approval of the proposed rule change.

Parameter Setting and Calibration

ICC's Risk Parameter Policy discusses the process of setting and reviewing the model core parameters and their underlying assumptions. The model requirements include bid/offer (''BO'') requirements, large position requirements, Jump-To-Default (''JTD'') requirements, interest rate (''IR'') sensitivity requirements, basis risk requirements, and integrated spread response (''iSR'') requirements. The parameters that are associated with the model requirements are listed in a table containing various parameter-related information, including the methods used to review parameter settings; the frequency of the reviews; and the groups involved in the review process (''reviewers''), such as the ICC Risk Management Department (''ICC Risk''), the Risk Working Group (''RWG''), or the Risk Committee. The parameters are described in more detail as follows.

The Risk Parameter Policy explains the process of setting and reviewing the liquidity charge parameters. The liquidity charge parameters are associated with BO requirements, also referred to as liquidity charges, which incorporate the transaction costs associated with liquidating the portfolio of a defaulting Clearing Participant (''CP''). With respect to index instruments, the Risk Parameter Policy specifies how ICC Risk estimates the BO Widths (''BOWs'') for indices across volatile and extreme market conditions, in addition to how ICC Risk recognizes long-short benefits when computing portfolio-level index liquidity charges. In reference to single-name (''SN'') instruments, the Risk Parameter Policy introduces certain parameters to incorporate a price-based BOW component and a spread-based BOW component into the liquidity charge. The Risk Parameter Policy requires ICC to estimate and review the liquidity charge parameters at least monthly and summarizes the associated governance process, including the reviewers and any prerequisites to the implementation of parameter updates (*e.g.,* review by the RWG or ''no objection'' ruling by the Risk Committee).

The Risk Parameter Policy discusses the estimation and the review of the concentration charge parameters, which are related to large position requirements. Large position requirements, also referred to as concentration charges, apply to positions that exceed a predefined notional amount threshold and increase as the amount above the threshold increases. The Risk Parameter Policy details how ICC Risk establishes series-specific or SN-specific concentration charge threshold levels for each index or SN Risk Factor (''RF''),[3] and how ICC Risk estimates concentration charge growth rates that determine how quickly concentration charges increase with position size. The Risk Parameter Policy directs ICC to estimate and review the concentration charge parameters at least monthly and provides information on the corresponding governance process, stating the reviewers and any prerequisites to implementing parameter updates.

The parameters impacting the JTD requirement are categorized as either Loss-Given-Default (''LGD'') or Wrong-Way Risk (''WWR'') parameters. ICC's risk management methodology incorporates considerations of idiosyncratic credit events and the associated potential losses. These credit event losses are termed LGD, and the Risk Parameter Policy discusses the determination and review of the associated LGD parameters. Specifically, the Risk Parameter Policy explains how, in order to measure credit event losses, ICC Risk constructs JTD scenarios in terms of anticipated recovery rate (''RR'') levels (''RR scenarios''). The Risk Parameter Policy references RR scenarios and estimations for corporate SNs, sectors, and sovereign reference entities, and notes foreign exchange rate risk considerations with respect to sovereign reference entities. Additionally, the LGD computations at the RF Group (''RFG'')[4] level depend on certain RFG-related parameters, which are specified in the Risk Parameter Policy. The Risk Parameter Policy requires ICC to estimate and review the LGD parameters at least monthly and describes the associated governance process, noting the reviewers and any prerequisites to the implementation of parameter updates.

The Risk Parameter Policy details the process of setting and reviewing the WWR parameters. WWR arises when there is a strong adverse correlation between a CP's default risk and the occurrence of large losses in a CP's portfolio. ICC considers three types of WWR: Specific WWR (''SWWR'') results from self-referencing trades; General WWR (''GWWR'') results from trades that involve RFs within the sovereign and banking sectors that are highly correlated with the CP, or with an entity that is guaranteed by, or affiliated with the CP; and Contagion WWR results from portfolio level aggregation of WWR exposure beyond a portfolio level WWR threshold. The Risk Parameter Policy contains information regarding the parameters that are used to quantify WWR dependence, compute WWR JTD requirements, and determine the level of WWR collateralization. The Risk Parameter Policy details the thresholds that are established as parameters for each RF generating WWR exposure, beyond which the increased level of WWR collateralization applies. Additionally, ICC estimates, reviews, and performs sensitivity analyses on the WWR parameters at least monthly, and the Risk Parameter Policy discusses the associated governance process, including the reviewers and any prerequisites to implementing parameter updates.

The Risk Parameter Policy contains information on the estimation and the review of the parameters that serve as inputs to the IR sensitivity requirement. The IR sensitivity requirement accounts for the risk associated with changes in the default-free discount term structure used to price CDS instruments. With respect to the IR sensitivity requirement parameters, the Risk Parameter Policy specifies how ICC Risk estimates the up and down parallel shifts for the US Dollar and Euro default-free discount term structures. The Risk Parameter Policy directs ICC to estimate and review the IR sensitivity requirement parameters at least monthly and specifies the corresponding governance process, noting the reviewers and any prerequisites to the implementation of parameter updates.

The Risk Parameter Policy discusses the setting and calibration of the parameters that are associated with the basis risk requirement. As index-derived SN positions and opposite ''outright'' SN positions are offset, the basis risk requirement is introduced to capture the differences between the trading characteristics of index instruments and their replicating baskets of SN constituents. In reference to the basis risk requirement parameters, the Risk Parameter Policy discusses how ICC Risk estimates the basis between index spreads for each index family and the basis attributable to the fact that the index and the SNs may have different coupons. ICC estimates and reviews the basis risk requirement parameters at least monthly, and the Risk Parameter Policy details the corresponding governance process, specifying the reviewers and any prerequisites to implementing parameter updates.

The parameters impacting the iSR requirement, which captures credit spread and RR fluctuations, are classified as either univariate or multivariate level. The standardized distributions that describe the behavior of credit spread log-returns are characterized by certain univariate level iSR parameters that are specified in the Risk Parameter Policy. Moreover, the Risk Parameter Policy discusses the estimation of the univariate level iSR parameters, including by considering time series analysis of credit spread log-returns. The Risk Parameter Policy explains how different mean absolute deviation (''MAD'') estimates are obtained for each time series. In addition, the Risk Parameter Policy references the setting of the exponentially weighted moving average (''EWMA'') decay rate (''EWMA factor''), along with the estimation of certain RF-specific parameters describing the SN RR distributions. The Risk Parameter Policy requires ICC to estimate, review, and perform sensitivity analyses on the univariate level iSR parameters at least

[3] ICC deems each index, sub-index, or underlying SN reference entity a separate RF.

[4] ICC deems a set of SN RFs related by a common parental ownership structure a RFG.

monthly and specifies the associated governance process, including the reviewers and any prerequisites to the implementation of parameter updates.

The Risk Parameter Policy contains information regarding the process of determining and reviewing the multivariate level iSR parameters. Using a simulation framework, ICC generates spread and RR scenarios by means of copulas to connect the univariate distributions that describe spread and RR fluctuations. The Risk Parameter Policy describes the multivariate parameters that serve as inputs to the copula simulations. Namely, the Risk Parameter Policy specifies the setting of a certain parameter to reflect tail dependence, a concept indicating the probability of extreme values occurring jointly. The Risk Parameter Policy also references the estimation of the Kendall tau rank-order correlations for the copula simulations. ICC estimates and reviews the multivariate level iSR parameters at least monthly, and the Risk Parameter Policy notes the corresponding governance process, including the reviewers.

Sensitivity Analysis

The Risk Parameter Policy details the sensitivity analyses that ICC Risk performs to explore the sensitivity of the risk management system's outputs to certain model core parameters that are calibrated on an ad-hoc basis and to alternative data analyses and parameter estimation techniques.

ICC conducts a sensitivity analysis on the univariate level iSR parameters by utilizing alternative techniques to estimate the parameters that fit the standardized distributions to the observed credit spread log-return data. The Risk Parameter Policy also considers the impact of the alternatively estimated parameters. This sensitivity analysis is reviewed with the RWG monthly and provides information if a change to the current estimation technique is considered. Further, the Risk Parameter Policy distinguishes two levels of sensitivity analyses, those that include a clearinghouse-wide portfolio impact study and those, such as this one, that do not include a portfolio impact study.

ICC performs a sensitivity analysis, which does not include a portfolio impact study, by introducing different values for the EWMA factor. The Risk Parameter Policy discusses the impact of using different values for this univariate level iSR parameter and requires ICC to review this sensitivity analysis monthly with the RWG.

Under the Risk Parameter Policy, ICC carries out a sensitivity analysis on the routinely updated parameters. The Risk Parameter Policy identifies certain parameters that are updated routinely (*i.e.,* daily or monthly) and are subject to a sensitivity analysis with a clearinghouse-wide portfolio impact study. The Risk Parameter Policy requires that the results of the proposed parameter updates are reviewed with the RWG prior to implementation and notes that this sensitivity analysis provides information regarding potential risk requirement changes due to routine parameter updates.

The portfolio benefits parameters are subject to a sensitivity analysis that includes a clearinghouse-wide portfolio impact study. Namely, ICC Risk estimates certain risk measures at pre-defined quantile levels by incorporating different dependence structures in order to guide ICC Risk in situations where back-testing results indicate excessive portfolio benefits. Under the Risk Parameter Policy, this sensitivity analysis is reviewed with the Risk Committee monthly.

Since the model allows the level of SWWR collateralization to be controlled by a model threshold, ICC conducts a sensitivity analysis for the SWWR threshold. ICC explores the maximum SWWR charges by requiring full collateralization of index-derived SWWR. This sensitivity analysis includes a clearinghouse-wide portfolio impact study and guides ICC Risk when there is a decision to fully collateralize SWWR. Under the Risk Parameter Policy, this sensitivity analysis is reviewed with the Risk Committee monthly.

ICC performs a sensitivity analysis on MAD levels by shifting all MAD estimates to their stress levels to provide information about the response of risk requirements to potential volatility shifts and to assess the viability of certain parameter-setting assumptions. This sensitivity analysis includes a clearinghouse-wide portfolio impact study and is reviewed monthly with the Risk Committee.

ICC Risk performs a sensitivity analysis for the Guaranty Fund (''GF'') JTD configuration. ICC's GF model aims to establish financial resources that are sufficient to cover hypothetical losses associated with simultaneous credit events where up to five SN RFGs are impacted. In that, two of the selected SN RFGs are CP SN RFGs (*i.e.,* Cover-2 GF sizing) and the other three SN RFGs are non-CP RFGs. ICC considers an alternative where three of the selected SN RFGs are CP SN RFGs (*i.e.,* Cover-3 GF sizing) and the other two are non-CP SN RFGs. This sensitivity analysis includes a clearinghouse-wide portfolio impact study, provides information when a change to the GF JTD configuration is considered, and is reviewed with the Risk Committee monthly.

(b) Statutory Basis

Section 17A(b)(3)(F) of the Act [5] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to the extent applicable, derivative agreements, contracts and transactions; to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible; in general, to protect investors and the public interest; and to comply with the provisions of the Act and the rules and regulations thereunder. ICC believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to ICC, in particular, to Section 17(A)(b)(3)(F),[6] because ICC believes that the proposed rule change to formalize the Risk Parameter Policy promotes the soundness of ICC's model. The Risk Parameter Policy describes ICC's process of setting and reviewing the model core parameters, in addition to the details surrounding ICC's performance of sensitivity analyses. The Risk Parameter Policy provides assurances as to the appropriateness of model core parameter settings and, accordingly, the appropriateness of margin requirements, thereby facilitating ICC's ability to promptly and accurately clear and settle its cleared CDS contracts; enhancing ICC's ability to assure the safeguarding of securities and funds which are in the custody or control of ICC or for which it is responsible; and protecting investors and the public interest. Moreover, ICC believes that having policies and procedures that clearly and accurately document ICC's process of setting and reviewing the model core parameters, along with ICC's performance of sensitivity analyses, is an important component to the effectiveness of ICC's risk management system, which promotes the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions; the safeguarding of securities and funds which are in the custody or control of ICC or for which it is responsible; and the protection of investors and the public interest. As such, the proposed

[5] 15 U.S.C. 78q–1(b)(3)(F).

[6] *Id.*

rule change is designed to promote the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions; to contribute to the safeguarding of securities and funds associated with security-based swap transactions in ICC's custody or control, or for which ICC is responsible; and, in general, to protect investors and the public interest within the meaning of Section 17A(b)(3)(F) of the Act.[7]

In addition, the proposed rule change is consistent with the relevant requirements of Rule 17Ad–22.[8] Rule 17Ad–22(b)(2)[9] requires ICC to establish, implement, maintain and enforce written policies and procedures reasonably designed to use margin requirements to limit its credit exposures to participants under normal market conditions and use risk-based models and parameters to set margin requirements and review such margin requirements and the related risk-based models and parameters at least monthly. Under the Risk Parameter Policy, ICC estimates and reviews the model core parameter settings at least monthly and performs and reviews sensitivity analyses related to certain parameter settings monthly. Such procedures serve to promote the soundness of ICC's model and to ensure that ICC's risk management system is effective and appropriate in addressing the risks associated with clearing security based swap-related portfolios. Namely, by requiring that ICC regularly review the model core parameter settings and sensitivity analyses related to certain parameter settings, the Risk Parameter Policy promotes ICC's use of margin requirements to limit its credit exposures to participants under normal market conditions and ICC's use of risk-based models and parameters to set margin requirements and review such margin requirements and the related risk-based models and parameters at least monthly, consistent with Rule 17Ad–22(b)(2).[10]

Rule 17Ad–22(b)(3)[11] requires ICC to establish, implement, maintain and enforce written policies and procedures reasonably designed to maintain sufficient financial resources to withstand, at a minimum, a default by the two CP families to which it has the largest exposures in extreme but plausible market conditions. The Risk Parameter Policy assures the appropriateness of model core parameter settings through a regular review process involving various reviewers, which supports ICC's ability to maintain sufficient margin requirements and enhances ICC's approach to identifying potential weaknesses, thereby ensuring that ICC continues to maintain sufficient financial resources to withstand, at a minimum, a default by the two CP families to which it has the largest exposures in extreme but plausible market conditions, consistent with the requirements of Rule 17Ad–22(b)(3).[12]

Rule 17Ad–22(d)(8)[13] requires ICC to establish, implement, maintain and enforce written policies and procedures reasonably designed to have governance arrangements that are clear and transparent to fulfill the public interest requirements in Section 17A of the Act.[14] The Risk Parameter Policy clearly assigns and documents responsibility and accountability for the estimation and review of the model core parameters and the performance of sensitivity analyses. Moreover, the Risk Parameter Policy describes the methods used to review parameter settings and perform sensitivity analyses, the frequency of the reviews, the groups involved in the review process, and any prerequisites to implementing parameter updates. These governance arrangements are clear and transparent, such that information relating to the assignment of responsibilities and the requisite involvement of ICC Risk, the RWG, and the Risk Committee is clearly documented, consistent with the requirements of Rule 17Ad–22(d)(8).[15]

(B) Clearing Agency's Statement on Burden on Competition

ICC does not believe the proposed rule change would have any impact, or impose any burden, on competition. The proposed change to formalize the Risk Parameter Policy will apply uniformly across all market participants. Therefore, ICC does not believe the proposed rule change imposes any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–ICC–2019–002 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–ICC–2019–002. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of

[7] *Id.*

[8] 17 CFR 240.17Ad–22.

[9] 17 CFR 240.17Ad–22(b)(2).

[10] *Id.*

[11] 17 CFR 240.17Ad–22(b)(3).

[12] *Id.*

[13] 17 CFR 240.17Ad–22(d)(8).

[14] 15 U.S.C. 78q–1.

[15] 17 CFR 240.17Ad–22(d)(8).

10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's website at *https://www.theice.com/clear-credit/regulation.*

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICC–2019–002 and should be submitted on or before March 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03038 Filed 2–21–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85153; File No. SR–NASDAQ–2019–007]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Proposed Rule Change To Reassign Certain Investigation and Enforcement Functions Under the Exchange's Authority and Supervision

February 15, 2019.

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 February 5, 2019, 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 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 proposes to assume operational responsibility for certain investigation and enforcement functions currently performed by the Financial Industry Regulatory Authority (''FINRA'') under the Exchange's authority and supervision. Nasdaq Rule 0150 requires Commission approval for this transfer of operational responsibility to Nasdaq. Nasdaq anticipates a phased transition, whereby Nasdaq would assume increasing responsibility throughout 2019 and into early 2020 for investigation and enforcement activities for certain conduct occurring on the Nasdaq and Nasdaq BX, Inc. (''BX'') markets (collectively, the ''Exchanges'').

The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the 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

Section 6 of the Act requires that national securities exchanges enforce their members' compliance with federal securities laws and rules as well as the exchanges' own rules.[3] As a self-regulatory organization (''SRO''), Nasdaq must have a comprehensive regulatory program that includes investigation and prosecution of suspicious activity. Since it became a national securities exchange, Nasdaq has contracted with FINRA through various regulatory services agreements (''RSAs'') to perform certain of these regulatory functions on its behalf. However, as the Commission has made clear, ''the Nasdaq Exchange bears the responsibility for self-regulatory conduct and primary liability for self-regulatory failures, not the SRO retained to perform regulatory functions on the Exchange's behalf.''[4]

Notwithstanding its use of FINRA, the Exchange has also retained operational responsibility for a number of regulatory functions, including real-time surveillance, qualification of companies listed on Nasdaq and most surveillance related to its affiliated options markets. Historically, Nasdaq retained operational responsibility in areas where Nasdaq's expertise regarding its own markets, technology and listed companies enhanced regulation. In recognition of this, on September 30, 2013, the Commission approved Nasdaq's proposal to reallocate operational responsibility from FINRA to Nasdaq for certain equities surveillance patterns and related review functions, focused on: (1) Manipulation patterns that monitor solely Nasdaq activity; and (2) monitoring of compliance by member firms with elements of the Commission's Regulation M and Nasdaq Rule 4619 compliance.[5]

Building on Nasdaq's experience and expertise, this proposal reflects a natural evolution of Nasdaq's proven model to assume and retain operational responsibility in areas where its in-depth knowledge of its markets and members enhances market regulation. For the reasons outlined below, Nasdaq now seeks Commission approval to reallocate operational responsibility from FINRA to Nasdaq Regulation[6] for certain investigation and enforcement activity, namely:

- Investigation and enforcement responsibilities for conduct occurring on its options markets (The BX Options Market and The Nasdaq Options Market), and
- investigation and enforcement responsibilities for conduct occurring on the Nasdaq and BX equity markets only, *i.e.,* not also on non-Nasdaq equities markets.[7]

Currently, under RSAs, FINRA is responsible for, among other things, the investigation of matters referred from Nasdaq MarketWatch and the Phlx Market Surveillance department. FINRA is also responsible for providing services related to Nasdaq's formal disciplinary process, including the issuance of Wells Notices, Cautionary Action Letters, Complaints, and settlement documents.

Nasdaq now proposes to perform these functions and is seeking Commission approval to do so. Nasdaq

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[16] 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. 78(f).

[4] Securities Exchange Act Release No. 53128 (January 13, 2006), 71 FR 3550, 3556 (January 23, 2006).

[5] Securities Exchange Act Release No. 70569 (September 30, 2013), 78 FR 62814 (October 22, 2013) (SR–NASDAQ–2013–102).

[6] Under Nasdaq Rule 9120(t), Nasdaq Regulation includes the Nasdaq Enforcement Department.

[7] Nasdaq Regulation currently performs these functions for the Nasdaq PHLX LLC (''Phlx''), Nasdaq ISE, LLC (''ISE''), Nasdaq GEMX, LLC (''GEMX''), and Nasdaq MRX, LLC (''MRX'') because there is no comparable rule to Rule 0150 on those markets.

believes that its expertise in its own market structure coupled with its expertise in surveillance activities will enable it to conduct investigation and enforcement responsibilities for the Exchanges effectively, efficiently and with immediacy. In addition, this proposal represents an incremental reallocation of operational responsibility because Nasdaq Regulation currently performs investigative and enforcement work on behalf of Phlx, ISE, GEMX, and MRX, providing it with relevant experience to perform these functions for the Exchanges as well. Most recently, Phlx filed for immediate effectiveness amendments to the Phlx's rules that vested its Regulation Department with investigation and enforcement authority.[8] Nasdaq now seeks Commission approval to exercise this same authority for conduct on the Exchanges that it already exercises for Phlx, ISE, GEMX, and MRX.

Notwithstanding this proposal, FINRA will continue to have responsibility for, among other things: (1) The investigation and enforcement of conduct occurring on the Nasdaq and BX equity markets that also relates to cross market activity on non-Nasdaq exchanges; (2) the handling of contested disciplinary proceedings arising out of Nasdaq Regulation-led investigation and enforcement activities; and (3) matters covered by agreements to allocate regulatory responsibility under Rule 17d–2 of the Act. As with all investigation and enforcement work, all tasks delegated to FINRA are subject to Nasdaq's supervision and ultimate responsibility.

Nasdaq Regulation has instituted the requisite infrastructure to accommodate the internalization of investigative and enforcement work on behalf of the Exchanges. Specifically, Nasdaq created a new investigation and enforcement group to perform the functions covered by this proposal, which included hiring additional staff. Nasdaq is also leveraging its existing staff of experienced analysts, lawyers, programmers, and market structure experts to assist, where necessary, with performing the new functions covered by this proposal. In addition, Nasdaq Regulation has developed comprehensive plans covering the transition and has met regularly for more than one year to ensure a smooth transition of the work and prevent any gaps in regulatory coverage. Finally, Nasdaq filed for immediate effectiveness amendments to its rules to vest the Nasdaq Enforcement Department with the investigative and enforcement authority that Nasdaq now seeks to exercise.[9]

Nasdaq anticipates a phased transition of investigative and enforcement responsibility, whereby Nasdaq would assume increasing investigation and enforcement responsibility throughout 2019 and into early 2020 for the conduct occurring on the Exchanges. Nasdaq also anticipates transitioning certain matters currently pending with FINRA to the Nasdaq Enforcement Department if Nasdaq Regulation believes doing so is consistent with ensuring prompt resolution of regulatory matters.

Nasdaq Rule 0150 requires that Nasdaq obtain Commission approval if regulatory functions subject to RSAs in effect at the time that Nasdaq began to operate as a national securities exchange are no longer performed by FINRA or another independent SRO. For the reasons stated above, Nasdaq believes that the reassignment of investigation and enforcement responsibility will further its regulatory program and benefit investors and the markets. Commission approval of the proposal would allow Nasdaq: To better leverage its surveillance, investigation, and enforcement teams; to deliver increased efficiencies in the regulation of its market; and to act promptly and provide more effective regulation.

In addition, Nasdaq notes that its proposal is consistent with, but more limited than, investigation and enforcement work performed by other national securities exchanges. For example, in 2015, the SEC approved the New York Stock Exchange's (''NYSE'') application whereby NYSE amended certain of its disciplinary rules to facilitate the reintegration of certain market surveillance, investigation and enforcement functions performed on behalf of NYSE by FINRA.[10] Unlike NYSE, however, Nasdaq will also continue to rely on FINRA to prosecute contested matters before a Hearing Panel.[11]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Section 6(b)(5) of the Act,[13] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange believes that this proposal is in keeping with those principles because it leverages Nasdaq's extensive operational experience and expertise in regulating its markets and marries Nasdaq's surveillance capabilities with its surveillance, investigation and enforcement staff, thereby increasing effectiveness and enabling prompt action. Nasdaq believes that it can achieve these important objectives because it is uniquely positioned to understand conduct on its own markets and take timely action when appropriate to investigate potential violations and enforce the rules to punish and deter misconduct, hold bad actors accountable, and protect investors and market integrity. In this regard, Nasdaq Regulation's surveillance, investigative and enforcement teams work together to identify and review potentially violative conduct. This results in more effective regulation because it facilitates timely and more efficient action. Indeed, the underlying driving force for the current proposal is Nasdaq's belief that it can conduct this regulatory work more effectively and efficiently given its technology, structure and in-depth knowledge of its markets and members. For these reasons, Nasdaq believes it can conduct investigative and enforcement functions in a thorough and timely manner, thereby promoting the fair and orderly operation of the markets and serving the interests of market participants and investors. In so doing, Nasdaq Regulation will fulfill the Commission's mandate that Nasdaq bear

[8] *See* Securities Exchange Act Release No. 82143 (November 22, 2017), 82 FR 56672 (November 29, 2017) (SR–Phlx–2017–92) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Investigatory and Disciplinary Processes Substantially Similar to Nasdaq BX, Inc. and The Nasdaq Stock Market LLC for Phlx, which, among other things, similarly enabled Phlx to retain discretion to perform these functions).

[9] Securities Exchange Act Release No. 84355 (October 3, 2018), 83 FR 51015 (October 10, 2018) (SR–NASDAQ–2018–066).

[10] *See* Securities Exchange Act Release No. 75721 (August 18, 2015), 80 FR 51334 (August 24, 2015) and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 3 and 5, Amending Exchange Disciplinary Rules to Facilitate the Reintegration of Certain Regulatory Functions from Financial Industry Regulatory Authority, Inc., Securities Exchange Act Release No. 76436 (November 13, 2015), 80 FR 72460 (November 19, 2015) (SR–NYSE–2015–35).

[11] *See* Nasdaq Rule 9120(q) (''The term ''Hearing Panel'' means an Adjudicator that is constituted under Rule 9231 to conduct a disciplinary proceeding governed by the Rule 9200 Series, that is constituted under the Rule 9520 Series or the Rule 9550 Series to conduct a proceeding, or that is constituted under the Rule 9800 Series to conduct a temporary cease and desist proceeding.'').

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

responsibility for self-regulatory conduct.[14]

Nasdaq will continue to refer certain potentially violative conduct to FINRA for further review, including matters covered by agreements to allocate regulatory responsibility under Rule 17d–2 of the Act. Moreover, FINRA will continue to have responsibility for, among other things, the investigation and enforcement of conduct occurring on the Nasdaq and BX equity markets that also occurs on non-Nasdaq exchanges, as well as the handling of contested disciplinary proceedings arising out of Nasdaq Regulation-led investigation and enforcement activities. All referrals to FINRA remain subject to Nasdaq's supervision and ultimate responsibility.

Nasdaq also believes that the proposal is consistent with the Act because, as the Commission has made clear, Nasdaq bears the ultimate responsibility for self-regulatory conduct and primary liability for self-regulatory failures.[15] In addition, Nasdaq notes that its proposal is consistent with, but more limited than, investigation and enforcement work performed by NYSE. As noted above, the SEC approved NYSE's application to amend certain of its disciplinary rules to facilitate the reintegration of certain market surveillance, investigation and enforcement functions performed on behalf of NYSE by FINRA.[16] Nasdaq believes it would therefore be consistent with the Act for Nasdaq to perform more limited investigation and enforcement work than NYSE.

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 is not intended to address competitive issues but rather to enable the Exchange to directly investigate and initiate disciplinary actions following the integration of certain regulatory functions from FINRA.

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.

[14] *See* supra note 4.

[15] *Id.*

[16] *See* supra note 10.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2019–007 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–2019–007. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2019–007 and should be submitted on or before March 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03040 Filed 2–21–19; 8:45 am]

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[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85160; File No. SR–NYSE–2018–28]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Make Permanent the Retail Liquidity Program Pilot, Rule 107C, Which is Set To Expire on June 30, 2019, Notice of Filing of Amendment No. 1, and Order Granting Limited Exemption Pursuant to Rule 612(c) of Regulation NMS

February 15, 2019.

I. Introduction

On June 4, 2018, New York Stock Exchange LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to make permanent Exchange Rule 107C governing the Exchange's Retail Liquidity Program Pilot (''Program''). The proposed rule change was published for comment in the **Federal Register** on June 21, 2018.[3] On July 31, 2018, pursuant to Section 19(b)(2) of the Act,[4] the Commission extended to September 19, 2018 the time period in which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 83454 (June 15, 2018), 83 FR 28874 (''Original Notice'').

[4] 15 U.S.C. 78s(b)(2).

determine whether to disapprove the proposed rule change.[5] On September 18, 2018, the Commission issued an order instituting proceedings under Section 19(b)(2)(B) of the Exchange Act,[6] to determine whether to approve or disapprove the proposed rule change.[7] On December 10, 2018, pursuant to Section 19(b)(2) of the Act,[8] the Commission extended to February 16, 2019 the time period in which to issue an order approving or disapproving the proposed rule change.[9]

The Commission received one comment letter on the proposed rule change.[10] On February 13, 2019, the Exchange filed Amendment No. 1 to the proposed rule change, which supersedes and replaces the original filing in its entirety.[11] In connection with the proposed rule change, as modified by Amendment No. 1, the Exchange requests exemptive relief from Rule 612 of Regulation NMS,[12] which, among other things, prohibits a national securities exchange from accepting or ranking orders priced greater than $1.00 per share in an increment smaller than $0.01.[13] The Commission is publishing this notice to solicit comments on Amendment No. 1 from interested persons, issuing this order approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis, and issuing this order granting to the Exchange a limited exemptive relief pursuant to Rule 612(c) of Regulation NMS.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1

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 those statements may be examined at the places specified in Item V 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 make permanent Rule 107C, which sets forth the Exchange's pilot Retail Liquidity Program (the ''Program''). In support of the proposal to make the pilot Program permanent, the Exchange believes it is appropriate to provide background on the Program and an analysis of the economic benefits for retail investors and the marketplace flowing from operation of the Program.

Background

In July 2012, the Securities and Exchange Commission (the ''Commission'') approved the Program on a pilot basis.[14] The purpose of the pilot was to analyze data and assess the impact of the Program on the marketplace. The pilot period was originally scheduled to end on July 31, 2013. The Exchange filed to extend the operation of the pilot on several occasions in order to prepare this rule filing. The pilot is currently set to expire on the earlier of approval of this filing or June 30, 2019.[15]

The Exchange established the Program to attract retail order flow to the Exchange, and allow such order flow to receive potential price improvement.[16] The Program is currently limited to trades occurring at prices equal to or greater than $1.00 a share.

As described in greater detail below, under Rule 107C, a new class of market participant called Retail Liquidity Providers (''RLPs'')[17] and non-RLP member organizations are able to provide potential price improvement to retail investor orders in the form of a non-displayed order that is priced better than the best protected bid or offer (''PBBO''), called a Retail Price Improvement Order (''RPI''). When there is an RPI in a particular security, the Exchange disseminates an indicator, known as the Retail Liquidity Identifier (''RLI''), that such interest exists. Retail Member Organizations (''RMOs'') can submit a Retail Order to the Exchange, which interacts, to the extent possible, with available contra-side RPIs and Mid-Point Passive Liquidity (''MPL'') Orders.[18] The segmentation in the Program allows retail order flow to receive potential price improvement as a result of their order flow being deemed more desirable by liquidity providers.[19]

In approving the pilot, the Commission concluded that the Program was reasonably designed to benefit retail investors by providing price improvement opportunities to retail order flow. Further, while the Commission noted that the Program would treat retail order flow differently from order flow submitted by other market participants, such segmentation would not be inconsistent with Section 6(b)(5) of the Act,[20] which requires that

[5] *See* Securities Exchange Act Release No. 83749, 83 FR 38393 (August 6, 2018).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 84183, 83 FR 48350 (September 24, 2018) (''Order Instituting Proceedings'').

[8] 15 U.S.C. 78s(b)(2).

[9] *See* Securities Exchange Act Release No. 84766, 83 FR 64414 (December 14, 2018).

[10] *See* Letter from Tyler Gellasch, Executive Director, Healthy Markets Association, dated December 20, 2018 (''HMA Letter'').

[11] *See infra* Section II.

[12] 17 CFR 242.612(c).

[13] *See* note 14 *infra*.

[14] *See* Securities Exchange Act Release No. 67347 (July 3, 2012), 77 FR 40673 (July 10, 2012) (SR–NYSE–2011–55) (''RLP Approval Order''). In addition to approving the Program on a pilot basis, the Commission granted the Exchange's request for exemptive relief from Rule 612 of Regulation NMS, 17 CFR 242.612 (''Sub-Penny Rule''), which among other things prohibits a national securities exchange from accepting or ranking orders priced greater than $1.00 per share in an increment smaller than $0.01. *See id.* As part of this filing, and pursuant to the Exchange's separate written request, the Exchange also requests that the exemptive relief from the Sub-Penny Rule be made permanent. *See* Letter from Martha Redding, Associate General Counsel and Assistant Corporate Secretary, New York Stock Exchange, to Brent J. Fields, Secretary, Securities and Exchange Commission, dated February 13, 2019 (''Sub-Penny Rule Exemption Request'').

[15] *See* Securities Exchange Act Release No. 84767 (December 10, 2018), 83 FR 64412 (December 14, 2018) (SR–NYSE–2018–59). *See also* Securities Exchange Act Release No. 82230 (December 7, 2017), 82 FR 58667 (December 13, 2017) (SR–NYSE–2017–64) (extending pilot to June 30, 2018); Securities Exchange Act Release No. 80844 (June 1, 2017), 82 FR 26562 (June 7, 2017) (SR–NYSE–2017–26) (extending pilot to December 31, 2017); Securities Exchange Act Release No. 79493 (December 7, 2016), 81 FR 90019 (December 13, 2016) (SR–NYSE–2016–82) (extending pilot to June 30, 2017); Securities Exchange Act Release No. 78600 (August 17, 2016), 81 FR 57642 (August 23, 2016) (SR–NYSE–2016–54) (extending pilot to December 31, 2016); Securities Exchange Act Release No. 77426 (March 23, 2016), 81 FR 17533 (March 29, 2016) (SR–NYSE–2016–25) (extending pilot to August 31, 2016); Securities Exchange Act Release No. 75993 (September 28, 2015), 80 FR 59844 (October 2, 2015) (SR–NYSE–2015–41) (extending pilot to March 31, 2016); Securities Exchange Act Release No. 74454 (March 6, 2015), 80 FR 13054 (March 12, 2015) (SR–NYSE–2015–10) (extending pilot until September 30, 2015); Securities Exchange Act Release No. 72629 (July 16, 2014), 79 FR 42564 (July 22, 2014) (NYSE–2014–35) (extending pilot until March 31, 2015); Securities Exchange Act Release No. 70096 (Aug. 2, 2013), 78 FR 48520 (Aug. 8, 2013) (SR–NYSE–2013–48) (extending pilot to July 31, 2014); and Securities Exchange Act Release No. 83540 (June 28, 2018), 83 FR 31234 (July 3, 2018) (SR–NYSE–2018–29) (extending pilot to December 31, 2018).

[16] RLP Approval Order, 77 FR at 40674.

[17] The Program also allows for RLPs to register with the Exchange. However, any firm can enter RPI orders into the system. Currently, four firms are registered as RLPs but are not registered in any symbols.

[18] The Exchange adopted MPL Orders in 2014 and amended Rule 107C to specify that MPL Orders could interact with incoming, contra-side Retail Orders submitted by a RMO in the Program. *See* Securities Exchange Act Release No. 71330 (January 16, 2014), 79 FR 3895 (January 23, 2014) (SR–NYSE–2013–71) (''Release No. 71330'').

[19] RLP Approval Order, 77 FR at 40679.

[20] 15 U.S.C. 78f(b)(5).

the rules of an exchange are not designed to permit unfair discrimination. As the Commission recognized, retail order segmentation was designed to create additional competition for retail order flow, leading to additional retail order flow to the exchange environment and ensuring that retail investors benefit from the better price that liquidity providers are willing to give their orders.[21]

As discussed below, the Exchange believes that the Program data supports these conclusions and that it is therefore appropriate to make the pilot Program permanent.[22]

Description of Pilot Rule 107C That Would Become Permanent

Definitions

Rule 107C(a) contains the following definitions:

• First, the term ''Retail Liquidity Provider'' is defined as a member organization that is approved by the Exchange under the Rule to act as such and to submit Retail Price Improvement Orders in accordance with the Rule.[23]

• Second, the term ''Retail Member Organization'' (''RMO'') is defined as a member organization (or a division thereof) that has been approved by the Exchange to submit Retail Orders.[24]

• Third, the term ''Retail Order'' means an agency order or a riskless principal order meeting the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a RMO, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. A Retail Order is an Immediate or Cancel Order and may be an odd lot, round lot, or partial round lot (''PRL'').[25]

• Finally, the term ''Retail Price Improvement Order'' means non-displayed interest in NYSE-listed securities that is better than the best protected bid (''PBB'') or best protected offer (''PBO'') by at least $0.001 and that is identified as a Retail Price Improvement Order in a manner prescribed by the Exchange.[26]

RMO Qualifications and Application Process

Under Rule 107C(b), any member organization [27] can qualify as an RMO if it conducts a retail business or routes [28] retail orders on behalf of another broker-dealer. For purposes of Rule 107C(b), conducting a retail business includes carrying retail customer accounts on a fully disclosed basis. To become an RMO, a member organization must submit: (1) An application form; (2) supporting documentation sufficient to demonstrate the retail nature and characteristics of the applicant's order flow; [29] and (3) an attestation, in a form prescribed by the Exchange, that any order submitted by the member organization as a Retail Order would meet the qualifications for such orders under Rule 107C.[30]

An RMO must have written policies and procedures reasonably designed to assure that it will only designate orders as Retail Orders if all requirements of a Retail Order are met. Such written policies and procedures must require the member organization to (i) exercise due diligence before entering a Retail Order to assure that entry as a Retail Order is in compliance with the requirements of Rule 107C, and (ii) monitor whether orders entered as Retail Orders meet the applicable requirements. If the RMO represents Retail Orders from another broker-dealer customer, the RMO's supervisory procedures must be reasonably designed to assure that the orders it receives from such broker-dealer customer that it designates as Retail Orders meet the definition of a Retail Order. The RMO must (i) obtain an annual written representation, in a form acceptable to the Exchange, from each broker-dealer customer that sends it orders to be designated as Retail Orders that entry of such orders as Retail Orders will be in compliance with the requirements of this rule, and (ii) monitor whether its broker-dealer customer's Retail Order flow continues to meet the applicable requirements.[31]

Following submission of the required materials, the Exchange provides written notice of its decision to the member organization.[32] A disapproved applicant can appeal the disapproval by the Exchange as provided in Rule 107C(4), and/or reapply for RMO status 90 days after the disapproval notice is issued by the Exchange. An RMO can also voluntarily withdraw from such status at any time by giving written notice to the Exchange.[33]

RLP Qualifications

To qualify as an RLP under Rule 107C(c), a member organization must: (1) Already be approved as a Designated Market Maker (''DMM'') or Supplemental Liquidity Provider (''SLP''); (2) demonstrate an ability to meet the requirements of an RLP; (3) have mnemonics or the ability to accommodate other Exchange-supplied designations that identify to the Exchange RLP trading activity in assigned RLP securities; and (4) have adequate trading infrastructure and technology to support electronic trading.[34]

[21] RLP Approval Order, 77 FR at 40679.

[22] Rule 107C has been amended several times. *See* Securities Exchange Act Release No. 68709 (January 23, 2013), 78 FR 6160 (January 29, 2013) (SR–NYSE–2013–04) (amending Rule 107C to clarify that Retail Liquidity Providers may enter Retail Price Improvement Orders in a non-RLP capacity for securities to which the RLP is not assigned); 69103 (March 11, 2013), 78 FR 16547 (March 15, 2013) (SR–NYSE–2013–20) (amending Rule 107C to clarify that a Retail Member Organization may submit Retail Orders to the Program in a riskless principal capacity as well as in an agency capacity, provided that (i) the entry of such riskless principal orders meets the requirements of FINRA Rule 5320.03, including that the RMO maintains supervisory systems to reconstruct, in a time-sequenced manner, all Retail Orders that are entered on a riskless principal basis; and (ii) the RMO does not include non-retail orders together with the Retail Orders as part of the riskless principal transaction); 69513 (May 3, 2013), 78 FR 27261 (May 9, 2013) (SR–NYSE–2013–08) (amending Rule 107C to allow Retail Member Organizations to attest that ''substantially all,'' rather than all, orders submitted to the Program qualifies as ''Retail Orders'' under the Rule); Release No. 71330, 79 FR at 3895 (amending Rule 107C to incorporate MPL Orders); and 76553 (December 3, 2015), 80 FR 76607 (December 9, 2015) (SR–NYSE–2015–59) (''Release No. 76553'') (amending Rule 107C to distinguish between retail orders routed on behalf of other broker-dealers and retail orders that are routed on behalf of introduced retail accounts that are carried on a fully disclosed basis).

[23] *See* Rule 107C(a)(1).

[24] *Id.* at (2).

[25] *Id.* at (3).

[26] *Id.* at (4). Exchange systems prevent Retail Orders from interacting with Retail Price Improvement Orders if the RPI is not priced at least $0.001 better than the PBBO. An RPI remains non-displayed in its entirety (the buy or sell interest, the offset, and the ceiling or floor). An RLP would only be permitted to enter a Retail Price Improvement Order for the particular security or securities to which it is assigned as RLP. An RLP is permitted, but not required, to submit RPIs for securities to which it is not assigned, and will be treated as a non-RLP member organization for those particular securities. Additionally, member organizations other than RLPs are permitted, but not required, to submit RPIs. An RPI may be an odd lot, round lot, or PRL. *See id.*

[27] An RLP may also act as an RMO for securities to which it is not assigned, subject to the qualification and approval process established by the proposed rule.

[28] *See* Release No. 76553, 80 FR at 76607 (clarifying that one way to qualify as an RMO is to route retail orders on behalf of other broker-dealers).

[29] The supporting documentation may include sample marketing literature, website screenshots, other publicly disclosed materials describing the member organization's retail order flow, and any other documentation and information requested by the Exchange in order to confirm that the applicant's order flow would meet the requirements of the Retail Order definition. *See* Rule 107C (b)(2)(B).

[30] *See id.* at (b)(2)(A)–(C).

[31] *Id.* at (b)(6).

[32] *Id.* at (b)(3).

[33] *Id.* at (b)(5).

[34] *Id.* at (c)(1)–(4).

RLP Application

Under Rule 107C(d), to become an RLP, a member organization must submit an RLP application form with all supporting documentation to the Exchange, which would determine whether an applicant was qualified to become an RLP as set forth above.[35] After an applicant submits an RLP application to the Exchange with supporting documentation, the Exchange would notify the applicant member organization of its decision. The Exchange could approve one or more member organizations to act as an RLP for a particular security. The Exchange could also approve a particular member organization to act as RLP for one or more securities. Approved RLPs would be assigned securities according to requests made to, and approved by, the Exchange.[36]

If an applicant were approved by the Exchange to act as an RLP, the applicant would be required to establish connectivity with relevant Exchange systems before the applicant would be permitted to trade as an RLP on the Exchange.[37] If the Exchange disapproves the application, the Exchange would provide a written notice to the member organization. The disapproved applicant could appeal the disapproval by the Exchange as provided in proposed Rule 107C(i) and/or reapply for RLP status 90 days after the disapproval notice is issued by the Exchange.[38]

Voluntary Withdrawal of RLP Status

An RLP would be permitted to withdraw its status as an RLP by giving notice to the Exchange under proposed NYSE Rule107C(e). The withdrawal would become effective when those securities assigned to the withdrawing RLP are reassigned to another RLP. After the Exchange receives the notice of withdrawal from the withdrawing RLP, the Exchange would reassign such securities as soon as practicable, but no later than 30 days after the date the notice is received by the Exchange. If the reassignment of securities takes longer than the 30-day period, the withdrawing RLP would have no further obligations and would not be held responsible for any matters concerning its previously assigned RLP securities.[39]

RLP Requirements

Under Rule 107C(f), an RLP may only enter Retail Price Improvement Orders electronically and directly into Exchange systems and facilities designated for this purpose and only for the securities to which it is assigned as RLP. An RLP entering Retail Price Improvement Orders in securities to which it is not assigned is not required to satisfy these requirements.[40]

In order to be eligible for execution fees that are lower than non-RLP rates, an RLP must maintain (1) a Retail Price Improvement Order that is better than the PBB at least five percent of the trading day for each assigned security; and (2) a Retail Price Improvement Order that is better than the PBO at least five percent of the trading day for each assigned security.[41] An RLP's five-percent requirements is calculated by determining the average percentage of time the RLP maintains a Retail Price Improvement Order in each of its RLP securities during the regular trading day, on a daily and monthly basis.[42] The Exchange determines whether an RLP has met this requirement by calculating the following:

- The ''Daily Bid Percentage,'' calculated by determining the percentage of time an RLP maintains a Retail Price Improvement Order with respect to the PBB during each trading day for a calendar month;
- The ''Daily Offer Percentage,'' calculated by determining the percentage of time an RLP maintains a Retail Price Improvement Order with respect to the PBO during each trading day for a calendar month;
- The ''Monthly Average Bid Percentage,'' calculated for each RLP security by summing the security's ''Daily Bid Percentages'' for each trading day in a calendar month then dividing the resulting sum by the total number of trading days in such calendar month; and
- The ''Monthly Average Offer Percentage,'' calculated for each RLP security by summing the security's ''Daily Offer Percentage'' for each trading day in a calendar month and then dividing the resulting sum by the total number of trading days in such calendar month.

Finally, only Retail Price Improvement Orders would be used when calculating whether an RLP is in compliance with its five-percent requirements.[43]

The five-percent requirement is not applicable in the first two calendar months a member organization operates as an RLP and takes effect on the first day of the third consecutive calendar month the member organization operates as an RLP.[44]

Failure of RLP To Meet Requirements

Rule 107C(g) addresses the consequences of an RLP's failure to meet its requirements. If, after the first two months an RLP acted as an RLP, an RLP fails to meet any of the Rule 107C(f) requirements for an assigned RLP security for three consecutive months, the Exchange could, in its discretion, take one or more of the following actions:

- Revoke the assignment of any or all of the affected securities from the RLP;
- revoke the assignment of unaffected securities from the RLP; or
- disqualify the member organization from its status as an RLP.[45]

The Exchange determines if and when a member organization is disqualified from its status as an RLP. One calendar month prior to any such determination, the Exchange notifies an RLP of such impending disqualification in writing. When disqualification determinations are made, the Exchange provides a written disqualification notice to the member organization.[46] A disqualified RLP could appeal the disqualification as provided in proposed Rule 107C(i) and/or reapply for RLP status 90 days after the disqualification notice is issued by the Exchange.[47]

Failure of RMO To Abide by Retail Order Requirements

Rule 107C(h) addresses an RMO's failure to abide by Retail Order requirements. If an RMO designates orders submitted to the Exchange as Retail Orders and the Exchange determines, in its sole discretion, that those orders fail to meet any of the requirements of Retail Orders, the Exchange may disqualify a member organization from its status as an RMO.[48] When disqualification determinations are made, the Exchange shall provide a written disqualification notice to the member organization.[49] A disqualified RMO could appeal the disqualification as provided in proposed Rule 107C(i) and/or reapply for RMO status 90 days after the disqualification notice is issued by the Exchange.[50]

[35] *Id.* at (d)(1).
[36] *Id.* at (d)(2).
[37] *Id.* at (d)(3).
[38] *Id.* at (d)(4).
[39] *See id.* at (e).
[40] *Id.* at (f)(1).
[41] *Id.* at (f)(1)(A)–(B).
[42] *Id.* at (f)(2).
[43] *Id.* at (f)(2)(A)–(E).
[44] *Id.* at (f)(3).
[45] *Id.* at (g)(1)(A)–(C).
[46] *Id.* at (2).
[47] *Id.* at (3).
[48] *Id.* at (h)(1).
[49] *Id.* at (2).
[50] *Id.* at (3).

Appeal of Disapproval or Disqualification

Rule 107C(i) describes the appeal rights of member organizations. A member organization that disputes the Exchange's decision to disapprove it under Rule 107C(b) or (d) or disqualify it under Rule 107C(g) or (h) may request, within five business days after notice of the decision is issued by the Exchange, that a Retail Liquidity Program Panel (''RLP Panel'') review the decision to determine if it was correct.[51] The RLP Panel would consist of the NYSE's Chief Regulatory Officer (''CRO''), or a designee of the CRO, and two officers of the Exchange designated by the CoHead of U.S. Listings and Cash Execution.[52] The RLP Panel would review the facts and render a decision within the time frame prescribed by the Exchange.[53] The RLP Panel can overturn or modify an action taken by the Exchange and all determinations by the RLP Panel would constitute final action by the Exchange on the matter at issue.[54]

Retail Liquidity Identifier

Under Rule 107C(j), the Exchange disseminates an identifier through proprietary Exchange data feeds or the Securities Information Processor (''SIP'') when RPI interest priced at least $0.001 better than the PBB or PBO for a particular security is available in Exchange systems (''Retail Liquidity Identifier''). The Retail Liquidity Identifier shall reflect the symbol for the particular security and the side (buy or sell) of the RPI interest, but shall not include the price or size of the RPI interest.[55]

Retail Order Designations

Under Rule 107C(k), an RMO can designate how a Retail Order would interact with available contra-side interest as follows:

- A Type 1-designated Retail Order interacts only with available contra-side Retail Price Improvement Orders and MPL Orders but would not interact with other available contra-side interest in Exchange systems or route to other markets. The portion of a Type 1-designated Retail Order that does not execute against contra-side Retail Price Improvement Orders would be immediately and automatically cancelled.[56]
- A Type 2-designated Retail Order interacts first with available contra-side Retail Price Improvement Orders and MPL Orders and any remaining portion of the Retail Order would be executed as a Regulation NMS-compliant Immediate or Cancel Order pursuant to Rule 13.[57]
- A Type 3-designated Retail Order interacts first with available contra-side Retail Price Improvement Orders and MPL Orders and any remaining portion of the Retail Order would be executed as an NYSE Immediate or Cancel Order pursuant to Rule 13.[58]

Priority and Order Allocation

Under Rule 107C(l), Retail Price Improvement Orders in the same security are ranked and allocated according to price then time of entry into Exchange systems. When determining the price to execute a Retail Order, Exchange systems consider all eligible RPIs and MPL Orders. If the only interest is RPIs, then the executions shall occur at the price level that completes the incoming order's execution. If the only interest is MPL Orders, the Retail Order shall execute at the midpoint of the PBBO. If both RPIs and MPL Orders are present, Exchange systems will evaluate at what price level the incoming Retail Order may be executed in full (''clean-up price''). If the clean-up price is equal to the midpoint of the PBBO, RPIs will receive priority over MPL Orders, and the Retail Order will execute against both RPIs and MPL Orders at the midpoint. If the clean-up price is worse than the midpoint of the PBBO, the Retail Order will execute first with the MPL Orders at the midpoint of the PBBO and any remaining quantity of the Retail Order will execute with the RPIs at the clean-up price. If the clean-up price is better than the midpoint of the PBBO, then the Retail Order will execute against the RPIs at the clean-up price and will ignore the MPL Orders. Any remaining unexecuted RPI interest and MPL Orders will remain available to interact with other incoming Retail Orders. Any remaining unexecuted portion of the Retail Order will cancel or execute in accordance with Rule 107C(k).

Examples of priority and order allocation are as follows:

Example 1:

PBBO for security ABC is $10.00–$10.05.

RLP 1 enters a Retail Price Improvement Order to buy ABC at $10.01 for 500.

RLP 2 then enters a Retail Price Improvement Order to buy ABC at $10.02 for 500.

RLP 3 then enters a Retail Price Improvement Order to buy ABC at $10.03 for 500.

An incoming Retail Order to sell ABC for 1,000 executes first against RLP 3's bid for 500, because it is the best priced bid, then against RLP 2's bid for 500, because it is the next best priced bid. RLP 1 is not filled because the entire size of the Retail Order to sell 1,000 is depleted. The Retail Order executes at the price that completes the order's execution. In this example, the entire 1,000 Retail Order to sell executes at $10.02 because it results in a complete fill.

However, assume the same facts above, except that RLP 2's Retail Price Improvement Order to buy ABC at $10.02 is for 100. The incoming Retail Order to sell 1,000 executes first against RLP 3's bid for 500, because it is the best priced bid, then against RLP 2's bid for 100, because it is the next best priced bid. RLP 1 then receives an execution for 400 of its bid for 500, at which point the entire size of the Retail Order to sell 1,000 is depleted. The Retail Order executes at the price that completes the order's execution, which is $10.01.

Example 2:

PBBO for security DEF is $10.00–10.01.

RLP 1 enters a Retail Price Improvement Order to buy DEF at $10.006 for 500.

RLP 2 enters a Retail Price Improvement Order to buy DEF at $10.005 for 500.

MPL 1 enters an MPL Order to buy DEF at $10.01 for 1000.

RLP 3 enters a Retail Price Improvement Order to buy DEF at $10.002 for 1000.

An incoming Retail Order to sell DEF for 2,500 arrives. The clean-up price is $10.002. Because the midpoint of the PBBO is priced better than the clean-up price, the Retail Order executes with MPL 1 for 1000 shares at $10.005. The Retail Order then executes at $10.002 against RLP 1's bid for 500, because it is the best-priced bid, then against RLP 2's bid for 500 because it is the next best-priced bid and then RLP 3 receives an execution for 500 of its bid for 1000, at which point the entire size of the Retail Order to sell 2,500 is depleted.

Assume the same facts above. An incoming Retail Order to sell DEF for 1,000 arrives. The clean-up price is $10.005. Because the clean-up price is

[51] *Id.* at (i)(1). In the event a member organization is disqualified from its status as an RLP pursuant to proposed Rule 107C(g), the Exchange would not reassign the appellant's securities to a different RLP until the RLP Panel has informed the appellant of its ruling. *Id.* at (i)(1)(A).

[52] *Id.* at (i)(2).

[53] *Id.* at (3).

[54] *Id.* at (4).

[55] *Id.* at (j).

[56] *Id.* at (k)(1). *See* note 18, *supra.*

[57] *Id.* at (2).

[58] *Id.* at (k)(3).

equal to the midpoint of the PBBO, RPIs will receive priority over MPL Orders. As a result, the Retail Order executes first against RLP 1's bid for 500, because it is the best-priced bid, then against RLP 2's bid for 500 because it is the next best-priced bid, at which point the entire size of the Retail Order to sell 1,000 is depleted.[59]

Rationale for Making Pilot Permanent

In approving the Program on a pilot basis, the Commission required the Exchange to ''monitor the scope and operation of the Program and study the data produced during that time with respect to such issues, and will propose any modifications to the Program that may be necessary or appropriate.''[60] As part of its assessment of the Program's potential impact, the Exchange posted core weekly and daily summary data on the Exchanges' website for public investors to review,[61] and provided additional data to the Commission regarding potential investor benefits, including the level of price improvement provided by the Program. This data included statistics about participation, frequency and level of price improvement and effective and realized spreads.

In the RLP Approval Order, the Commission observed that the Program could promote competition for retail order flow among execution venues, and that this could benefit retail investors by creating additional price improvement opportunities for marketable retail order flow, most of which is currently executed in the Over-the-Counter (''OTC'') markets without ever reaching a public exchange.[62] The Exchange sought, and believes it has achieved, the Program's goal of attracting retail order flow to the Exchange, and allowing such order flow to receive potential price improvement. As the Exchange's analysis of the Program data below demonstrates, the Program provided tangible price improvement to retail investors through a competitive pricing process. The data also demonstrates that the Program had an overall negligible impact on ''broader market structure.''[63]

Between August 1, 2012, when the Program began, and January 2, 2018, orders totaling in excess of 6.8 billion shares were executed through the Program, providing retail investors with $12.3 million in price improvement. As Table 1 shows, during 2016, an average of 2–3 million shares per day was executed in the Program. In 2017, an average of 3–4 million shares per day were executed in the Program. During the period 2016–17, average effective spreads in RLP executions ranged between $0.012 and $0.019. Fill rates reached as high as 25.7% in May 2018. Overall price improvement averaged $0.0014 per share, approximately 40% above the minimum of $0.001.[64]

TABLE 1—SUMMARY EXECUTION AND MARKET QUALITY STATISTICS

Date	RPI Average volume	Average daily orders	Effective spread	Effective/ quoted ratio	Price improve-ment	Realized spread	Fill rate %
Jan–16	3,257,495	11,495	$0.0167	0.736	$0.0017	$0.0051	14.7
Feb–16	3,119,642	10,400	0.0163	0.713	0.0018	0.0041	15.3
Mar–16	2,760,731	9,179	0.0142	0.706	0.0018	0.0029	16.5
Apr–16	2,277,189	8,432	0.0143	0.703	0.0018	0.0042	17.6
May–16	1,727,219	6,931	0.0151	0.693	0.0019	0.0054	16.4
Jun–16	2,003,149	9,122	0.0134	0.667	0.0019	0.0060	14.4
Jul–16	2,265,579	7,880	0.0126	0.668	0.0019	0.0034	18.1
Aug–16	2,009,630	5,626	0.0122	0.699	0.0017	−0.0019	16.4
Sep–16	1,620,236	4,801	0.0136	0.696	0.0017	0.0035	15.6
Oct–16	2,355,292	8,055	0.0143	0.693	0.0017	0.0041	19.7
Nov–16	2,702,894	9,915	0.0161	0.700	0.0018	0.0040	17.3
Dec–16	4,380,164	15,036	0.0142	0.710	0.0017	0.0034	20.5
Jan–17	2,921,604	11,184	0.0148	0.730	0.0016	0.0011	21.4
Feb–17	2,508,810	9,801	0.0165	0.754	0.0015	0.0023	20.3
Mar–17	2,585,694	9,517	0.0175	0.770	0.0015	0.0060	20.9
Apr–17	2,875,573	10,174	0.0156	0.764	0.0014	0.0056	23.5
May–17	3,741,955	15,179	0.0150	0.763	0.0014	0.0026	25.7
Jun–17	5,040,922	17,245	0.0155	0.688	0.0018	0.0046	19.2
Jul–17	3,906,133	14,582	0.0154	0.712	0.0017	0.0020	19.8
Aug–17	3,803,586	14,841	0.0174	0.700	0.0018	0.0055	19.5
Sep–17	3,398,110	12,782	0.0152	0.773	0.0014	0.0017	23.2
Oct–17	3,839,683	13,467	0.0156	0.773	0.0014	0.0022	25.2
Nov–17	4,193,873	14,499	0.0161	0.775	0.0014	0.0028	24.2
Dec–17	3,673,405	19,036	0.0180	0.782	0.0014	0.0027	19.0

As Table 2 shows, approximately 45% of all orders in the Program in 2016–17 were for a round lot or fewer shares. More than 60% of retail orders removing liquidity from the Exchange were for 300 shares or less. Further, the number of very large orders was relatively steady, with orders larger than 7,500 shares typically accounting for 4–5% of orders received. Despite relatively low fill rates, large orders account for a sizable portion of the shares executed in the Program.

[59] *Id.* at (l).

[60] RLP Approval Order, 77 FR at 40681.

[61] *See https://www.nyse.com/markets/liquidity-programs#nyse-nyse-mkt-rlp.*

[62] RLP Approval Order, 77 FR at 40679.

[63] *See id.* at 40682.

[64] In 2016, the average price improvement reached as high as $0.0017–$0.0018.

TABLE 2—COMPOSITION OF RETAIL TAKING ORDERS BY ORDER SIZE CATEGORY

	<100 %	101–300 %	301–500 %	501–1000 %	1001–2000 %	2001–4000 %	4001–7500 %	7500–15000 %	>15000 %
Jan–16	36.31	19.06	9.74	11.64	7.60	6.48	4.38	2.70	2.09
Feb–16	35.88	18.81	9.96	11.82	7.72	6.42	4.31	2.82	2.26
Mar–16	35.67	18.69	9.90	11.83	7.82	6.70	4.52	2.92	1.94
Apr–16	38.22	19.39	9.87	11.48	7.16	5.73	3.89	2.54	1.73
May–16	37.64	19.81	10.12	11.57	7.51	5.60	3.74	2.35	1.65
Jun–16	39.46	18.98	9.66	11.22	7.13	5.32	3.95	2.60	1.68
Jul–16	40.22	18.59	9.45	11.10	6.75	5.40	4.05	2.65	1.78
Aug–16	33.59	17.45	9.24	11.66	8.30	7.17	5.71	4.33	2.54
Sep–16	33.40	17.83	9.13	11.55	8.33	7.32	5.69	4.17	2.59
Oct–16	39.50	19.03	9.42	11.16	7.33	5.66	3.77	2.53	1.59
Nov–16	38.72	19.67	9.80	11.40	7.19	5.27	3.63	2.64	1.70
Dec–16	39.41	19.52	9.41	11.26	7.33	5.40	3.55	2.66	1.47
Jan–17	42.16	19.82	9.22	10.62	6.92	4.84	3.05	2.08	1.30
Feb–17	41.90	19.51	9.34	10.79	7.03	4.82	3.09	2.08	1.44
Mar–17	41.55	18.98	9.12	11.04	7.30	5.18	3.40	2.07	1.36
Apr–17	44.32	18.50	8.55	10.21	6.65	5.07	3.31	2.17	1.21
May–17	52.39	17.82	7.14	8.08	5.32	4.03	2.64	1.72	0.87
Jun–17	44.76	15.48	7.53	9.59	6.87	6.06	4.67	3.50	1.53
Jul–17	45.33	15.98	8.05	10.21	7.08	5.61	3.70	2.62	1.43
Aug–17	43.83	16.68	8.39	10.58	7.48	5.67	3.46	2.51	1.41
Sep–17	46.15	17.81	8.26	9.93	6.78	4.85	2.93	2.09	1.20
Oct–17	45.53	18.30	8.47	10.06	6.88	4.82	2.79	2.00	1.15
Nov–17	45.14	17.37	8.63	10.37	7.13	5.02	2.90	2.15	1.29
Dec–17	45.96	17.62	8.89	10.60	6.62	4.55	2.72	1.99	1.05

Tables 3 and 4 show the distribution of orders received by size and shares executed in 2016–17. During that period, the Program saw much lower execution sizes due to smaller retail providing orders (typically around 300 shares) breaking up fills and as a result of liquidity at multiple price improvement points.

TABLE 3—COMPOSITION OF SHARES PLACED BY ORDER SIZE CATEGORY

	<100 %	101–300 %	301–500 %	501–1000 %	1001–2000 %	2001–4000 %	4001–7500 %	7500–15000 %	>15000 %
Jan–16	1.11	2.17	2.28	5.01	6.21	10.14	12.73	14.71	45.64
Feb–16	1.09	2.09	2.25	4.92	6.09	9.67	12.01	14.90	46.97
Mar–16	1.15	2.23	2.40	5.28	6.61	10.79	13.50	16.37	41.68
Apr–16	1.45	2.75	2.84	6.09	7.21	10.93	13.90	16.82	38.02
May–16	1.47	2.81	2.93	6.16	7.59	10.70	13.39	15.81	39.14
Jun–16	1.43	2.67	2.80	6.06	7.29	10.28	14.15	17.28	38.04
Jul–16	1.38	2.50	2.61	5.67	6.57	10.05	13.95	16.71	40.57
Aug–16	0.88	1.71	1.86	4.30	5.88	9.78	14.44	19.69	41.45
Sep–16	0.92	1.78	1.84	4.24	5.89	10.04	14.44	19.38	41.48
Oct–16	1.60	2.76	2.77	6.00	7.52	11.19	13.79	17.15	37.21
Nov–16	1.49	2.70	2.72	5.84	6.99	9.77	12.62	16.97	40.90
Dec–16	1.69	2.98	2.88	6.29	7.82	11.13	13.57	18.68	34.96
Jan–17	2.08	3.51	3.29	6.89	8.59	11.57	13.51	17.30	33.26
Feb–17	1.96	3.33	3.21	6.70	8.39	11.12	13.29	16.59	35.40
Mar–17	1.90	3.16	3.05	6.72	8.50	11.64	14.12	15.93	34.97
Apr–17	2.29	3.34	3.10	6.72	8.38	12.32	15.07	18.00	30.78
May–17	4.06	4.02	3.23	6.65	8.42	12.26	14.97	17.66	28.74
Jun–17	1.36	2.15	2.15	5.07	6.99	11.88	16.71	22.63	31.06
Jul–17	1.45	2.49	2.58	6.02	8.03	12.20	14.85	19.55	32.83
Aug–17	1.52	2.67	2.76	6.42	8.79	12.70	14.21	19.41	31.50
Sep–17	2.01	3.29	3.08	6.74	8.98	12.38	13.73	18.52	31.27
Oct–17	1.99	3.45	3.21	6.94	9.26	12.39	13.30	18.03	31.42
Nov–17	1.85	3.10	3.11	6.80	9.07	12.20	13.06	18.30	32.51
Dec–17	2.06	3.54	3.60	7.78	9.43	12.58	13.73	19.12	28.16

TABLE 4—COMPOSITION OF SHARES EXECUTED BY ORDER SIZE CATEGORY

	<100 %	101–300 %	301–500 %	501–1000 %	1001–2000 %	2001–4000 %	4001–7500 %	7500–15000 %	>15000 %
Jan–16	6.25	10.48	9.45	17.31	14.62	10.14	10.60	8.43	8.90
Feb–16	5.94	9.72	9.20	16.39	13.89	9.67	10.88	9.53	11.14
Mar–16	5.79	9.59	9.07	16.56	14.13	10.79	11.31	9.99	9.13
Apr–16	6.84	11.14	10.10	17.62	13.89	10.93	10.47	9.28	7.38

TABLE 4—COMPOSITION OF SHARES EXECUTED BY ORDER SIZE CATEGORY—Continued

	<100 %	101–300 %	301–500 %	501–1000 %	1001–2000 %	2001–4000 %	4001–7500 %	7500–15000 %	>15000 %
May–16	7.38	11.61	10.14	17.20	13.47	10.70	9.84	8.47	8.99
Jun–16	7.10	10.66	9.04	15.22	13.52	10.28	11.45	10.13	10.13
Jul–16	6.18	9.52	8.28	14.74	12.55	10.05	13.28	11.29	10.57
Aug–16	4.48	7.45	6.93	12.87	12.48	9.78	15.50	15.54	10.23
Sep–16	4.73	7.83	6.94	12.86	12.43	10.04	16.13	14.42	10.16
Oct–16	6.76	10.32	8.76	15.87	14.13	11.19	11.68	10.00	8.23
Nov–16	7.02	11.19	9.76	17.17	14.19	9.77	10.31	8.99	8.58
Dec–16	6.99	10.91	9.22	17.06	15.32	11.13	10.68	9.16	6.67
Jan–17	8.21	12.23	9.82	17.25	15.76	11.57	9.59	7.24	6.40
Feb–17	8.20	12.39	10.36	18.42	15.80	11.12	9.45	6.93	5.64
Mar–17	7.67	11.72	10.02	19.32	16.40	11.64	9.76	6.64	4.93
Apr–17	8.48	11.45	9.57	18.22	15.60	12.32	10.32	7.81	4.50
May–17	14.15	12.70	9.29	16.65	14.45	12.26	9.45	7.18	3.52
Jun–17	5.58	8.07	7.39	15.41	14.63	11.88	13.89	13.50	6.20
Jul–17	5.67	9.03	8.53	17.83	16.45	12.20	11.56	9.71	6.11
Aug–17	5.78	9.30	8.88	18.25	17.51	12.70	10.54	8.75	5.72
Sep–17	7.32	10.97	9.79	18.78	17.26	12.38	9.53	7.60	4.98
Oct–17	6.53	10.74	9.74	18.74	17.63	12.39	9.21	8.01	5.35
Nov–17	6.28	10.18	9.41	18.28	17.38	12.20	9.80	8.44	6.08
Dec–17	6.50	10.99	10.31	20.09	16.89	12.58	9.35	7.30	4.60

As Table 5 shows, during 2016—17, fill rates trended near 80 for orders up to 300 shares, while the average shares available at the inside was 300 shares. Data published to the SIP indicates when liquidity is available for retail liquidity seekers inside the spread, and on which side.

TABLE 5—FILL RATES BY RETAIL TAKE ORDER SIZE

	<100 %	101–300 %	301–500 %	501–1000 %	1001–2000 %	2001–4000 %	4001–7500 %	7500–15000 %	>15000 %
Jan–16	85.30	72.92	62.76	52.36	35.67	20.84	12.61	8.68	2.95
Feb–16	83.81	71.47	62.76	51.21	35.07	21.18	13.92	9.84	3.65
Mar–16	82.78	70.92	62.38	51.69	35.25	22.06	13.80	10.06	3.61
Apr–16	83.19	71.37	62.58	50.99	33.95	21.41	13.27	9.72	3.42
May–16	82.49	67.65	56.62	45.70	29.09	19.75	12.04	8.77	3.76
Jun–16	71.79	57.72	46.59	36.28	26.76	17.91	11.69	8.46	3.84
Jul–16	80.95	68.80	57.26	46.92	34.50	24.39	17.19	12.20	4.71
Aug–16	83.54	71.79	61.39	49.17	34.92	24.40	17.64	12.97	4.06
Sep–16	80.06	69.04	59.19	47.50	33.04	22.58	17.49	11.65	3.83
Oct–16	83.10	73.58	62.22	52.05	36.97	25.09	16.67	11.48	4.35
Nov–16	81.40	71.75	62.28	50.90	35.15	22.68	14.15	9.18	3.63
Dec–16	84.73	75.04	65.56	55.67	40.18	25.76	16.14	10.06	3.91
Jan–17	84.49	74.69	64.07	53.69	39.35	24.97	15.22	8.98	4.13
Feb–17	84.49	75.25	65.39	55.64	38.16	23.34	14.40	8.46	3.23
Mar–17	84.31	77.43	68.69	60.00	40.26	24.26	14.42	8.70	2.95
Apr–17	86.84	80.63	72.49	63.69	43.71	26.79	16.10	10.19	3.44
May–17	89.57	81.19	73.95	64.31	44.07	26.41	16.22	10.45	3.15
Jun–17	78.80	72.17	66.04	58.35	40.20	24.80	15.96	11.46	3.83
Jul–17	77.45	71.84	65.58	58.68	40.59	24.56	15.42	9.85	3.69
Aug–17	74.17	67.92	62.76	55.48	38.88	23.48	14.48	8.80	3.54
Sep–17	84.30	77.24	73.73	64.64	44.56	25.81	16.11	9.51	3.69
Oct–17	82.84	78.51	76.55	68.14	48.06	28.59	17.47	11.21	4.30
Nov–17	82.32	79.42	73.12	65.08	46.34	28.08	18.16	11.17	4.52
Dec–17	81.62	80.19	74.12	66.68	46.28	28.70	17.60	9.86	4.22

Table 6 shows the development of orders sizes received in the Program over time. Orders adding liquidity to the Exchange averaged in the mid-300 share range for most of the Program's recent history, although the median size has increased since August 2016. (The Exchange notes that the median order size is the average of the daily median order sizes across all orders received on a trade date for NYSE symbols). After averaging near 2,000 shares at times, the size of retail orders removing liquidity from the Exchange has dropped over time, with median sizes periodically exceeding 300 shares. The slightly smaller take order sizes helps explain the better overall fill rates and improved effective spreads in the Program's recent history. However, as shown by the occasional oversized orders, there remains ample liquidity and opportunity in the Program to satisfy liquidity takers with meaningful price improvement.

TABLE 6—ORDER SIZE DETAILS

	Provide orders		Take orders	
	Average	Median	Average	Median
Jan–16	297	157	1,941	259
Feb–16	314	191	1,958	272
Mar–16	312	182	1,787	267
Apr–16	306	176	1,523	215
May–16	294	100	1,542	217
Jun–16	314	100	1,508	207
Jul–16	323	105	1,585	202
Aug–16	340	194	2,230	338
Sep–16	338	200	2,212	336
Oct–16	357	200	1,494	204
Nov–16	382	200	1,623	212
Dec–16	367	200	1,398	206
Jan–17	361	200	1,217	199
Feb–17	350	200	1,264	200
Mar–17	360	200	1,304	200
Apr–17	353	200	1,223	189
May–17	416	200	961	105
Jun–17	370	200	1,517	190
Jul–17	355	200	1,364	180
Aug–17	360	200	1,310	196
Sep–17	391	200	1,141	164
Oct–17	444	200	1,127	172
Nov–17	422	200	1,193	184
Dec–17	395	200	1,026	195

Although the Program provides the opportunity to achieve significant price improvement, the Program has not generated significant activity. As Table 1 shows, the average daily volume for the Program has hovered in the three to four million share range, and has accounted for less than 0.1% of consolidated NYSE-listed volume in 2016–17. The Program's share of NYSE volume during that period was below 0.4%. Moreover, no symbol during the past two years achieved as much as 1.6% of their consolidated average daily volume (''CADV'') in the Program. As Table 7 shows, during the 2016–2017 period, less than 0.5% of all day/symbol pairs exceeded 5% share of CADV, with another 3.7% of day/symbol pairs achieving a share of CADV between 1% and 5%. Fully 88% of all day/symbol pairs exhibited RLP share of 0.25% or less during that time. For ticker symbols that traded at least 100 days during the two-year period, more than half of all symbols over that period had less than 0.10% of their consolidated volume executed in the program, and 96% less than 0.50%. Of the symbols that achieved greater than 0.50% CADV in the Program during 2016–2017, only two had a CADV above 500,000, and neither was chosen in the matched sample described below. The Program's share of the total market in NYSE-listed securities is tiny considering that non-ATS activity in the U.S. equity markets, based on FINRA transparency data and NYSE Trade and Quote (''TAQ'') volume statistics, is estimated to be approximately 20–25% of all US equity volume.

In short, the Program represents a minor participant in the overall market to price improve marketable retail order flow. While participation was low, as noted above, retail investors that participated in the Program received price improvement on their orders, which was one of the stated goals of the Program. The NYSE therefore believes that this pilot data supports making the Program permanent.

Table 7				
	Daily Results		Two Year Aggregate	
Distribution	Count	Percentage	Count	Percentage
> 50%	63	0.0040%	0	0.0000%
25-50%	180	0.0113%	0	0.0000%
10-25%	1,619	0.1016%	0	0.0000%
5-10%	5,675	0.3562%	0	0.0000%
1-5%	59,284	3.7210%	14	0.3504%
0.75%-1%	18,756	1.1772%	26	0.6507%
0.50%-0.75%	30,210	1.8961%	130	3.2533%
0.25%-0.50%	65,026	4.0814%	797	19.9449%
0.10%-0.25%	116,882	7.3361%	773	19.3443%
0.05%-0.10%	102,209	6.4152%	562	14.0641%
0.01%-0.05%	181,846	11.4136%	1,223	30.6056%
< 0.01%	1,011,493	63.4864%	471	11.7868%

Moreover, beyond providing a meaningful price improvement to retail investors through a competitive and transparent pricing process unavailable in non-exchange venues, the data collected during the Program supports the conclusion that the Program has not had any significant negative market impact. As set forth in Table 8, the Exchange measured the correlation between several critical market quality statistics and either RLP share of CADV, shares posted dark by providers seeking to interact with retail orders or the amount of time during the trading day that RLP liquidity was available. The correlations the Exchange measured were levels, not changes. As a result, fairly high correlation coefficients should suggest that the Program had a meaningful impact on the statistics. In no case did the Exchange observe a single correlation greater than an absolute value of 0.10, and even at the 90th percentile of all symbols, there was no correlation of even 0.30. In short, these results support the conclusion that the Program does not negatively impact market quality.

TABLE 8

Statistic 1	Statistic 2	Average correlation	90th Percentile correlation
% Time With RLP Liquidity	Consolidated Spread	0.0001	0.0003
% Time With RLP Liquidity	Eff. Sprd. Ex RPI	0.0943	0.2925
RLP Size at PBBO	Consolidated Spread	0.0003	0.0005
RLP Size at PBBO	Eff. Sprd. Ex RPI	0.0617	0.2348
RLP Share of CADV	Eff. Sprd. Ex RPI	0.0010	0.1091
RLP Share of CADV	Share wtd. NBBO Spread	0.0152	0.1357
RLP Share of CADV	Time wtd. NBBO Spread	0.0002	0.0002
RLP Share of CADV	Time wtd. NYSE BBO Spread	0.0002	0.0002

Difference in Differences Analysis

In addition to demonstrating that changes in Program activity had no impact on market quality on a day-to-day basis, the Exchange also analyzed market quality impact by using the difference in differences statistical technique.

Difference in differences (''DID'') requires studying the differential effect of data measured between a treatment group and a control group. The two groups are measured during two or more different time periods, usually a period before ''treatment'' and at least one time period after ''treatment,'' that is, a time period after which the treatment group is impacted but the control group is not. The assumption is that the control group and the treatment group are otherwise impacted equally by extraneous factors, *i.e.,* that the other impacts are parallel. For example, when measuring average quoted spreads, if spreads increased by 10 basis points in the control group and by 12 basis points in the test group, the assumption would be that the two basis point differential was caused by the treatment.

Because all Exchange-traded symbols were eligible to participate in the Program, a natural control group does not exist for the securities participating in the Program. Hence, there is a possibility that the lack of activity in the Program could have been the result of factors that DID cannot measure. Nonetheless, to produce a control group, the Exchange identified the 50 most active ticker symbols in the Program as measured by share of consolidated volume following launch of the Program. The Exchange then determined a matched sample, without replacement, using consolidated volume, volume weighted average price, and consolidated quoted spread in basis points. The matched sample compared the 50 most active ticker symbols in the Program with all securities that had very low Program volume. The matching criteria minimized the sum of the squares of the percent difference between the top 50 active ticker symbols and potential matches.

The Exchange executed four DID analyses:

1. Six months prior to launch of the Program (February 2012–July 2012) compared to six months following launch, excluding the first month of the Program (September 2012–February 2013) for securities with a CADV of at least 500,000 during the pre-treatment and treatment periods.

2. Six months prior to launch of the Program (February 2012–July 2012) compared to all of 2016 and 2017 for securities with a CADV of at least 500,000 during the pre-treatment and treatment periods.

3. Six months prior to launch of the Program (February 2012–July 2012) compared to six months following launch, excluding the first month of the program (September 2012–February 2013) for securities with a CADV of at least 50,000 and less than 500,000, during the pre-treatment and treatment periods.

4. Six months prior to launch of the Program (February 2012–July 2012) compared to all of 2016 and 2017 for securities with a CADV of at least 50,000 and less than 500,000, during the pre-treatment and treatment periods.

Because there was no natural control group, the Exchange employed flexible matching criteria. In addition to the CADV restrictions, the Exchange utilized a control of CADV ratio of 3:1, a volume weighted average price (''VWAP'') of 2:1, and a spread of 2:1. The Exchange also required potential control group stocks to have a share of Program trading less than 1/10th of the lowest of the top 50 securities for the first trading period. The Exchange excluded securities that were in the test groups of the Tick Size Pilot Program from consideration in matching securities for the DID analysis of the 2016–2017 period.[65] Preferred stocks, warrants and rights were excluded from the DID analysis for both periods. Finally, because the Program is only valid for stocks trading at or above $1.00, any security with a low price during the pre-treatment or the treatment period below $1.00 was also excluded. Securities also had to be listed on the NYSE during the pre-treatment period and during the treatment period.

The Exchange selected the top 25 securities by minimum differences as described above.

Results for Securities With CADV at Least 500,000 Shares

As noted above, the Program began in August 2012. The Exchange selected February–July 2012 as the relevant six month pre-period. The first post-period used was September 2012–February 2013, as the Program was not rolled out to all securities immediately. Tables 9A and 9B show the matched sample securities with key attributes for the first comparison period for symbols with a CADV of at least 500,000. Tables 10A and 10B show the selected securities for the second comparison period with CADV of at least 500,000.

[65] The Tick Size Pilot Program is a National Market System (''NMS'') plan designed to allow the Commission, market participants and the public to assess the impact of wider minimum quoting and trading increments—or tick sizes—on the liquidity and trading of the common stocks of certain small capitalization companies.

Table 9A: Retail Program Matched Sample (Feb. - July 2012 vs. Sep. 2012 - Feb. 2013)

Treatment Symbol	Pre-period CADV	Pre-period VWAP	Pre-period Spread	Control Symbol	Pre-period CADV	Pre-period VWAP	Pre-period Spread
GLW	15,533,350	$13.25	7.58	VALEP	7,987,249	$20.96	4.75
SCHW	12,425,085	$13.34	7.57	BBD	9,826,140	$15.82	6.16
MGM	12,194,154	$12.58	8.22	ITUB	14,382,571	$16.68	6.13
NLY	10,622,520	$16.49	6.00	HST	8,152,479	$15.75	6.37
ARR	5,701,535	$7.06	14.19	SWC	1,986,888	$11.09	11.01
HUN	5,075,055	$13.45	7.65	MBT	2,717,909	$17.69	6.02
TEF	4,517,965	$13.88	7.14	NRG	3,561,399	$16.59	6.37
TWO	4,405,643	$10.44	9.81	UBS	3,919,778	$12.62	8.06
MCP	3,403,308	$26.48	9.05	CIE	2,782,833	$26.80	8.24
LNKD	3,374,585	$98.90	8.48	EQT	1,760,916	$50.23	4.25
TSL	3,000,964	$7.66	16.12	DCT	3,167,224	$5.86	17.11
LGF	2,940,312	$13.53	9.06	DDR	2,999,057	$14.35	7.04
KORS	2,872,499	$42.42	8.00	PXP	2,400,816	$39.96	5.70
SAN	2,799,280	$10.01	11.68	VIP	1,991,387	$9.74	11.10
MUX	2,458,917	$3.60	29.56	HT	1,186,652	$5.29	19.31
BBVA	2,052,893	$7.15	14.17	SWFT	1,600,993	$10.30	11.95
ERF	1,806,818	$17.01	7.33	CBL	1,883,227	$18.50	6.17
OPK	1,477,637	$4.74	21.71	ASX	1,240,964	$4.60	21.95
PGH	1,380,933	$8.01	12.83	LXP	1,151,087	$8.67	11.96
NBG	1,281,865	$2.39	49.96	ZTR	504,899	$3.58	28.01
ANH	1,225,499	$6.66	14.93	SLT	1,006,495	$8.56	13.35
KCG	1,021,164	$12.32	8.46	KT	1,094,900	$13.60	7.84
AOD	979,755	$4.50	22.44	IRE	1,075,990	$6.62	23.05
KMP	707,377	$82.04	5.24	DVA	843,969	$87.26	4.72
MWE	637,554	$54.95	7.82	WCC	657,039	$60.60	8.04

Table 9B: Additional Comparative Statistics

Treatment Symbol	Pre-Period TRF	Post-Period TRF	RTO Share of CADV	Control Symbol	Pre-Period TRF	Post-Period TRF	RTO Share of CADV
GLW	32.08%	33.81%	0.3833%	VALEP	14.32%	10.87%	0.0011%
SCHW	26.97%	27.14%	0.2193%	BBD	20.90%	18.17%	0.0085%
MGM	35.71%	32.84%	0.2158%	ITUB	22.87%	22.23%	0.0174%
NLY	45.36%	41.72%	0.4556%	HST	28.97%	28.89%	0.0182%
ARR	47.61%	49.25%	0.8358%	SWC	30.05%	36.49%	0.0171%
HUN	32.66%	35.16%	0.2620%	MBT	28.49%	30.25%	0.0081%
TEF	40.49%	29.97%	0.7724%	NRG	28.92%	33.23%	0.0103%
TWO	40.95%	41.10%	0.4312%	UBS	20.64%	25.03%	0.0037%
MCP	40.60%	45.83%	0.2783%	CIE	27.88%	36.21%	0.0152%
LNKD	36.29%	36.32%	0.2466%	EQT	25.46%	29.20%	0.0152%
TSL	39.50%	39.64%	0.2216%	DCT	33.61%	35.98%	0.0131%
LGF	39.10%	38.40%	0.2290%	DDR	33.38%	37.09%	0.0056%
KORS	38.82%	35.84%	0.2057%	PXP	23.13%	33.81%	0.0158%
SAN	35.89%	38.18%	0.2265%	VIP	26.93%	26.30%	0.0131%
MUX	37.95%	35.19%	0.2381%	HT	31.79%	40.15%	0.0182%
BBVA	33.42%	34.84%	0.7064%	SWFT	36.44%	39.57%	0.0172%
ERF	36.13%	35.54%	0.2268%	CBL	34.33%	36.29%	0.0133%
OPK	40.27%	47.95%	0.2854%	ASX	41.57%	39.82%	0.0156%
PGH	42.81%	45.20%	0.2500%	LXP	33.90%	34.81%	0.0079%
NBG	42.73%	45.12%	0.5979%	ZTR	42.23%	46.82%	0.0143%
ANH	40.67%	39.66%	0.2532%	SLT	28.44%	30.84%	0.0196%
KCG	28.33%	39.02%	0.2388%	KT	35.43%	31.17%	0.0026%
AOD	57.75%	57.87%	0.5156%	IRE	42.21%	47.44%	0.0187%
KMP	43.32%	46.26%	0.2346%	DVA	28.66%	29.83%	0.0198%
MWE	40.12%	42.06%	0.2063%	WCC	30.35%	39.26%	0.0076%

Table 10A Retail Program Matched Sample (Feb. - July 2012 vs.2016 - 2017)

Treatment Symbol	Pre-period CADV	Pre-period VWAP	Pre-period Spread	Control Symbol	Pre-period CADV	Pre-period VWAP	Pre-period Spread
X	10,198,354.6	$25.09	4.53	PBRA	8,215,851	$22.47	4.47
KGC	9,317,602.7	$9.15	10.98	LSI	10,998,995	$7.62	13.50
M	6,187,172.5	$37.16	3.00	STT	3,724,572	$42.78	2.87
HTZ	5,191,738.0	$13.58	7.51	IPG	6,581,255	$11.00	9.10
CLF	3,885,797.3	$57.89	4.68	FTI	2,561,023	$45.91	3.98
IAG	3,024,442.8	$12.51	8.30	DRE	2,933,467	$14.17	7.06
SAN	2,799,280.0	$10.01	11.68	DRH	1,524,537	$10.11	10.18
CIG	2,481,352.0	$21.33	4.87	UNM	2,639,498	$21.49	4.63
STM	2,170,712.1	$6.18	16.72	DCT	3,167,224	$5.86	17.11
SUN	2,042,126.7	$43.87	3.83	EIX	1,888,883	$43.94	2.98
VRX	1,737,832.3	$49.75	4.16	TS	1,671,801	$36.62	4.16
SNE	1,698,085.1	$16.41	6.58	FBHS	1,466,438	$21.40	7.41
CBI	1,242,219.7	$39.89	6.25	AGCO	1,447,398	$45.47	5.71
EXK	1,239,438.6	$9.18	12.98	SHO	1,318,481	$9.94	10.84
UA	1,222,025.2	$82.15	7.58	CXO	1,121,123	$95.21	9.36
WTW	1,059,789.4	$68.07	6.92	GDI	912,411	$61.48	8.31
EXG	1,006,827.5	$8.68	11.57	CUBE	1,086,346	$11.67	9.79
DDD	964,142.2	$28.40	14.48	LHO	836,218	$27.73	7.99
OZM	906,907.3	$8.54	16.54	CUZ	463,857	$7.47	14.10
WTI	828,906.6	$18.09	12.94	PHH	1,020,754	$15.44	11.52
AG	709,316.3	$16.33	10.72	FCEA	632,662	$14.66	11.05
LL	642,972.0	$28.53	12.21	WBS	543,423	$21.71	9.52
VVR	631,877.8	$4.75	21.66	GPK	640,549	$5.29	20.05
DSX	595,860.9	$8.22	15.80	EDR	663,389	$10.89	10.48
NAT	541,332.5	$13.95	14.92	POL	576,970	$13.78	11.94

Table 10B: Additional Comparative Statistics

Treatment Symbol	Pre-Period TRF	Post-Period TRF	RTO Share of CADV	Control Symbol	Pre-Period TRF	Post-Period TRF	RTO Share of CADV
X	30.61%	35.27%	0.2954%	PBRA	37.24%	41.75%	0.0112%
KGC	30.19%	38.34%	0.1834%	LSI	24.50%	27.13%	0.0123%
M	22.81%	32.01%	0.1563%	STT	24.24%	24.08%	0.0111%
HTZ	31.39%	44.75%	0.2009%	IPG	23.82%	27.00%	0.0118%
CLF	38.97%	36.42%	0.2291%	FTI	27.31%	30.32%	0.0123%
IAG	39.54%	43.79%	0.1872%	DRE	32.30%	24.93%	0.0108%
SAN	57.82%	60.57%	0.1982%	DRH	40.94%	30.65%	0.0046%
CIG	34.91%	36.95%	0.1688%	UNM	33.02%	30.93%	0.0085%
STM	30.77%	39.27%	0.2142%	DCT	27.56%	34.92%	0.0055%
SUN	22.97%	32.49%	0.1956%	EIX	32.24%	30.09%	0.0131%
VRX	25.94%	31.31%	0.2200%	TS	30.32%	31.16%	0.0092%
SNE	31.85%	41.02%	0.1609%	FBHS	20.44%	25.08%	0.0120%
CBI	26.77%	36.56%	0.2119%	AGCO	25.76%	27.55%	0.0138%
EXK	38.99%	47.69%	0.1832%	SHO	25.71%	27.44%	0.0046%
UA	39.99%	50.81%	0.1744%	CXO	31.63%	32.54%	0.0141%
WTW	35.89%	36.69%	0.2310%	GDI	30.60%	31.89%	0.0148%
EXG	31.18%	32.31%	0.4050%	CUBE	45.29%	31.81%	0.0138%
DDD	30.01%	39.89%	0.1679%	LHO	33.61%	25.49%	0.0109%
OZM	27.18%	46.63%	0.1573%	CUZ	30.11%	27.33%	0.0086%
WTI	30.03%	41.34%	0.2805%	PHH	26.57%	28.72%	0.0105%
AG	30.23%	49.58%	0.1987%	FCEA	24.82%	25.21%	0.0046%
LL	44.08%	51.80%	0.2096%	WBS	36.88%	36.51%	0.0067%
VVR	22.71%	46.94%	0.2493%	GPK	37.43%	31.22%	0.0106%
DSX	32.28%	45.71%	0.2869%	EDR	27.56%	38.78%	0.0125%
NAT	36.55%	46.17%	0.2673%	POL	13.46%	21.30%	0.0148%

The Exchange's DID analysis utilized the 25 securities noted above on the following 15 statistics:

- Time-weighted NYSE quoted spread in basis points.
- Time-weighted NYSE quoted spread in dollars and cents.
- Time-weighted Consolidated quoted spread in basis points.
- Time-weighted Consolidated quoted spread in dollars and cents.
- Volume-weighted Effective spread in basis points * measured against the NYSE quote.
- Volume-weighted Effective spread in basis points * measured against the NBBO.
- Volume-weighted Effective spread in basis points * measured against the PBBO.
- Volume-weighted Quoted spread in basis points * measured against the NYSE quote.
- Volume-weighted Quoted spread in basis points * measured against the NBBO.
- Volume-weighted Quoted spread in basis points* measured against the PBBO.
- Trade Reporting Facility (''TRF'') share of volume during regular trading hours, excluding auctions.
- TRF share of volume, full day, including auctions.
- NYSE share of volume during regular trading hours, excluding auctions.
- NYSE share of volume, full day, including auctions.

* Volume weighted basis points were estimated using cents spreads and dividing by daily VWAPs.

• Trade-to-trade price change in basis points.

The Exchange calculated the DID regression for each of these statistics using the following formula:

$$Y_{it} = B_0 + B_1T + B_2I + B_3IT$$

where T equals 0 during the pre-period and equals 1 during the treatment period, and where I is the Intervention.

Table 11: DiD Results (Feb. 2012 - July 2012 vs. Sep. 2012 - Feb. 2013)

Estimated Measure	Estimate	Standard Error
Time-weighted NYSE Spread^	2.4352	3.9173
Time-weighted NYSE $ Spread	-0.0035	0.0086
Time-weighted Consolidated Spread	2.6562	3.5251
Time-weighted Consolidated $ Spread	-0.0030	0.0059
Volume-weighted Effective Spread vs. NYSE Quote	2.3934	3.7208
Volume-weighted Effective Spread vs. NBBO	2.4523	3.5545
Volume-weighted Effective Spread vs. PBBO	2.4862	3.5959
Volume-weighted Quoted Spread vs. NYSE Quote	2.5582	3.7304
Volume-weighted Quoted Spread vs. NBBO	2.5826	3.5000
Volume-weighted Quoted Spread vs. PBBO	2.6627	3.5518
NYSE Regular Hours Share, no auctions	0.0031	0.0171
NYSE Full Day Share	0.0057	0.0172
TRF Regular Hours Share, no auctions	-0.0225	0.0303
TRF Full Day Share	-0.0202	0.0282
Trade-to-trade price change	0.3872	0.7279

^ - Spreads in basis points unless otherwise noted

Significance: *** = 99.9%, ** = 99%, * = 95%, . = 90%

As Table 11 shows, none of the 15 regressions performed by the Exchange showed statistical significance for the September 2012–February 2013 period.

The Exchange also calculated the DID regression for the 2016–2017 period, as shown in Table 12. Several spread measures showed statistically significant increases at the 99% confidence level, as did the full-day share of trading on the TRF. However, time-weighted consolidated dollar spreads fell and were significant at the 90% confidence level. NYSE dollar spreads fell and were significant at the 95% level. As described below, the Exchange believes that the apparent spread widening and TRF market share increase are an artifact of the study methodology and not attributable to the Program.

Table 12: DiD Results (Feb. 2012 - July 2012 vs. 2016 -2017)		
Estimated Measure	Estimate	Standard Error
Time-weighted NYSE Spread^	8.968**	3.2760
Time-weighted NYSE $ Spread	-0.0224*	0.0110
Time-weighted Consolidated Spread	10.0349**	2.9952
Time-weighted Consolidated $ Spread	-0.01455.	0.0074
Volume-weighted Effective Spread vs. NYSE Quote	8.605**	2.6130
Volume-weighted Effective Spread vs. NBBO	8.6483***	2.4915
Volume-weighted Effective Spread vs. PBBO	8.7177***	2.5111
Volume-weighted Quoted Spread vs. NYSE Quote	9.903***	2.8810
Volume-weighted Quoted Spread vs. NBBO	9.8191***	2.7361
Volume-weighted Quoted Spread vs. PBBO	9.9825***	2.7589
NYSE Regular Hours Share, no auctions	-0.0260	0.0170
NYSE Full Day Share	-0.0288	0.0175
TRF Regular Hours Share, no auctions	0.09959***	0.0287
TRF Full Day Share	0.08245**	0.0268
Trade-to-trade price change	1.619*	0.6673

^ - Spreads in basis points unless otherwise noted

Significance *** = 99.9%, ** = 99%, * = 95%, . = 90%

As noted above, because all Exchange-traded symbols were eligible to participate in the Program when it began as a pilot in August 2012, there was no control group that would permit a classic DID examination of the results. Instead, for purposes of making the Program permanent, the Exchange created an artificial control group and treatment group by coming up with a matched sample based on the securities with the highest share of consolidated volume in the Program and matching these securities based on volume weighted average price, time-weighted quoted spread, and CADV during the pre-treatment period (subject to the criteria noted above). By necessity, however, the percent of activity in the Program itself had to be based on the post-treatment period.

This methodology provided several insights and permitted the Exchange to offer a more thorough analysis of the Program's impact. However, the Exchange believes that selection of securities with the highest share of consolidated volume in the Program for the treatment group created a biased treatment group. Securities with lower prices tend to trade more actively in the TRF as well as in the Program; the percentage value of price improvement on a low-price stocks provides greater savings to investors. For example, $0.0010 price improvement per share for a $5.00 stock saves an investor $2.00 per $10,000 invested. The same per share price improvement on a $50 stock is worth just $0.20. Table 13 shows this relationship for the 2016–2017 treatment period used in the analysis.

TABLE 13—SHARE OF VOLUME BASED ON DAILY VWAP

	<$5.00 (%)	$5–$10 (%)	$10–$25 (%)	$25–$50 (%)	$50–$100 (%)	>$100 (%)
TRF Share	41.86	37.97	36.02	32.92	30.97	31.58
NYSE RLP % of CADV	0.30	0.23	0.20	0.13	0.10	0.11

By utilizing securities that traded more heavily in the Program, the treatment stocks selected for the DID analysis were mostly lower priced securities. However, the matching criteria does not restrict stock price during the pre-treatment period. The large time gap between the pre-treatment and treatment period resulted in the selection of many stocks that were relatively lower-priced during the treatment period, but may not have been in that category during the pre-treatment period. Since the study period also sought control stocks that were not heavily traded in the Program, this resulted in a concentration of mostly higher priced treatment period securities in the control group.

Many of the treatment securities chosen for the 2016–2017 period suffered sharp price declines compared to their 2012 pre-treatment period levels. On its own, a price drop would not necessarily be problematic. However, many of these stocks were already tick constrained—that is, they traded with time-weighted quoted spreads near $0.01. As a consequence, any price drop would necessarily result in an almost equal and opposite percentage increase in the spread. This change in spread was not caused by the Program but rather by the fact the symbols were already tick constrained.

Table 14 details the VWAP, dollar and basis point spreads of all of the stocks in the 2016–2017 treatment and control group samples. The final two columns show the ratio of pre-period VWAP to post-period VWAP and compares that to the post- and pre-treatment period spreads in basis points. While, on average, control stock prices rose, treatment stock prices fell. In most

cases, treatment group basis point spreads increased, although often by less than by the percentage that VWAPs dropped, thus highlighting the impact of tick constraints on our results. However, the DID approach compared the raw increase in spreads, resulting in a statistically significant increase in spreads due to differing price performance between the control group and treatment group.

The Exchange further notes that the average pre-treatment VWAP price of the treatment stocks was $25.51 versus $24.96 for the control group stocks. However, the average post-period prices were $13.75and $37.74, respectively. The Exchange believes that these differences explain the statistically significant increase in TRF market share for the treatment stocks as well as the increases in spreads in basis points (due to the lower prices) in treatment securities versus the more than 50% average price increase in control stocks. As detailed in Table 15, this difference in performance was not present in the matched sample produced for the study covering the initial launch of the program. The treatment group saw prices *rise* from $20.11 to $20.26 during the treatment period. Control group securities saw a slightly larger increase, rising from $20.07 to $22.60.

Table 14: Time-weighted Consolidated Spread and VWAP Comparison of 2016 -2017 Sample								
Treatment Securities								
Symbol	Pre-VWAP	Post-VWAP	Pre-$ Spread	Post $ Spread	Pre BP Spread	Post BP Spread	VWAP Pre/Post	BP Post/Pre
AG	$16.33	$9.44	0.017	0.010	10.72	13.35	1.7	1.2
CBI	$39.89	$23.37	0.025	0.020	6.25	7.46	1.7	1.2
CIG	$21.33	$2.44	0.010	0.010	4.87	44.34	8.8	9.1
CLF	$57.89	$7.02	0.027	0.010	4.68	20.26	8.2	4.3
DDD	$28.40	$14.19	0.041	0.012	14.48	8.62	2.0	0.6
DSX	$8.22	$3.58	0.013	0.012	15.80	37.33	2.3	2.4
EXG	$8.68	$8.67	0.010	0.010	11.57	11.59	1.0	1.0
EXK	$9.18	$3.53	0.012	0.010	12.98	35.59	2.6	2.7
HTZ	$13.58	$15.26	0.010	0.021	7.51	9.90	0.9	1.3
IAG	$12.51	$4.20	0.010	0.010	8.30	26.72	3.0	3.2
KGC	$9.15	$3.97	0.010	0.010	10.98	26.84	2.3	2.4
LL	$28.53	$20.69	0.033	0.028	12.21	13.26	1.4	1.1
M	$37.16	$29.44	0.011	0.011	3.00	3.72	1.3	1.2
NAT	$13.95	$9.23	0.020	0.011	14.92	14.32	1.5	1.0
OZM	$8.54	$3.42	0.014	0.012	16.54	35.94	2.5	2.2
SAN	$10.01	$5.33	0.044	0.010	11.68	19.22	1.9	1.6
SNE	$16.41	$31.21	0.011	0.011	6.58	3.49	0.5	0.5
STM	$6.18	$14.32	0.010	0.010	16.72	10.46	0.4	0.6
SUN	$43.87	$28.80	0.017	0.057	3.83	18.79	1.5	4.9
UA	$82.15	$31.83	0.068	0.017	7.58	5.36	2.6	0.7
VRX	$49.75	$23.40	0.021	0.021	4.16	7.09	2.1	1.7
VVR	$4.75	$4.35	0.010	0.010	21.66	23.12	1.1	1.1
WTI	$18.09	$2.43	0.024	0.010	12.94	47.28	7.4	3.7
WTW	$68.07	$20.26	0.044	0.028	6.92	13.68	3.4	2.0
X	$25.09	$23.45	0.011	0.011	4.53	5.38	1.1	1.2
Average	$25.51	$13.75	$0.02	$0.02	$10.06	$18.53	$2.53	2.1
Control Securities								
Symbol	Pre-VWAP	Post-VWAP	Pre-$ Spread	Post $ Spread	Pre BP Spread	Post BP Spread	VWAP Pre/Post	BP Post/Pre
FCEA	$14.66	$22.04	0.016	0.015	11.05	6.76	0.7	0.6
AGCO	$45.47	$56.74	0.025	0.040	5.71	6.77	0.8	1.2
UNM	$21.49	$39.65	0.010	0.016	4.63	3.89	0.5	0.8
FTI	$45.91	$29.28	0.018	0.011	3.98	3.78	1.6	0.9
LHO	$27.73	$26.80	0.022	0.015	7.99	5.67	1.0	0.7
EDR	$10.89	$40.38	0.011	0.032	10.48	7.95	0.3	0.8
CUBE	$11.67	$27.54	0.011	0.012	9.79	4.50	0.4	0.5
SHO	$9.94	$14.11	0.011	0.010	10.84	7.41	0.7	0.7
IPG	$11.00	$22.37	0.010	0.010	9.10	4.69	0.5	0.5
DRE	$14.17	$26.04	0.010	0.011	7.06	4.17	0.5	0.6
LSI	$7.62	$82.00	0.010	0.089	13.50	10.82	0.1	0.8
WBS	$21.71	$44.40	0.020	0.039	9.52	8.38	0.5	0.9
STT	$42.78	$72.81	0.012	0.026	2.87	3.36	0.6	1.2
POL	$13.78	$34.49	0.016	0.033	11.94	9.58	0.4	0.8
CUZ	$7.47	$9.04	0.011	0.010	14.10	11.23	0.8	0.8
DRH	$10.11	$10.26	0.010	0.010	10.18	10.01	1.0	1.0
FBHS	$21.40	$58.29	0.016	0.026	7.41	4.48	0.4	0.6
DCT	$5.86	$46.65	0.010	0.030	17.11	6.14	0.1	0.4
EIX	$43.94	$73.23	0.012	0.023	2.98	3.08	0.6	1.0
CXO	$95.21	$119.66	0.089	0.130	9.36	10.70	0.8	1.1
TS	$36.62	$28.56	0.015	0.010	4.16	3.72	1.3	0.9
GPK	$5.29	$13.21	0.011	0.010	20.05	7.70	0.4	0.4
PHH	$15.44	$13.17	0.018	0.018	11.52	13.68	1.2	1.2
GDI	$61.48	$25.40	0.050	0.038	8.31	15.08	2.4	1.8
PBRA	$22.47	$7.36	0.010	0.010	4.47	15.37	3.1	3.4
Average	$24.96	$37.74	$0.02	$0.03	$9.12	$7.56	$0.83	0.9

Table 15: Time-weighted Consolidated Spread and VWAP Comparison of 2012 - 2013 Sample

Treatment Securities								
Symbol	**Pre-VWAP**	**Post-VWAP**	**Pre-$ Spread**	**Post $ Spread**	**Pre BP Spread**	**Post BP Spread**	**VWAP Pre/Post**	**BP Post/Pre**
ANH	$6.66	$6.13	0.044	0.010	11.68	12.88	1.1	1.1
AOD	$4.50	$4.13	0.010	0.010	7.14	7.48	1.1	1.0
ARR	$7.06	$6.97	0.012	0.012	7.33	8.77	1.0	1.2
BBVA	$7.15	$8.93	0.010	0.010	29.56	26.52	0.8	0.9
ERF	$17.01	$14.25	0.010	0.010	6.00	6.63	1.2	1.1
GLW	$13.25	$12.44	0.010	0.012	49.96	58.23	1.1	1.2
HUN	$13.45	$16.52	0.010	0.010	14.93	16.23	0.8	1.1
KCG	$12.32	$3.15	0.010	0.010	7.58	8.03	3.9	1.1
KMP	$82.04	$83.32	0.010	0.010	7.57	7.11	1.0	0.9
KORS	$42.42	$55.06	0.011	0.010	16.12	25.28	0.8	1.6
LGF	$13.53	$16.89	0.022	0.011	9.05	12.39	0.8	1.4
LNKD	$98.90	$121.92	0.083	0.086	8.48	7.37	0.8	0.9
MCP	$26.48	$9.49	0.033	0.026	8.00	4.87	2.8	0.6
MGM	$12.58	$11.41	0.043	0.043	5.24	5.16	1.1	1.0
MUX	$3.60	$3.90	0.010	0.010	14.19	14.10	0.9	1.0
MWE	$54.95	$51.92	0.010	0.010	8.22	8.94	1.1	1.1
NBG	$2.39	$1.92	0.010	0.010	9.81	8.52	1.2	0.9
NLY	$16.49	$15.38	0.010	0.010	14.17	11.56	1.1	0.8
OPK	$4.74	$5.49	0.010	0.010	21.71	21.09	0.9	1.0
PGH	$8.01	$5.25	0.010	0.010	12.83	18.69	1.5	1.5
SAN	$10.01	$7.79	0.043	0.037	7.82	6.96	1.3	0.9
SCHW	$13.34	$14.31	0.010	0.010	22.44	23.93	0.9	1.1
TEF	$13.88	$13.58	0.010	0.010	7.65	6.43	1.0	0.8
TSL	$7.66	$4.51	0.012	0.013	9.06	7.62	1.7	0.8
TWO	$10.44	$11.74	0.010	0.010	8.46	33.06	0.9	3.9
Average	$20.11	$20.26	0.019	0.016	13.00	14.71	1.2	1.1
Control Securities								
Symbol	**Pre-VWAP**	**Post-VWAP**	**Pre-$ Spread**	**Post $ Spread**	**Pre BP Spread**	**Post BP Spread**	**VWAP Change**	**BP Spread Change**
ASX	$4.60	$3.96	0.010	0.010	21.95	25.32	1.2	1.2
BBD	$15.82	$16.97	0.014	0.014	23.05	22.41	0.9	1.0
CBL	$18.50	$21.77	0.011	0.016	28.01	12.58	0.8	0.4
CIE	$26.80	$24.31	0.042	0.051	4.72	4.67	1.1	1.0
DCT	$5.86	$6.64	0.010	0.010	8.06	6.72	0.9	0.8
DDR	$14.35	$15.76	0.010	0.010	7.04	6.69	0.9	1.0
DVA	$87.26	$109.34	0.021	0.025	4.25	4.26	0.8	1.0
EQT	$50.23	$59.41	0.010	0.010	17.11	15.32	0.8	0.9
HST	$15.75	$15.86	0.022	0.018	5.70	4.50	1.0	0.8
HT	$5.29	$4.94	0.012	0.012	11.95	11.91	1.1	1.0
IRE	$6.62	$7.30	0.010	0.010	6.13	6.33	0.9	1.0
ITUB	$16.68	$16.08	0.010	0.011	6.37	4.75	1.0	0.7
KT	$13.60	$16.85	0.011	0.012	11.01	9.92	0.8	0.9
LXP	$8.67	$10.12	0.010	0.010	6.37	6.40	0.9	1.0
MBT	$17.69	$18.31	0.010	0.010	6.16	5.83	1.0	0.9
NRG	$16.59	$22.42	0.010	0.010	11.96	10.13	0.7	0.8
PXP	$39.96	$41.71	0.010	0.010	4.75	5.54	1.0	1.2
SLT	$8.56	$7.84	0.010	0.011	6.02	5.91	1.1	1.0
SWC	$11.09	$12.12	0.021	0.015	8.24	6.69	0.9	0.8
SWFT	$10.30	$10.32	0.010	0.011	11.10	9.87	1.0	0.9
UBS	$12.62	$15.12	0.011	0.012	6.17	5.47	0.8	0.9
VALEP	$20.96	$18.25	0.010	0.010	19.31	20.31	1.1	1.1
VIP	$9.74	$11.41	0.011	0.010	7.84	6.22	0.9	0.8
WCC	$60.60	$65.55	0.011	0.011	13.35	14.12	0.9	1.1
ZTR	$3.58	$12.56	0.049	0.060	8.04	9.22	0.3	1.1
Average	$20.07	$22.60	0.015	0.016	10.59	9.64	0.9	0.9

DID Analysis for Lower Volume Securities

The Exchange also performed a set of DID analyses for securities with average daily volumes between 50,000 and 500,000 shares for the two post-treatment periods covered above.

Table 16 shows the results for the analysis of eligible securities for the six-month pre-period, and the six months following the complete rollout of the Program. Although spreads increased, except for NYSE spreads in dollars, neither the spread-based, market share or trade-to-trade price change studies showed statistical significance. Table 17 shows pre- and post-treatment statistics for the control group and the treatment group. Ten of the 25 treatment securities spreads narrowed, while 14 of 25 control stocks narrowed. There is too much noise in the result to produce statistical significance.

Table 16: DiD Results Lower Volume (Feb. 2012 - July 2012 vs. Sep. 2012 - Feb. 2013)

Estimated Measure	Estimate	Standard Error
Time-weighted NYSE Spread^	4.7620	5.3480
Time-weighted NYSE $ Spread	-0.0128	0.0098
Time-weighted Consolidated Spread	3.3920	3.3040
Time-weighted Consolidated $ Spread	0.0074	0.0064
Volume-weighted Effective Spread vs. NYSE Quote	3.0210	3.8420
Volume-weighted Effective Spread vs. NBBO	2.7023	2.9437
Volume-weighted Effective Spread vs. PBBO	2.7477	2.9722
Volume-weighted Quoted Spread vs. NYSE Quote	3.2340	3.8650
Volume-weighted Quoted Spread vs. NBBO	2.8340	2.9070
Volume-weighted Quoted Spread vs. PBBO	2.8830	2.9368
NYSE Regular Hours Share, no auctions	-0.0117	0.0284
NYSE Full Day Share	-0.0057	0.0271
TRF Regular Hours Share, no auctions	0.0096	0.0491
TRF Full Day Share	0.0125	0.0449
Trade-to-trade price change	0.9963	1.1806

^ - Spreads in basis points unless otherwise noted

Significance: *** = 99.9%, ** = 99%, * = 95%, . = 90%

Table 17 Lower Volume Time-weighted Consolidated Spread and VWAP Comparison of 2012 - 2013 Sample								
Treatment Securities								
Symbol	Pre-VWAP	Post-VWAP	Pre-$ Spread	Post $ Spread	Pre BP Spread	Post BP Spread	VWAP Pre/Post	BP Post/Pre
BPL	$55.77	$49.93	0.055	0.063	12.25	11.97	1.1	1.0
CFR	$57.28	$56.77	0.055	0.057	27.25	37.95	1.0	1.4
CODI	$13.81	$14.97	0.039	0.077	5.19	9.96	0.9	1.9
GTY	$16.42	$17.95	0.038	0.059	8.93	13.62	0.9	1.5
ITC	$72.80	$77.70	0.026	0.035	12.52	13.53	0.9	1.1
JE	$12.32	$9.09	0.018	0.017	10.33	11.19	1.4	1.1
MIC	$32.63	$45.35	0.052	0.047	9.65	9.53	0.7	1.0
NM	$3.81	$3.73	0.038	0.019	31.21	19.19	1.0	0.6
OKS	$56.35	$57.27	0.044	0.051	7.67	8.08	1.0	1.1
PER	$22.20	$18.01	0.073	0.076	9.82	8.79	1.2	0.9
PNG	$18.49	$19.64	0.032	0.041	19.82	20.76	0.9	1.0
RST	$11.50	$12.56	0.036	0.054	31.89	43.39	0.9	1.4
SMP	$16.59	$20.96	0.038	0.033	17.94	17.93	0.8	1.0
STON	$24.94	$23.45	0.059	0.061	10.68	10.48	1.1	1.0
SWX	$42.91	$43.18	0.021	0.030	15.25	20.45	1.0	1.3
SXL	$37.43	$51.63	0.045	0.057	17.67	24.16	0.7	1.4
TAC	$17.57	$15.47	0.065	0.082	14.48	16.18	1.1	1.1
TCAP	$20.36	$25.88	0.027	0.039	15.94	21.54	0.8	1.4
TGP	$38.79	$38.45	0.053	0.046	13.75	11.90	1.0	0.9
TNP	$6.19	$4.38	0.018	0.016	30.07	36.81	1.4	1.2
TRGP	$44.28	$53.62	0.051	0.070	13.68	13.48	0.8	1.0
TUP	$58.80	$65.31	0.031	0.034	5.40	5.97	0.9	1.1
VOC	$20.66	$14.59	0.048	0.044	14.60	9.80	1.4	0.7
WAB	$75.14	$86.66	0.040	0.058	21.87	29.41	0.9	1.3
WES	$44.24	$50.13	0.012	0.012	32.81	32.13	0.9	1.0
Average	$32.85	$35.07	0.041	0.047	16.43	18.33	1.0	1.1
Control Securities								
Symbol	Pre-VWAP	Post-VWAP	Pre-$ Spread	Post $ Spread	Pre BP Spread	Post BP Spread	VWAP Change	BP Spread Change
AFF	$23.88	$25.14	0.042	0.041	11.12	12.26	0.9	1.1
ALE	$40.88	$42.08	0.037	0.032	6.60	5.52	1.0	0.8
ARB	$35.78	$45.40	0.020	0.029	11.10	14.51	0.8	1.3
AXE	$62.21	$63.92	0.072	0.073	11.53	11.92	1.0	1.0
BBN	$22.15	$22.81	0.048	0.045	13.50	11.73	1.0	0.9
BYI	$45.76	$47.00	0.044	0.035	22.87	18.56	1.0	0.8
CDR	$4.94	$5.37	0.032	0.036	30.60	31.91	0.9	1.0
CHH	$37.90	$33.10	0.063	0.040	9.73	9.47	1.1	1.0
CUK	$31.93	$39.02	0.030	0.027	13.35	9.24	0.8	0.7
FFC	$18.39	$19.74	0.026	0.033	15.21	16.84	0.9	1.1
FIX	$10.45	$11.64	0.039	0.023	16.56	9.31	0.9	0.6
FMO	$22.28	$22.86	0.062	0.052	28.04	22.81	1.0	0.8
HII	$38.26	$42.44	0.022	0.025	15.19	16.33	0.9	1.1
HMN	$17.34	$19.65	0.026	0.026	11.74	11.40	0.9	1.0
HPP	$15.93	$20.55	0.032	0.035	6.89	7.35	0.8	1.1
HYI	$18.77	$18.80	0.013	0.013	26.16	24.34	1.0	0.9
KNL	$14.61	$15.23	0.029	0.027	25.43	22.74	1.0	0.9
LTM	$46.46	$44.97	0.039	0.038	12.21	9.82	1.0	0.8
OGE	$52.85	$56.76	0.030	0.030	18.72	15.34	0.9	0.8
RCS	$11.46	$11.60	0.039	0.039	10.73	11.45	1.0	1.1
SNX	$37.43	$34.41	0.029	0.030	5.53	5.25	1.1	0.9
SQM	$56.85	$58.73	0.030	0.032	7.21	7.55	1.0	1.0
TMH	$23.44	$30.06	0.011	0.017	28.79	13.69	0.8	0.5
TTC	$61.29	$42.13	0.049	0.060	10.59	12.71	1.5	1.2
ZF	$3.54	$12.44	0.042	0.047	11.01	11.07	0.3	1.0
Average	$30.19	$31.43	0.036	0.035	15.22	13.72	0.9	0.9

Tables 18A and 18B summarize data used to create the matched sample: VWAP, CADV, and spread in basis points. The tables also provide information on the Program's share of consolidated volume since the sample was created by finding the stocks with the highest share of volume over the treatment period in the Program, and required control stocks to exhibit share of CADV no more than 1/10th the lowest security chosen for the matched sample.

Table 18A: Lower Volume Retail Program Matched Sample (Feb. - July 2012 vs. Sep. 2012 - Feb. 2013)

Treatment Symbol	Pre-period CADV	Pre-period VWAP	Pre-period Spread	Control Symbol	Pre-period CADV	Pre-period VWAP	Pre-period Spread
ITC	466,165	$72.80	5.19	OGE	469,043	$52.85	5.53
TUP	461,730	$58.80	7.67	BYI	463,042	$45.76	6.89
CFR	458,088	$57.28	5.40	SQM	364,490	$56.85	6.60
BPL	421,219	$55.77	9.65	LTM	465,751	$46.46	10.59
OKS	336,853	$56.35	10.68	AXE	306,847	$62.21	11.53
NM	333,179	$3.81	32.81	ZF	273,496	$3.54	28.79
PER	323,068	$22.20	17.94	TMH	321,166	$23.44	13.35
WAB	310,460	$75.14	9.82	TTC	266,687	$61.29	9.73
TNP	286,896	$6.19	30.07	CDR	253,878	$4.94	26.16
CODI	266,134	$13.81	15.25	KNL	288,960	$14.61	15.19
TRGP	256,081	$44.28	12.25	SNX	273,480	$37.43	10.73
WES	250,703	$44.24	14.48	ARB	205,221	$35.78	13.50
TCAP	246,651	$20.36	12.52	BBN	228,523	$22.15	11.74
SMP	210,383	$16.59	19.82	HPP	211,333	$15.93	18.72
SXL	199,616	$37.43	13.68	HII	219,277	$38.26	11.01
GTY	195,074	$16.42	15.94	HMN	204,650	$17.34	15.21
SWX	186,059	$42.91	8.93	ALE	178,379	$40.88	7.21
TGP	182,932	$38.79	13.75	CHH	150,577	$37.90	11.12
MIC	139,817	$32.63	14.60	CUK	132,300	$31.93	12.21
PNG	128,088	$18.49	21.87	HYI	106,275	$18.77	22.87
TAC	106,489	$17.57	10.33	FFC	109,209	$18.39	11.10
STON	104,507	$24.94	17.67	AFF	98,288	$23.88	16.56
RST	98,362	$11.50	31.89	FIX	101,525	$10.45	30.60
JE	95,867	$12.32	31.21	RCS	90,262	$11.46	25.43
VOC	92,453	$20.66	27.25	FMO	72,315	$22.28	28.04

Table 18B: Additional Comparative Statistics

Treatment Symbol	Pre-Period TRF	Post-Period TRF	RTO Share of CADV	Control Symbol	Pre-Period TRF	Post-Period TRF	RTO Share of CADV
ITC	26.82%	43.06%	0.3833%	OGE	23.17%	29.53%	0.0011%
TUP	24.64%	29.70%	0.2193%	BYI	21.57%	28.73%	0.0085%
CFR	17.91%	28.07%	0.2158%	SQM	22.29%	24.74%	0.0174%
BPL	41.04%	44.33%	0.4556%	LTM	29.08%	29.97%	0.0182%
OKS	34.83%	41.65%	0.8358%	AXE	31.97%	31.46%	0.0171%
NM	46.71%	49.95%	0.2620%	ZF	44.16%	47.28%	0.0081%
PER	53.26%	55.94%	0.7724%	TMH	40.80%	40.33%	0.0103%
WAB	23.37%	28.15%	0.4312%	TTC	22.70%	28.28%	0.0037%
TNP	36.70%	47.21%	0.2783%	CDR	37.32%	47.85%	0.0152%
CODI	35.24%	47.94%	0.2466%	KNL	24.96%	32.85%	0.0152%
TRGP	30.89%	37.72%	0.2216%	SNX	32.69%	40.48%	0.0131%
WES	31.34%	39.78%	0.2290%	ARB	22.94%	34.92%	0.0056%
TCAP	40.70%	41.69%	0.2057%	BBN	65.12%	61.66%	0.0158%
SMP	29.99%	33.97%	0.2265%	HPP	39.20%	38.36%	0.0131%
SXL	37.24%	43.60%	0.2381%	HII	30.94%	32.81%	0.0182%
GTY	31.76%	33.57%	0.7064%	HMN	25.51%	26.43%	0.0172%
SWX	20.90%	25.59%	0.2268%	ALE	22.82%	28.27%	0.0133%
TGP	43.79%	47.16%	0.2854%	CHH	23.02%	29.31%	0.0156%
MIC	30.37%	44.78%	0.2500%	CUK	12.16%	21.83%	0.0079%
PNG	54.57%	51.61%	0.5979%	HYI	52.40%	45.77%	0.0143%
TAC	28.18%	36.24%	0.2532%	FFC	55.36%	57.90%	0.0196%
STON	53.56%	54.02%	0.2388%	AFF	40.54%	50.07%	0.0026%
RST	39.86%	36.83%	0.5156%	FIX	29.24%	31.74%	0.0187%
JE	46.00%	44.11%	0.2346%	RCS	58.77%	55.97%	0.0198%
VOC	49.37%	49.32%	0.2063%	FMO	51.13%	58.91%	0.0076%

Table 19 shows the results for the lower volume stocks study comparing the six month pre-Program period to 2016–2017. Time-weighted consolidated and NYSE spreads in basis points increased and were statistically significant at the 95% level. Other basis point spreads were also statistically significant at either the 95% or 99% level. TRF share excluding auctions increased at the 99% level, and including auctions increased at the 99.9% level. NYSE share changes were not statistically significant. Trade-to-trade price changes (in basis points) rose and were significant at the 95% level. The Exchange notes, however, that time-weighted consolidated spreads in dollars decreased and were significant at the 90% level. NYSE dollar spreads also decreased, but were not statistically significant.

Table 19 Lower Volume DiD Results (Feb. 2012 - July 2012 vs. 2016 - 2017)

Estimated Measure	Estimate	Standard Error
Time-weighted NYSE Spread^	13.740*	6.6250
Time-weighted NYSE $ Spread	-0.0343	0.0213
Time-weighted Consolidated Spread	9.478*	4.3300
Time-weighted Consolidated $ Spread	-0.0281.	0.0154
Volume-weighted Effective Spread vs. NYSE Quote	8.820*	3.7820
Volume-weighted Effective Spread vs. NBBO	7.766**	2.9050
Volume-weighted Effective Spread vs. PBBO	7.750**	2.9080
Volume-weighted Quoted Spread vs. NYSE Quote	9.436*	3.8440
Volume-weighted Quoted Spread vs. NBBO	8.8367**	2.9000
Volume-weighted Quoted Spread vs. PBBO	8.345**	2.9050
NYSE Regular Hours Share, no auctions	-0.0142	0.0177
NYSE Full Day Share	0.0010	0.0171
TRF Regular Hours Share, no auctions	0.073**	0.0248
TRF Full Day Share	0.0824***	0.0224
Trade-to-trade price change	2.6672*	1.4707

^ - Spreads in basis points unless otherwise noted

Significance *** = 99.9%, ** = 99%, * = 95%, . = 90%

Table 20 provides evidence for the possible cause of the inconsistency in the results. The average dollar spread in the treatment stocks dropped slightly, while dollar spreads in the control stocks rose 82%. Spreads in basis points were unchanged for treatment stocks, but dropped 30% in the control group. Price changes tended to be positive in the control stocks and were little changed in the treatment group. The statistical significance appears to be driven by changes in the control stocks.

Table 20: Lower Volume Time-weighted Consolidated Spread and VWAP Comparison of 2016 -2017 Sample								
Treatment Securities								
Symbol	Pre-VWAP	Post-VWAP	Pre-$ Spread	Post $ Spread	Pre BP Spread	Post BP Spread	VWAP Pre/Post	BP Post/Pre
AFT	$17.92	$16.31	0.030	0.026	16.60	15.71	1.1	0.9
BLW	$17.28	$15.29	0.026	0.017	15.22	11.20	1.1	0.7
DBL	$26.03	$24.59	0.041	0.068	15.50	27.12	1.1	1.7
ETV	$12.67	$14.95	0.014	0.020	11.29	13.27	0.8	1.2
FENG	$5.98	$5.00	0.034	0.019	58.46	49.20	1.2	0.8
GIM	$9.52	$6.45	0.015	0.011	15.83	16.62	1.5	1.0
GPM	$9.23	$8.17	0.030	0.018	32.88	23.41	1.1	0.7
HPS	$18.62	$18.57	0.035	0.032	18.58	17.30	1.0	0.9
JQC	$9.10	$8.37	0.014	0.011	15.15	12.79	1.1	0.8
MUA	$13.13	$14.60	0.022	0.030	16.54	20.63	0.9	1.2
NCZ	$8.39	$5.61	0.016	0.011	19.48	19.81	1.5	1.0
NUV	$10.13	$10.06	0.012	0.012	12.11	12.21	1.0	1.0
PBT	$20.04	$7.89	0.034	0.032	17.37	42.60	2.5	2.5
PCK	$10.13	$10.11	0.019	0.027	18.60	26.47	1.0	1.4
PCN	$16.38	$15.49	0.024	0.029	14.43	18.67	1.1	1.3
PHD	$12.85	$11.60	0.022	0.021	17.09	18.27	1.1	1.1
PHT	$17.21	$9.88	0.028	0.022	16.10	22.06	1.7	1.4
PIM	$5.09	$4.56	0.011	0.011	21.39	24.41	1.1	1.1
PMX	$12.10	$11.92	0.023	0.019	18.66	16.21	1.0	0.9
PTY	$18.59	$15.21	0.025	0.020	13.23	13.54	1.2	1.0
RA	$23.72	$23.29	0.036	0.031	16.44	13.55	1.0	0.8
SJT	$16.71	$6.79	0.030	0.036	18.41	55.77	2.5	3.0
TSI	$5.14	$5.42	0.014	0.015	28.10	26.86	0.9	1.0
UTF	$17.16	$20.99	0.024	0.026	13.80	12.18	0.8	0.9
WIW	$12.95	$11.03	0.013	0.014	9.78	12.32	1.2	1.3
Average	$13.84	$12.09	0.024	0.023	18.84	21.69	1.2	1.2
Control Securities								
Symbol	Pre-VWAP	Post-VWAP	Pre-$ Spread	Post $ Spread	Pre BP Spread	Post BP Spread	VWAP Pre/Post	BP Post/Pre
AAT	$23.10	$40.71	0.019	0.016	8.45	3.81	0.6	0.5
AER	$11.73	$40.57	0.029	0.011	14.97	3.51	0.3	0.2
CHSP	$17.73	$25.05	0.091	0.294	23.52	33.79	0.7	1.4
CIR	$32.92	$54.01	0.020	0.036	13.69	15.41	0.6	1.1
COR	$23.78	$88.08	0.036	0.012	67.86	7.62	0.3	0.1
CRH	$19.15	$32.94	0.020	0.025	15.60	13.32	0.6	0.9
CSU	$9.83	$15.49	0.073	0.039	50.33	14.08	0.6	0.3
DK	$16.08	$20.78	0.080	0.219	23.90	40.36	0.8	1.7
FSS	$5.21	$15.43	0.013	0.033	13.36	17.02	0.3	1.3
HRG	$6.91	$15.95	0.049	0.055	29.17	26.85	0.4	0.9
HTH	$9.56	$23.63	0.017	0.023	18.25	12.89	0.4	0.7
ITG	$10.18	$18.93	0.014	0.021	11.82	4.90	0.5	0.4
KAR	$16.27	$41.75	0.039	0.106	16.43	12.06	0.4	0.7
KRG	$5.04	$22.91	0.030	0.032	31.13	20.22	0.2	0.6
LAD	$24.94	$91.60	0.032	0.028	18.31	11.14	0.3	0.6
NCI	$13.13	$19.29	0.018	0.033	19.19	14.16	0.7	0.7
ORA	$19.54	$51.98	0.047	0.046	22.49	23.89	0.4	1.1
PFS	$14.43	$23.71	0.012	0.025	24.32	16.44	0.6	0.7
PRO	$17.19	$20.72	0.031	0.083	21.63	20.73	0.8	1.0
PUK	$23.11	$38.57	0.036	0.055	15.67	13.49	0.6	0.9
ROG	$38.80	$87.75	0.041	0.208	16.27	21.97	0.4	1.4
SSP	$9.27	$17.54	0.024	0.022	15.25	10.97	0.5	0.7
STC	$14.50	$41.42	0.014	0.019	27.20	8.06	0.4	0.3
THR	$20.63	$19.10	0.029	0.019	17.80	4.43	1.1	0.2
TRNO	$14.49	$30.05	0.028	0.071	14.50	14.10	0.5	1.0
Average	$16.70	$35.92	0.034	0.061	22.04	15.41	0.5	0.8

As previously noted, the Exchange's selection methodology focused on finding securities that traded most heavily in the Program. As discussed above in the section covering higher volume securities and as shown in

Table 13, both TRF share and Program activity are higher in low priced stocks. This constraint did not impact the control stocks, as the selection methodology requires control stocks to have significantly lower share of the market. However, it did result in control stocks that traded largely in line with the overall market, resulting in price increases over the 2012 to 2016–2017 time period. Table 21B highlights the constraint on Program share for the treatment and control stocks. Table 21A presents additional matched sample population statistics.

Table 21A Lower Volume Retail Program Matched Sample (Feb. - July 2012 vs.2016 - 2017)

Treatment Symbol	Pre-period CADV	Pre-period VWAP	Pre-period Spread	Control Symbol	Pre-period CADV	Pre-period VWAP	Pre-period Spread
JQC	369,780	$9.10	15.15	ITG	408,461	$10.18	13.36
RA	322,887	$23.72	16.44	LAD	383,601	$24.94	16.27
SJT	321,395	$16.71	18.41	DK	271,741	$16.08	15.25
NUV	297,752	$10.13	12.11	AER	395,314	$11.73	11.82
GIM	230,462	$9.52	15.83	NCI	208,759	$13.13	15.60
ETV	192,598	$12.67	11.29	PFS	220,318	$14.43	13.69
PBT	186,841	$20.04	17.37	COR	178,141	$23.78	16.43
NCZ	173,121	$8.39	19.48	SSP	211,122	$9.27	18.25
PIM	166,347	$5.09	21.39	FSS	248,554	$5.21	24.32
UTF	162,477	$17.16	13.80	KAR	133,654	$16.27	17.80
PTY	158,023	$18.59	13.23	AAT	160,197	$23.10	15.67
BLW	142,198	$17.28	15.22	CRH	220,462	$19.15	14.97
WIW	128,003	$12.95	9.78	ORA	159,691	$19.54	14.50
AFT	110,279	$17.92	16.60	PUK	216,892	$23.11	8.45
TSI	102,390	$5.14	28.10	KRG	155,926	$5.04	27.20
PHD	95,377	$12.85	17.09	HTH	136,956	$9.56	19.19
HPS	95,354	$18.62	18.58	CIR	101,115	$32.92	23.90
PCN	93,385	$16.38	14.43	CHSP	142,605	$17.73	18.31
FENG	91,064	$5.98	58.46	HRG	140,599	$6.91	67.86
PMX	79,724	$12.10	18.66	STC	130,592	$14.50	21.63
DBL	79,546	$26.03	15.50	ROG	77,121	$38.80	23.52
PHT	74,858	$17.21	16.10	THR	131,374	$20.63	22.49
MUA	68,289	$13.13	16.54	PRO	123,042	$17.19	29.17
PCK	65,854	$10.13	18.60	CSU	114,894	$9.83	31.13
GPM	65,699	$9.23	32.88	TRNO	42,586	$14.49	50.33

Table 21B: Lower Volume Additional Comparative Statistics

Treatment Symbol	Pre-Period TRF	Post-Period TRF	RTO Share of CADV	Control Symbol	Pre-Period TRF	Post-Period TRF	RTO Share of CADV
JQC	53.45%	55.77%	0.3976%	ITG	28.34%	28.58%	0.0931%
RA	31.22%	61.42%	0.4457%	LAD	29.41%	30.97%	0.0719%
SJT	48.63%	56.58%	0.4925%	DK	28.80%	29.07%	0.1062%
NUV	57.90%	62.72%	0.3850%	AER	32.99%	29.54%	0.0635%
GIM	57.10%	59.93%	0.3806%	NCI	24.04%	29.26%	0.0842%
ETV	45.63%	59.43%	0.3909%	PFS	16.77%	26.40%	0.0409%
PBT	47.98%	53.79%	0.4060%	COR	39.92%	32.55%	0.1254%
NCZ	55.52%	60.23%	0.3975%	SSP	18.94%	27.92%	0.0767%
PIM	53.47%	53.69%	0.3881%	FSS	27.48%	32.29%	0.0913%
UTF	58.75%	61.54%	0.3789%	KAR	40.73%	32.64%	0.0582%
PTY	51.39%	61.88%	0.3985%	AAT	32.49%	31.45%	0.0465%
BLW	55.54%	62.10%	0.4304%	CRH	44.17%	35.53%	0.0567%
WIW	50.93%	55.79%	0.3763%	ORA	20.06%	27.46%	0.1029%
AFT	56.03%	48.47%	0.4002%	PUK	29.91%	22.84%	0.1404%
TSI	48.42%	59.76%	0.4596%	KRG	32.63%	28.55%	0.0853%
PHD	46.77%	56.16%	0.4382%	HTH	30.78%	30.89%	0.1034%
HPS	56.21%	61.50%	0.3977%	CIR	26.84%	25.96%	0.0862%
PCN	54.41%	62.59%	0.3803%	CHSP	38.40%	32.94%	0.0464%
FENG	38.56%	44.38%	0.6027%	HRG	34.33%	30.91%	0.0603%
PMX	48.90%	57.41%	0.4050%	STC	36.56%	31.37%	0.0501%
DBL	52.89%	61.96%	0.3880%	ROG	27.11%	30.05%	0.1075%
PHT	54.28%	52.30%	0.4071%	THR	34.43%	35.10%	0.0924%
MUA	49.27%	60.68%	0.4349%	PRO	32.32%	34.09%	0.0936%
PCK	46.86%	57.25%	0.4788%	CSU	43.41%	34.77%	0.0917%
GPM	49.04%	56.77%	0.5087%	TRNO	44.43%	33.11%	0.0327%

In conclusion, the Exchange believes that the Program was a positive experiment in attracting retail order flow to a public exchange. The order flow the Program attracted to the Exchange provided tangible price improvement to retail investors through a competitive pricing process unavailable in non-exchange venues. As such, despite the low volumes, the Exchange believes that the Program satisfied the twin goals of attracting retail order flow to the Exchange and allowing such order flow to receive potential price improvement. Moreover, the Exchange believes that the data collected during the Program supports the conclusion that the Program's overall impact on market quality and structure was not negative. Although the results of the Program highlight the substantial advantages that broker-dealers retain when managing the benefits of retail order flow, the Exchange believes that the level of price improvement guaranteed by the Program justifies making the Program

permanent. The Exchange accordingly believes that the pilot Program's rules, as amended, should be made permanent.

The Exchange notes that the proposed change is not otherwise intended to address any other issues and the Exchange is not aware of any problems that member organizations would have in complying with the proposed rule change.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[66] in general, and Section 6(b)(5) of the Act,[67] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposal is consistent with these principles because it seeks to make permanent a pilot and associated rule changes that were previously approved by the Commission as a pilot for which the Exchange has subsequently provided data and analysis to the Commission, and that this data and analysis, as well as the further analysis in this filing, shows that the Program has operated as intended and is consistent with the Act. The Exchange also believes that the proposed rule change is consistent with these principles because it would increase competition among execution venues, encourage additional liquidity, and offer the potential for price improvement to retail investors.

The Exchange also believes the proposed rule change is designed to facilitate transactions in securities and to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system because making the Program permanent would attract retail order flow to a public exchange and allow such order flow to receive potential price improvement. The data provided by the Exchange to the Commission staff demonstrates that the Program provided tangible price improvement to retail investors through a competitive pricing process unavailable in non-exchange venues and otherwise had an insignificant impact on the marketplace. The Exchange believes that making the Program permanent would encourage the additional utilization of, and interaction with, the NYSE and provide retail customers with an additional venue for price discovery, liquidity, competitive quotes, and price improvement. For the same reasons, the Exchange believes that making the Program permanent would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market.

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. For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that making the Program permanent would continue to promote competition for retail order flow among execution venues. The Exchange also believes that making the Program permanent will promote competition between execution venues operating their own retail liquidity programs. Such competition will lead to innovation within the market, thereby increasing the quality of the national market system. Finally, the Exchange notes that it operates in a highly competitive market in which market participants can easily direct their orders to competing venues, including off-exchange venues. In such an environment, the Exchange must continually review, and consider adjusting the services it offers and the requirements it imposes to remain competitive with other U.S. equity 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. Summary of Comment Letter

After the Commission instituted proceedings, the Commission received a comment letter on the proposed rule change.[68] In support of the proposal to the make the Program permanent, the commenter states that the Program seems to have offered significant price improvement during the course of its pilot period.[69] Citing the Exchange's analysis in the Original Notice of trading activity during the pilot period, the commenter notes that between August 1, 2012 and January 2, 2018, orders totaling in excess of 6.8 billion shares were executed through the Program, providing improvements of $12.3 million dollars.[70] The commenter observes that these statistics indicate that the Program has provided greater than the average price improvement provided through other common execution avenues.[71] The commenter notes that fill rates have also been, at times, significant.[72] The commenter also believes that the Program offers the Commission a unique opportunity to explore brokers' fulfillment of their best execution obligations.[73]

IV. Discussion and Commission Findings

After careful review, the Commission finds that the Exchange's proposal to make permanent the Retail Liquidity Program Pilot, Rule 107C, as modified by Amendment No. 1, is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.[74] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Sections 6(b)(5)[75] and 6(b)(8)[76] of the Exchange Act. Section 6(b)(5) of the Exchange Act requires that the rules of a national securities exchange be designed, among other things, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. Section 6(b)(8) of the Exchange Act requires that the rules of a national securities exchange not impose any burden on competition that is not

[66] 15 U.S.C. 78f(b).

[67] 15 U.S.C. 78f(b)(5).

[68] *See* HMA Letter, *supra* note 10.

[69] *See id.* at 2.

[70] *See id.* at 3.

[71] *See id.*

[72] *See id.*

[73] *See id.* at 2–3.

[74] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[75] 15 U.S.C. 78f(b)(5).

[76] 15 U.S.C. 78f(b)(8).

necessary or appropriate in furtherance of the purposes of the Exchange Act.

As noted above, the Commission approved the Program on a pilot basis to allow the Exchange and market participants to gain valuable practical experience with the Program during the pilot period, and to allow the Commission to determine whether modifications to the Program were necessary or appropriate prior to any Commission decision to approve the Program on a permanent basis.[77] Indeed, the Exchange has modified aspects of the Program on several occasions since initial approval of the Program on a pilot basis.[78] As set forth in the RLP Approval Order, the Exchange agreed to provide the Commission with a significant amount of data to assist the Commission's evaluation of the Program prior to any permanent approval of the Program.[79] Specifically, the Exchange represented that it would ''produce data throughout the pilot, which will include statistics about participation, the frequency and level of price improvement provided by the Program, and any effects on the broader market structure.'' [80] The Commission expected the Exchange to monitor the scope and operation of the Program and study the data produced during that time with respect to such issues.[81]

Although the pilot period was originally scheduled to end on July 31, 2013, the Exchange filed to extend the operation of the pilot on several occasions.[82] The pilot is now set to expire on June 30, 2019, and the Exchange proposes to make the Program, Rule 107C, permanent. In its proposal, as modified by Amendment No. 1, the Exchange provides data and analysis which it believes justifies permanent approval of the Program.

In the Original Notice, the Exchange provided data indicating that the Program provided $12.3 million in price improvement to retail investors between August 21, 2012 and January 2, 2018, as well as data showing overall average price improvement of $0.0014 per share (approximately 40% above the minimum of $0.001), with average price improvement exceeding that level in 2016.[83] In the Original Notice, the Exchange also stated its belief that receipt of price improvement by retail investors, the Program's low volume levels, and other data, similar to that provided in Tables 1 through 8 above, were sufficient to conclude that the Program had achieved its goals without negatively impacting the broader market.[84] In the Commission's Order Instituting Proceedings, the Commission questioned whether the information and analysis provided by the Exchange in the Original Notice supported the Exchange's conclusions that the Program had achieved its goals, including whether the Exchange had provided data and analysis to support its conclusion that the Program had an overall negligible impact on broader market structure.[85]

In Amendment No. 1, the Exchange has provided data and analysis concerning the Program during the pilot period in addition to that provided in the Original Notice. In particular, the Commission notes that in Amendment No. 1, the Exchange undertook to provide a more in-depth analysis of the Program's impact on market quality by using the difference-in-differences (''DID'') statistical technique, the methodology for which it explains above.[86] Although the Program was not initially designed to produce a DID analysis, the Exchange identified the most active stocks in the Program to establish a treatment group of stocks and then used securities with similar pre-treatment spread, price, and CADV but very low Program activity as a control group. Using this methodology, the Exchange produced four DID analyses that the Commission believes are useful to assess the Program's impact on market quality, as measured by a variety of market quality statistics including: (1) Time-weighted NYSE quoted spread in basis points; (2) time-weighted NYSE quoted spread in dollars and cents; (3) time-weighted consolidated quoted spread in basis points; (4) time-weighted consolidated quoted spread in dollars and cents; (5) volume-weighted effective spread in basis points measured against the NYSE quote; (6) volume-weighted effective spread in basis points measured against the national best bid or offer (''NBBO''); (7) volume-weighted effective spread in basis points measured against the protected best bid or offer (''PBBO''); (8) volume-weighted quoted spread in basis points measured against the NYSE quote; (9) volume-weighted quoted spread in basis points measured against the NBBO; (10) volume-weighted quoted spread in basis points measured against the PBBO; (11) Trade Reporting Facility (''TRF'') share of volume during regular trading hours, excluding auctions; (12) TRF share of volume, full day, including auctions; (13) NYSE share of volume during regular trading hours, excluding auctions; (14) NYSE share of volume, full day, including auctions; and (15) trade-to-trade price change in basis points of the Program.[87]

In its first set of DID analyses, the Exchange studies stocks that had a CADV of at least 500,000 shares during both a pre-treatment and a treatment period. For these stocks, the Exchange compares changes in market quality statistics between the pre-treatment and treatment period for the treatment group stocks and the control group stocks. The Exchange conducts this study using two different treatment periods. More specifically, the Exchange examines market quality statistics for:

- Six months prior to launch of the Program (February 2012–July 2012) as compared to six months following launch, excluding the first month of the Program (September 2012–February 2013) for securities with a CADV of at least 500,000 during the pre-treatment and treatment periods, and
- Six months prior to launch of the Program (February 2012–July 2012) as compared to all of 2016 and 2017 for securities with a CADV of at least 500,000 during the pre-treatment and treatment periods.

As summarized in Table 11 above, when analyzing stocks with a CADV of at least 500,000 shares, and when comparing changes between the pre-treatment period and the 2012–2013 treatment period, the Exchange finds no statistically significant differences between treatment and control group

[77] *See* RLP Approval Order *supra* note 14, at 40674.

[78] *See supra,* note 22.

[79] *See* RLP Approval Order, *supra* note 14, at 40681.

[80] *See id.*

[81] *See id.*

[82] *See supra,* note 15.

[83] *See* Original Notice, *supra* note 3, at 28879.

[84] *See id.* at 2882–83.

[85] *See* Order Instituting Proceedings, *supra* note 7, at 48352. In the Order Instituting Proceedings, the Commission sought additional information and analysis concerning the Program's impact on the broader market, for example, additional information to support the view that the Program has not had a material adverse impact on market quality and consideration of any effects that fees and rebates may have had on the operation of the Program. *See id.*

[86] A DID statistical technique allows studying the differential effect of a treatment on data measured between a treatment group and a control group. The two groups are measured during two or more different time periods, usually a period before ''treatment'' and at least one time period after ''treatment,'' that is, a time period after which the treatment group is impacted but the control group is not. For each group, the difference between a measure in the pre-treatment and the treatment period is computed. Those differences for a measure for the two groups are then compared to each other by taking the difference between them.

[87] In its analyses, the Exchange notes that lower-priced securities tend to be most active in the Program, and as a result, its artificially created treatment group includes securities that were relatively low-priced during the treatment period, but may not have been similarly low-priced during the pre-treatment period.

stocks for the changes in time-weighted NYSE or time-weighted consolidated spreads (whether measured in basis points or in dollars).[88]

As summarized in Table 12 above, when comparing changes between the pre-treatment period and the 2016–2017 treatment period, the analysis shows statistically significant positive differences between treatment and control stocks for changes in several spread measures in basis points, as well as for changes in the share of trading on the TRF, which could suggest a negative effect of the Program.[89] However, the Exchange's analysis further reveals that the treatment stocks for the 2016–2017 treatment period saw sharp price declines as compared to their 2012 pre-treatment period levels.[90] In addition, many of the treatment stocks traded with quoted spreads near $0.01 (*i.e.,* they were tick-constrained), so that any price drop would necessarily result in an almost equal and opposite percentage increase in the spreads measured in basis points. After careful consideration, the Commission believes that the DID and additional analysis performed by the Exchange for stocks with a CADV of at least 500,000 shares, support the conclusion that positive DID results for spreads and TRF activity observed in Table 12 above are unlikely to be caused by the Program.

In its other set of DID analyses, the Exchange studies stocks that had a CADV of at least 50,000 shares and less than 500,000 shares during both a pre-treatment and a treatment period, for the same two treatment time periods. For these stocks, the Exchange likewise compares changes in market quality statistics between the pre-treatment and the treatment periods for the treatment group stocks and the control group stocks. Specifically, to assess whether the results differ for lower-volume stocks, the Exchange examines the same market quality statistics for:

- Six months prior to launch of the Program (February 2012–July 2012) compared to six months following launch, excluding the first month of the Program (September 2012–February 2013) for securities with a CADV of at least 50,000 and less than 500,000, during the pre-treatment and treatment periods; and
- Six months prior to launch of the Program (February 2012–July 2012) compared to all of 2016 and 2017 for securities with a CADV of at least 50,000 and less than 500,000, during the pre-treatment and treatment periods.

As summarized in Table 16 above, when analyzing these lower-volume stocks, and when comparing changes between the pre-treatment period and the 2012–2013 treatment period, the Exchange similarly finds no statistically significant differences between treatment and control group stocks for the changes in time-weighted NYSE or time-weighted consolidated spreads (whether measured in basis points or in dollars).[91]

As summarized in Table 19 above, when comparing changes between the pre-treatment period and the 2016–2017 treatment period, the analysis shows statistically significant positive differences between treatment and control stocks for changes in several spread measures in basis points, as well as for changes in the share of trading on the TRF. In assessing the observed positive differences for changes in spread measures in basis points, the Exchange's analysis further reveals that these differences are attributable mostly to changes in the control stocks rather than to changes in the treatment stocks. In particular, as shown in Table 20, between the pre-treatment period and the 2016–2017 treatment period, the treatment stocks experienced virtually no change in dollar spreads and only a small increase in spreads measured in basis points (driven by a small decline in their prices (VWAP)).[92] In contrast, in the same time period, the control stocks experienced a large decrease in spreads measured in basis points, driven by the fact that their average price (VWAP) more than doubled.[93] Thus, the large increase in the prices of the control stocks (which did not occur for the treatment stocks) contributes significantly to the observed positive differences between treatment and control stocks for changes in basis point spread measures. After careful consideration, the Commission believes that the DID and additional analysis performed by the Exchange for stocks with a CADV of at least 50,000 and less than 500,000 shares support the conclusion that the positive DID results in spreads and TRF observed in Table 19 are unlikely to be caused by the Program.

As noted, in the Order Instituting Proceedings, the Commission questioned whether the Exchange provided sufficient data and analysis in the Original Notice to support its conclusions that the Program had achieved its goals and had an overall negligible impact on broader market structure.[94] In Amendment No. 1, the Exchange provides data and analysis to further support its assertions in the Original Notice. The Commission believes that the data and analysis provided by the Exchange support the conclusion that the Program provides meaningful price improvement to retail investors on a regulated exchange venue and has not demonstrably caused harm to the broader market. Based on the foregoing, and after careful consideration of the Exchange's analysis of the data generated by the Program and the comment received, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Exchange Act.

V. Solicitation of Comments on Amendment No. 1

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 to the proposed rule change is consistent with the Exchange Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

[88] More broadly, the Exchange finds no statistically significant difference between treatment and control group stocks for any of the analyzed measures of market quality when comparing the pre-treatment period with the 2012–2013 treatment period.

[89] In addition, the results in Table 12 show negative differences between the treatment and control stocks for changes in time-weighted consolidated dollar spreads (statistically significant at the 90% confidence level) and for changes in time-weighted NYSE dollar spreads (statistically significant at the 95% confidence level).

[90] Table 14 above shows a decrease in the average value weighted average price (VWAP) of treatment stocks from $25.51 (pre-treatment period) to $13.75 (2016–2017 treatment period) and an increase in the average VWAP of control group stocks from $24.96 (pre-treatment period) to $37.74 (2016–2017 treatment period). In contrast, Table 15 above shows that similar price changes are not present in the analysis focusing on the 2012–2013 treatment period.

[91] More broadly, the Exchange finds no statistically significant difference between treatment and control group stocks for any of the analyzed measures of market quality when comparing the pre-treatment period with the 2012–2013 treatment period.

[92] Table 20 shows that between the pre-treatment period and the 2016–2017 treatment period, the treatment stocks experienced a slight decrease in average dollar spread from $0.024 to $0.023, a small decline in average VWAP from $13.84 to $12.09, and a small increase in basis point spread from 18.84 to 21.69 basis points.

[93] Table 20 shows that between the pre-treatment period and the 2016–2017 treatment period, the control stocks experienced a large increase in average VWAP from $16.70 to $35.92, a smaller percentage increase in average dollar spread from $0.034 to $0.061, and a large decrease in basis point spread from 22.04 to 15.41 basis points.

[94] *See supra* note 85 and accompanying text.

• Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2018–28 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–NYSE–2018–28. 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 (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of this filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2018–28 and should be submitted on or before March 15, 2019.

VI. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the 30th day after the date of publication of notice of Amendment No. 1 in the **Federal Register**. Amendment No. 1 supplements the proposal by providing additional analysis of the Program's impact on the market to address concerns raised in Commission's Order Instituting Proceedings. Specifically, in Amendment No. 1, the Exchange presents and discusses four DID analyses it performed to assess the Program, as measured by a variety of market quality statistics. These DID analyses and the additional analysis provided by the Exchange assisted the Commission in evaluating the Program's impact on the broader market and in determining that permanent approval of the Program, Rule 107C, is reasonably designed to perfect the mechanism of a free and open market and the national market system, protect investors and the public interest, and not be unfairly discriminatory, or impose an unnecessary or inappropriate burden on competition. Accordingly, pursuant to Section 19(b)(2) of the Exchange Act,[95] the Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VII. Limited Exemption From the Sub-Penny Rule

Pursuant to its authority under Rule 612(c) of Regulation NMS,[96] the Commission hereby grants the Exchange a limited exemption from the Sub-Penny Rule to operate the Program. For the reasons discussed below, the Commission determines that such action is necessary or appropriate in the public interest, and is consistent with the protection of investors.

When the Commission adopted the Sub-Penny Rule in 2005, the Commission identified a variety of problems caused by sub-pennies that the Sub-Penny Rule was designed to address:

• If investors' limit orders lose execution priority for a nominal amount, investors may over time decline to use them, thus depriving the markets of liquidity.

• When market participants can gain execution priority for a nominal amount, important customer protection rules such as exchange priority rules and the Manning Rule[97] could be undermined.

• Flickering quotations that can result from widespread sub-penny pricing could make it more difficult for broker-dealers to satisfy their best execution obligations and other regulatory responsibilities.

• Widespread sub-penny quoting could decrease market depth and lead to higher transaction costs.

• Decreasing depth at the inside could cause institutions to rely more on execution alternatives away from the exchanges, potentially increasing fragmentation in the securities markets.[98]

The Commission believes that the limited exemption granted today should continue to promote competition between exchanges and OTC market makers in a manner that is reasonably designed to minimize the problems that the Commission identified when adopting the Sub-Penny Rule. Under the Program, sub-penny prices will not be disseminated through the consolidated quotation data stream, which should avoid quote flickering and its reduced depth at the inside quotation.

Furthermore, the Commission does not believe that granting this limited exemption and approving the proposal would reduce incentives for market participants to display limit orders. As noted in the RLP Approval Order, market participants that displayed limit orders at the time were not able to interact with marketable retail order flow because that order flow was almost entirely routed to internalizing OTC market makers that offered sub-penny executions,[99] and, as noted in Amendment No. 1, the Program has attracted a small volume from the OTC market makers. As a result, enabling the Exchange to continue to compete for retail order flow through the Program should not materially detract from the current incentives to display limit orders, while potentially resulting in greater order interaction and price improvement for marketable retail orders on a public national securities exchange. To the extent that the Program may raise Manning and best execution issues for broker-dealers, these issues are already presented by the existing practices of OTC market makers.

This permanent and limited exemption from the Sub-Penny Rule is limited solely to the operation of the Program by the Exchange. This exemption does *not* extend beyond the scope of Exchange Rule 107C. In addition, this exemption is conditioned on the Exchange continuing to conduct the Program, in accordance with Exchange Rule 107C and substantially as described in the Exchange's request for exemptive relief and the proposed rule change, as modified by Amendment No. 1.[100] Any changes in Exchange Rule 107C may cause the Commission to reconsider this exemption.

[95] 15 U.S.C. 78s(b)(2).

[96] 17 CFR 242.612(c).

[97] *See* Financial Industry Regulatory Authority Rule 5320 (Prohibition Against Trading Ahead of Customer Orders).

[98] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[99] *See* RLP Approval Order, *supra* note 14, at 40682.

[100] *See supra* note 13.

VIII. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,[101] that the proposed rule change (SR–NYSE–2018–28), as modified by Amendment No. 1, be, and it hereby is, approved on an accelerated basis.

It is further ordered that, pursuant to Rule 612(c) under Regulation NMS, that the Exchange shall be exempt from Rule 612(a) of Regulation NMS with respect to the operation of the Program as set forth in Exchange Rule 107C as described herein.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[102]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03043 Filed 2–21–19; 8:45 am]

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[101] 15 U.S.C. 78s(b)(2).

[102] 17 CFR 200.30–3(a)(12) and 17 CFR 200.30–3(a)(83).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–122, OMB Control No. 3235–0111]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Form T–2

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Form T–2 (17 CFR 269.2) is a statement of eligibility of an individual trustee under the Trust Indenture Act of 1939. The information is used to determine whether the individual is qualified to serve as a trustee under the indenture. Form T–2 is filed on occasion. The information required by Form T–2 is mandatory. This information is publicly available on EDGAR. Form T–2 takes approximately 9 hours per response to prepare and is filed by approximately 9 respondents. We estimate that 25% of the 9 hours per response (2 hours) is prepared by the filer for a total annual reporting burden of 18 hours (2 hours per response × 9 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following website, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Lindsay.M.Abate@omb.eop.gov;* and (ii) Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: February 19, 2019.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03088 Filed 2–21–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85162; File No. SR–MIAX–2019–01]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend its Options Regulatory Fee

February 15, 2019.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 1, 2019, Miami International Securities Exchange LLC (''MIAX Options'' 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.

[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 is filing a proposal to amend the MIAX Options Fee Schedule (the ''Fee Schedule'') to amend its Options Regulatory Fee (''ORF'').

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange charges an ORF in the amount of $0.0045 per contract side. The Exchange proposes to decrease this ORF to $0.0029 per contract side. In light of historical and projected volume changes and shifts in the industry and on the Exchange, as well as changes to the Exchange's regulatory cost structure, the Exchange is proposing to change the amount of ORF that will be collected by the Exchange. The Exchange's proposed change to the ORF should balance the Exchange's regulatory revenue against the anticipated regulatory costs.

The per-contract ORF will continue to be assessed by MIAX Options to each MIAX Options Member for all options transactions, including Mini Options, cleared or ultimately cleared by the Member which are cleared by the Options Clearing Corporation (''OCC'') in the ''customer'' range, regardless of the exchange on which the transaction occurs. The ORF will be collected by OCC on behalf of MIAX Options from either (1) a Member that was the ultimate clearing firm for the transaction or (2) a non-Member that was the ultimate clearing firm where a Member was the executing clearing firm for the transaction. The Exchange uses reports

from OCC to determine the identity of the executing clearing firm and ultimate clearing firm.

To illustrate how the ORF is assessed and collected, the Exchange provides the following set of examples. If the transaction is executed on the Exchange and the ORF is assessed, if there is no change to the clearing account of the original transaction, then the ORF is collected from the Member that is the executing clearing firm for the transaction. (The Exchange notes that, for purposes of the Fee Schedule, when there is no change to the clearing account of the original transaction, the executing clearing firm is deemed to be the ultimate clearing firm.) If there is a change to the clearing account of the original transaction (*i.e.,* the executing clearing firm ''gives-up'' or ''CMTAs'' the transaction to another clearing firm), then the ORF is collected from the clearing firm that ultimately clears the transaction- the ultimate clearing firm. The ultimate clearing firm may be either a Member or non-Member of the Exchange. If the transaction is executed on an away exchange and the ORF is assessed, then the ORF is collected from the ultimate clearing firm for the transaction. Again, the ultimate clearing firm may be either a Member or non-Member of the Exchange. The Exchange notes, however, that when the transaction is executed on an away exchange, the Exchange does not assess the ORF when neither the executing clearing firm nor the ultimate clearing firm is a Member (even if a Member is ''given-up'' or ''CMTAed'' and then such Member subsequently ''gives-up'' or ''CMTAs'' the transaction to another non-Member via a CMTA reversal). Finally, the Exchange will not assess the ORF on outbound linkage trades, whether executed at the Exchange or an away exchange. ''Linkage trades'' are tagged in the Exchange's system, so the Exchange can readily tell them apart from other trades. A customer order routed to another exchange results in two customer trades, one from the originating exchange and one from the recipient exchange. Charging ORF on both trades could result in double-billing of ORF for a single customer order, thus the Exchange will not assess ORF on outbound linkage trades in a linkage scenario. This assessment practice is identical to the assessment practice currently utilized by the Exchange's affiliate, MIAX PEARL, LLC (''MIAX PEARL'').[3]

As a practical matter, when a transaction that is subject to the ORF is not executed on the Exchange, the Exchange lacks the information necessary to identify the order entering member for that transaction. There are countless order entering market participants, and each day such participants can and often do drop their connection to one market center and establish themselves as participants on another. For these reasons, it is not possible for the Exchange to identify, and thus assess fees such as an ORF, on order entering participants on away markets on a given trading day. Clearing members, however, are distinguished from order entering participants because they remain identified to the Exchange on information the Exchange receives from OCC regardless of the identity of the order entering participant, their location, and the market center on which they execute transactions. Therefore, the Exchange believes it is more efficient for the operation of the Exchange and for the marketplace as a whole to collect the ORF from clearing members.

The Exchange monitors the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange reviews all costs and makes determinations if there is a nexus between the expense and a regulatory function. The Exchange notes that fines collected by the Exchange in connection with a disciplinary matter offset ORF.

As discussed below, the Exchange believes it is appropriate to charge the ORF only to transactions that clear as customer at the OCC. The Exchange believes that its broad regulatory responsibilities with respect to a Member's activities supports applying the ORF to transactions cleared but not executed by a Member. The Exchange's regulatory responsibilities are the same regardless of whether a Member enters a transaction or clears a transaction executed on its behalf. The Exchange regularly reviews all such activities, including performing surveillance for position limit violations, manipulation, front-running, contrary exercise advice violations and insider trading. These activities span across multiple exchanges.

The ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of Members' customer options business, including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The Exchange believes that revenue generated from the ORF, when combined with all of the Exchange's other regulatory fees and fines, will cover a material portion, but not all, of the Exchange's regulatory costs. The Exchange notes that its regulatory responsibilities with respect to Member compliance with options sales practice rules have been allocated to the Financial Industry Regulatory Authority (''FINRA'') under a 17d–2 Agreement. The ORF is not designed to cover the cost of options sales practice regulation.

The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange will continue to monitor MIAX Options regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission. The Exchange will notify Members of adjustments to the ORF via regulatory circular at least 30 days prior to the effective date of the change.

The Exchange believes it is reasonable and appropriate for the Exchange to charge the ORF for options transactions regardless of the exchange on which the transactions occur. The Exchange has a statutory obligation to enforce compliance by Members and their associated persons under the Act and the rules of the Exchange and to surveil for other manipulative conduct by market participants (including non-Members) trading on the Exchange. The Exchange cannot effectively surveil for such conduct without looking at and evaluating activity across all options markets. Many of the Exchange's market surveillance programs require the Exchange to look at and evaluate activity across all options markets, such as surveillance for position limit violations, manipulation, front-running and contrary exercise advice violations/expiring exercise declarations. While much of this activity relates to the execution of orders, the ORF is assessed on and collected from clearing firms. The Exchange, because it lacks access to information on the identity of the entering firm for executions that occur on away markets, believes it is appropriate to assess the ORF on its Members' clearing activity, based on information the Exchange receives from OCC, including for away market activity. Among other reasons, doing so

[3] *See* Securities Exchange Act Release No. 80875 (June 7, 2017), 82 FR 27096 (June 13, 2017)(SR–PEARL–2017–26).

better and more accurately captures activity that occurs away from the Exchange over which the Exchange has a degree of regulatory responsibility. In so doing, the Exchange believes that assessing ORF on Member clearing firms equitably distributes the collection of ORF in a fair and reasonable manner. Also, the Exchange and the other options exchanges are required to populate a consolidated options audit trail (''COATS'')[4] system in order to surveil a Member's activities across markets.

In addition to its own surveillance programs, the Exchange works with other SROs and exchanges on intermarket surveillance related issues. Through its participation in the Intermarket Surveillance Group (''ISG''),[5] the Exchange shares information and coordinates inquiries and investigations with other exchanges designed to address potential intermarket manipulation and trading abuses. The Exchange's participation in ISG helps it to satisfy the requirement that it has coordinated surveillance with markets on which security futures are traded and markets on which any security underlying security futures are traded to detect manipulation and insider trading.[6]

The Exchange believes that charging the ORF across markets avoids having Members direct their trades to other markets in order to avoid the fee and to thereby avoid paying for their fair share for regulation. If the ORF did not apply to activity across markets then a Member would send their orders to the least cost, least regulated exchange. Other exchanges do impose a similar fee on their members' activity,[7] including the activity of those members on MIAX Options and MIAX PEARL.[8]

The Exchange notes that there is established precedent for an SRO charging a fee across markets, namely, FINRAs Trading Activity Fee[9] and the NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), Cboe Exchange, Inc. (''CBOE''), Nasdaq PHLX LLC (''Phlx''), Nasdaq ISE, LLC (''ISE''), Nasdaq GEMX, LLC (''GEMX'') and BOX Exchange LLC (''BOX'') ORF. While the Exchange does not have all the same regulatory responsibilities as FINRA, the Exchange believes that, like other exchanges that have adopted an ORF, its broad regulatory responsibilities with respect to a Member's activities, irrespective of where their transactions take place, supports a regulatory fee applicable to transactions on other markets. Unlike FINRA's Trading Activity Fee, the ORF applies only to a Member's customer options transactions.

Additionally, the Exchange specifies in the Fee Schedule that the Exchange may only increase or decrease the ORF semi-annually, and any such fee change will be effective on the first business day of February or August. In addition to submitting a proposed rule change to the Commission as required by the Act to increase or decrease the ORF, the Exchange will notify participants via a Regulatory Circular of any anticipated change in the amount of the fee at least 30 calendar days prior to the effective date of the change. The Exchange believes that by providing guidance on the timing of any changes to the ORF, the Exchange would make it easier for participants to ensure their systems are configured to properly account for the ORF.

The Exchange is proposing to decrease the ORF from $0.0045 to $0.0029, as of February 1, 2019. In light of recent market volumes on the Exchange and changes to the Exchange's regulatory costs, the Exchange is proposing to decrease the amount of ORF that will be collected by the Exchange. As noted above, the Exchange regularly reviews its ORF to ensure that the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. The Exchange believes this adjustment will permit the Exchange to cover a material portion of its regulatory costs, while not exceeding regulatory costs.

The Exchange notified Members via a Regulatory Circular of the proposed change to the ORF at least thirty (30) calendar days prior to the proposed operative date, on December 31, 2018.[10] The Exchange believes that the prior notification to market participants will ensure market participants are prepared to configure their systems to properly account for the ORF.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[11] in general, and furthers the objectives of Section 6(b)(4) of the Act[12] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act[13] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that decreasing the ORF from $0.0045 to $0.0029, as of February 1, 2019 is reasonable because the Exchange's collection of ORF needs to be balanced against the amount of regulatory costs incurred by the Exchange. The Exchange believes that the proposed adjustments noted herein will serve to balance the Exchange's regulatory revenue against the anticipated regulatory costs.

The Exchange believes that amending the ORF from $0.0045 to $0.0029, as of February 1, 2019 is equitable and not unfairly discriminatory because it is objectively allocated to Members in that it is charged to all Members on all their transactions that clear as customer at the OCC. Moreover, the Exchange believes the ORF ensures fairness by assessing fees to those Members that are directly based on the amount of customer options business they conduct. Regulating customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are

[4] COATS effectively enhances intermarket options surveillance by enabling the options exchanges to reconstruct the market promptly to effectively surveil certain rules.

[5] ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by co-operatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

[6] *See* Section 6(h)(3)(I) of the Act.

[7] Similar regulatory fees have been instituted by Nasdaq PHLX LLC (''Phlx'') (*See* Securities Exchange Act Release No. 61133 (December 9, 2009), 74 FR 66715 (December 16, 2009) (SR–Phlx–2009–100)); Nasdaq ISE, LLC (''ISE'') (*See* Securities Exchange Act Release No. 61154 (December 11, 2009), 74 FR 67278 (December 18, 2009) (SR–ISE–2009–105)); and Nasdaq GEMX, LLC (''GEMX'') (*See* Securities Exchange Act Release No. 70200 (August 14, 2013) 78 FR 51242 (August 20, 2013)(SR–Topaz–2013–01)).

[8] *See supra* note 3.

[9] *See* Securities Exchange Act Release No. 47946 (May 30, 2003), 68 FR 34021 (June 6, 2003)(SR–NASD–2002–148).

[10] *See* MIAX Options Regulatory Circular 2018–74 available at *https://www.miaxoptions.com/sites/default/files/circular-files/MIAX_Options_RC_2018_74.pdf.*

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78f(b)(5).

materially higher than the costs associated with administering the non-customer component (*e.g.,* Member proprietary transactions) of its regulatory program.

The ORF is designed to recover a material portion of the costs of supervising and regulating Members' customer options business including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange has designed the ORF to generate revenues that, when combined with all of the Exchange's other regulatory fees, will be less than or equal to the Exchange's regulatory costs, which is consistent with the Commission's view that regulatory fees be used for regulatory purposes and not to support the Exchange's business side. In this regard, the Exchange believes that the proposed decrease to the fee is reasonable.

The Exchange believes that continuing to limit changes to the ORF to twice a year on specific dates with advance notice is reasonable because it gives participants certainty on the timing of changes, if any, and better enables them to properly account for ORF charges among their customers. The Exchange believes that continuing to limit changes to the ORF to twice a year on specific dates is equitable and not unfairly discriminatory because it will apply in the same manner to all Members that are subject to the ORF and provide them with additional advance notice of changes to that fee.

The Exchange believes that collecting the ORF from non-Members when such non-Members ultimately clear the transaction (that is, when the non-Member is the ''ultimate clearing firm'' for a transaction in which a Member was assessed the ORF) is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange notes that there is a material distinction between ''assessing'' the ORF and ''collecting'' the ORF. The ORF is only assessed to a Member with respect to a particular transaction in which it is either the executing clearing firm or ultimate clearing firm. The Exchange does not assess the ORF to non-Members. Once, however, the ORF is assessed to a Member for a particular transaction, the ORF may be collected from the Member or a non-Member, depending on how the transaction is cleared at OCC. If there was no change to the clearing account of the original transaction, the ORF would be collected from the Member. If there was a change to the clearing account of the original transaction and a non-Member becomes the ultimate clearing firm for that transaction, then the ORF will be collected from that non-Member. The Exchange believes that this collection practice continues to be reasonable and appropriate, and was originally instituted for the benefit of clearing firms that desired to have the ORF be collected from the clearing firm that ultimately clears the transaction.

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. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the ORF applies to all customer activity, and is designed to enable the Exchange to recover a material portion of the Exchange's cost related to its regulatory activities. It also supplements the regulatory revenue derived from non-customer activity. This proposal does not create an unnecessary or inappropriate inter-market burden on competition because it is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. Unilateral action by MIAX Options in establishing fees for services provided to its Members and others using its facilities will not have an impact on competition. In the highly competitive environment for equity options trading, MIAX Options does not have the market power necessary to set prices for services that are unreasonable or unfairly discriminatory in violation of the Act. The Exchange's ORF, as described herein, is comparable to fees charged by other options exchanges for the same or similar services. The Exchange believes that continuing to limit the changes to the ORF to twice a year on specific dates with advance notice is not intended to address a competitive issue but rather to provide Members with better notice of any change that the Exchange may make to the ORF.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[14] and Rule 19b–4(f)(2) [15] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–MIAX–2019–01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR–MIAX–2019–01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the

[14] 15 U.S.C. 78s(b)(3)(A)(ii).

[15] 17 CFR 240.19b–4(f)(2).

proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–MIAX–2019–01, and should be submitted on or before March 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03032 Filed 2–21–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85156; File No. SR–NASDAQ–2019–001]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Listing Standards for Direct Listings and Clarify Related Rules

February 15, 2019.

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 February 14, 2019, The Nasdaq Stock Market LLC (''Nasdaq'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[16] 17 CFR 200.30–3(a)(12).

[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 and clarify certain aspects of the listing process for Direct Listings.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the 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 recognizes that some companies that have sold common equity securities in private placements, which have not been listed on a national securities exchange or traded in the over-the-counter market pursuant to FINRA Form 211 immediately prior to the initial pricing, may wish to list those securities to allow existing shareholders to sell their shares. In particular, a company whose stock is not previously registered under the Exchange Act may wish to list on the Nasdaq Global Select Market without a related underwritten offering upon effectiveness of a registration statement registering only the resale of shares sold by the company in earlier private placements. The proposed Listing Rule IM–5315–1 sets forth listing requirements for such securities (a ''Direct Listing'') and describes how the Exchange will calculate compliance with the Nasdaq Global Select Market initial listing standards related to the requirements based on the price of a security, including the bid price, market capitalization and Market Value of Publicly Held Shares.

Nasdaq also proposes to modify Nasdaq Rule 4753 to more clearly describe the role of a broker-dealer serving as a financial advisor to the issuer of a security listing on the Nasdaq Global Select Market under proposed Rule IM–5315–1.

Calculation of Price-Based Initial Listing Requirements

Direct Listings are subject to all initial listing requirements applicable to equity securities and, subject to applicable exemptions, the corporate governance requirements set forth in the Rule 5600 Series. To provide transparency to the initial listing process, the Exchange proposes to adopt Listing Rule IM–5315–1, which will state how the Exchange calculates the initial listing requirements based on the price of a security, including the bid price, market capitalization and market value of publicly held shares for a Direct Listing on the Nasdaq Global Select Market.[3]

Nasdaq also proposes to require that a company that lists on the Nasdaq Global Select Market through a Direct Listing do so at the time of effectiveness of a registration statement filed under the Securities Act of 1933 solely for the purpose of allowing existing shareholders to sell their shares. This interpretative material would describe when a company whose stock is not previously registered under the Exchange Act may list on the Nasdaq Global Select Market, where such company is listing without a related underwritten offering upon effectiveness of a registration statement registering only the resale of shares sold by the company in earlier private placements.

Under IM–5315–1, Nasdaq would require that a company listing on the Nasdaq Global Select Market through a Direct Listing provide Nasdaq an independent third-party valuation (a ''Valuation''). Any Valuation used for this purpose must be provided by an entity that has significant experience and demonstrable competence in the provision of such valuations. The Valuation must be of a recent date as of the time of the approval of the company for listing and the evaluator must have considered, among other factors, the annual financial statements required to be included in the registration statement, along with financial statements for any completed fiscal

[3] This rule filing affects only companies listing on the Nasdaq Global Select Market. Nasdaq intends to subsequently file a proposed rule change under Section 19(b) of the Act to adopt requirements for the Nasdaq Capital and Global Markets applicable to companies which have not been listed on a national securities exchange or traded in the over-the-counter market pursuant to FINRA Form 211 immediately prior to the initial pricing and wish to list their securities to allow existing shareholders to sell their shares and clarify the use of the IPO Cross for initial pricing of such securities.

quarters subsequent to the end of the last year of audited financials included in the registration statement. Nasdaq will consider any market factors or factors particular to the listing applicant that would cause concern that the value of the company had diminished since the date of the Valuation and will continue to monitor the company and the appropriateness of relying on the Valuation up to the time of listing. Nasdaq may withdraw its approval of the listing at any time prior to the listing date if it believes that the Valuation no longer accurately reflects the company's likely market value.[4]

Nasdaq proposes to require that a valuation agent will not be considered independent if:

- At the time it provides such Valuation, the valuation agent or any affiliated person or persons beneficially own in the aggregate as of the date of the valuation, more than 5% of the class of securities to be listed, including any right to receive any such securities exercisable within 60 days.
- The valuation agent or any affiliated entity has provided any investment banking services to the listing applicant within the 12 months preceding the date of the Valuation. For purposes of this provision, ''investment banking services'' includes, without limitation, acting as an underwriter in an offering for the issuer; acting as a financial adviser in a merger or acquisition; providing venture capital, equity lines of credit, PIPEs (private investment, public equity transactions), or similar investments; serving as placement agent for the issuer; or acting as a member of a selling group in a securities underwriting.
- The valuation agent or any affiliated entity has been engaged to provide investment banking services to the listing applicant in connection with the proposed listing or any related financings or other related transactions.

For a security that has had sustained recent trading in a Private Placement Market[5] prior to listing, Nasdaq will determine a company's price, market capitalization and market value of publicly held shares based on the lesser of: (i) The value calculable based on the Valuation; and (ii) the value calculable based on the most recent trading price in a Private Placement Market.

As set forth in IM–5315–1(d), to determine compliance with the price-based requirements and suitability for listing on the Exchange, Nasdaq will examine the trading price trends for the stock in the Private Placement Market over a period of several months prior to listing and will only rely on a Private Placement Market price if it is consistent with a sustained history over that several month period evidencing a market value in excess of Nasdaq's market value requirement. Nasdaq believes that the price from such sustained trading in a Private Placement Market for the issuer's securities is predictive of the price in the market for the common stock that will develop upon listing of the securities on Nasdaq.

Alternatively, in the absence of any recent sustained trading in a Private Placement Market over a period of several months,[6] Nasdaq will determine that the company has met the market value of publicly held shares requirement for listing on the Nasdaq Global Select Market if the company provides a Valuation evidencing a market value of publicly held shares of at least $250,000,000. Nasdaq believes that some companies that are clearly large enough to be suitable for listing on the Exchange do not have sustained trading in their securities on a Private Placement Market prior to going public and that a recent Valuation indicating at least $250 million in market value of publicly held shares will give a significant degree of comfort that the company will meet the applicable market value of publicly held shares requirement upon commencement of trading.[7] Nasdaq believes that it is unlikely that any Valuation would reach a conclusion that is incorrect to the degree necessary for a company using this provision to fail to meet the applicable requirement upon listing, in particular because any Valuation used for this purpose must be provided by a valuation agent that meets the independence requirements of proposed Listing Rule IM–5315–1(f) and has significant experience and demonstrable competence in the provision of such valuations. Nasdaq will also determine the bid price and market capitalization based on such Valuation.[8]

Foreign Exchange Listings

For a company transferring from a foreign regulated exchange where there is a broad, liquid market for the company's shares, or listing on Nasdaq while trading on such exchange, Nasdaq will determine that the company has met the applicable price-based requirements based on the recent trading in such market. Nasdaq believes that the price of the issuer's securities from such broad and liquid trading is predictive of the price in the market for the common stock that will develop upon listing of the securities on Nasdaq. While this is consistent with Nasdaq's current practice, Listing Rule IM–5315–1(c) will clarify that a company transferring from a foreign regulated exchange where there is a broad, liquid market for the company's shares or listing on Nasdaq while trading on such exchange is not subject to the new requirements applicable to Direct Listings.

Clarification of the Role of a Financial Advisor in a Direct Listing

In 2014, Nasdaq first adopted rules to allow the use of the Nasdaq IPO Halt Cross to initiate trading in securities that have not been listed on a national securities exchange or traded in the over-the-counter market pursuant to FINRA Form 211 immediately prior to the initial pricing and described the role of financial advisors in that process.[9] At that time, the Exchange added new Rule 4120(c)(9)[10] to set forth the process by which trading commences in such securities. Under that rule, securities of companies that have not previously been listed on a national securities exchange or traded in the over the counter market pursuant to FINRA Form 211 immediately prior to listing on Nasdaq can be launched for trading using the same crossing mechanism available for IPOs outlined in Rule 4120(c)(8) and Rule 4753 (the ''IPO

[4] In addition, under Listing Rule 5101 Nasdaq has broad discretionary authority to deny initial listing, apply additional or more stringent criteria for the initial or continued listing of particular securities, or suspend or delist particular securities based on any event, condition, or circumstance that exists or occurs that makes initial or continued listing of the securities on Nasdaq inadvisable or unwarranted in the opinion of Nasdaq, even though the securities meet all enumerated criteria for initial or continued listing on Nasdaq.

[5] Nasdaq proposes to define ''Private Placement Market'' in Listing Rule 5005(a)(34) as a trading system for unregistered securities operated by a national securities exchange or a registered broker-dealer.

[6] Limited trading in the Private Placement Market may not be sufficient for the Exchange to reach a conclusion that the company meets the applicable price-based requirements.

[7] *See* Listing Rule 5315(f)(2), which generally requires a market value of publicly held shares of at least $110 million or $100 million if the company has stockholders' equity of at least $110 million.

[8] Nasdaq will calculate a per share price by dividing the Market Value of Publicly Held Shares evidenced by the Valuation by the number of Publicly Held Shares and the market capitalization by multiplying that per share price by the total number of shares outstanding.

[9] Securities Exchange Act Release No. 71931 (April 11, 2014), 79 FR 21829 (April 17, 2014) (SR–NASDAQ–2014–032) (the ''2014 Rule Change'').

[10] In 2014, Nasdaq filed SR–NASDAQ–2014–081 modifying the functions that are performed by an underwriter with respect to an initial public offering and renumbered certain paragraphs of Rule 4120. Securities Exchange Act Release No. 73399 (October 21, 2014), 79 FR 63981 (October 27, 2014) (approving SR–NASDAQ–2014–81). All references in this filing are to the renumbered rules, as currently in effect.

Cross''). Prior to that rule change, securities of companies that were not conducting IPOs were released using the Halt Cross outlined in Rule 4120(c)(7), which differed from the IPO Cross.[11]

The 2014 Rule Change extended the safeguards contained in the IPO Cross to securities that have not been listed on a national securities exchange or traded in the over-the-counter market pursuant to FINRA Form 211 immediately prior to the initial pricing and established that a broker-dealer serving in the role of financial advisor to the issuer could serve in the same capacity for such securities as the underwriter does for IPOs. Specifically, Rule 4120(c)(9) provides that the IPO Cross process described in Rules 4120 and 4753 is available to securities that have not been listed on a national securities exchange or traded in the over-the-counter market pursuant to FINRA Form 211 immediately prior to the initial pricing where ''a broker-dealer serving in the role of financial advisor to the issuer of the securities being listed is willing to perform the functions under Rule 4120(c)(8) that are performed by an underwriter with respect to an initial public offering.'' [12]

Rule 4753 provides the definition of Current Reference Price and a description of the calculation of the price at which the Nasdaq Halt Cross will occur.[13] In each case, the applicable price could be determined based on the issuer's IPO price.[14] In the absence of an IPO price from the underwriter, Nasdaq believes that the only viable options are to rely on a price from recent sustained trading the Private Placement Market [15] or one provided by the financial advisor to the company.

When Nasdaq added Rule 4120(c)(9) in 2014, it cross-referenced Rule 4753 but did not modify it. Nasdaq now proposes to amend Rule 4753, based on the same rationale that supported the 2014 Rule Change, to elaborate in its rules the role of a financial advisor to the issuer of a security that is listing under IM–5315–1.[16] Nasdaq has successfully employed, in limited circumstances, the IPO Cross for securities that have not been listed on a national securities exchange or traded in the over-the-counter market pursuant to FINRA Form 211 immediately prior to the initial pricing since 2014 [17] and continues to believe that financial advisors to issuers seeking to utilize that process are well placed to perform the functions that are currently performed by underwriters with respect to an initial public offering.

Specifically, Nasdaq proposes to amend Rules 4753(a)(3)(A)(iv) and 4753(b)(2)(D) [18] to state that in the case of the initial pricing of a Direct Listing (*i.e.,* a security qualifying for listing under Listing Rule IM–5315–1), the fourth tie-breaker in calculating each of the Current Reference Price disseminated in the Nasdaq Order Imbalance Indicator and the price at which the Nasdaq Halt Cross will occur, respectively, shall be: (i) For a security that has had recent sustained trading in a Private Placement Market prior to listing,[19] the most recent transaction price in that market or, (ii) if there is not such sustained trading in a Private Placement Market, a price determined by the Exchange in consultation with the financial advisor to the issuer identified pursuant to Rule 4120(c)(9). As described above, where there is recent sustained trading in a Private Placement Market, Nasdaq believes that the price from such recent sustained trading in a Private Placement Market for the issuer's securities is predictive of the price in the market for the common stock that will develop upon listing of the securities on Nasdaq and that it is therefore appropriate to use the price from such trading to determine the Current Reference Price and the price at which the Nasdaq Halt Cross will occur. In cases where there is not recent sustained trading in the Private Placement Market, Nasdaq believes that the financial advisor to the issuer of a Direct Listing security is well suited to advise the company and Nasdaq as to the appropriate price to determine the forth tie-breaker in calculating the Current Reference Price for the security and the price at which the Nasdaq Halt Cross will occur because of the financial advisor's market knowledge of buying and selling interest and understanding of the company and its security.[20]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[21] in general, and furthers the objectives of Section 6(b)(5) of the Act,[22] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transaction 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.

Calculation of Price-Based Initial Listing Requirements

The proposed rule change to require a Valuation and describe how Nasdaq will calculate compliance with the price-based requirements for listing on the Nasdaq Global Select Market is designed to protect investors and the public interest because any company relying solely on a Valuation will have to evidence at least $250 million in market value of publicly held shares, which will give a significant degree of comfort that the company will meet the applicable market value of publicly held shares requirement upon commencement of trading.[23] Nasdaq's existing requirements, including the generally applicable $110 million

[11] The Halt Cross process has a shorter quoting period (five minutes) and provides no ability to extend the quoting period in the event trading interest or volatility in the market appears likely to have a material impact on the security, unless there is an order imbalance as defined in the rule. *See* the 2014 Rule Change for additional details on the differences between the Halt Cross and the IPO Cross.

[12] Subsequent to the 2014 Rule Change Nasdaq expanded and elaborated the functions that are performed by an underwriter with respect to an initial public offering. *See* footnote 10, above. Rule 4120(c)(9) requires a broker-dealer serving in the role of a financial advisor to the issuer of the securities being listed to perform all such functions in order for the issuer to utilize the IPO Cross for the initial pricing of the security.

[13] Rules 4753(a)(3)(A) and 4753(b)(2)(D).

[14] Rules 4753(a)(3)(A)(iv)a. and 4753(b)(2)(D)(i). The price closest to the ''Issuer's Initial Public Offering Price'' is the fourth tie-breaker in these rules, applicable when no single price is determined from the three prior tests.

[15] As described above, Nasdaq believes that the price from such recent sustained trading in a Private Placement Market for the issuer's securities is predictive of the price in the market for the common stock that will develop upon listing of the securities on Nasdaq.

[16] Specifically, Nasdaq stated that ''an advisor, with market knowledge of the book and an understanding of the company and its security, would be well placed to provide advice on when the security should be released for trading.'' The 2014 Rule Change at 21830.

[17] Among other instances, Nasdaq utilized the IPO Cross for the initial pricing of the common stock of American Realty Capital Healthcare Trust, Inc. as indicated in the 2014 Rule Change.

[18] Nasdaq also proposes to make non-substantive changes to renumber the subparagraphs of these rules to reflect the proposed additional rule text.

[19] The term ''recent sustained trading'' in proposed Rules 4753(a)(3)(A)(iv)b. and (b)(2)(D)(ii) relies on the requirement in proposed Rule IM–5315–1(d) that there be a sustained history of trading over a period of several months prior to listing in order for Nasdaq to rely on a Private Placement Market price.

[20] While Nasdaq and NYSE each have different market structures, the proposed calculation of Current Reference Price is similar to how ''Reference Price'' is calculated under NYSE Rule 15.

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(5).

[23] *See* Listing Rule 5315(f)(2), which generally requires a market value of publicly held shares of at least $110 million or $100 million if the company has stockholders' equity of at least $110 million.

requirement for market value of publicly held on the Nasdaq Global Select Market, are designed to protect investors and serve to help assure that securities listed on Nasdaq have sufficient investor interest and will trade in a liquid manner. In addition, establishing independence standards for the party providing a Valuation will ensure that the entity providing a Valuation for purposes of listing on Nasdaq will have a significant level of independence from the listing applicant and thereby enhance the reliability of such Valuation. Finally, in addition to the proposed new requirements, Direct Listings are subject to all initial listing requirements applicable to equity securities and, subject to applicable exemptions, the corporate governance requirements set forth in the Rule 5600 Series. As such, Nasdaq believes these provisions protect investors and the public interest in accordance with Section 6(b)(5) of the Exchange Act.

The proposed rule change also protects investors and the public interest by requiring either that there be sustained recent trading in the Private Placement Market or that the company provide a Valuation demonstrating $250 million market value of publicly held shares. Nasdaq believes that the price from such sustained trading in the Private Placement Market for the issuer's securities is predictive of the price in the market for the common stock that will develop upon listing of the securities on Nasdaq and that qualifying a company based on the lower of that trading price or the Valuation helps assure that the company satisfies Nasdaq's requirements. Alternatively, in the absence of recent sustained trading in the Private Placement Market, the requirement to demonstrate a market value of publicly held shares of at least $250 million, similarly helps assure that the company satisfies Nasdaq's requirement by imposing a standard that is more than double the otherwise applicable standard.[24]

The proposed requirement that a company that lists on the Nasdaq Global Select Market through a Direct Listing must do so at the time of effectiveness of a registration statement filed under the Securities Act of 1933 solely for the purpose of allowing existing shareholders to sell their shares is designed to protect investors and the public interest, because it will ensure such companies satisfy the rigorous disclosure requirements under the Securities Act of 1933 and are subject to review by Commission staff.

[24] *See* footnote 7, above.

Finally, the proposal to rely on the price from the existing trading market for a company transferring from a foreign regulated exchange or listing on Nasdaq while trading on such exchange is consistent with the protection of investors because the price from the broad and liquid trading market for the issuer's securities is predictive of the price in the market for the common stock that will develop upon listing of the securities on Nasdaq. This provision applies only where there is a broad, liquid market for the company's shares in its country of origin and is designed to clarify that a company transferring from a foreign regulated exchange or listing on Nasdaq while trading on such exchange that satisfies Listing Rule IM–5315–1(c) is not subject to the new requirements applicable to Direct Listings. Enhancing transparency around this requirement will promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transaction in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system and protect investors and the public interest.

Clarification of the Role of a Financial Advisor in a Direct Listing

The proposed rule change to clarify the fourth tie-breaker used in calculating the Current Reference Price disseminated in the Nasdaq Order Imbalance Indicator and the price at which the Nasdaq Halt Cross will occur, protects investors and the public interest by more fully describing the role of a financial advisor to the issuer of a Direct Listing security that is not the subject of an IPO, but that has not been listed on a national securities exchange or traded in the over-the-counter market pursuant to FINRA Form 211 immediately prior to the initiation of trading on Nasdaq. The proposed rule change establishes that in such a case the Current Reference Price and price at which the Nasdaq Halt Cross will occur will be the most recent transaction price in a Private Placement Market where the security has had recent sustained trading in such a market over several months; otherwise the price will be determined by the Exchange in consultation with a financial advisor to the issuer. Where there has been sustained recent trading on a Private Placement Market over several months, Nasdaq believes the most recent price from such trading is predictive of the price that will develop upon listing of the securities on Nasdaq. Where there is not such sustained recent trading, Nasdaq notes that financial advisors have been performing the functions of the underwriter in the IPO Halt Cross on a limited basis since 2014 and have market knowledge of buying and selling interest and an understanding of the company and its security. As such, Nasdaq believes that the rule change will promote fair and orderly markets because these mechanisms of establishing the Current Reference Price and the price at which the Nasdaq Halt Cross will occur will help protect against volatility in the pricing and initial trading of the securities covered by the proposed rule change. Accordingly, Nasdaq believes these changes, as required by Section 6(b)(5) of the Exchange Act, are reasonably designed to protect investors and the public interest and promote just and equitable principles of trade for the opening of securities listing in connection with a Direct Listing.

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 to adopt IM–5315–1 is designed to provide transparency to the mechanism of listing securities in connection with a Direct Listing that is appropriately protective of investors and is not designed to limit the ability of the issuers of those securities to list them on any other national securities exchange. The market for listing services is extremely competitive and the proposed rule change adopts changes similar to those already approved for another market.[25] Because issuers have a choice to list their securities on a different national securities exchange, the Exchange does not believe that the proposed listing standards impose a burden on competition.

In addition, the proposed change is designed to more fully describe the application of the IPO Halt Cross to a Direct Listing and the role of a financial advisor in the determination of the forth tie-breaker in calculating the Current Reference Price for the security and the price at which the Nasdaq Halt Cross will occur. The proposed rule change

[25] *See* Securities Exchange Act Release No. 82627 (February 2, 2018), 83 FR 5650 (February 8, 2018) (Approving SR–NYSE–2017–30 to amend NYSE Listed Company Manual to provide for the listing of companies that list without a prior Exchange Act registration and that are not listing in connection with an underwritten initial public offering and certain related changes).

will have no impact on competition as it merely designed to insure that the Current Reference Price and the price at which the Nasdaq Halt Cross will occur is appropriately calculated for listings under IM–5315–1.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [26] and Rule 19b–4(f)(6) thereunder.[27] 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 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 and Rule 19b–4(f)(6)(iii) thereunder. [28]

A proposed rule change filed under Rule 19b–4(f)(6) [29] normally does not become operative for 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[30] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. In its filing with the Commission, Nasdaq has asked the Commission to waive the 30-day operative delay to allow Nasdaq to apply the proposed rules to the initial listing and pricing of potential listings on the Nasdaq Global Select Market where the company's stock is not previously registered under the Exchange Act and the company is seeking to list without a related underwritten offering upon effectiveness of a registration statement registering only the resale of shares sold by the company in earlier private placements. Nasdaq stated that Nasdaq believes that no benefit would be served by delaying the application of the rule.

The Commission notes that Nasdaq's proposed rule changes are substantially similar to the rules of another exchange that were approved previously by the Commission as consistent with the Act after being published in the **Federal Register** for notice and comment.[31] For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest and hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[32]

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) [33] 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2019–001 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2019–001. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2019–001, and should be submitted on or before March 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03033 Filed 2–21–19; 8:45 am]

BILLING CODE 8011–01–P

[26] 15 U.S.C. 78s(b)(3)(A)(iii).

[27] 17 CFR 240.19b–4(f)(6).

[28] In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change 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.

[29] 17 CFR 240.19b–4(f)(6).

[30] 17 CFR 240.19b–4(f)(6)(iii).

[31] *See* Securities Exchange Act Release No. 82627, note 25, *supra;* Securities Exchange Act Release No. 58550 (September 15, 2008), 73 FR 54442 (September 19, 2008) (SR–NYSE–2008–68).

[32] For purposes only of waiving the operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[33] 15 U.S.C. 78s(b)(2)(B).

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–247, OMB Control No. 3235–0259]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 19h–1

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 19h–1 (17 CFR 240.19h–1), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to

the Office of Management and Budget (''OMB'') for extension and approval.

Rule 19h–1 prescribes the form and content of notices and applications by self-regulatory organizations (''SROs'') regarding proposed admissions to, or continuances in, membership, participation or association with a member of any person subject to a statutory disqualification.

The Commission uses the information provided in the submissions filed pursuant to Rule 19h–1 to review decisions by SROs to permit the entry into or continuance in the securities business of persons who have committed serious misconduct. The filings submitted pursuant to the Rule also permit inclusion of an application to the Commission for consent to associate with a member of an SRO notwithstanding a Commission order barring such association.

The Commission reviews filings made pursuant to the Rule to ascertain whether it is in the public interest to permit the employment in the securities business of persons subject to statutory disqualification. The filings contain information that is essential to the staff's review and ultimate determination on whether an association or employment is in the public interest and consistent with investor protection.

It is estimated that approximately 20 respondents will make submissions pursuant to this Rule annually. With respect to submissions for Rule 19h–1(a) notices, and based upon past submissions, the staff estimates that respondents will make a total of 11 submissions per year. The staff estimates that the average number of hours necessary to complete a submission pursuant to Rule 19h–1(a) notices is 80 hours (for a total annual burden for all respondents in the amount of 17,600 hours). With respect to submissions for Rule 19h–1(a)(4) notifications, and based upon past submissions, the staff estimates that respondents will make a total of 9 submissions per year. The staff estimates that the average number of hours necessary to complete a submission pursuant to Rule 19h–1(a)(4) notifications is 80 hours (for a total annual burden for all respondents in the amount of 14,400 hours). With respect to submissions for Rule 19h–1(b), and based upon past submissions, the staff estimates that respondents will make a total of 28 submissions per year. The staff estimates that the average number of hours necessary to complete a submission pursuant to Rule 19h–1(b) is 13 hours (for a total annual burden for all respondents in the amount of 7,280 hours). With respect to submissions for Rule 19h–1(d), and based upon past submissions, the staff estimates that respondents will make a total of 5 submissions per year. The staff estimates that the average number of hours necessary to complete a submission pursuant to Rule 19h–1(d) is 80 hours (for a total annual burden for all respondents in the amount of 8,000 hours). The aggregate annual burden for all respondents is thus 47,280 hours (17,600 +14,400 + 7,280 + 8,000).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: February 19, 2019.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03086 Filed 2–21–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–330, OMB Control No. 3235–0645]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Interactive Data

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

The ''Interactive Data'' collection of information requires issuers filing registration statements under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) and reports under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) to submit specified financial information to the Commission and post it on their corporate websites, if any, in interactive data format using eXtensible Business Reporting Language (XBRL). This collection of information is located primarily in registration statement and report exhibit provisions, which require interactive data, and Rule 405 of Regulation S–T (17 CFR 232.405), which specifies how to submit and post interactive data. The exhibit provisions are in Item 601(b)(101) of Regulation S–K (17 CFR 229.601(b)(101)), Form F–10 under the Securities Act (17 CFR 239.40) and Forms 20–F, 40–F and 6–K under the Exchange Act (17 CFR 249.220f, 17 CFR 249.240f and 17 CFR 249.306).

In interactive data format, financial statement information could be downloaded directly into spreedsheets and analyzed in a variety of ways using commercial off-the-shelf software. The specified financial information already is and will continue to be required to be submitted to the Commission in traditional format under existing requirements. The purpose of the interactive data requirement is to make financial information easier for investors to analyze and assist issuers in automating regulatory filings and business information processing. We estimate that 8601 respondents per year will each submit an average of 4.5 reponses per year for an estimated total of 38,705 responses. We further estimate an internal burden of 56 hours per response for a total annual internal burden of 2,167,480 hours (56 hours per response × 38,705 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following website, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive

Office Building, Washington, DC 20503, or by sending an email to: *Lindsay.M.Abate@omb.eop.gov*; and (ii) Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: February 19, 2019.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03085 Filed 2–21–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–338, OMB Control No. 3235–0376]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Schedule 14D–1F

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Schedule 14D–1F (17 CFR 240.14d–102) is a form that may be used by any person (the ''bidder'') making a cash tender or exchange offer for securities of any issuer (the ''target'') incorporated or organized under the laws of Canada or any Canadian province or territory that is a foreign private issuer, where less than 40% of the outstanding class of the target's securities that is the subject of the offer is held by U.S. holders. Schedule 14D–1F is designed to facilitate cross-border transactions in the securities of Canadian issuers. The information required to be filed with the Commission provides security holders with material information regarding the bidder as well as the transaction so that they may make informed investment decisions. The information provided is mandatory and all information is made available to the public upon request. Schedule 14D–1F takes approximately 2 hours per response to prepare and is filed by approximately 2 respondents annually for a total reporting burden of 4 hours (2 hours per response × 2 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following website, *www.reginfo.gov* . Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Lindsay.M.Abate@omb.eop.gov*; and (ii) Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: February 19, 2019.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03081 Filed 2–21–19; 8:45 am]

BILLING CODE P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–306, OMB Control No. 3235–0522]

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 701

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rule 701(17 CFR 230.701) under the Securities Act of 1933 (''Securities Act'') (15 U.S.C. 77a *et seq.*) provides an exemption for certain issuers from the registration requirements of the Securities Act for limited offerings and sales of securities issued under compensatory benefit plans or contracts. The purpose of Rule 701 is to ensure that a basic level of information is available to employees and others when substantial amounts of securities are issued in compensatory arrangements. We estimate that approximately 800 companies annually rely on the Rule 701 exemption and that it takes 2 hours to prepare each response. We estimate that 25% of the 2 hours per response (0.5 hours) is prepared by the company for a total annual reporting burden of 400 hours (0.5 hours per response × 800 responses).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Please direct your written comment to Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: February 19, 2019.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03082 Filed 2–21–19; 8:45 am]

BILLING CODE P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–357, OMB Control No. 3235–0404]

Submission for OMB Review Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Form F–80

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Form F–80 (17 CFR 239.41) is a registration form used by large, publicly-traded Canadian issuers to register securities that will be offered in a business combination, exchange offer or other reorganization requiring the vote of shareholders of the participating companies. The information collected is intended to make available material information upon which shareholders and investors can make informed voting and investment decisions. The information provided is mandatory and all information is made available to the public upon request. Form F–80 takes approximately 2 hours per response and is filed by approximately 4 issuers for a total annual reporting burden of 8 hours (2 hours per response × 4 responses). The estimated burden of 2 hours per response was based upon the amount of time necessary to compile the registration statement using the existing Canadian prospectus plus any additional information required by the Commission.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following website, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Lindsay.M.Abate@omb.eop.gov;* and (ii) Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: February 19, 2019.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03084 Filed 2–21–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85154; File No. SR–NYSEArca–2018–54]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Withdrawal of a Proposed Rule Change To Amend Commentary .01 to NYSE Arca Rule 8.600–E Relating to Certain Generic Listing Standards for Managed Fund Shares

February 15, 2019.

On July 18, 2018, NYSE Arca, Inc. (''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend certain generic listing standards for Managed Fund Shares. The proposed rule change was published for comment in the **Federal Register** on August 7, 2018.[3] On September 19, 2018, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change.[5] On November 1, 2018, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule change.[6] On February 1, 2019, the Commission designated a longer period for Commission action on the proceedings to determine whether to approve or disapprove the proposed rule change.[7]

On February 14, 2019, NYSE Arca withdrew the proposed rule change (SR–NYSEArca–2018–54).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03031 Filed 2–21–19; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 83759 (August 1, 2018), 83 FR 38753.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 84195, 83 FR 48474 (September 25, 2018).

[6] *See* Securities Exchange Act Release No. 84517, 83 FR 55773 (November 7, 2018).

[7] *See* Securities Exchange Act Release No. 85026, 84 FR 2637 (February 7, 2019).

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85158; File No. SR–NYSE–2018–52]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Granting Approval of a Proposed Rule Change To Amend NYSE Rule 7.31 Relating to Discretionary Orders, Auction-Only Orders, Discretionary Modifier, and Yielding Modifier and Related Amendments to Rules 7.16, 7.34, 7.36, and 7.37

February 15, 2019.

I. Introduction

On November 29, 2018, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend NYSE Rule 7.31 (Orders and Modifiers) to: (i) Add a new order type, Discretionary Orders; (ii) add two new order type modifiers, the Last Sale Peg Modifier and the Yielding Modifier; and (iii) make related changes to NYSE Rules 7.16, 7.34, 7.36, and 7.37 for trading on Pillar.[3] The proposed rule change was published for comment in the **Federal Register** on December 18, 2018.[4] The Commission has received no comments on the proposal. This order approves the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange proposes to amend NYSE Rule 7.31 (Orders and Modifiers) to: (i) Add a new order type, Discretionary Orders; (ii) add two new order type modifiers, the Last Sale Peg Modifier and the Yielding Modifier; and (iii) make related changes to NYSE Rules 7.16, 7.34, 7.36, and 7.37.

Discretionary Order Overview

Proposed NYSE Rule 7.31(d)(4) sets forth the general requirements for a new order type, a Discretionary Order or ''D Order,'' for securities trading on Pillar.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Pillar is a new trading technology for the Exchange that currently trades securities pursuant to unlisted trading privileges (''UTP''). The Exchange intends to migrate trading in NYSE-listed securities to Pillar at a later date. *See* Securities Exchange Release No. 82945 (Mar. 26, 2018), 83 FR 13553 (Mar. 29, 2018) (Order approving equity trading rules for UTP securities on Pillar)(''Pillar Trading Rules Approval'').

[4] *See* Securities Exchange Act Release No. 84806 (Dec. 12, 2018), 83 FR 64913 (Dec. 18, 2018) (''Notice'').

Specifically, a D Order would be a Limit Order that: (1) May trade at an undisplayed discretionary price; (2) must be designated as ''Day;'' (3) may be designated as routable or non-routable; (4) must have a minimum of one round lot displayed on entry; and (5) is only available to Floor Brokers during the Core Trading Session.[5] D Orders, like d-Quotes, may be combined with a Reserve Order.[6] However, unlike d-Quotes, D Orders would be required to have a display quantity.

Upon Arrival

Proposed NYSE Rule 7.34(c)(1)(A) specifies that a D Order must be designated as either a: (i) Limit Price D Order or (ii) Midpoint Price D Order. Proposed NYSE Rule 7.31(d)(4)(A)(i) specifies that an arriving Limit Price D Order to buy (sell) would trade with sell (buy) orders on the Exchange Book, or, if designated as routable, route to an Away Market up (down) to the limit price of the order. If after trading or routing the PBBO is locked or crossed or there is no PBB (PBO), a Limit Price D Order would be canceled. For a Limit Price D Order that is partially routed to an Away Market on arrival, any returned quantity of such D Order would join the working price of the resting odd-lot quantity of the D Order.

Proposed NYSE Rule 7.31(d)(4)(A)(ii) sets forth that an arriving Midpoint Price D Order to buy (sell) would trade with sell (buy) orders on the Exchange Book up (down) to the lower (higher) of the midpoint of the PBBO (''Midpoint Price'') or the order's limit price. The proposed rule also provides that a Midpoint Price D Order would not route on arrival, even if designated as routable. If designated as routable, a Midpoint Price D Order combined with a Reserve Order would be evaluated for routing each time the display quantity is replenished as provided for in NYSE Rule 7.31(d)(1)(D).[7] The proposed rule further provides that if the PBBO is locked or crossed or if the Midpoint Price is unavailable, the Midpoint Price D Order would be rejected.

Working and Display Price

Proposed NYSE Rule 7.31(d)(4)(B) provides that the working and display price for a D Order to buy (sell) would be pegged to the PBB (PBO).[8] If the PBB (PBO) is higher (lower) than the limit price of a D Order to buy (sell), the working and display price would be the limit price of the order. The proposed rule also provides that a D Order to buy (sell) would be canceled if there is no PBB (PBO) against which to peg. As proposed, the rule further provides that, at its display price, a D Order would be ranked Priority 2—Display Orders.[9]

Discretion

Proposed NYSE Rule 7.31(d)(4)(C) provides that a resting D Order to buy (sell) would be eligible to exercise discretion up (down) to the limit price of the order. This proposed rule further provides that the display price of a D Order would: (i) Be pegged to the same-side PBBO; (ii) not be based on the limit price; and (iii) not exercise discretion if the PBBO is locked or crossed or if there is no Midpoint Price.

Proposed NYSE Rule 7.31(d)(4)(C)(i) provides that a D Order to buy (sell) would be triggered to exercise discretion if the price of an Aggressing Order to sell (buy) is above (below) the PBB (PBO) and at or below (above) the Midpoint Price (the ''discretionary price range'').[10]

Proposed NYSE Rule 7.31(d)(4)(C)(ii) provides that the discretionary price at which a D Order to buy (sell) would trade would be the price of the sell (buy) order. In addition, proposed NYSE Rule 7.36(a)(7) defines the term ''discretionary price'' as the undisplayed price at which a D Order would trade if it exercises discretion.

Proposed NYSE Rule 7.31(d)(4)(C)(ii) provides that if other interest to buy (sell) priced equal to or higher (lower) than the price of the sell (buy) order is present on the Exchange Book, the discretionary price would be one MPV higher (lower) than the highest (lowest) priced resting order to buy (sell), capped by the Midpoint Price.[11]

Ranking and Working Time

Proposed NYSE Rule 7.31(d)(4)(D)(i) provides that a D Order would be assigned a new temporary working time that is later than any same-side resting interest at its discretionary price. Proposed NYSE Rule 7.31(d)(4)(D)(ii) provides that multiple D Orders, when eligible to trade at the same discretionary price, would be ranked by limit price and time. Finally, proposed NYSE Rule 7.31(d)(4)(D)(iii) provides that the unexecuted portion of a D Order at its discretionary price would be given the working time associated with its working and display price.

Resting D Order That Becomes Marketable

Proposed NYSE Rule 7.31(d)(4)(E) provides that after the PBBO unlocks or uncrosses or a Midpoint Price becomes accessible, resting D Orders to buy (sell) would be ranked based on the lower (higher) of the Midpoint Price or limit price of the order to determine whether a D Order is marketable within its discretionary price range with contra-side orders on the Exchange Book.

D Orders Rejected and Modifiers

Proposed NYSE Rule 7.31(d)(4)(F) provides that a D Order may be designated with a Self Trade Prevention Modifier (''STP'') and would be rejected if combined with any other modifiers or if the same-side PBBO is zero.

Proposed NYSE Rule 7.31(i)(2)(C) provides that a resting D Order with an STP Modifier that is triggered to exercise discretion, and is not an Aggressing Order, will not trade at a discretionary price against a contra-side order that is also designated with an STP Modifier and from the same Client ID, and that, in such case, the D Order would not be canceled.

Last 10 Seconds of Trading

Proposed NYSE Rule 7.31(d)(4)(G) provides that a request to enter a D Order in any security 10 seconds or less before the scheduled close of trading would be rejected.

Allocation of D Orders

Proposed NYSE Rule 7.37(b) sets forth the allocation process for D Orders. Pursuant to NYSE Rule 7.37(b)(1) the allocation sequence would be as follows: (1) Market Orders trade first based on time; (2) orders with Setter

[5] The Core Trading Session begins at 9:30 a.m. Eastern Time and ends at the conclusion of Core Trading Hours. *See* NYSE Rule 7.34(a)(2). The term ''Core Trading Hours'' means ''the hours of 9:30 a.m. Easter Time through 4:00 p.m. Eastern Time or such other hours as may be determined by the Exchange from time to time.'' *See* NYSE Rule 1.1(d).

[6] *See* proposed NYSE Rule 7.31(d)(1)(C).

[7] NYSE Rule 7.31(d)(1)(D) provides that a routable Reserve Order will be evaluated for routing both on arrival and each time the display quantity is replenished.

[8] ''Working price'' means the price at which an order is eligible to trade at any given time, which may be different from the limit price or display price of the order. *See* NYSE Rule 7.36(a)(3). ''Display price'' means the price at which a Limit Order is displayed, which may be different from the limit price or working price of the order. *See* NYSE Rule 7.36(a)(1).

[9] NYSE Rule 7.36(e) governs execution priority for orders resting on the Exchange Book and currently sets forth three priority categories: Priority 1—Market Orders, Priority 2—Display Orders, and Priority 3—Non-Display Orders. If a D Order is combined with a Reserve Order, the reserve interest of such order would be ranked Priority 3—Non-Display Orders. *See* NYSE Rule 7.31(d)(1).

[10] An Aggressing Order is a buy (sell) order that is or becomes marketable against sell (buy) interest on the Exchange Book. *See* Rule 7.36(a)(6). A resting order may become an Aggressing Order if its working price changes, if the PBBO or NBBO is updated, because of changes to other orders on the Exchange Book, or when processing inbound messages. *Id.*

[11] The MPV for securities is defined in NYSE Rule 7.6.

Priority as described in NYSE Rule 7.36(h) receive an allocation; (3) orders ranked Priority 2—Displayed Orders are allocated on parity by Participant; (4) orders ranked Priority 3—Non-Display Orders, other than Mid-Point Liquidity (''MPL'') Orders [12] with an MTS Modifier, are allocated on parity by Participant; [13] and then (5) MPL Orders with an MTS Modifier are allocated based on MTS size (smallest to largest) and time. After these order types have been allocated, D Orders trading at a discretionary price would be allocated next on parity by a Floor Broker Participant pursuant to proposed NYSE Rule 7.37(b)(1)(F).[14] Specifically, at their discretionary price, D Orders would be allocated after all other orders at that price, except for Yielding Orders, which are described below.

NYSE Rule 7.37(b)(2) describes the process for the parity allocation wheel. Currently, the Exchange creates separate allocation wheels for orders ranked Priority 2—Display Orders and orders ranked Priority 3—Non-Display Orders. The Exchange proposes to create a third allocation wheel if there is more than one D Order eligible to trade at a discretionary price. In that case, the Exchange would create an allocation wheel for D Orders at that discretionary price.[15]

The Exchange proposes to amend NYSE Rule 7.37(b)(2)(A) to provide that for each D Order parity allocation wheel, a D Order to buy (sell) with the highest (lowest) limit price would establish the first position on that allocation wheel.

Re-Pricing of D Orders During a Short Sale Period

The Exchange proposes to amend NYSE Rule 7.16(f)(5)(C) to specify that, during a Short Sale Period,[16] the Exchange proposes to process sell short D Orders as Pegged Orders and MPL Orders are processed under the current rules. Thus, under proposed NYSE Rule 7.16(f)(5)(C), D Orders—including orders marked buy, sell long, and sell short exempt—would use the National Best Bid and Offer (''NBBO'') instead of the PBBO as the reference price. The proposed rule also provides that the Midpoint Price of D Orders would be the midpoint price of the NBBO, including situations in which the midpoint is less than one minimum price increment above the National Best Bid (''NBB'').

Last Sale Peg Modifier

Proposed Rule 7.31(i)(4) would add a new order type modifier, Last Sale Peg, that would be similar to the current Buy Minus Zero Plus (''BMZP'') [17] instruction for trading in Exchange-listed securities, with specified differences to reflect Pillar functionality and terminology.

Pursuant to proposed Rule 7.31(i)(4), a Non-Routable Limit Order to buy may be designated with a Last Sale Peg modifier and would be referred to as a ''Last Sale Peg Order.'' Proposed Rule 7.31(i)(4) also provides that a Last Sale Peg Order would not trade or be displayed at a price higher than the later of the most recent last-sale eligible trade executed on the Exchange or the most recent consolidated last-sale eligible trade, which would be defined, for purposes of this rule, as the ''last-sale price.'' [18]

Proposed NYSE Rule 7.31(i)(4)(A) provides that the working price of a Last Sale Peg Order would be pegged to the lower of the last-sale price, the limit price of the order, or the PBO. Proposed NYSE Rule 7.31(i)(4)(A) also provides that the working price of a resting Last Sale Peg Order would not be adjusted until an Aggressing Order is fully processed. In other words, if an Aggressing Order trades at multiple prices, the Exchange would wait for the last price at which that order trades to determine the last-sale price for purposes of re-pricing the working price of a resting Last Sale Peg Order. The proposed rule further provides that if the last-sale price is not at a permissible MPV, the working price of the order would be rounded down to the nearest MPV.

Pursuant to proposed NYSE Rule 7.31(i)(4)(B), the display price of a Last Sale Peg Order would be the same as the working price, unless the working price is pegged to the PBO, in which case, the display price would be determined pursuant to NYSE Rule 7.31(e)(1).

Proposed NYSE Rule 7.31(i)(4)(C) provides that a Last Sale Peg Order may be designated with an STP Modifier and would be rejected if combined with any other modifiers or if there is no last-sale price.

NYSE Rule 7.34(c)(1)(A) is being amended to add Last Sale Peg Orders to the description of orders that may be accepted, but not eligible to trade, during the Early Trading Session.

Yielding Modifier

Proposed NYSE Rule 7.31(i)(5) sets forth the requirements for the Yielding Modifier and provides that a Limit Order, Non-Routable Limit Order, or Reserve Order may be designated with a Yielding Modifier, which, for purposes of this proposed rule, would be referred to as ''Yielding Order.'' A Yielding Order would yield priority to all other displayed and non-displayed orders at the same price, and, similar to g-Quotes,[19] may only be entered by Floor brokers and would be ranked Priority 4—Yielding Orders. Proposed NYSE Rule 7.36(e)(4) would add this additional priority category and provide that Priority 4—Yielding Orders have fourth priority.

Proposed NYSE Rule 7.31(i)(5)(A) provides that an Aggressing Yielding Order to buy (sell) with a limit price higher (lower) than the limit price of a resting order to buy (sell) would trade ahead of the resting order.

Proposed NYSE Rule 7.31(i)(5)(B) provides that an Aggressing Yielding Order to buy (sell) with a limit price equal to the limit price of a resting order to buy (sell) would either: (i) Trigger the resting order to become an Aggressing Order, unless the order to sell (buy) is an MPL–ALO Order or an MPL Order with an MTS Modifier,[20] in which case neither the Yielding Order nor the same-side resting order would trade; or (ii)

[12] *See* NYSE Rule 7.31(d)(3) for a description of MPL Orders.

[13] An order with an MTS Modifier would only trade with contra-side orders that, either individually or in the aggregate, satisfy the order's minimum trade size condition. *See* NYSE Rule 7.31(i)(3) for a full description of the MTS Modifier.

[14] *See* NYSE Rule 7.36(a)(5) for the definition of the term ''Floor Broker Participant.''

[15] *See* proposed NYSE Rule 7.37(b)(2).

[16] A ''Short Sale Period'' is defined in NYSE Rule 7.16(f)(4) to mean the period when a Short Sale Price Test is in effect. A ''Short Sale Price Test'' is defined in NYSE Rule 7.16(f)(3) to mean the period during which Exchange systems will not execute or display a short sale order with respect to a covered security at a price that is less than or equal to the current NBB in compliance with Rule 201 of Regulation SHO (''Rule 201''). 17 CFR 242.201. The Commission notes that the re-pricing of D Orders during a Short Sale Period would need to be compliant with the requirements of Rule 201.

[17] *See* NYSE Rule 13(f)(4).

[18] A consolidated last-sale eligible trade is the last-sale eligible trade reported to the responsible single plan processor. *See* Notice, *supra* note 4, 83 FR at 64917, n.50. A last-sale eligible trade must be of at least one round lot. *See id.* at 64917, n.49.

[19] *See* Rule 70(a)(ii) and (iii). The Exchange states that g-Quotes are designed to assist Floor Brokers with compliance with Section 11(a)(1) of the Act. *See* Notice, *supra* note 4, 83 FR at 64918. Section 11(a)(1) of the Act generally prohibits a member of a national securities exchange from effecting transactions on that exchange for its own account, the account of an associated person, or any account over which it or an associated person exercises discretion. Subsection (G) of Section 11(a)(1) provides an exemption from this prohibition, allowing an exchange member to have its own floor broker execute a proprietary order, also known as a ''G order,'' provided such order yields priority, parity, and precedence (the ''G Rule''). Under the G Rule, G orders are not required to yield to other orders that are for the account of a member, *e.g.,* Designated Market Maker (''DMM'') interest or other g-Quotes. *See id.* at 64918, n.54.

[20] *See* Rule 7.31(e)(2) for a description of the ALO Order. An MPL Order may be designated with the ALO modifier. *See* Rule 7.31(d)(3)(E).

trade ahead of the resting order if the resting order is not eligible to trade (*e.g.,* an ALO Order or an order with an MTS Modifier).

Similar to the proposed Last Sale Peg Order, proposed NYSE Rule 7.31(i)(5)(C) provides that a Yielding Order may be designated with an STP Modifier and would be rejected if combined with any other modifiers.

NYSE Rule 7.37(b) would also be amended to describe how orders with a Yielding Modifier would participate in the allocation process. The Exchange proposes that after the allocation of all other displayed and non-displayed orders, D Orders would be allocated on parity. Proposed NYSE Rule 7.37(b)(1)(G) provides that after D Orders have been allocated, the display quantity of orders ranked Priority 4—Yielding Orders would be allocated based on time. Proposed NYSE Rule 7.37(b)(1)(H) would provide that, next, the non-display quantity of orders ranked Priority 4—Yielding Orders would be allocated based on time.

The Exchange asserts that by extending the availability of order types that are currently available for Exchange-listed securities to trading on Pillar, the Exchange would provide its members with consistency across trading of all securities on the Exchange, thus promoting just and equitable principals of trade and promoting a fair and open market. Specifically, the Exchange states that the proposed D Order is based in part on current d-Quote functionality, which is available only to Floor brokers, and is designed to replicate electronically the Floor broker's agency role to exercise price discretion on behalf of its customer.[21] The Exchange asserts that differences between g-Quotes and the proposed D Orders are aimed at simplifying and streamlining D Order functionality, while allowing such orders to contribute to the display of liquidity at the Exchange and offering price improvement opportunities to contra-side orders.[22] Similarly, the Exchange states that the proposed Last Sale Peg Modifier would offer functionality based on the existing BMZP instruction,[23] with differences designed to streamline the operation of the modifier, while maintaining its core purpose.[24] In addition, the Exchange states that the proposed Yielding Modifier is based on current g-Quote functionality, including its availability to Floor brokers only. The Exchange notes that, because this modifier provides Floor brokers with an electronic method for representing orders on Pillar that is in compliance with the G Rule,[25] offering this modifier to non-Floor brokers in unnecessary, because Floor brokers are the only members with the specified G Rule obligation today.[26] The Exchange states that it believes the proposed rule change will contribute to the protection of investors and the public interest by enhancing transparency with respect to system functionality across trading of all securities in the Exchange.

With respect to making the proposed D Order available only to Floor brokers, the Exchange states that D Orders are based on current d-Quote functionality, which is available only to Floor brokers and is designed to replicate electronically the Floor broker's agency role to exercise price discretion on an order on behalf of a customer. Additionally, the Exchange asserts that Floor brokers fulfill an agency broker role on behalf of their customers without conflicts and fill a void for firms that have chosen to allocate resources away from trading desks. In addition to this role, according to the Exchange, Floor brokers provide services for more illiquid securities, which upstairs trading desks may not be staffed to manage. The Exchange asserts that use of the D Order would facilitate this agency function by allowing Floor brokers to enter orders on behalf of their customers without pricing impact because the discretionary price range would be undisplayed and that, when managing this customer order flow, Floor brokers trading in UTP Securities would continue to be subject to Exchange rules that are unique to Floor brokers, including Rules 95, 122, 123, and paragraphs (d)–(j) of Rule 134.[27]

In addition, the Exchange notes that, while D Orders would be available only to Floor brokers, any member organization can choose to have a Floor broker operation and thus have direct access to D Orders on behalf of its customers, and that any such orders would not receive any execution priority or benefit when trading at a discretionary price. To the contrary, the Exchange asserts, if a D Order were to exercise discretion and trade at an undisplayed, discretionary price, that D Order would be ranked behind all other same-side orders at that price, except for a Yielding Order, which by definition yields to all other orders and can only be entered by another Floor broker.[28]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[29] In particular, the Commission finds that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act,[30] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and are not designed to permit unfair discrimination between customers, issuers, brokers or dealers.

The Commission finds that the proposed rule change would extend the availability of certain orders and modifiers—which are currently available for the trading of Exchange-listed securities on the Exchange's existing technology platform—to trading on Pillar. Specifically, the D Order, Last Sale Peg Modifier, and Yielding Modifier that the Exchange proposes for Pillar would operate in a manner similar to the Exchange's existing d-Quotes, BMZP, and g-Quotes, respectively.

[21] In the Notice, the Exchange represents that Floor brokers provide services certain illiquid securities, which upstairs trading desks may not be staffed to manage, without any conflict of interest because they are is not trading for her their account and do not sell research to customers. This allows Floor brokers to manage order flow with a focus on price discovery and volume discovery in order to minimize price impact on the market. *See* Notice, *supra* note 4, 83 FR at 13569.

[22] *See* Notice, *supra* note 4, 83 FR at 64920. The Exchange states proposed NYSE Rule 7.16(f)(5)(C) to add D Orders, like Pegged Orders and MPL Orders today, including orders marked buy, sell long, and sell short exempt, is based on the existing Pillar logic for D Orders that peg to the PBBO. *See* Notice, *supra* note 4, 83 FR at 63917.

[23] The Exchange states that the Last Sale Peg Modifier is based on the existing Buy Minus Zero Plus Instruction available to buy orders, and is designed to facilitate compliance with the safe harbor provisions of Rule 10b–18 under the Act. *See, e.g.,* Notice, *supra* note 4, 83 FR at 64921; NYSE Rule 13(f)(4).

[24] For example, the Exchange states that limiting this modifier to Non-Routable Limit Orders would simplify its operation, because the Exchange would not be able to assist a member organization to comply with Rule 10b–18 if such order were routed to an away market. *See* Notice, *supra* note 4, 83 FR at 64921.

[25] *See, e.g., supra,* note 23 and accompanying text; Notice, *supra* note 4, 83 FR at 64918, 64921.

[26] Exchange asserts that the electronic, off-Floor entry of orders is subject to an exception to the G Rule. *See* Notice, *supra,* note 4, 83 FR at 64918, 64021.

[27] *See* Notice, *supra* note 4, 83 FR at 64920.

[28] *See id.*

[29] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[30] 15 U.S.C. 78f(b)(5).

Additionally, the Commission notes that—after considering the potential effects on competition and the potential for discrimination against other exchange participants—it previously approved the extension of parity allocations to Floor brokers with respect to trading UTP Securities.[31] The Commission believes that the rules that the Exchange now proposes with respect to the use of D Orders by Floor brokers are similarly designed to ensure that the benefits of this order type will flow to the customers of the Floor brokers.[32]

The Exchange also proposes to amend NYSE Rule 7.16(f)(5)(C) to specify that D Orders—including orders marked buy, sell long, and sell short exempt—would use the NBBO instead of the PBBO as the reference price. The Commission notes that any repricing of orders by the Exchange must be done consistent with applicable rules and regulations, including Rule 201 of Regulation SHO.[33]

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[34] that the proposed rule change (SR–NYSE–2018–52) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[35]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03035 Filed 2–21–19; 8:45 am]

BILLING CODE 8011–01–P

[31] *See* Pillar Trading Rules Approval, *supra,* note 3, 83 FR at 13572.

[32] *See supra* notes 27–28 and accompanying text. *See also* Pillar Trading Rules Approval, *supra,* note 3, 83 FR at 13572 (finding that the Exchange's proposal to provide Floor brokers with parity allocation in UTP Securities was designed to ensure that the benefit of parity allocation would flow to customers of the floor brokers).

[33] *See* 17 CFR 242.201.

[34] 15 U.S.C. 78s(b)(2).

[35] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–105, OMB Control No. 3235–0121]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Form 18

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Form 18 (17 CFR 249.218) is a registration form used for by a foreign government or political subdivision to register securities for listing on a U.S. exchange. The information collected is intended to ensure that the information required by the Commission to be filed permits verification of compliance with securities law requirements and assures the public availability of the information. The information provided is mandatory and all information is made available to the public upon request. Form 18 takes approximately 8 hours per response and is filed by approximately 5 respondents for a total of 40 annual burden hours (8 hours per response × 5 responses). It is estimated that 100% of the total reporting burden is prepared by the company.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following website, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Lindsay.M.Abate@omb.eop.gov*; and (ii) Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: February 19, 2019.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03087 Filed 2–21–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85163; File No. SR–PEARL–2019–01]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Options Regulatory Fee

February 15, 2019.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 1, 2019, MIAX PEARL, LLC (''MIAX PEARL'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX PEARL Fee Schedule (the ''Fee Schedule'') to amend its Options Regulatory Fee (''ORF'').

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX PEARL's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange charges an ORF in the amount of $0.0010 per

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

contract side. The Exchange proposes to increase this ORF to $0.0028 per contract side. In light of historical and projected volume changes and shifts in the industry and on the Exchange, as well as changes to the Exchange's regulatory cost structure, the Exchange is proposing to change the amount of ORF that will be collected by the Exchange. The Exchange's proposed change to the ORF should balance the Exchange's regulatory revenue against the anticipated regulatory costs.

The per-contract ORF will continue to be assessed by MIAX PEARL to each MIAX PEARL Member for all options transactions, including Mini Options, cleared or ultimately cleared by the Member which are cleared by the Options Clearing Corporation (''OCC'') in the ''customer'' range, regardless of the exchange on which the transaction occurs. The ORF will be collected by OCC on behalf of MIAX PEARL from either (1) a Member that was the ultimate clearing firm for the transaction or (2) a non-Member that was the ultimate clearing firm where a Member was the executing clearing firm for the transaction. The Exchange uses reports from OCC to determine the identity of the executing clearing firm and ultimate clearing firm.

To illustrate how the ORF is assessed and collected, the Exchange provides the following set of examples. If the transaction is executed on the Exchange and the ORF is assessed, if there is no change to the clearing account of the original transaction, then the ORF is collected from the Member that is the executing clearing firm for the transaction. (The Exchange notes that, for purposes of the Fee Schedule, when there is no change to the clearing account of the original transaction, the executing clearing firm is deemed to be the ultimate clearing firm.) If there is a change to the clearing account of the original transaction (*i.e.,* the executing clearing firm ''gives-up'' or ''CMTAs'' the transaction to another clearing firm), then the ORF is collected from the clearing firm that ultimately clears the transaction—the ultimate clearing firm. The ultimate clearing firm may be either a Member or non-Member of the Exchange. If the transaction is executed on an away exchange and the ORF is assessed, then the ORF is collected from the ultimate clearing firm for the transaction. Again, the ultimate clearing firm may be either a Member or non-Member of the Exchange. The Exchange notes, however, that when the transaction is executed on an away exchange, the Exchange does not assess the ORF when neither the executing clearing firm nor the ultimate clearing firm is a Member (even if a Member is ''given-up'' or ''CMTAed'' and then such Member subsequently ''gives-up'' or ''CMTAs'' the transaction to another non-Member via a CMTA reversal). Finally, the Exchange will not assess the ORF on outbound linkage trades, whether executed at the Exchange or an away exchange. ''Linkage trades'' are tagged in the Exchange's system, so the Exchange can readily tell them apart from other trades. A customer order routed to another exchange results in two customer trades, one from the originating exchange and one from the recipient exchange. Charging ORF on both trades could result in double-billing of ORF for a single customer order, thus the Exchange will not assess ORF on outbound linkage trades in a linkage scenario. This assessment practice is identical to the assessment practice currently utilized by the Exchange's affiliate, Miami International Securities Exchange, LLC (''MIAX Options'').[3]

As a practical matter, when a transaction that is subject to the ORF is not executed on the Exchange, the Exchange lacks the information necessary to identify the order entering member for that transaction. There are countless order entering market participants, and each day such participants can and often do drop their connection to one market center and establish themselves as participants on another. For these reasons, it is not possible for the Exchange to identify, and thus assess fees such as an ORF, on order entering participants on away markets on a given trading day. Clearing members, however, are distinguished from order entering participants because they remain identified to the Exchange on information the Exchange receives from OCC regardless of the identity of the order entering participant, their location, and the market center on which they execute transactions. Therefore, the Exchange believes it is more efficient for the operation of the Exchange and for the marketplace as a whole to collect the ORF from clearing members.

The Exchange monitors the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange reviews all costs and makes determinations if there is a nexus between the expense and a regulatory function. The Exchange notes that fines collected by the Exchange in connection with a disciplinary matter offset ORF.

As discussed below, the Exchange believes it is appropriate to charge the ORF only to transactions that clear as customer at the OCC. The Exchange believes that its broad regulatory responsibilities with respect to a Member's activities supports applying the ORF to transactions cleared but not executed by a Member. The Exchange's regulatory responsibilities are the same regardless of whether a Member enters a transaction or clears a transaction executed on its behalf. The Exchange regularly reviews all such activities, including performing surveillance for position limit violations, manipulation, front-running, contrary exercise advice violations and insider trading. These activities span across multiple exchanges.

The ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of Members' customer options business, including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The Exchange believes that revenue generated from the ORF, when combined with all of the Exchange's other regulatory fees and fines, will cover a material portion, but not all, of the Exchange's regulatory costs. The Exchange notes that its regulatory responsibilities with respect to Member compliance with options sales practice rules have been allocated to the Financial Industry Regulatory Authority (''FINRA'') under a 17d–2 Agreement. The ORF is not designed to cover the cost of options sales practice regulation.

The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange will continue to monitor MIAX PEARL regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission. The Exchange will notify Members of adjustments to the ORF via regulatory circular at least 30 days prior to the effective date of the change.

The Exchange believes it is reasonable and appropriate for the Exchange to charge the ORF for options transactions regardless of the exchange on which the transactions occur. The Exchange has a

[3] *See* Securities Exchange Act Release No. 81063 (June 30, 2017), 82 FR 31668 (July 7, 2017) (SR–MIAX–2017–31).

statutory obligation to enforce compliance by Members and their associated persons under the Act and the rules of the Exchange and to surveil for other manipulative conduct by market participants (including non-Members) trading on the Exchange. The Exchange cannot effectively surveil for such conduct without looking at and evaluating activity across all options markets. Many of the Exchange's market surveillance programs require the Exchange to look at and evaluate activity across all options markets, such as surveillance for position limit violations, manipulation, front-running and contrary exercise advice violations/expiring exercise declarations. While much of this activity relates to the execution of orders, the ORF is assessed on and collected from clearing firms. The Exchange, because it lacks access to information on the identity of the entering firm for executions that occur on away markets, believes it is appropriate to assess the ORF on its Members' clearing activity, based on information the Exchange receives from OCC, including for away market activity. Among other reasons, doing so better and more accurately captures activity that occurs away from the Exchange over which the Exchange has a degree of regulatory responsibility. In so doing, the Exchange believes that assessing ORF on Member clearing firms equitably distributes the collection of ORF in a fair and reasonable manner. Also, the Exchange and the other options exchanges are required to populate a consolidated options audit trail (''COATS'')[4] system in order to surveil a Member's activities across markets.

In addition to its own surveillance programs, the Exchange works with other SROs and exchanges on intermarket surveillance related issues. Through its participation in the Intermarket Surveillance Group (''ISG''),[5] the Exchange shares information and coordinates inquiries and investigations with other exchanges designed to address potential intermarket manipulation and trading abuses. The Exchange's participation in ISG helps it to satisfy the requirement that it has coordinated surveillance with markets on which security futures are traded and markets on which any security underlying security futures are traded to detect manipulation and insider trading.[6]

The Exchange believes that charging the ORF across markets avoids having Members direct their trades to other markets in order to avoid the fee and to thereby avoid paying for their fair share for regulation. If the ORF did not apply to activity across markets then a Member would send their orders to the least cost, least regulated exchange. Other exchanges do impose a similar fee on their members' activity,[7] including the activity of those members on MIAX PEARL and MIAX Options.[8]

The Exchange notes that there is established precedent for an SRO charging a fee across markets, namely, FINRAs Trading Activity Fee[9] and the NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), Cboe Exchange, Inc. (''CBOE''), Nasdaq PHLX LLC (''Phlx''), Nasdaq ISE, LLC (''ISE''), Nasdaq GEMX, LLC (''GEMX'') and BOX Exchange LLC (''BOX'') ORF. While the Exchange does not have all the same regulatory responsibilities as FINRA, the Exchange believes that, like other exchanges that have adopted an ORF, its broad regulatory responsibilities with respect to a Member's activities, irrespective of where their transactions take place, supports a regulatory fee applicable to transactions on other markets. Unlike FINRA's Trading Activity Fee, the ORF applies only to a Member's customer options transactions.

Additionally, the Exchange specifies in the Fee Schedule that the Exchange may only increase or decrease the ORF semi-annually, and any such fee change will be effective on the first business day of February or August. In addition to submitting a proposed rule change to the Commission as required by the Act to increase or decrease the ORF, the Exchange will notify participants via a Regulatory Circular of any anticipated change in the amount of the fee at least 30 calendar days prior to the effective date of the change. The Exchange believes that by providing guidance on the timing of any changes to the ORF, the Exchange would make it easier for participants to ensure their systems are configured to properly account for the ORF.

The Exchange is proposing to increase the ORF from $0.0010 to $0.0028, as of February 1, 2019. In light of recent market volumes on the Exchange and changes to the Exchange's regulatory costs, the Exchange is proposing to increase the amount of ORF that will be collected by the Exchange. As noted above, the Exchange regularly reviews its ORF to ensure that the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. The Exchange believes this adjustment will permit the Exchange to cover a material portion of its regulatory costs, while not exceeding regulatory costs.

The Exchange notified Members via a Regulatory Circular of the proposed change to the ORF at least thirty (30) calendar days prior to the proposed operative date, on December 31, 2018.[10] The Exchange believes that the prior notification to market participants will ensure market participants are prepared to configure their systems to properly account for the ORF.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[11] in general, and furthers the objectives of Section 6(b)(4) of the Act[12] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act[13] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that increasing the ORF from $0.0010 to $0.0028, as of February 1, 2019 is reasonable because the Exchange's collection of ORF needs to be balanced against the amount of

[4] COATS effectively enhances intermarket options surveillance by enabling the options exchanges to reconstruct the market promptly to effectively surveil certain rules.

[5] ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by co-operatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

[6] *See* Section 6(h)(3)(I) of the Act.

[7] Similar regulatory fees have been instituted by Nasdaq PHLX LLC (''Phlx'') (*See* Securities Exchange Act Release No. 61133 (December 9, 2009), 74 FR 66715 (December 16, 2009) (SR–Phlx–2009–100)); Nasdaq ISE, LLC (''ISE'') (*See* Securities Exchange Act Release No. 61154 (December 11, 2009), 74 FR 67278 (December 18, 2009) (SR–ISE–2009–105)); and Nasdaq GEMX, LLC (''GEMX'') (*See* Securities Exchange Act Release No. 70200 (August 14, 2013) 78 FR 51242 (August 20, 2013) (SR–Topaz–2013–01)).

[8] *See supra* note 3.

[9] *See* Securities Exchange Act Release No. 47946 (May 30, 2003), 68 FR 34021 (June 6, 2003) (SR–NASD–2002–148).

[10] *See* MIAX PEARL Regulatory Circular 2018–55 available at *https://www.miaxoptions.com/sites/default/files/circular-files/MIAX_PEARL_RC_2018_55.pdf.*

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78f(b)(5).

regulatory costs incurred by the Exchange. The Exchange believes that the proposed adjustments noted herein will serve to balance the Exchange's regulatory revenue against the anticipated regulatory costs.

The Exchange believes that amending the ORF from $0.0010 to $0.0028, as of February 1, 2019 is equitable and not unfairly discriminatory because it is objectively allocated to Members in that it is charged to all Members on all their transactions that clear as customer at the OCC. Moreover, the Exchange believes the ORF ensures fairness by assessing fees to those Members that are directly based on the amount of customer options business they conduct. Regulating customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (*e.g.,* Member proprietary transactions) of its regulatory program.

The ORF is designed to recover a material portion of the costs of supervising and regulating Members' customer options business including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange has designed the ORF to generate revenues that, when combined with all of the Exchange's other regulatory fees, will be less than or equal to the Exchange's regulatory costs, which is consistent with the Commission's view that regulatory fees be used for regulatory purposes and not to support the Exchange's business side. In this regard, the Exchange believes that the proposed increase to the fee is reasonable.

The Exchange believes that continuing to limit changes to the ORF to twice a year on specific dates with advance notice is reasonable because it gives participants certainty on the timing of changes, if any, and better enables them to properly account for ORF charges among their customers. The Exchange believes that continuing to limit changes to the ORF to twice a year on specific dates is equitable and not unfairly discriminatory because it will apply in the same manner to all Members that are subject to the ORF and provide them with additional advance notice of changes to that fee.

The Exchange believes that collecting the ORF from non-Members when such non-Members ultimately clear the transaction (that is, when the non-Member is the ''ultimate clearing firm'' for a transaction in which a Member was assessed the ORF) is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange notes that there is a material distinction between ''assessing'' the ORF and ''collecting'' the ORF. The ORF is only assessed to a Member with respect to a particular transaction in which it is either the executing clearing firm or ultimate clearing firm. The Exchange does not assess the ORF to non-Members. Once, however, the ORF is assessed to a Member for a particular transaction, the ORF may be collected from the Member or a non-Member, depending on how the transaction is cleared at OCC. If there was no change to the clearing account of the original transaction, the ORF would be collected from the Member. If there was a change to the clearing account of the original transaction and a non-Member becomes the ultimate clearing firm for that transaction, then the ORF will be collected from that non-Member. The Exchange believes that this collection practice continues to be reasonable and appropriate, and was originally instituted for the benefit of clearing firms that desired to have the ORF be collected from the clearing firm that ultimately clears the transaction.

B. Self-Regulatory Organization's Statement on Burden on Competition

MIAX PEARL 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. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the ORF applies to all customer activity, and is designed to enable the Exchange to recover a material portion of the Exchange's cost related to its regulatory activities. It also supplements the regulatory revenue derived from non-customer activity. This proposal does not create an unnecessary or inappropriate inter-market burden on competition because it is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. Unilateral action by MIAX PEARL in establishing fees for services provided to its Members and others using its facilities will not have an impact on competition. In the highly competitive environment for equity options trading, MIAX PEARL does not have the market power necessary to set prices for services that are unreasonable or unfairly discriminatory in violation of the Act. The Exchange's ORF, as described herein, is comparable to fees charged by other options exchanges for the same or similar services. The Exchange believes that continuing to limit the changes to the ORF to twice a year on specific dates with advance notice is not intended to address a competitive issue but rather to provide Members with better notice of any change that the Exchange may make to the ORF.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[14] and Rule 19b–4(f)(2) [15] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[14] 15 U.S.C. 78s(b)(3)(A)(ii).

[15] 17 CFR 240.19b–4(f)(2).

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–PEARL–2019–01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR–PEARL–2019–01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml.*) Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–PEARL–2019–01, and should be submitted on or before March 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03037 Filed 2–21–19; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 10678]

Notice of Information Collection Under OMB Emergency Review: Three Information Collections Related to the United States Munitions List, Categories I, II and III; Correction

ACTION: Notice of request for emergency OMB approval and public comment; correction.

SUMMARY: The Department of State published a **Federal Register** Notice on February 12, 2019, notifying the public of the Emergency processing and approval of this collection by April 1, 2019. The Notice using Docket Number: DOS–2018–0063 contained an incorrect date when all comments must be received. This document corrects the date to March 14, 2019.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents to Andrea Battista who may be reached on 202–663–3136 or at *battistaal@state.gov*.

Correction

In the **Federal Register**, published on February 12, 2019, in FR Doc. 2019–01983, on page 3528, in the first column, the correct date when all comments must be received is March 14, 2019.

Anthony M. Dearth

Chief of Staff, Directorate of Defense Trade Controls, Department of State.

[FR Doc. 2019–03091 Filed 2–21–19; 8:45 am]

BILLING CODE 4710–25–P

SURFACE TRANSPORTATION BOARD

[Docket No. MCF 21084]

Variant Equity I, LP, and Project Kenwood Acquistion, LLC—Acquisition of Control—Coach USA Administration, Inc., and Coach USA, Inc.

AGENCY: Surface Transportation Board.

ACTION: Notice tentatively approving and authorizing finance transaction.

SUMMARY: On December 20, 2018, Variant Equity I, LP (Variant), and Project Kenwood Acquisition, LLC (collectively, Applicants), both noncarriers, jointly filed an application to acquire from SCUSI Limited 100% of the stock in Coach USA Administration, Inc., a noncarrier that owns 100% of Coach USA, Inc., another noncarrier, that controls 29 motor passenger carriers that hold federally-issued interstate operating authority. The Board is tentatively approving and authorizing the transaction,[1] and, if no opposing comments are timely filed, this notice will be the final Board action. Persons wishing to oppose the application must follow the rules.

DATES: Comments must be filed by April 8, 2019. Applicants may file a reply by April 23, 2019. If no opposing comments are filed by April 8, 2019, this notice shall be effective on April 9, 2019.

ADDRESSES: Send an original and 10 copies of any comments referring to Docket No. MCF 21084 to: Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, send one copy of comments to Applicants' Representative: Matthew J. Warren, Sidley Austin LLP, 1501 K Street NW, Washington DC 20005.

FOR FURTHER INFORMATION CONTACT: Matthew Bornstein at (202) 245–0385. Assistance for the hearing impaired available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Applicants explain that Variant is a private equity firm organized under the laws of the State of Delaware. (Appl. 2.) It controls 100% of the equity and vote of Project Kenwood Acquisition, LLC, which is also organized under the laws of the State of Delaware. Applicants assert that neither Variant nor any entity currently under its control holds motor carrier authority or a U.S. Department of Transportation number or safety rating.[2] (*Id.*)

Applicants state that Coach USA, Inc., which is a Delaware corporation, controls 29 motor passenger carriers that hold federally issued interstate operating authority [3] and operate, in total, approximately 2,213 buses.[4]

[1] Due to the partial shutdown of the Federal government from December 22, 2018, through January 25, 2019, the Board was not able to act within the period set forth in 49 U.S.C. 14303(c). On January 28, 2019, Applicants filed a motion seeking expedited review of the application and publication of a notice in the **Federal Register**. On January 30, 2019, Stagecoach Group plc filed a reply in support of Applicants' motion to expedite.

[2] Applicants state that Variant controls multiple assets, including Curb Mobility, which provides a comprehensive mobility platform that serves taxi and other for-hire ride operators, regulators, service providers, and riders. (Appl. 2.)

[3] A 30th Coach USA-owned carrier, Community Transportation, Inc., operates only on intrastate routes in New Jersey. (*See id.* at 6.)

[4] This figure is derived from Exhibit 1 of the verified application, which lists, among other things, the approximate number of buses operated

Coach USA, Inc., is a wholly owned subsidiary of Coach USA Administration, Inc., a Nevada corporation. (*Id.* at 3–4.) All the equity interests in Coach USA Administration, Inc., are held by SCUSI Limited, a public limited holding company organized under the laws of England and Wales. Stagecoach Group plc is the ultimate parent of SCUSI Limited and is organized under the laws of Scotland. (*Id.* at 3.) [5]

The 29 interstate motor carriers are described in Exhibit 1 of the application as follows: [6]

- Airport Supersaver Inc., which primarily operates in Illinois;
- All West Coachlines, Inc., which primarily operates in California and Nevada;
- American Coach Lines of Atlanta, Inc., which primarily operates in Georgia, Florida, Alabama, and South Carolina;
- Butler Motor Transit, Inc., which primarily operates in Pennsylvania, New Jersey, New York, and Michigan;
- Central Cab Company which primarily operates in Pennsylvania, Ohio, and West Virginia;
- Chenango Valley Bus Lines., Inc., which primarily operates in New Jersey, New York, and Pennsylvania;
- Community Coach, Inc., which primarily operates in New Jersey, New York, Ohio, and Pennsylvania;
- Community Transit Lines, Inc., which primarily operates in New Jersey;
- Dillon's Bus Service, Inc., which primarily operates in Maryland, Virginia, and the District of Columbia;
- Elko, Inc., which primarily operates in Nevada;
- Hudson Transit Lines, Inc., which primarily operates in New Jersey, New York, and Pennsylvania;
- Independent Bus Company, Inc., which primarily operates in New Jersey;
- Kerrville Bus Company, Inc., which primarily operates in Texas, Arkansas, and Louisiana;
- Lakefront Lines, Inc., which primarily operates in Illinois, Indiana, Ohio, Pennsylvania, Michigan, Tennessee, and New York;
- Megabus Northeast, LLC, which primarily operates in Connecticut, the District of Columbia, Georgia, Massachusetts, Maryland, North Carolina, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Virginia, West Virginia, and Maine;
- Megabus Southeast, LLC, which primarily operates in Alabama, the District of Columbia, Florida, Georgia, Kentucky, Louisiana, North Carolina, Tennessee, and Virginia;
- Megabus Southwest, LLC, which primarily operates in Arkansas, Texas, Louisiana, Tennessee, and Missouri;
- Megabus West, LLC, which primarily operates in California and Nevada;
- Olympia Trails Bus Company, Inc., which primarily operates in New Jersey and New York;
- Orange, Newark, Elizabeth Bus, Inc., which primarily operates in New Jersey;
- Pacific Coast Sightseeing Tours & Charters, Inc., which primarily operates in California and Nevada;
- Powder River Transportation Services, Inc., which primarily operates in Wyoming and Montana;
- Rockland Coaches, Inc., which primarily operates in New York and New Jersey;
- Sam Van Galder, Inc., which primarily operates in Wisconsin, Illinois, and Minnesota;
- Suburban Trails, Inc., which primarily operates in New Jersey and New York;
- Transportation Management Services, Inc. (d/b/a Lenzner Coach Lines), which primarily operates in Pennsylvania;
- Trentway-Wagar, Inc., which primarily operates in New York and Canada;
- Tri-State Coach Lines Inc., is not currently operating; and
- Wisconsin Coach Lines, Inc., which primarily operates in Wisconsin and Illinois.

Applicants state that the purpose of the transaction is to transfer the ultimate ownership of the 29 carriers from Stagecoach Group plc and SCUSI Limited to Variant. Variant seeks to acquire the carriers as an investment and plans to manage the assets with the goal of continuing to provide safe and reliable motor passenger transportation, while at the same time improving long-term value. (Appl. 1.)

Under 49 U.S.C. 14303(b), the Board must approve and authorize a transaction subject to section 14303 that it finds consistent with the public interest, taking into consideration at least: (1) The effect of the proposed transaction on the adequacy of transportation to the public, (2) the total fixed charges that result, and (3) the interest of affected carrier employees. Applicants have submitted information required by 49 CFR 1182.2, including information to demonstrate that the proposed transaction is consistent with the public interest under 49 U.S.C. 14303(b), *see* 49 CFR 1182.2(a)(7), and a statement that the aggregate gross operating revenues of the involved carriers exceeded $2 million during the preceding 12-month period. *See* 49 U.S.C. 14303(g).[7]

Applicants assert that the proposed transaction would have a positive effect on the adequacy of transportation services for the public. They state that, at the current time, Variant has no intention of materially altering the nature, extent, or frequency of the service provided by the 29 motor carriers. (Appl. 12.) Applicants state that the carriers would continue to operate as they have been with their existing names and trade names, but under new ultimate ownership. Applicants further state that Variant would use its management experience to enhance the carriers' overall financial viability while providing safe and quality service to customers. (*Id.*)

Applicants argue that the proposed transaction would have no negative impact on competition because Variant is not a carrier and does not own or control any carriers. (*Id.*) They assert that there would be continued competition in each of the categories of service provided by the carriers because they would continue to face actual and potential competition from numerous modes of transportation, including competing bus services, automobiles, and more. (*Id.* at 12–13.)

Applicants state that the proposed transaction would increase fixed charges, in the form of interest expense, because funds would be borrowed to assist in financing the transaction. (*Id.* at 13.) They claim, however, that such an increase would not affect the provision of transportation services to the public. Applicants also cite to *Sureride Charter, Inc.—Acquisition of Control—McClintock Enterprises, Inc.,* MCF 21077 (STB served Nov. 2, 2017), where the Board approved a transaction envisioning debt financing and the possibility of an increase in interest expenses.

Regarding the interests of employees, Applicants claim that there would be no material effect on employee or labor conditions because the proposed transaction does not envision any immediate change in the day-to-day operations of the carriers that could

by each Coach USA carrier with active federal operating authority.

[5] The Board has approved several acquisitions by Stagecoach Group plc and Coach USA, Inc., the most recent of which was in *Stagecoach Group plc—Acquisition of Control of Assets—American Coach Lines of Atlanta, Inc.,* MCF 21045 (STB served Aug. 15, 2012).

[6] Additional information about the motor carriers, including USDOT numbers and motor carrier numbers, can be found in the application.

[7] Parties must certify that the transaction involves carriers whose aggregate gross operating revenues exceed $2 million, as required under 49 CFR 1182.2(a)(5).

negatively impact employees. (Appl. 14.)

The Board finds that the acquisition proposed in the application is consistent with the public interest and should be tentatively approved and authorized. If any opposing comments are timely filed, these findings will be deemed vacated, and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the application. *See* 49 CFR 1182.6(c). If no opposing comments are filed by the expiration of the comment period, this notice will take effect automatically and will be the final Board action.

This action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available at *www.stb.gov.*

It is ordered:

1. The proposed transaction is approved and authorized, subject to the filing of opposing comments.

2. If opposing comments are timely filed, the findings made in this notice will be deemed vacated.

3. This notice will be effective April 9, 2019, unless opposing comments are filed by April 8, 2019.

4. A copy of this notice will be served on: (1) The U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590; (2) the U.S. Department of Justice, Antitrust Division, 10th Street & Pennsylvania Avenue NW, Washington, DC 20530; and (3) the U.S. Department of Transportation, Office of the General Counsel, 1200 New Jersey Avenue SE, Washington, DC 20590.

Decided: February 15, 2019.

By the Board, Board Members Begeman, Fuchs, and Oberman.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2019–03115 Filed 2–21–19; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36259]

Kean Burenga and Chesapeake and Delaware, LLC—Continuance in Control Exemption—Dover and Delaware River Railroad, LLC

AGENCY: Surface Transportation Board.

ACTION: Notice of exemption.

SUMMARY: The Board is granting an exemption for Kean Burenga (Burenga) and Chesapeake and Delaware, LLC (CAD), both noncarriers, to continue in control of Dover and Delaware River Railroad, LLC (DDRR), when DDRR becomes a Class III rail carrier in a related transaction involving DDRR's lease and operation of 27.2 miles of rail lines owned by Norfolk Southern Railway Company (NSR) and operation of 80.7 miles of rail lines pursuant to a trackage rights agreement among DDRR, New Jersey Transit Corporation, and NSR.[1] All of the affected lines are located in the State of New Jersey. The lines over which DDRR will operate connect with lines operated by Dover and Rockaway River Railroad, LCC (Rockaway), another Class III carrier that CAD controls.[2] Because all of the carriers involved are Class III carriers, this continuance-in-control exemption is not subject to labor protective conditions.

DATES: This exemption will be effective on February 25, 2019. Petitions to stay must be filed by February 20, 2019. Petitions to reopen must be filed by March 7, 2019.

ADDRESSES: Send an original and 10 copies of all pleadings, referring to Docket No. FD 36259, to: Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Eric M. Hocky, Clark Hill PLC, One Commerce Square, 2005 Market Street, Suite 1000, Philadelphia, PA 19103.

FOR FURTHER INFORMATION CONTACT: Sarah Fancher, (202) 245–0355. Federal Information Relay Service (FIRS) for the hearing impaired: (800) 877–8339.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision served on February 15, 2019, which is available at *www.stb.gov.*

Decided: February 14, 2019.

By the Board, Board Members Begeman, Fuchs, and Oberman.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2019–03012 Filed 2–21–19; 8:45 am]

BILLING CODE 4915–01–P

[1] *See Dover & Del. River R.R.—Lease with Interchange Commitment & Trackage Rights Exemption—Norfolk S. R.R.,* FD 36258 (STB served Dec. 20, 2018).

[2] Burenga previously sought authority to continue in control of Rockaway once Rockaway became a Class III rail carrier. (*See* Pet. 2 (citing *Burenga—Continuance in Control Exemption—Dover & Rockaway River R.R.,* FD 36125, slip op. at 1 (STB served June 16, 2017)).) The Board found it unnecessary to resolve the issue of Burenga's control in that proceeding.

SURFACE TRANSPORTATION BOARD

[Docket No. AB 312 (Sub-No. 4X); Docket No. AB 1000 (Sub-No. 4X)]

South Carolina Central Railroad Company, LLC—Abandonment Exemption—in Terrell County, GA; Georgia Southwestern Railroad, Inc.—Discontinuance Exemption—in Terrell County, GA

South Carolina Central Railroad Company, LLC (SCRF), and Georgia Southwestern Railroad, Inc. (GSWR) (collectively, Applicants), have jointly filed a verified notice of exemption under 49 CFR pt. 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* for SCRF to abandon, and for GSWR to discontinue service over, approximately 1,350 feet of rail line between milepost 72.88 and milepost 72.63 in the Town of Sasser, Terrell County, GA (the Line). The Line traverses U.S. Postal Service Zip Code 39885.

Applicants have certified that: (1) No local or overhead traffic has moved over the Line for at least two years; (2) because the Line is not a ''through line,'' there is no overhead traffic on the Line; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7(c) (environmental report), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to these exemptions, any employee adversely affected by the abandonment and discontinuance of service 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)[1] has been received,

[1] The Board modified its OFA procedures effective July 29, 2017. Among other things, the OFA process now requires potential offerors, in their formal expression of intent, to make a preliminary financial responsibility showing based on a calculation using information contained in the carrier's filing and publicly available information. *See Offers of Financial Assistance,* EP 729 (STB served June 29, 2017); 82 FR 30,997 (July 5, 2017).

these exemptions will be effective on March 26, 2019, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[2] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[3] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by March 4, 2019. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by March 14, 2019, with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to Eric M. Hocky, Clark Hill, PLC, One Commerce Square, 2005 Market Street, Suite 1000, Philadelphia, PA 19103.

If the verified notice contains false or misleading information, the exemptions are void ab initio.

Applicants have filed a combined environmental and historic report that addresses the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by March 1, 2019. Interested persons may obtain a copy of the EA by writing to OEA (Surface Transportation Board, Washington, DC 20423–0001) or by calling OEA at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), SCRF 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 SCRF's filing of a notice of consummation by February 22, 2020, 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: February 15, 2019.

By the Board, Allison C. Davis, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2019–03061 Filed 2–21–19; 8:45 am]

BILLING CODE 4915–01–P

[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 exemptions' 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 exemptions' effective date.

[3] Each OFA must be accompanied by the filing fee, which is currently set at $1,800. *See* 49 CFR 1002.2(f)(25).

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2019–0004–N–3]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA seeks approval of the Information Collection Request (ICR) abstracted below. Before submitting this ICR to the Office of Management and Budget (OMB) for approval, FRA is soliciting public comment on specific aspects of the activities identified below.

DATES: Interested persons are invited to submit comments on or before April 23, 2019.

ADDRESSES: Submit written comments on the ICR activities by mail to either: Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W33–497, Washington, DC 20590; or Ms. Kim Toone, Information Collection Clearance Officer, Office of Information Technology, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W34–212, Washington, DC 20590. Commenters requesting FRA to acknowledge receipt of their respective comments must include a self-addressed stamped postcard stating, ''Comments on OMB Control Number 2130–NEW'' and should also include the title of the ICR. Alternatively, comments may be faxed to (202) 493–6216 or (202) 493–6497, or emailed to Mr. Brogan at *robert.brogan@dot.gov,* or Ms. Toone at *kim.toone@dot.gov.* Please refer to the assigned OMB control number in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W33–497, Washington, DC 20590 (telephone: 202–493–6292) or Ms. Kim Toone, Information Collection Clearance Officer, Office of Information Technology, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W34–212, Washington, DC 20590 (telephone: 202–493–6132).

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60-days' notice to the public to allow comment on information collection activities before seeking OMB approval of the activities. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. Specifically, FRA invites interested parties to comment on the following ICR regarding: (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways for FRA to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology. *See* 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1).

FRA believes that soliciting public comment may reduce the administrative and paperwork burdens associated with the collection of information that Federal regulations require. In summary, FRA reasons that comments received will advance three objectives: (1) Reduce reporting burdens; (2) organize information collection requirements in a ''user-friendly'' format to improve the use of such information; and (3) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Federal Railroad Administration Disadvantaged Business Enterprise (DBE) Disparity Study.

OMB Control Number: 2130–NEW.

Abstract: The objective of this work is to complete a congressionally-mandated disparity study evaluating the participation by small and disadvantaged businesses in railroad contracting that meets the requirements of the Disadvantaged Business Enterprise (DBE) program for federally-funded projects administered by the Federal Highway Administration (FHWA) or the Federal Transit Administration (FTA), 49 CFR part 26. The purpose of this disparity study is to evaluate the market for the availability and utilization of small and disadvantaged businesses in publicly-funded railroad contracting. The study will be used as evidence to inform FRA and DOT on the state of small and disadvantaged business contracting in the railroad industry and will be a component in the FRA's Title VI compliance program.

FRA does not currently have statutory authority to administer a DBE program like those in place at FHWA, FTA, and the Federal Aviation Administration (FAA). DOT DBE regulations applicable to FHWA, FTA and FAA require state and local transportation agencies that receive DOT financial assistance to establish goals for the participation of DBEs. Each DOT-assisted State and local transportation agency is required to establish annual DBE goals, review the scopes of anticipated large prime contracts, and establish contract-specific DBE subcontracting goals. Without statutory DBE authority, FRA can only encourage recipients of its Federal financial assistance to use in their projects small business concerns owned and controlled by socially and economically disadvantaged individuals. These types of small business concerns include small businesses, DBEs, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses. Despite the lack of a formal DBE program, FRA fully supports the objectives of DBE programs and all FRA's grantees are required to avoid discrimination in contracting.

In addition, in late 2015, Congress passed the ''Fixing America's Surface Transportation Act'' (FAST Act), (Pub. L. 114–94). The FAST Act codified the requirement for FRA to conduct ''a nationwide disparity and availability study on the availability and use of small business concerns owned and controlled by socially and economically disadvantaged individuals and veteran-owned small businesses in publicly funded intercity rail passenger transportation projects.'' *See* FAST Act, sec. 11310, Small Business Participation Study. The legislation requires that: ''Not later than 2 years after the date of enactment of this Act, the Secretary shall submit a report containing the results of the study . . . to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Transportation and Infrastructure of the House of Representatives.'' *Id.*

The collection of information for the study includes three surveys and a series of webinar focus groups. In Survey #1, FRA's study contractor (*i.e.,* the Jack Faucett Associates team) will contact all FRA grant recipients and work with them to identify all of the prime contractors, consultants, and vendors with whom they spent grant funds and the amount of those funds. Next, the study team will contact the sub-grantees, prime contractors, consultants and suppliers that the study identified, and work with them to identify all subcontractors, sub-consultants, and suppliers that they utilize and the amount of those contracts. This survey is necessary to develop estimates of the amount of FRA grants and contracts that flow to DBEs.

In Survey #2, the study team will survey DBE and non-DBE firms in the railroad industry. The survey will elicit data on firms' experiences with discrimination, as well as experiences in bidding with the grantees and their prime contractors and consultants. This approach ensures that anecdotal findings are corroborated by an actual representation of the DBE and non-DBE communities at large in the relevant markets. The personal experiences of disparate treatment suffered by minorities or women in seeking and performing public and private sector work in the relevant marketplace reinforce buttress sound statistical evidence of disparate impacts. Since response rates to voluntary surveys tend to be fairly low, the study team will take additional steps to increase responsiveness, including an outreach campaign, professionally designed surveys, cover letters signed by top FRA officials, multiple reminders, and a devoted wide-area telephone service line and email address for requesting replacement surveys and addressing other inquiries. Moreover, the study team will statistically validate representativeness using surveys of non-respondents.

In the focus groups, the study team will also collect qualitative anecdotal information through in-depth webinar focus groups of DBE and non-DBE business owners, as well as procurement personnel at FRA and its grantees. These focus groups likewise will explore barriers to the full and fair participation of DBEs in FRA's market area and that of its grantees. The focus groups also will investigate whether the USDOT programs and policies, as they apply to FRA and its grantees, adequately address these challenges. These focus groups will yield valuable information about the day-to-day realities affecting DBE firms and will inform how to develop FRA's policy responses to those challenges.

In Survey #3, the study team will survey firms to verify their DBE status. The comparison of FRA's use of DBEs versus their prevalence by industry and geography is crucial to developing the sound statistical evidence of discrimination the courts have required. Starting from known business establishment lists (such as those from Dun & Bradstreet), the study will cross-reference numerous additional listings and directories of DBE firms in the relevant geographic and product markets in order to improve the classification of firms according to their status. Next, the study team will take the additional step of validating putative assignments using telephone surveys of a statistically random sample of businesses from the master database.

Type of Request: Approval of a new collection of information.

Affected Public: Businesses.

Form(s): FRA F 6180.171; FRA F 6180.172; FRA F 6180.173; FRA F 6180.174.

Respondent Universe: 35,000 Grantees, Sub-Grantees, Prime Contractors, Sub-Contractors, DBEs, and Non-Disadvantaged Business Firms.

Frequency of Submission: On occasion.

Reporting Burden:

Form No.	Respondent universe	Total annual responses	Average time per response (hours)	Total annual burden hours	Total annual burden cost *
Survey #1: Grantee and Contractor Collection Form.	1,250 Grantees, Sub-grantees, Prime-Contractors, and Sub-Contractors.	500 surveys	4	2,000	$115,300
Survey #2: Experiences with Discrimination.	35,000 DBE and non-DBE firms	2,750 surveys	.25	688	39,663
Focus Groups on Experiences with Discrimination.	20,000 DBE and non-DBE firms	250 focus group participants.	1	250	14,413
Survey #3: DBE Status Verification	28,000 DBE and non-DBE firms	4,250 surveys	.05	213	12,279

Note: The annual hourly wage rate for the above calculations is $57.65 and is derived from the Management Occupations (Occupational Code 11–0000) Bureau of Labor Statistics of the U.S. Department of Labor: Occupational Employment Statistics, May 2017, National Occupational Employment and Wage Estimates.

Total Estimated Annual Responses: 7,750.

Total Estimated Annual Burden: 3,151 hours.

Total Estimated Dollar Cost: $181,655.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Brett A. Jortland,

Acting Chief Counsel.

[FR Doc. 2019–03049 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2019–0004–N–2]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA seeks approval of the Information Collection Requests (ICRs) abstracted below. Before submitting these ICRs to the Office of Management and Budget (OMB) for approval, FRA is soliciting public comment on specific aspects of the activities identified below.

DATES: Interested persons are invited to submit comments on or before April 23, 2019.

ADDRESSES: Submit written comments on the ICRs activities by mail to either: Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W33–497, Washington, DC 20590; or Ms. Kim Toone, Information Collection Clearance Officer, Office of Information Technology, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W34–212, Washington, DC 20590. Commenters requesting FRA to acknowledge receipt of their respective comments must include a self-addressed stamped postcard stating, ''Comments on OMB Control Number 2130–XXXX,'' (the relevant OMB control number for each ICR is listed below) and should also include the title of the ICR. Alternatively, comments may be faxed to (202) 493–6216 or (202) 493–6497, or emailed to Mr. Brogan at *Robert.Brogan@dot.gov,* or Ms. Toone at *Kim.Toone@dot.gov.* Please refer to the assigned OMB control number in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W33–497, Washington, DC 20590 (telephone: (202) 493–6292) or Ms. Kim Toone, Information Collection Clearance Officer, Office of Information Technology, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W34–212, Washington, DC 20590 (telephone: (202) 493–6132).

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60-days' notice to the public to allow comment on information collection activities before seeking OMB approval of the activities. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. Specifically, FRA invites interested parties to comment on the following ICRs regarding: (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways for FRA to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology. *See* 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1).

FRA believes that soliciting public comment may reduce the administrative and paperwork burdens associated with the collection of information that Federal regulations mandate. In summary, FRA reasons that comments received will advance three objectives: (1) Reduce reporting burdens; (2) organize information collection requirements in a ''user-friendly'' format to improve the use of such information; and (3) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

The summaries below describe the ICRs that FRA will submit for OMB clearance as the PRA requires:

Title: Safety Appliance Standards Guidance Checklist Forms.

OMB Control Number: 2130–0565.

Abstract: Sample car/locomotive inspections are performed upon request as a courtesy to the car manufacturers to ensure that the equipment is built in accordance with the Code of Federal

Regulations (CFR). Car manufacturers that desire to have FRA review their equipment for compliance with the CFR, may submit their request to FRA for review at least 60 days prior to initial construction. Although a sample car inspection is not required, most car manufacturers today request the inspection. By helping ensure that rolling stock equipment is built compliant with the CFR, the sample car inspection program reduces the safety risk to railroad employees, passengers, and the general public.

In an ongoing effort to conduct more thorough and effective inspections of freight railroad equipment and to further enhance safe rail operations, FRA has developed a group of guidance checklist forms that facilitate railroad, rail car owner, and rail equipment manufacturer compliance with 49 CFR part 231, Railroad Safety Appliance Standards. Because 49 CFR part 231 was supplemented and expanded several years ago, FRA developed Forms FRA F 6180.161(a)–(k) to cover new types of cars. For these new types of cars, FRA follows the standard established by the Association of American Railroads (AAR), Standard 2044 or S–2044.

A car manufacturer's request to FRA for a sample car inspection generally includes a logo, company name, signature block, specific drawings, reflectorization application, and engineering information, such as test or modeling of components. In addition, the request may include car reporting marks and the number of cars that would be constructed in the car series. The request would also provide the inspection location, contact person, title, and contact information. The request typically contains several paragraphs explaining the cited regulations that the car manufacturer believes are related to the car construction. For the many cars built today considered cars of special construction, detailed information explaining the similarities between the car being built and the nearest car type identified in the regulation are provided to help determine which regulatory requirements are applicable. Based on the information submitted, a formal on-site inspection may be required. FRA reviews the information and responds to the car manufacturer.

Type of Request: Extension without change of a currently approved information collection.

Affected Public: Businesses.

Form(s): FRA F 6180.161(a)–(k).

Respondent Universe: Car manufacturers/State Inspectors.

Frequency of Submission: Annually.

Reporting Burden:

Form	Respondent universe	Total annual responses	Average time per response (minutes)	Total annual burden hours	Total annual dollar cost equivalent [1]
Form FRA F 6180.161a	Car manufacturers/State Inspectors	20 forms	60	20	$1,224
Form FRA F 6180.161b	Car manufacturers/State Inspectors	7 forms	60	7	428
Form FRA F 6180.161c	Car manufacturers/State Inspectors	15 forms	60	15	918
Form FRA F 6180.161d	Car manufacturers/State Inspectors	15 forms	60	15	918
Form FRA F 6180.161e	Car manufacturers/State Inspectors	15 forms	60	15	918
Form FRA F 6180.161f	Car manufacturers/State Inspectors	10 forms	60	10	612
Form FRA F 6180.161g	Car manufacturers/State Inspectors	3 forms	60	3	184
Form FRA F 6180.161h	Car manufacturers/State Inspectors	3 forms	60	3	184
Form FRA F 6180.161i	Car manufacturers/State Inspectors	20 forms	60	20	1,224
Form FRA F 6180.161j	Car manufacturers/State Inspectors	3 forms	60	3	184
Form FRA F 6180.161a	Car manufacturers/State Inspectors	10 forms	60	10	612

Total Estimated Annual Responses: 121.

Total Estimated Annual Burden: 121 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $7,406.

Title: System for Telephonic Notification of Unsafe Conditions at Highway-Rail and Pathway Grade Crossings.

OMB Control Number: 2130–0591.

Abstract: The collection of information is set forth under 49 CFR part 234, Grade Crossing Safety, implementing Section 205 of the Rail Safety Improvement Act of 2008 (RSIA), Public Law 110–432, Div. A (Oct. 16, 2008). Generally, the rule is intended to increase safety at highway-rail and pathway grade crossings. Section 205 of the RSIA mandates that the Secretary of Transportation require certain railroad carriers to take a series of specified actions related to setting up and using systems by which the public can notify the railroads by toll-free telephone number of safety problems at their highway-rail and pathway grade crossings. Such systems are commonly known as Emergency Notification Systems or ENS. The information collected is used by FRA to ensure that railroad carriers establish and maintain a toll-free telephone service to report unsafe conditions at public and private highway-rail and pathway grade crossings for rights-of-way over which they dispatch trains.

Type of Request: Extension with change (revised estimates) of a currently approved information collection.

Affected Public: Businesses.

Form(s): N/A.

Respondent Universe: 625 Railroads.

Frequency of Submission: On occasion.

Reporting Burden:

[1] The hourly wage rate to calculate the dollar cost equivalent for customers and state employees amounts to $61.20 per hour, which includes an hourly wage rate of $42.84 plus an hourly benefit of $18.34. FRA obtained this information from the Department of Labor, Bureau of Labor Statistics (BLS), Occupational Employment Statistics (OES) 11–3011, classified within NAICS 999200, State Government—excluding schools and hospitals. *See https://www.bls.gov/oes/current/naics4_999200.htm.*

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent [2]
234.303(c)—Receipt by dispatching RR of report of unsafe condition at highway-rail grade crossing.	625 railroads	63,891 reports	1 minute	1,065	$28,755
—(d)—Receipt by dispatching RR of report of unsafe condition at pathway grade crossing.	625 railroads	1,860 reports/1,860 records.	1 minute + 1 minute	62	4,526
234.305(a)(2)—Prompt contact by dispatching RR not having maintenance responsibility of all trains authorized to operate through the crossing in response to credible report of warning system malfunction at highway-rail grade crossing.	625 railroads	465 contacts	1 minute	8	576
—(a)(2)—Contact of crossing maintenance RR by dispatching RR not having maintenance responsibility in response to credible report of warning system malfunction at highway-rail grade crossing.	625 railroads	465 contacts + 465 records.	1 minute + 1 minute	16	1,168
—(b)(1)—In response to public report of warning system malfunction at highway-rail grade crossing, prompt contact by dispatching RR having maintenance duty for crossing of all trains authorized to operate through that crossing.	625 railroads	925 contacts + 925 records.	1 minute + 1 minute	31	2,232
—Dispatching RR having maintenance duty for crossing contact of appropriate law enforcement authority with necessary information regarding reported malfunction.	625 railroads	925 contacts	1 minute	15	1,095
234.305(b)(2)—In response to public report of warning system malfunction at highway-rail grade crossing, prompt contact by dispatching RR not having maintenance duty for that crossing of all trains authorized to operate through that crossing.	625 railroads	920 contacts	1 minute	15	1,095
—Dispatching RR contact of law enforcement authority to direct traffic/maintain safety.	625 railroads	920 contacts	1 minute	15	1,095
—Dispatching RR contact of maintaining RR re: reported malfunction and maintaining record of unsafe condition.	625 railroads	920 contacts + 920 records.	1 minute + 1 minute	31	2,263
—(c)(1)-In response to report of warning system failure at pathway grade crossing, dispatching RR having maintenance duty contacts all trains authorized to operate through it and record unsafe condition.	625 railroads	2 contacts + 2 records.	1 minute	.06666	5
—(c)(1)-Dispatching RR having maintenance duty for crossing contact of law enforcement authority to direct traffic/maintain safety after above report.	625 railroads	2 contacts	1 minute	.03333	2
234.305(d)(1)—Dispatching RR having maintenance authority contact of all trains operating through highway-rail or pathway grade crossing after report of disabled vehicle/other obstruction.	625 railroads	7,440 contacts + 7,440 unsafe condition records.	1 minute + 1 minute	248	17,980
—Dispatching RR having maintenance duty contact of law enforcement authority after report of disabled vehicle/other obstruction.	625 railroads	7,440 contacts	1 minute	124	9,052

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent [2]
(d)(2)—Dispatching RR not having maintenance authority contact of all trains operating through highway-rail or pathway grade crossing after report of disabled vehicle/other obstruction.	625 railroads	2,556 contacts	1 minute	43	3,066
—Dispatching RR not having maintenance authority contact of law enforcement authority after report of disabled vehicle/other obstruction.	625 railroads	2,556 contacts	1 minute	43	3,139
—Dispatching RR contact of maintaining RR regarding report of disabled vehicle/other obstruction and maintaining record of reported obstruction.	625 railroads	2,556 contacts + 2,556 records.	1 minute + 1 minute	86	6,278
(h)—Provision of contact information by maintaining RR to dispatching RR for reports of unsafe conditions at highway-rail and pathway grade crossings.	625 railroads	10 contacts	x1 minute	.1667	12
234.306(a)—Appointment of one dispatching RR as primary dispatching RR where multiple RRs dispatch trains through the same highway-rail and pathway grade crossing to provide info. for ENS sign.	625 railroads	50 indications/records.	60 minutes	50	3,650
(b)—Appointment of one maintaining RR as primary maintaining RR where multiple RRs dispatch trains through the same highway-rail and pathway grade crossing to place and maintain ENS sign.	625 railroads	50 indications/records.	60 minutes	50	3,650
234.307(b)—Third-party telephone service report of unsafe condition at highway-rail or pathway grade crossing to maintaining RR and maintaining RR record of unsafe condition.	625 railroads	50 reports + 50 records.	1 minute + 1 minute	2	146
(c)—Third-party telephone service report to dispatching RR of unsafe condition.	625 railroads	50 reports	1 minute	1	73
(d)(1)—Provision of contact information to third-party telephone service to receive reports of unsafe condition at highway-rail or pathway grade crossings.	625 railroads	5 contact calls	15 minutes	1	73
(d)(2)—Written notice by RR to FRA of intent to use third-party service.	625 railroads	5 letters	60 minutes	5	365
(d)(3)—RR written notification by RR of any changes in use or discontinuance of third-party service.	625 railroads	1 letter	60 minutes	1	73
234.309(a)—ENS Signs—General—Provision of ENS telephone number to maintaining RR by dispatching RR if two RRs are not the same.	625 railroads	10 contacts	30 minutes	5	365
234.311(c)—Repair or replacement of ENS after discovery by responsible railroad of missing, damaged, or otherwise unusable/illegible sign to vehicular/pedestrian traffic.	625 railroads	4,000 signs	15 minutes	1,000	66,000
234.313—Recordkeeping—Records of reported unsafe conditions pursuant to § 234.303.	625 railroads	186,000 signs	4 minutes	12,400	905,200

Total Estimated Annual Responses: 298,292.

[2] FRA consulted AAR publication *Railroad Facts,* 2017 (p.57), to calculate the dollar equivalent cost for burden hours associated with this particular information collection. The hourly wage rate for each appropriate employee group is burdened with 75-percent overhead costs. The two most common employee groups for this table pertain to professional/administrative staff and transportation, other than train and engine. The hourly wage for the first group is $73 per hour ($41.97 plus 75-percent overhead costs), and the hourly wage rate for the second group is $72 per hour ($42.27 plus

Total Estimated Annual Burden: 15,305 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $1,091,934.

Title: Control of Alcohol and Drug Use in Railroad Operations: Addition of Post-Accident Toxicological Testing for Non-Controlled Substances.

OMB Control Number: 2130–0598.

Abstract: Since 1985, as part of its accident investigation program, FRA has conducted post-accident alcohol and drug tests on railroad employees who have been involved in serious train accidents (50 FR 31508, Aug. 2, 1985). If an accident meets FRA's criteria for post-accident testing (*see* 49 CFR 219.201), FRA conducts tests for alcohol and for certain drugs classified as controlled substances under the Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention Substances Act of 1970 (CSA, 21 U.S.C. 801 *et seq.*). The Drug Enforcement Agency, which is primarily responsible for enforcing the CSA, oversees the classification of controlled substances into five schedules. Schedule I contains illicit drugs, such as heroin, which has no legitimate medical use under Federal law. Currently, FRA routinely conducts post-accident tests for: Marijuana, cocaine, phencyclidine, and certain opiates, amphetamines, barbiturates, and benzodiazepines. Controlled substances are drugs or chemicals that are prohibited or strictly regulated because of their potential for abuse or addiction.

Since its inception, FRA's post-accident testing program has had the ability to test for ''other impairing substances specified by FRA as necessary to the particular accident investigation.'' *See* 49 CFR 219.211(a). This flexibility allows FRA to conduct post-accident tests for any substance (*e.g.,* carbon monoxide) that its preliminary investigation shows may have played a role in an accident. Because FRA research indicates that prescription and over-the-counter (OTC) drug use has become prevalent among railroad employees, FRA has added sedating antihistamines, a commonly used category of OTC drugs, to its standard post-accident testing panel to determine whether use of these drugs contributes to the cause or severity of train accidents.

FRA uses its post-accident testing data for monitoring, research, and accident investigation purposes. Research generated by post-accident testing data may result in the addition of other non-controlled substances to FRA's standard post-accident testing panel.

Type of Request: Extension with change (revised estimates) of a currently approved information collection.

Affected Public: Businesses.

Form(s): N/A.

Respondent Universe: 692 Railroads.

Frequency of Submission: On occasion.

Reporting Burden:

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual dollar cost equivalent [3]
219.211(a)(b)(c)—RR Medical Review Officer (MRO) review of employee post-accident toxicological testing result reported as positive for alcohol or a controlled substance by designated laboratory and MRO report to FRA of Review Results.	692 railroads	9 reports + 9 report copies.	15 minutes + 5 minutes.	3	$330

Total Estimated Annual Responses: 18.

Total Estimated Annual Burden: 3 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $330.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Brett A. Jortland,

Acting Chief Counsel.

[FR Doc. 2019–03050 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2019–0004–N–1]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA), this notice announces that FRA is forwarding the Information Collection Requests (ICRs) abstracted below to the Office of Management and Budget (OMB) for review and comment. The ICRs describe the information collections and their expected burden. On November 14, 2018, FRA published a notice providing a 60-day period for public comment on the ICRs.

DATES: Interested persons are invited to submit comments on or before March 25, 2019.

ADDRESSES: Submit written comments on the ICRs to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: FRA Desk Officer. Comments may also be sent via email to OMB at the following address: *oira_submissions@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W33–497, Washington, DC 20590 (telephone: 202–493–6292); or Ms. Kim Toone, Information Collection Clearance Officer, Office of Administration, Office

75-percent overhead costs). FRA used an hourly rate of $27 per hour for the value of the public's time.

[3] Again, as noted in the footnote above, FRA consulted the AAR publication *Railroad Facts,* 2017 (p. 57) to determine the hourly wage rate for the dollar equivalent cost of the specified burden hours. FRA used the hourly wage rate of $62.98 for executives, officials, and staff assistants plus 75-percent overhead costs. Thus, the hourly wage rate for this group comes to $110.

of Information Technology, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W34–212, Washington, DC 20590 (telephone: 202–493–6132).

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. On November 14, 2018, FRA published a 60-day notice in the **Federal Register** soliciting comment on the ICRs for which it is now seeking OMB approval. *See* 83 FR 56909. FRA received no comments in response to this notice.

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect.

Comments are invited on the following ICRs regarding: (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the information will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology.

The summaries below describe the ICRs that FRA will submit for OMB clearance as the PRA requires:

Title: State Safety Participation Regulations and Reporting of Remedial Actions.

OMB Control Number: 2130–0509.

Abstract: The collection of information is set forth under 49 CFR part 212, and requires qualified state inspectors to provide various reports to FRA for monitoring and enforcement purposes concerning state investigative, inspection, and surveillance activities regarding railroad compliance with Federal railroad safety laws and regulations. Additionally, under 49 CFR part 209, subpart E, railroads are required to report to FRA actions taken to remedy certain alleged violations of law.

Type of Request: Extension with change (revised estimates) of a currently approved information collection.

Form(s): FRA F 6180.33/61/67/96/96A/109/110/111/112/144.

Respondent Universe: States and Railroads.

Frequency of Submission: On occasion.

Total Estimated Annual Responses: 82,402.

Total Estimated Annual Burden: 49,047 hours.

Total Estimated Burden Hours Dollar Equivalent Cost: $3,629,478.

Title: Use of Locomotive Horns at Highway-Rail Grade Crossings.

OMB Control Number: 2130–0560.

Abstract: Under 49 CFR part 222, FRA seeks to collect information from railroads and public authorities in order to increase safety at public highway-rail grade crossings nationwide by requiring that locomotive horns be sounded when trains approach and pass through these crossings or by ensuring that a safety level at least equivalent to that provided by routine locomotive horn sounding exists for quiet zone corridors in which horns are silenced. FRA reviews applications by public authorities intending to establish new quiet zones or, in some cases, continue pre-rule quiet zones to ensure the necessary level of safety is achieved.

Type of Request: Extension with change (revised estimates) of a currently approved information collection.

Form(s): N/A.

Respondent Universe: 728 Railroads/340 Public Authorities.

Frequency of Submission: On occasion.

Total Estimated Annual Responses: 4,362.

Total Estimated Annual Burden: 9,236 hours.

Total Estimated Burden Hours Dollar Equivalent Cost: $681,983.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Brett A. Jortland,

Acting Chief Counsel.

[FR Doc. 2019–03051 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

[Docket No. DOT–OST–2019–0028]

Notice of Request for Clearance of a Revision a Currently Approved Information Collection: National Census of Ferry Operators

AGENCY: Bureau of Transportation Statistics (BTS) Office of the Assistant Secretary for Research and Technology (OST–R), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, this notice announces the intention of the BTS to request the Office of Management and Budget's (OMB's) approval for new iterations of an on-going biennial information collection related to the nation's ferry operations. The information collected from each Census will be used to produce a descriptive database of existing ferry operations. A summary report of survey findings will also be published by BTS on the BTS web page: *www.bts.gov/ncfo*.

DATES: Comments must be submitted on or before April 23, 2019.

ADDRESSES: You may submit comments identified by DOT Docket ID Number DOT–OST–2019–0028 to the U.S. Department of Transportation (DOT), Dockets Management System (DMS). You may submit your comments by mail or in person to the Docket Clerk, Docket No., U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Room W12–140, Washington, DC 20590. Comments should identify the docket number as indicated above. Paper comments should be submitted in duplicate. The DMS is open for examination and copying, at the above address, from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays. If you wish to receive confirmation of receipt of your written comments, please include a self-addressed, stamped postcard with the following statement: ''Comments on Docket DOT–OST–2019–0028.'' The Docket Clerk will date stamp the postcard prior to returning it to you via the U.S. mail. Please note that due to delays in the delivery of U.S. mail to Federal offices in Washington, DC, we recommend that persons consider an alternative method

(the internet, fax, or professional delivery service) to submit comments to the docket and ensure their timely receipt at U.S. DOT. You may fax your comments to the DMS at (202) 493–2251. Comments can also be viewed and/or submitted via the Federal Rulemaking Portal: *http://www.regulations.gov*.

Please note that anyone is able to electronically search all comments received into our docket management system by the name of the individual submitting the comment (or signing the comment if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; pages 19475–19570) or you may review the Privacy Act Statement at *http://www.gpoaccess.gov/fr/*.

FOR FURTHER INFORMATION CONTACT: Janine L. McFadden, (202) 366–2468, NCFO Project Manager, BTS, OST–R, Department of Transportation, 1200 New Jersey Ave. SE, Room E32–316, Washington, DC 20590. Office hours are from 8:00 a.m. to 5:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: National Census of Ferry Operators (NCFO)

Background: The Transportation Equity Act for the 21st Century (TEA–21) (Pub. L. 105–178), section 1207(c), directed the Secretary of Transportation to conduct a study of ferry transportation in the United States and its possessions. In 2000, the Federal Highway Administration (FHWA) Office of Intermodal and Statewide Planning conducted a survey of approximately 250 ferry operators to identify: (1) Existing ferry operations including the location and routes served; (2) source and amount, if any, of funds derived from Federal, State, or local governments supporting ferry construction or operations; (3) potential domestic ferry routes in the United States and its possessions and to develop information on those routes; and (4) potential for use of high speed ferry services and alternative-fueled ferry services. The Safe, Accountable, Flexible Efficient Transportation Equity Act—A Legacy for Users (SAFETEA–LU) Pub. L. 109–59, Section 1801(e)) required that the Secretary, acting through the BTS, shall establish and maintain a national ferry database containing current information regarding routes, vessels, passengers and vehicles carried, funding sources and such other information as the Secretary considers useful. MAP–21 legislation [Moving Ahead for Progress in the 21st Century Act (Pub. L. 112–141),] continued the BTS mandate to conduct the NCFO and also required that the Federal Highway Administration (FHWA) use the NCFO data to set the specific formula for allocating federal ferry funds. The funding allocations were based on a percentage of the number of passenger boardings, vehicle boardings, and route miles served.

BTS conducted the first Census of Ferry Operators in 2006, and again in 2008, 2010, 2014, 2016 and 2018, and plans are underway for the conduct of the next NCFO in the Spring of 2020. These information collections were originally approved by OMB under Control Number 2139–0009.

The recently enacted FAST Act legislation [Fixing America's Surface Transportation Act (Pub. L. 114–94, sec. 1112)] continues the BTS mandate to conduct the NCFO on a biennial basis, and extended the requirement that the Federal Highway Administration (FHWA) use the NCFO data to set the specific formula for allocating federal ferry funds based on a percentage of the number of passenger boardings, vehicle boardings, and route miles served. The overall length of the revised questionnaire for the 2020 NCFO will remain consistent with that of previous years.

The survey will be administered to the entire population of ferry operators (estimate of 250 or less). The survey will request the respondents to provide information such as: the points served; the type of ownership; the number of passengers and vehicles carried in the past 12 months; vessel descriptions (including type of fuel), federal, state and local funding sources, and intermodal connectivity. All data collected in 2020 will be added to the existing NCFO database.

Respondents: The target population for the survey will be all of the approximately 250 ferry operators existing in the United States.

Estimated Average Burden per Response: The burden per respondent is estimated to be an average of 30 minutes. This average is based on an estimate of 20 minutes to answer new questions and an additional 10 minutes to review (and revise as needed) previously submitted data that will be pre-populated for each ferry operation.

Estimated Total Annual Burden: The total annual burden (in the year that the survey is conducted) is estimated to be just under 125 hours (that is 30 minutes per respondent for 250 respondents equals 7,500 minutes).

Frequency: This survey will be updated every other year.

Public Comments Invited: Interested parties are invited to send comments regarding any aspect of this information collection, including, but not limited to: (1) The necessity and utility of the information collection for the proper performance of the functions of the DOT; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, clarity and content of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB's clearance of this information collection.

Authority: The Transportation Equity Act for the 21st Century, P.L. 105–178, section 1207(c), The Safe, Accountable, Flexible Efficient Transportation Equity Act—A Legacy for Users (SAFETEA–LU), P.L. 109–59, Moving Ahead for Progress in the 21st Century Act (MAP–21), P.L. 112–141, 49 CFR 1.46, and Fixing America's Surface Transportation Act (FAST Act), P.L. 114–94, sec. 1112.

Issued in Washington, DC on the 14th of February 2019.

Patricia Hu,

Director, Bureau of Transportation Statistics, Office of the Assistant Secretary for Research and Technology.

[FR Doc. 2019–03080 Filed 2–21–19; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0358]

Agency Information Collection Activity: Supplemental Information for Change of Program or Reenrollment After Unsatisfactory Attendance, Conduct, or Progress

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before April 23, 2019.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0358'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Danny S. Green at (202) 421–1354.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, Veterans Benefits Administration (VBA) invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA' functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Supplemental Information for Change of Program or Reenrollment After Unsatisfactory Attendance, Conduct, or Progress, VA Form 22–8873.

OMB Control Number: 2900–0358.

Type of Review: Revision of a currently approved collection.

Abstract: Students use the form to change programs of education or to notify VA that they are making unsatisfactory progress in their programs of education.

VA uses the information provided from the current collection to ensure (1) that programs are suitable to a claimant's aptitudes, interests, and abilities and (2) that the cause of any past unsatisfactory attendance, progress, or conduct has been resolved. Without this information, VA could not determine further entitlement to education benefits.

Affected Public: Individual and households.

Estimated Annual Burden: 8,860 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: Annual.

Estimated Number of Respondents: 17,720.

By direction of the Secretary.

Danny S. Green,

VA Interim Clearance Officer, Office of Quality Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2019–03116 Filed 2–21–19; 8:45 am]

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Part II

Environmental Protection Agency

40 CFR Parts 261, 262, 264, et al.
Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 261, 262, 264, 265, 266, 268, 270, and 273

[EPA–HQ–RCRA–2007–0932; FRL–9988–26–OLEM]

RIN 2050–AG39

Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Some pharmaceuticals are regulated as hazardous waste under the Resource Conservation and Recovery Act (RCRA) when discarded. This final rule adds regulations for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. Healthcare facilities (for both humans and animals) and reverse distributors will manage their hazardous waste pharmaceuticals under this new set of sector-specific standards in lieu of the existing hazardous waste generator regulations. Among other things, these new regulations prohibit the disposal of hazardous waste pharmaceuticals down the drain and eliminates the dual regulation of RCRA hazardous waste pharmaceuticals that are also Drug Enforcement Administration (DEA) controlled substances. The new rules also maintain the household hazardous waste exemption for pharmaceuticals collected during pharmaceutical take-back programs and events, while ensuring their proper disposal. The new rules codify Environmental Protection Agency (EPA)'s prior policy on the regulatory status of nonprescription pharmaceuticals going through reverse logistics. Additionally, EPA is excluding certain U.S. Food and Drug Administration (FDA) approved over-the-counter (OTC) nicotine replacement therapies (NRTs) from regulation as hazardous waste and is establishing a policy on the regulatory status of unsold retail items that are not pharmaceuticals and are managed via reverse logistics, fulfilling the commitment we made in the Retail Strategy of September 2016.

DATES: This final rule is effective on August 21, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–RCRA–2007–0932. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Kristin Fitzgerald, Materials Recovery and Waste Management Division, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (703) 308–8286; email address: *Fitzgerald.Kristin@epa.gov*, or Brian Knieser, Materials Recovery and Waste Management Division, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (703) 347–8769; email address: *Knieser.Brian@epa.gov.* Also see the EPA's website at *https://www.epa.gov/hwgenerators/management-pharmaceutical-hazardous-waste.*

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I. General Information

A. Does this action apply to me?

This final rule applies to healthcare facilities that generate, accumulate, or otherwise handle hazardous waste pharmaceuticals and reverse distributors engaged in the management of prescription hazardous waste pharmaceuticals. The list of North American Industry Classification System (NAICS) codes for the potentially affected entities, other than RCRA transfer, storage, and disposal facilities (TSDFs), are presented in Table 1. More detailed information on the potentially affected entities is presented in sections VII and IX of this preamble and the Regulatory Impact Analysis (RIA) which is available in the docket for this final rule.[1]

TABLE 1—NAICS CODES OF ENTITIES POTENTIALLY AFFECTED BY THIS FINAL RULE: HEALTHCARE FACILITIES AND REVERSE DISTRIBUTORS

NAICS codes	Description of NAICS code
4242	Drug Wholesalers.
44511	Supermarkets and Other Grocery (except convenience) Stores.
44611	Pharmacies and Drug Stores.
452311	Warehouse Clubs and Supercenters.
54194	Veterinary Services.
6211	Physicians' Offices.
6212	Dentists' Offices.
6213	Other Health Practitioners (e.g., chiropractors).
6214	Outpatient Care Centers.
6219	Other Ambulatory Health Care Services.
622	Hospitals.

[1] EPA–HQ–RCRA–2007–0932.

TABLE 1—NAICS CODES OF ENTITIES POTENTIALLY AFFECTED BY THIS FINAL RULE: HEALTHCARE FACILITIES AND REVERSE DISTRIBUTORS—Continued

NAICS codes	Description of NAICS code
6231	Nursing Care Facilities (e.g., assisted living facilities, nursing homes).
623311	Continuing Care Retirement Communities (e.g., assisted living facilities with on-site nursing facilities).
Various NAICS	Reverse Distributors.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities potentially impacted by this action. This table lists examples of the types of entities EPA knows could potentially be affected by this action. Other types of entities not listed could also be affected. To determine whether your entity, company, business, organization, etc., is affected by this action, you should examine the applicability criteria in this rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this document.

B. What action is the Agency taking?

On September 25, 2015, EPA proposed new regulations under part 266 subpart P for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors.[2] This final rule promulgates part 266 subpart P. However, in response to public comments, we have made a number of changes to the proposed rulemaking. The comments and the changes are discussed in detail below. When this final rule becomes effective in their states, a process that is explained in section XX of this preamble, healthcare facilities and reverse distributors must manage their hazardous waste pharmaceuticals under this new set of regulations in part 266 subpart P in lieu of operating under part 262 as they have been. These operating standards include a prohibition on the sewering of hazardous waste pharmaceuticals. Part 266 subpart P also includes a conditional exemption for hazardous waste pharmaceuticals that are also identified as controlled substances by the Drug Enforcement Administration (DEA). Further, subpart P redefines when containers that held hazardous waste pharmaceuticals are considered ''RCRA empty.'' Healthcare facilities that are very small quantity generators (VSQGs) must comply with the sewer prohibition for their hazardous waste pharmaceuticals under part 266 subpart P and have the option of complying with the entire subpart in lieu of operating under the conditional exemption of § 262.14.

EPA is also taking two actions in addition to promulgating part 266 subpart P. First, this final rule amends the P075 acute hazardous waste listing for nicotine and salts to indicate that U.S. Food and Drug Administration (FDA)-approved over-the counter (OTC) nicotine replacement therapies (NRTs) are not included in the listing. Second, the preamble to this final rule also establishes EPA's policy on the regulatory status of unsold retail items, including nonprescription pharmaceuticals, managed at reverse logistics centers, fulfilling the commitment we made in the Retail Strategy of September 2016.

Although the proposed rulemaking sought comment on ideas for how to expand the universe of pharmaceuticals that are hazardous waste, this final rule does not add pharmaceuticals to the hazardous waste listings or expand the hazardous waste characteristics to include additional pharmaceuticals. At the time of proposal, we indicated that any action to expand the universe of hazardous waste pharmaceuticals would be part of a separate, future action.

Note that throughout the preamble and the RIA for this final rule, the terms ''EPA,'' ''Agency'' and ''we'' are used interchangeably.

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

These regulations are promulgated under the authority of §§ 2002, 3001, 3002, 3004, and 3018 of the Solid Waste Disposal Act (SWDA) of 1970, as amended by the Resource Conservation and Recovery Act (RCRA) of 1976, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6912, 6921, 6922, 6924, and 6939.

D. What are the incremental costs and benefits of this action?

As discussed in section XXI, the Regulatory Impact Analysis (RIA) for this rule estimates the annualized cost to industry to comply with the requirements is between $6.59 and $7.99 million (at a 7 percent discount rate).[3] The streamlined management standards for healthcare facilities and the regulatory relief in regard to FDA-approved OTC NRT products (*i.e.,* patches, gums and lozenges) is estimated to result in an annualized cost-savings of between $19.58 and $22.95 million (at a 7 percent discount rate). This results in a net annualized cost savings for the rule of $12.99 to $14.96 million at a 7 percent discount rate.

The provisions of the final rule are expected to improve regulatory clarity and reduce regulatory burden. As an example of the increased regulatory clarity and certainty provided in the rule, EPA eliminated the dual regulation of RCRA hazardous waste pharmaceuticals that are also DEA controlled substances by finalizing a conditional exemption. Additionally, to the extent that the rule reduces concentrations of hazardous waste pharmaceuticals in surface and drinking waters, this rule may result in improved ecosystems and human health outcomes. Ideally, the Agency would prefer to quantify and monetize the rule's human health benefits. However, only some categories of cost savings are quantifiable; sufficient data are not available to support a detailed quantitative analysis for many benefit categories. In these cases, the benefits are described qualitatively.

II. List of Acronyms

3PL Third Party Logistics Provider
AARP American Association of Retired Persons
AEA Atomic Energy Act
API Active Pharmaceutical Ingredient
ASHP American Society of Hospital Pharmacists
BDAT Best Demonstrated Available Technology
BR Biennial Report
CAA Central Accumulation Area
CCP Commercial Chemical Product
CERCLA Comprehensive Environmental Response, Compensation and Liability Act
CFR Code of Federal Regulations
CISWI Commercial, Industrial Solid Waste Incinerator
CMS Centers for Medicare and Medicaid Services
CPSC Consumer Product Safety Commission
CWA Clean Water Act
DEA Drug Enforcement Administration
DOE Department of Energy
DOT Department of Transportation
DSCSA Drug Supply Chain Security Act
DQSA Drug Quality and Security Act
EPA Environmental Protection Agency
E.O. Executive Order
FDA Food and Drug Administration

[2] September 25, 2015; 80 FR 58014.

[3] See the Regulatory Impact Analysis for the final rule in the rulemaking docket EPA–HQ–RCRA–2007–0932.

FD&C Act Federal Food, Drug, and Cosmetic Act
FR Federal Register
HIPAA Health Insurance Portability and Accountability Act
HMIWI Hospital, Medical, Infectious Waste Incinerator
HSWA Hazardous and Solid Waste Amendments
LQG Large Quantity Generator
LTCF Long-term Care Facility
LTCP Long-term Care Pharmacy
MSWLF Municipal Solid Waste Landfill
MWC Municipal Waste Combustor
NAICS North American Industry Classification System
NIOSH National Institute for Occupational Safety and Health
NODA Notice of Data Availability
NPRM Notice of Proposed Rulemaking
NRC Nuclear Regulatory Commission
NRT Nicotine Replacement Therapy
OIG Office of Inspector General
OLEM Office of Land and Emergency Management
OMB Office of Management and Budget
ONDCP Office of National Drug Control Policy
OSHA Occupational Safety and Health Administration
OSWER Office of Solid Waste and Emergency Response
OSWI Other Solid Waste Incinerators
OTC Over-the-counter
POTW Publicly Owned Treatment Works
RCRA Resource Conservation and Recovery Act
SAA Satellite Accumulation Area
SQG Small Quantity Generator
SWDA Solid Waste Disposal Act
TC Toxicity Characteristic
TCLP Toxicity Characteristic Leaching Procedure
TSDF Treatment, Storage and Disposal Facility
VSQG Very Small Quantity Generator

III. Rationale for the Final Rule

The impetus behind this final rule is to address the various concerns raised by stakeholders regarding the difficulty in implementing the RCRA Subtitle C hazardous waste regulations for the management of hazardous waste pharmaceuticals generated at healthcare facilities. EPA has met with various stakeholders to learn about compliance challenges and has received input from stakeholders through more formal mechanisms. For instance, when EPA solicited stakeholder input in a notice of data availability (NODA) and request for comment, ''Hazardous Waste Management and the Retail Sector: Providing and Seeking Information on Practices to Enhance Effectiveness to the Resource Conservation and Recovery Act Program'' (''Retail NODA''), retailers submitted comments detailing compliance challenges with hazardous waste pharmaceuticals in their stores.[4] Further, EPA's Office of Inspector General (OIG) published a report citing the need to clarify how hazardous waste pharmaceuticals are regulated (for more information on the Retail NODA and the OIG report, see section VI of this preamble).[5] The Retail NODA and the OIG Report, along with input from healthcare facilities and retailers, identified a number of ways in which a healthcare facility differs from a manufacturing facility when it comes to applying the RCRA Subtitle C program to the generation and management of hazardous waste pharmaceuticals.

First, under the current hazardous waste regulatory scheme, healthcare personnel, whose primary focus is to provide care for patients, are typically responsible for making hazardous waste determinations since they are at the point of generation (*e.g.,* a patient's bedside). Yet, healthcare personnel, such as nurses and doctors, do not typically have the expertise to make hazardous waste determinations. In general, healthcare personnel are not prepared to assume hazardous waste management responsibilities, nor is it EPA's expectation that they assume primary hazardous waste management responsibilities. EPA recognizes this challenge and provides a framework through this final rule that allows healthcare personnel to focus on healthcare while still ensuring that hazardous waste is directed to proper management.

Second, in the healthcare setting, a wide variety of hazardous waste pharmaceuticals are generated in relatively small quantities by a number of different employees across the facility. This situation differs from a typical manufacturing facility where fewer employees in a few locations generate comparatively much larger volumes of a smaller range of hazardous wastes. Data from the Biennial Report (BR) show that in 2013, approximately 46 percent of large quantity generators (LQGs) generated between one and five waste streams.[6] Further, a typical manufacturing facility generates a more predictable set of hazardous waste streams. In contrast, a healthcare facility can have thousands of items in its inventory at any one time and these may vary over time, based on the needs of the patients. In addition, pharmaceutical wastes come in many different forms, such as tablets (pills), transdermal patches, lozenges, gums, creams, and liquids, and are delivered by a variety of devices, such as nebulizers, intravenous (IV) tubing, syringes, etc. The combination of having thousands of different pharmaceutical products and little expertise in hazardous waste regulations makes it difficult for healthcare personnel to make appropriate hazardous waste determinations when pharmaceuticals are disposed.

Third, several of the hazardous waste pharmaceuticals that are generated by healthcare facilities are P-listed acute hazardous wastes (see § 261.33(e)), which are regulated with more stringent requirements at much smaller amounts. If a facility generates more than 1 kg of acute hazardous waste per calendar month, it is regulated more rigorously as an LQG. Aside from the pharmaceuticals themselves, residues within pharmaceutical containers that contained P-listed commercial chemical products (CCPs) must be managed as acute hazardous waste even if the pharmaceutical was fully administered, unless the container is RCRA-empty (*e.g.,* by triple-rinsing the container).[7] Triple rinsing can be impractical with certain medical devices, such as syringes and paper cups, so healthcare facilities often manage these containers as hazardous waste, which can result in being subject to the most stringently regulated generator category (*i.e.,* LQG).[8]

To facilitate compliance among healthcare facilities and to respond to these concerns, EPA is finalizing a new set of sector-specific regulations to improve the management and disposal of hazardous waste pharmaceuticals at healthcare facilities.

In addition to improving compliance and responding to stakeholder concerns, the Agency has three additional goals for this final rule. The first is to reduce

[4] See 79 FR 8926; February 14, 2014 for the Retail NODA. Also see the associated docket EPA–HQ–RCRA–2012–0426 for public comments.

[5] EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal, Report No. 12–P–0508, dated May 25, 2012). For a copy of the report, please see: *https://www.epa.gov/sites/production/files/2015-10/documents/20120525-12-p-0508.pdf* or see the docket for this final rule: EPA–HQ–RCRA–2007–0932–0177.

[6] 81 FR 85735; November 28, 2016, Hazardous Waste Generator Improvements Final Rule.

[7] P-listed hazardous waste residues in containers are themselves considered P-listed hazardous wastes (see § 261.33(c)), unless the container is considered ''RCRA empty'' either by undergoing triple-rinsing with an appropriate solvent; or cleaning with a method that has been proven in scientific literature or tests conducted by the generator to achieve equivalent removal (see § 261.7(b)(3)).

[8] On November 4, 2011, ORCR issued a memo to the Regional RCRA Division Directors highlighting three acceptable approaches, beyond triple-rinsing containers, that healthcare facilities can employ when managing P-listed container residues. Please see: Memo from Suzanne Rudzinski to RCRA Division Directors (RCRA Online #14827). As discussed in section XV of this preamble, this final rule supersedes this memo.

the amount of pharmaceuticals that are disposed of down the drain. Studies have found that many healthcare facilities, particularly long term-care facilities, are using drain disposal (*e.g.,* flushing) as a routine disposal method for pharmaceutical wastes, including those that are hazardous waste. Until this final rule, drain disposal has been an allowable disposal method for hazardous waste pharmaceuticals under RCRA (however, since 1990, the Clean Water Act regulations have prohibited the drain disposal of ignitable wastes and those wastes that result in toxic gases, vapors of fumes within the publicly owned treatment works.) [9] Although pharmaceuticals are thought to be primarily entering the environment through excretion, reducing intentional sewer disposal is one mechanism to help reduce the environmental loading of pharmaceuticals into our Nation's waters.[10] See section XIII for more information about how this final rule reduces sewer disposal and pharmaceuticals in water.

The second goal is to address the overlap between EPA's RCRA hazardous waste regulations and the DEA regulations for controlled substances. Some stakeholders have indicated that hazardous waste pharmaceuticals that are also controlled substances are stringently regulated and therefore are expensive to manage and dispose of in accordance with both sets of regulations. In addition, stakeholders have indicated that the RCRA hazardous waste pharmaceuticals that are also DEA controlled substances are most likely to be sewer disposed to avoid the costs of compliant incineration. EPA eliminates this regulatory overlap in this final rule, as it has been an unnecessary burden for healthcare facilities. Additionally, we expect that eliminating the overlap will help reduce intentional sewer disposal of pharmaceuticals.

The third goal is to clarify the regulatory status of a major practice used by healthcare facilities, including retailers in particular, for the management of unused and/or expired pharmaceuticals, known as reverse distribution (see section VI for a detailed discussion of reverse distribution). A number of states have taken enforcement actions against retailers that have raised awareness about the reverse distribution of pharmaceuticals. In particular, California has taken numerous enforcement actions against national retail chains with pharmacies for not complying with the RCRA hazardous waste regulations. In recent years, the state took enforcement actions and imposed fines on the following chains: Kmart (2009), Walmart (2010), Target (2011), CVS (2012), Costco (2012), Walgreens (2012), Rite-Aid (2013), and Safeway (2015). In at least two settlement agreements, California directed the defendants (CVS and Costco) to ''initiate work with appropriate stakeholders from business and government, including the U.S. Environmental Protection Agency, the U.S. Food and Drug Administration, and the DTSC [Department of Toxic Substances Control], and thereafter either directly or through trade associations or informal coalitions of interested parties, undertake to promote federal regulatory reform regarding the proper management of non-dispensable pharmaceuticals, including OTC medications, through 'reverse distribution.' '' [11] Through these settlement agreements, California is seeking clarity from EPA about its longstanding interpretation about the regulatory status of pharmaceuticals that are routed through pharmaceutical reverse distribution systems.

Additionally, the California legislature directed the DTSC to convene a Retail Waste Working Group with the aim of developing recommendations to the legislature for how to address many retail waste issues, including reverse distribution/logistics.[12] The Retail Waste Working Group, which consisted of large retailers, small retailers, district attorneys, certified unified program agencies, non-government organizations, local governments, other relevant state agencies as determined by DTSC (such as the California Department of Public Health, and the California Department of Resources Recycling and Recovery), manufacturers, reverse distributors, and other interested stakeholders, produced their final report in August 2017.[13] Although the group was convened by and reported to the California legislature, its membership was drawn from across the country. EPA participated in an observer role, but neither contributed to developing recommendations nor to writing the group's report. The group's work has highlighted the need for a national policy in this area.

IV. Background

A. Summary of the Proposal

On September 25, 2015, EPA proposed to add subpart P under 40 CFR part 266 (see 80 FR 58014). Part 266 is entitled ''Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities.'' In this new subpart P, we proposed a tailored, sector-specific regulatory framework for managing hazardous waste pharmaceuticals at healthcare facilities and reverse distributors. We proposed that healthcare facilities that are small quantity generators (SQGs) or LQGs and all reverse distributors, regardless of their RCRA generator category, would be required to manage their hazardous waste pharmaceuticals under subpart P of 40 CFR part 266, instead of the generator regulations in 40 CFR part 262. The standards were not proposed as a voluntary or optional alternative to managing hazardous waste pharmaceuticals under 40 CFR part 262; they were proposed as mandatory standards.

We discuss the proposed provisions in greater detail in subsequent sections of the preamble, but offer a brief summary of the proposal here. For healthcare facilities, we proposed different management standards for non-creditable and potentially creditable hazardous waste pharmaceuticals. We proposed that non-creditable hazardous waste pharmaceuticals (*i.e.,* those that are not expected to be eligible to receive manufacturer credit) would be managed on site at the healthcare facility similar to how they would have been under a previous proposal for managing these wastes: The 2008 Universal Waste proposal for pharmaceutical waste.[14] We proposed that when shipped off site, the non-creditable hazardous waste pharmaceuticals must be transported as hazardous wastes, including the use of the hazardous waste manifest, and sent to a RCRA-designated facility, such as an interim status or permitted TSDF. Additionally, we proposed to revise our policy regarding pharmaceuticals going through reverse distribution (*i.e.,* those which are ''potentially creditable'') such that they would be considered hazardous wastes at the healthcare facility. However, given the value associated with these potentially

[9] See the Clean Water Act regulations of 40 CFR 403.5(b)(1) and (7).

[10] C.G. Daughton, I.S. Ruhoy, Environmental footprint of pharmaceuticals: The significance of factors beyond direct excretion to sewers, Environ. Toxicol. Chem., 28 (2009), pp. 2495–2521, 10.1897/08–382.1.

[11] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0169.

[12] California SB–423. *http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520160SB423.*

[13] *https://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

[14] 73 FR 73520; December 2, 2008.

creditable hazardous waste pharmaceuticals, EPA proposed flexibilities for some of the regulatory requirements. For instance, we proposed that healthcare facilities would continue to be allowed to send potentially creditable hazardous waste pharmaceuticals to reverse distributors for them to be evaluated for manufacturer credit. After considering comments received on the prior Universal Waste proposal regarding the lack of tracking of shipments, EPA's 2015 proposed standards included provisions to ensure the safe, secure and documented delivery of the potentially creditable hazardous waste pharmaceuticals to reverse distributors.

Under the proposal, reverse distributors would no longer be regulated under 40 CFR part 262 as hazardous waste generators, nor would they be regulated under 40 CFR parts 264, 265, and 270 as TSDFs. Rather, the proposal established a new category of hazardous waste entity, called pharmaceutical reverse distributors. EPA also proposed that reverse distributors would have different standards for those hazardous waste pharmaceuticals destined for another reverse distributor (and still considered potentially creditable hazardous waste pharmaceuticals) versus those that are destined for a TSDF (considered to be evaluated hazardous waste pharmaceuticals.) [15] The proposed standards for pharmaceutical reverse distributors were, in many respects, similar to the LQG standards, but with additional standards to respond to concerns expressed by commenters to the proposal to add pharmaceuticals to the Universal Waste program.

EPA proposed several additional standards that apply to both healthcare facilities and reverse distributors. First, EPA proposed to prohibit healthcare facilities and reverse distributors from disposing of hazardous waste pharmaceuticals down a toilet or drain (*i.e.,* flushed or sewered). Second, EPA proposed that hazardous waste pharmaceuticals managed under subpart P would not be counted toward calculating the site's generator category. Third, EPA proposed a conditional exemption for hazardous waste pharmaceuticals that are also DEA controlled substances. Fourth, EPA proposed management standards for determining when a container with hazardous waste pharmaceutical residues is considered RCRA empty.

B. Retail Sector Notice of Data Availability (NODA)

In 2014, EPA published a NODA for the Retail Sector, in which the Agency requested, among other things, comment on a series of topics related to retail operations in order to better understand the issues retail stores face in complying with RCRA regulations.[16] Many retail commenters to the NODA mentioned that because nicotine is an acute hazardous waste (P075), retailers are considered LQGs when they discard more than 1 kg per month of unused nicotine-containing products (*e.g.,* e-cigarettes and smoking cessation products such as gums, patches and lozenges). Retailers discard these products mainly because they are either expired or they are returned by customers and the retailer does not restock them due to safety concerns. In comments to the NODA, retailers urged the EPA to provide some regulatory relief with regard to nicotine-containing products. See section V of this preamble for a discussion of EPA's amendment of the acute hazardous waste listing for nicotine and salts (P075).

C. Retail Strategy

On September 12, 2016, as a follow-up to the comments we received on the Retail NODA, EPA released its Retail Strategy. In the strategy, EPA committed to two sets of activities. First, we committed to completing rulemakings that were already underway, that, although were not specifically developed with retail in mind, contained provisions that might be helpful in resolving some issues that retailers faced in complying with RCRA regulations. This included completing the 2016 Hazardous Waste Generator Improvements final rule and the Hazardous Waste Pharmaceuticals final rule. Second, we committed to three new activities that specifically address concerns identified by commenters. First, EPA committed to developing guidance on aerosol cans. Second, EPA committed to exploring the potential for adding certain retail items, such as aerosol cans, pesticides, and/or electronics, to the federal universal waste regulations. A proposed rulemaking for adding aerosol cans to the federal universal waste regulations was published in **Federal Register** on March 16, 2018.[17] Third, EPA committed to developing a policy that addresses the reverse distribution process for the retail sector as a whole. This policy is articulated in detail in section VI of the preamble of this final rule.

D. EPA Inspector General Report

On May 25, 2012, the EPA's Office of Inspector General (OIG) issued the report, ''EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal.'' [18] The OIG reviewed EPA's process for identifying and listing pharmaceuticals as hazardous wastes. Because of this review, the OIG provided the following recommendations to the Assistant Administrator for the Office of Solid Waste and Emergency Response (OSWER): [19]

(1) Identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

(2) Establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

(3) Develop a nationally consistent outreach and compliance assistance plan to help states address challenges that healthcare facilities, and others as needed, have in complying with RCRA regulations for managing hazardous waste pharmaceuticals.

As detailed in OSWER's response to OIG, this final rule fulfills our obligation for addressing the third recommendation.[20] In the preamble to the proposed rulemaking we solicited comment as part of our ongoing efforts to identify additional pharmaceuticals as hazardous wastes. EPA does not address the OIG's first two recommendations as part of this final rulemaking directly. That said, the Agency believes that provisions in the final rule, such as the streamlined standards for healthcare facilities and the elimination of LQG status for the management of hazardous waste pharmaceuticals, address the first two recommendations indirectly by encouraging healthcare facilities to manage their non-hazardous waste pharmaceuticals as hazardous waste pharmaceuticals.

[15] The final rule defines an ''evaluated hazardous waste pharmaceutical'' as a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributed in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

[16] February 14, 2014; 79 FR 8926.

[17] See 83 FR 11654; March 16, 2018.

[18] EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal, Report No. 12–P–0508, dated May 25, 2012). For a copy of the report, please see: *https://www.epa.gov/sites/production/files/2015-10/documents/20120525-12-p-0508.pdf* or see the docket for this final rule: EPA–HQ–RCRA–2007–0932–0177.

[19] OSWER has since been renamed the Office of Land and Emergency Management (OLEM).

[20] For a copy of OSWER's full response to OIG, please see: *http://www.epa.gov/oig/reports/2012/12-P-0508_Agency%20Response.pdf.*

V. Amendment to the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075)

A. Background

In 1980, EPA promulgated the P- and U-lists of CCPs or manufacturing chemical intermediates that are hazardous wastes if they are discarded or intended to be discarded (40 CFR 261.33(e) and (f)). Several hundred CCPs were listed on the P- and U-lists, including *nicotine and salts.*[21] The phrase ''commercial chemical product or manufacturing chemical intermediate'' refers to a ''chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed, and all formulations in which the chemical is the sole active ingredient'' (see the *comment* following 40 CFR 261.33(d)).

The P-listed chemicals are identified as acute hazardous wastes and U-listed chemicals are identified as non-acute hazardous wastes when discarded in unused form. EPA listed nicotine and salts (referred to commonly as just nicotine) as acute hazardous waste P075 in 261.33(e). A chemical substance is listed in 40 CFR 261.33(e) as an acute hazardous waste if it meets any of the criteria in 40 CFR 261.11(a)(2), which, as described below, are based on human toxicity data, or dose of a chemical given orally or dermally that is lethal to 50 percent of the test animals (LD50), or the concentration of a chemical in the air that is lethal to 50 percent of the test animals (LC50). That is, when the solid waste ''has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, it has been shown in studies to have an oral LD50 toxicity (rat) of less than 50 milligrams per kilogram, an inhalation LC50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD50 toxicity (rabbit) of less than 200 milligrams per kilogram or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness.''

EPA listed nicotine as an acute hazardous waste based on an estimated oral LD50 toxicity to humans of 1 mg/kg and a dermal LD50 toxicity to rabbits of 50 mg/kg. The acute toxicity criterion for humans, as discussed above, is ''fatal to humans in low doses'' (see § 261.11(a)(2)).

EPA's Background Document from April 1981 prepared in support of the commercial chemical product hazardous waste listings in § 261.33 provides a basis for what is meant by ''fatal to humans in low doses'' for chemicals that have been given through the oral route: ''fatal to humans upon ingestion of ≤100 mg/kg''.[22] This Background Document cites an estimated oral LD50 toxicity to humans for nicotine and salts as 1 mg/kg, which corresponds to 50–60 mg of nicotine as a lethal dose for an adult weighing 50–60 kg, and this estimated LD50 value falls within the criterion for ''fatal to humans in low doses.'' However, the Background Document does not provide any information regarding the nicotine product or concentration of nicotine that was used to establish this estimated oral LD50 toxicity in humans for nicotine. According to comments submitted to EPA on the proposal by the retailers, tobacco companies, and trade associations, the only nicotine products being marketed at the time when EPA listed nicotine were pesticides containing up to 40 percent nicotine sulfate. These commenters note that the low-concentration nicotine-containing products (specifically smoking cessation or NRT products) had not yet been developed and, therefore, were not considered when EPA listed nicotine as an acute hazardous waste.

Once the Agency lists chemicals on either the P- or U-lists, these chemicals are P- or U-listed hazardous wastes when discarded or intended to be discarded regardless of chemical concentrations, with two exceptions: Warfarin and salts (which are listed as waste number P001 when present at concentrations greater than 0.3% and U248 when present at concentrations of 0.3% or less) and zinc phosphide (which is listed as Waste Code P122 when present at concentrations greater than 10% and Waste Code U249 when present at concentrations of 10% or less). Therefore, the P075 hazardous waste listing is applicable to the commercial chemical product nicotine or a commercial chemical product containing nicotine as the sole active ingredient when disposed regardless of the concentration of nicotine. The Agency has previously stated that unused dermal patches containing nicotine, nicotine gum, and nicotine lozenges are listed hazardous waste P075 when discarded.[23] The Agency stated this because nicotine is a listed hazardous waste P075 when discarded, and nicotine is the sole active ingredient in patches containing nicotine, nicotine gum, and nicotine lozenges. However, once the nicotine patches, gums, and lozenges have been used for their intended purpose, regardless of the length of use, they are no longer commercial chemical products and would not be listed hazardous waste P075 when discarded.

B. Summary of Proposal

In the preamble to the proposed rulemaking, EPA provided a rationale for why it is considering the possibility of amending the P075 acute hazardous waste listing for nicotine and salts. Primarily, the retail associations, representing a broad range of retailers within the retail industry, asked EPA to undertake a rulemaking to remove low-concentration nicotine products from the P075 hazardous waste listing under RCRA. This is because the retailers did not believe their low-concentration nicotine products meet RCRA's requirements for acute hazardous waste, when discarded. Thus, according to the retailers, the acute hazardous waste classification for their discarded low-concentration nicotine products is inappropriately making them subject to RCRA's LQG requirements. (for more information, see 80 FR 58071; September 25, 2015). Consequently, EPA, in the preamble to the proposed rulemaking, presented and sought comment on two possible approaches for amending the acute hazardous waste listing for nicotine and salts and stated that, depending on the information received during the comment period, EPA could finalize one of them. Under the first approach, EPA would exempt FDA-approved OTC nicotine-containing smoking cessation products (nicotine patches, gums, and lozenges) from the P075 hazardous waste listing if toxicity information received or collected for these products supported a finding that these products, when disposed, do not warrant regulation as acute hazardous wastes under RCRA Subtitle C. We note that this preamble will collectively refer to nicotine patches, gums, and lozenges as FDA-approved OTC NRTs. EPA also stated in the preamble to the proposed rulemaking that e-cigarettes would not be exempted under this approach, because they have not been approved by FDA and the concentration of nicotine in e-cigarettes is not limited by regulation (for more information, see discussion under Comments and Responses included later in this section). Under the second approach, EPA would establish a concentration-based exemption from the P075 listing for low-concentration nicotine-

[21] See 45 FR 33124, May 19, 1980.

[22] See pp. 21–22 and 33 in Background Document dated April 1981 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0171.

[23] See letter from Robert Dellinger, USEPA to Charlotte Smith, WM Healthcare Solutions, Inc., dated August 23, 2010, RCRA Online #14817.

containing products (including e-cigarettes); in other words, a maximum concentration of nicotine in these products below which the P075 listing would not apply. This approach would require submission to EPA of supporting human toxicological data or animal LD50 data for these products at the maximum concentration of nicotine found in these products.

C. Summary of Comments

The comments received were mainly from retailers, tobacco companies, individual states, trade and government associations. The retailers, tobacco companies, and trade associations supported an exemption from the P075 hazardous waste listing for FDA-approved OTC NRTs. In addition, these commenters also generally favored an exemption from the P075 listing for all other nicotine-containing products which they considered to have low nicotine concentrations, including e-cigarettes and e-liquids. Alternatively, if the EPA decided not to exempt all low-concentration nicotine-containing products from the P075 listing, the commenters indicated they would support the reclassification of such products as non-acute (*i.e.,* U-listed) hazardous wastes or otherwise require these products to be managed as hazardous waste pharmaceuticals under 40 CFR part 266 subpart P. These commenters stated that classification of low-concentration nicotine-containing products as acute hazardous waste is unjustified. The commenters also expressed a concern that, because of this inappropriate classification, anyone generating more than 1 kg per month of this acute hazardous waste becomes subject to RCRA's LQG regulations, which result in increased economic burdens and reporting requirements. The commenters asserted that the original P075 listing was likely based on a concentration of nicotine that is orders of magnitude greater than today's low-concentration NRTs, and the human toxicity data that EPA relied upon to support the original P075 listing have been recently reassessed and could not be substantiated. They stated further that a U.S. Surgeon General's Report issued in 2014 could not find support for the 1 mg/kg median lethal dose for humans used to support the original listing.

Additionally, the retailers, tobacco companies, and the trade associations commented that EPA listed nicotine and salts as P075 acutely toxic hazardous wastes long before NRT products were in use and thus EPA did not consider if they presented a risk that should be covered by the P075 listing. According to these commenters, because the OTC NRTs (nicotine patches, gums, and lozenges) contain very low concentrations of nicotine, they clearly do not meet EPA's listing criteria for acute toxicity and in addition have been approved by FDA to be sold to the public over-the-counter (meaning these products can be purchased without a prescription). In summary, these commenters urged EPA to amend the P075 listing to exempt the low-concentration nicotine-containing products based on either (1) type of product and/or (2) a specified concentration of nicotine in these products below which the product would be exempt, because there are no credible toxicity data that would support keeping low-concentration nicotine-containing products listed as acute hazardous wastes.

All of the states and one government association (Northeast Waste Management Officials' Association or NEWMOA) that submitted comments on the proposal generally supported exempting FDA-approved OTC NRTs from the P075 listing, if EPA obtained the necessary toxicity data to show that these products are not acutely toxic. These same commenters, except for one (Oklahoma), did not support exempting e-cigarettes or nicotine-containing e-liquids from the P075 listing. Almost all of the states and NEWMOA wanted continued regulation of e-cigarettes and nicotine-containing e-liquids because the safety of these products is less widely accepted.

In summary, the Agency did not receive any comments that disagreed with the proposed approach to exempt FDA-approved OTC NRTs from the P075 listing, provided this approach is supported by sufficient toxicity information to conclude that concentrations of nicotine contained in these products are not acutely toxic.

D. Final Rule Provisions

The Agency is finalizing the first approach for amending the P075 listing discussed in preamble of the proposal. That is, EPA is amending the hazardous waste listing for hazardous waste number (commonly called ''hazardous waste code'') P075 in § 261.33(e) to exempt FDA-approved OTC NRTs. Specifically, the P075 listing for nicotine is being amended with a parenthetical phrase stating that the listing does not include patches, gums, and lozenges that are FDA-approved over-the-counter nicotine replacement therapies.

The Agency has concluded that FDA-approved OTC NRTs do not meet the acute listing criteria under 40 CFR 261.11(a)(2), based on review of available toxicity information for nicotine and nicotine-containing FDA-approved OTC NRTs (see discussion under Comments and Responses below).

E. Comments and Responses

1. Nicotine Toxicity Data

Some commenters stated that human toxicity data that EPA originally relied upon to list nicotine as P075 acutely toxic hazardous wastes are not credible and do not support classifying low-concentration nicotine-containing products as acutely toxic hazardous wastes. In addition, they also stated that available animal toxicity data do not support classifying low-concentration nicotine-containing products as acutely toxic hazardous wastes. The commenters provided references to several recent reports and an article (see discussion of these references in the following paragraphs) to support their assertions. The commenters stated that these recent reports and article provide evidence that nicotine is not as toxic as originally thought.

Commenters argued that the validity of an estimated oral LD50 toxicity to humans of 1 mg/kg (corresponding to 50–60 mg of nicotine as a lethal dose for an adult weighing 50–60 kg) for nicotine used by EPA to support the acute hazardous waste listing for nicotine has been questioned by government entities and researchers, most recently by the U.S. Surgeon General's Report, ''The Health Consequences of Smoking—50 Years of Progress'' (2014) [24] and in an article published in *Archives of Toxicology,* ''How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century'' (Mayer, 2014).[25] The U.S. Surgeon General's Report cited by commenters states that the toxicity of nicotine is dependent on dose, dose duration and frequency, route of exposure, formulation of the nicotine product, and interpersonal variability. This report also states that numerous poisonings have been documented in the literature since the use of nicotine as a pesticide became widespread in the early part of twentieth century; however, there has not been a systematic assessment of the literature to characterize the dose-response relationship. Furthermore, based on an extensive literature search, the report states that no study was located as a source for the 50–60 mg estimated dose that is commonly

[24] *https://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf.*

[25] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3880486/.*

reported to be fatal to humans. Finally, according to the report, the literature has also shown that in one case a relatively large dose of 240 mg nicotine administered to a patient accidently did not prove to be fatal.

The Mayer article cited by commenters also points out that fatal nicotine intoxications are relatively rare and that there are countless records of subjects who have survived consumption of nicotine in amounts far higher than 60 mg. One example referenced by Mayer in his article was a person surviving following a suicide attempt with 4 grams (4000 milligrams) of pure nicotine. Mayer asserts that this example and many other literature reports on nonfatal nicotine poisonings show that the oral LD50 toxicity of nicotine to humans of 1 mg/kg does not appear to be reliable. Although Mayer did not conduct any lab testing on nicotine, he uses previously reported nonfatal poisonings to develop an estimate of the oral LD50 toxicity of nicotine to humans in the range of 6.5–13 mg/kg (based on an adult weight of 50–60 kg, this would correspond to an estimated range of 325–780 mg of nicotine as the lethal dose for adults). Mayer concludes that nicotine is less toxic than originally thought. That said, his new estimate of the oral LD50 toxicity of nicotine to humans still falls well within the range of ≤ 100 mg/kg, which was one of the reasons for listing nicotine and salts as P075 acute hazardous waste.

EPA regulations in § 261.11(a)(2) state that, in the absence of adequate human toxicity data, the criteria for identifying acute toxicity should be based on the toxicity of the materials to laboratory animals. Commenters directed us to a recently-issued report summarizing available toxicity information on nicotine by the Committee for Risk Assessment of the European Chemicals Agency (ECHA).[26] The acute toxicity of nicotine to laboratory animals presented in the report issued by the Committee for Risk Assessment in comparison to the regulatory criteria for these animals presented in 40 CFR 261.11(a)(2) are as follows: The acute oral LD50 for rat is in the range of 52.5–70 mg/kg (ECHA) compared to the acute oral LD50 regulatory criterion for rat of < 50 mg/kg (§ 261.11(a)(2)). The acute oral LD50 values for rats reported by ECHA fall just outside the acute toxicity criterion in EPA's regulations. The acute dermal LD50 for rabbit is 70.4 mg/kg (ECHA) compared to acute dermal LD50 regulatory criterion for rabbit of < 200 mg/kg (§ 261.11(a)(2)). The acute dermal LD50 for rabbit falls well below the acute toxicity criterion in our regulations. There were no comparable data available for the acute inhalation LC50 for rat.

Based on the toxicity information discussed above, and the listing criteria in 40 CFR 262.11(a)(2), the evidence is clear that nicotine is still acutely toxic to both humans and animals under the RCRA hazardous waste regulations and must continue to be listed as acute hazardous waste number P075 under § 261.33(e). As already noted, under the hazardous waste regulations the Agency generally lists commercial chemical products, if they are discarded or intended to be discarded, regardless of chemical concentrations. However, EPA is not precluded from amending (through rulemaking) an existing listing, for example, if a particular subset of wastes within that listing can be identified as not posing the risk for which the original listing was established.

2. Food and Drug Administration-Approved Nicotine Replacement Therapies

A number of commenters urged EPA to exempt low-concentration nicotine-containing products (specifically OTC NRTs) from the P075 listing. The commenters stated that millions of people use OTC NRTs daily without showing any signs of acute toxicity, and these products have been approved by FDA to be sold over the counter without a prescription. Therefore, they believe this is the best evidence that these products are not acutely toxic and safe for people to use.

As noted above, the Agency stated in the proposal that if it obtained toxicity data to support the conclusion that FDA-approved OTC NRTs do not meet the criteria for listing as an acutely hazardous waste, then it will exempt these products from the P075 listing. The FDA-approved OTC NRTs are designed to help people quit smoking by delivering controlled amounts of nicotine to ease symptoms of withdrawal and craving. The Consumer Health Products Association stated in its comments that nicotine gums and lozenges contain 2–4 mg nicotine (approximately 0.2–2 percent by weight depending on lozenge size) and nicotine patches contain 7 mg, 14 mg, or 21 mg of nicotine (approximately 2–7 percent by weight). Comments from Reynolds American Inc. Services Company (RAI Services or RAI) provided similar information on the amount of nicotine in these FDA-approved OTC NRTs.[27] According to information on FDA's website, FDA regulations ensure that OTC drug products are safe and effective for people to use.[28] In most cases, OTC drug products are regulated by FDA through OTC drug monographs. OTC drug monographs state the active ingredients and other conditions of use (including dose, dosage form, and route of administration) that are generally recognized as safe and effective to treat certain diseases or conditions without a prescription. OTC drug products that conform to a final monograph and other relevant requirements are not required to be reviewed by FDA before marketing. Products that do not conform to a final monograph must be reviewed under the new drug application process. The new drug application process is how manufacturers provide evidence to FDA to demonstrate that the new drug product is safe and effective for use as recommended in the product's labeling. Sometimes, an OTC drug product begins as an approved prescription drug and then a drug company will submit an application to FDA to switch the drug product from prescription status to OTC status. FDA reviews the information in the application, along with information about adverse events associated with the use of the drug, and determines whether the prescription drug can be used safely and effectively as an OTC drug. FDA allowed nicotine patches and gums, which were initially available by prescription only, to be switched to OTC status between 1996 and 2002. The nicotine lozenge and mini-lozenge were approved by FDA directly for OTC use in 2002 and 2009 via new drug applications.[29] [30]

FDA has determined that OTC NRTs can be used safely and effectively by people without a healthcare professional's supervision when used in accordance with their label instructions. Since FDA first approved NRTs for OTC use, FDA has reviewed a number of studies that examined use of OTC NRTs, including use of OTC NRTs in combination with other nicotine-containing products, use of OTC NRTs at higher than standard-dose, and use of OTC NRTs over periods longer than recommended, and it has not identified

[26] See ECHA's Committee for Risk Assessment Opinion Proposing Harmonized Classification and Labeling at EU Level of Nicotine, adopted 10 September 2015 (*https://echa.europa.eu/documents/10162/23665416/clh_opinion_nicotine_5579_en.pdf/0103fadb-e945-4839-c4f4-17d20854adf0).*

[27] See P.9 of RAI's comments dated December 23, 2015 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0329.

[28] *https://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm342560.htm.*

[29] See 78 FR 19718; April 2, 2013.

[30] See FDA materials for New Drug Application Numbers 21–330 and 22–360 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

any significant safety concerns.[31] It is useful to recognize one characteristic of FDA-approved OTC NRTs when considering the toxicity of nicotine contained in these products, which is that they are designed for controlled release of nicotine to approximate the nicotine amounts obtained from smoking. This characteristic of FDA-approved OTC NRTs means that nicotine enters the body over a period of time and there is a gradual increase in the level of nicotine in the blood when used in accordance with the accompanying label. According to EPA's review of FDA information and RAI's comments, FDA's Center for Drug Evaluation and Research reviewed pharmacology and toxicology data for nicotine polacrilex lozenges and made a number of observations concerning nicotine's toxicology. FDA stated that ''oral doses of nicotine that have been reported to be lethal in animals are approximately 8- to 150-fold greater than nicotine exposures that would result from use of Nicotine Polacrilex Lozenges.'' In addition, the FDA noted that ''the toxicological profile of nicotine in animals has been largely superseded by the extensive human experience with this agent. Based on the established clinical experience with similar nicotine replacement therapy products, acute toxic reactions would not be anticipated from use of Nicotine Polacrilex Lozenges at the recommended dosage.'' [32]

In summary, the most common dosage of nicotine from OTC nicotine gums and lozenges (2–4 mg) and OTC nicotine patches (7–21 mg) is absorbed slowly and results in significantly lower concentrations of nicotine in blood levels compared to the amount of nicotine that has been determined or estimated to be lethal to animals and humans. The OTC nicotine patch, the strongest of which contains 114 mg of nicotine, delivers 21 mg of nicotine at a relatively steady rate over a 24-hour period when the patch is applied to the skin. The most frequently reported side effects from use of patches are local skin reactions, which can be reduced by moving the site of the patch application daily as instructed.[33] In addition, FDA has reviewed and approved these products as being safe and effective for people to use without a prescription. Furthermore, the FDA-approved OTC NRTs have been in the market for over two decades and although some serious adverse events have been reported, based on the available information, EPA has concluded that the serious adverse events do not meet EPA's criteria for acute toxicity under 40 CFR 261.11(a)(2) (*i.e.,* fatal to humans in low doses or capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness).[34] Finally, the serious adverse events that have been reported have not caused FDA to reverse its decision to allow the NRTs to be sold as OTCs. Therefore, the Agency finds that FDA-approved OTC NRTs are not acutely toxic and is exempting them from the P075 listing.

The FDA-approved OTC NRTs, prior to the effective date of this rule, were listed hazardous waste P075 when discarded. Therefore, these wastes have been required to be managed under RCRA Subtitle C hazardous waste regulations. Following exemption from the P075 listing, these OTC NRT wastes will be considered non-hazardous wastes and can be managed under applicable non-hazardous solid waste regulations. The Agency does not have any information at this time to suggest that these wastes will be improperly managed as non-hazardous wastes or have the potential to cause human or environmental exposures. The Agency believes, because of the low concentrations of nicotine in these wastes and their design to slowly release the nicotine, any risk from plausible mismanagement scenarios would not be sufficient to cause a substantial present or potential hazard to human health or the environment. Nevertheless, the Agency encourages healthcare facilities to first consider if their unused nicotine-containing products, which are to be discarded, can be legitimately recycled to recover the nicotine. The Agency has recently stated to one recycler that legitimately recycled nicotine-containing products would not be considered solid waste and thus would not be subject to RCRA hazardous waste regulation.[35] In addition, the Agency reminds healthcare facilities, especially retail-sector pharmacies, who may decide to discard expired FDA-approved OTC NRTs in their dumpsters or regular trash, that products' labels direct them to ensure that these products are kept out of the reach of children and pets. Therefore, the Agency recommends that healthcare facilities, including retailers, take the necessary security measures to discard unused, unwanted, or expired OTC NRTs where they are not freely accessible to the public. The recommended security measures could be simple as having locks on the dumpsters and trash cans that are used for discarding OTC NRTs or placing the dumpsters and trash cans in locked areas.

3. E-Cigarettes, E-Liquids, and Prescription Nicotine Replacement Therapies

There were mixed comments on exempting e-cigarettes, nicotine containing e-liquids, and NRTs requiring a prescription from the P075 hazardous waste listing when discarded (for more information, see Summary of Comments included previously in this section). The comments from retailers, tobacco companies, and trade associations generally favored exempting these categories of products from the P075 listing when discarded, whereas comments from four of five states and NEWMOA did not support exempting these products from the P075 listing when discarded.

The e-cigarettes and nicotine-containing e-liquids (or just e-liquids) are currently not regulated by FDA in the same manner as NRTs. NRTs are regulated as drugs by FDA while e-cigarettes and e-liquids are regulated as tobacco products by FDA. Consequently, the FDA has not been able to evaluate the health risks to the public from e-cigarettes and e-liquids to the same extent as it has been able to for drugs. Moreover, the concentrations of nicotine in e-cigarettes and e-liquids are not limited by any FDA regulation or approval process and are therefore unpredictable. The supplemental comments on the proposal submitted to EPA by the Retail Associations (June 29, 2016) [36] stated that a recent promulgation of a final rule by FDA referred to as the ''Deeming Rule'' (81 FR 28973; May 10, 2016) will ensure against ''unpredictable'' nicotine concentrations in e-cigarette products and, therefore, strengthens the case for reclassification or exemption of these

[31] See 78 FR 19718; April 2, 2013.

[32] See pages 5 and 6 of the Pharmacology Review for the New Drug Application Number 21–330 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

[33] *International Journal of Health Sciences (Qassim).* ''Nicotine Replacement Therapy: An Overview'' (July, 2016) 10(3): pp. 425–435.

[34] See the following four FDA documents included in the docket for this rulemaking EPA–HQ–RCRA–2007–0932: (1) Letter from Janet Woodcock responding to a citizen petition, dated June 4, 2015; (2) Memo from Kellie Taylor et al. on citizen petition response, dated May 8, 2015; (3) Memo from Joslyn Swann providing a review of Abuse, Misuse, and Overdose associated with Nicotine Replacement Therapy products, dated October 1, 2010; and (4) Nicoderm OTC Switch Medical Officer Review (NDA 20–165), dated August 7, 1995.

[35] See letter from Barnes Johnson, USEPA to Scott DeMuth, g² Revolution, LLC., dated May 8, 2015, RCRAOnline #14851.

[36] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0392.

products from the P075 listing. The Deeming Rule extended FDA's regulatory authority to all tobacco products, including electronic nicotine delivery systems (or e-cigarettes). This rule allows FDA to evaluate factors such as ingredients (*e.g.,* nicotine and its concentration), product design, and health risks to both users and non-users. The Deeming Rule ensures that newly regulated tobacco products, before they are introduced into the market, meet certain requirements, including warning labels, prohibiting sales to minors, registering with FDA, and obtaining marketing authorization from FDA. It is, however, important to note that FDA's review and approval process for introducing new tobacco products to the market is not as rigorous in assessing their safe use as review and approval of drug products. Furthermore, in August 2017, the FDA extended the compliance deadline for the newly regulated noncombustible tobacco products in the Deeming Rule, such as e-cigarettes, from November 8, 2017 to August 8, 2022. Therefore, without controls on the concentration of nicotine in e-cigarettes and e-liquids or FDA's approval of these products as being safe and effective for people to use, the Agency lacks adequate information and certainty to conclude that these nicotine-containing products will not pose the risks similar to those for which the P075 listing was established. For all of the above reasons, at this time the Agency cannot support exempting e-cigarettes and nicotine-containing e-liquids from the P075 listing.

Furthermore, in the short time that e-cigarettes have been in the U. S. marketplace (since about 2007), the calls to poison control centers related to exposures to this product, mostly among young children, have increased substantially. This significant increase can be attributed largely to the rapid rise in the use of e-cigarettes by the public. According to an article published in the Journal *Pediatrics,* ''Pediatric Exposure to E-Cigarettes, Nicotine, and Tobacco Products in the United States'' (May 2016), the monthly number of exposures among young children (younger than six years old) associated with e-cigarettes increased by almost 1500 percent from January 1, 2012 (14 exposures) to April 30, 2015 (223 exposures).[37] During the same period, children under two years old accounted for 44.1 percent of the exposures associated with e-cigarettes. Exposures of children to unregulated nicotine concentrations in e-cigarette cartridges and refill solutions (e-liquids) have the potential to cause much more severe toxic effects compared to exposures of children to FDA-approved OTC NRTs. This is because e-liquid refill containers are available in concentrations up to 100 mg/mL that are then diluted before use. The liquid nicotine, ingested or absorbed through skin, is likely to result in more severe toxic effects because it is available in higher concentrations and absorbed rapidly by the body. In December 2014, a 1-year old child died from liquid nicotine poisoning, the first such death in the U.S.[38]

Prescription NRTs, like OTC NRTs, must be approved for use by FDA as drugs. However, the FDA considers OTC drug products to be safe enough to take without the guidance of a health professional. A prescription for a drug is written by a health professional for an individual at a specific dose after the health professional has diagnosed an illness. Generally, nicotine-containing prescription drugs (*e.g.,* nicotine inhaler and nicotine spray) contain an aqueous solution intended for administration as a metered spray, which means, in comparison to FDA-approved OTC NRTs, nicotine can be delivered rapidly to the body. When a prescription pharmaceutical is transitioned to OTC status, the key question for FDA is whether consumers can achieve the desired medical result without the intervention of a health care professional and without endangering their safety.[39] For example, FDA has to review information about adverse events and serious adverse events resulting from use of a prescription drug before it can make a determination on whether a prescription drug is safe to switch over to an OTC drug. FDA has not yet made that determination for the existing prescription NRTs and EPA also did not receive any toxicity or health effects information on prescription NRTs. Prescription NRTs are also expected to be used less frequently than FDA-approved OTC NRTs, and, thus, should not exist in the same quantities at retailers as FDA-approved OTC NRTs. Furthermore, prescription NRTs are not expected to be returned to retailers like FDA-approved OTC NRTs, because they are prescribed by health professionals for specific individuals and can't be resold once dispensed. Therefore, the comments from retailers also expressed less concern about the disposal of prescription NRTs causing a change in their hazardous waste generator category.

Based on the information discussed above and the comments from a majority of the states and NEWMOA, the Agency is not exempting e-cigarettes, e-liquids, or prescription NRTs from the P075 hazardous waste listing. The Agency believes that any plausible mismanagement or diversion of these waste products, if exempted and allowed to be managed as non-hazardous wastes, has the ability to cause substantial present or potential hazard to human health and the environment. This is because prescription NRT products can contain nicotine at much higher concentrations and in a more readily available form (*i.e.,* in liquid and mist), which acts faster on the body, than the nicotine contained in FDA-approved OTC NRTs. Instead, the Agency is allowing e-cigarettes, e-liquids, and prescription NRTs to be managed as hazardous waste pharmaceuticals under 40 CFR part 266 subpart P when they are discarded.

4. Concentration-Based Exemption

Some commenters stated that the data and information they provided to EPA should be adequate to support a concentration-based exemption for nicotine-containing products. These commenters requested that EPA exempt from the P075 listing all present and future nicotine-containing products with less than a particular nicotine concentration (*e.g.,* less than 3% or 5%).

The Agency stated in the proposal that it would consider a concentration-based exemption for low-concentration nicotine-containing products if toxicology data (*e.g.,* animal LD50 data) for nicotine-containing products at maximum concentration of nicotine in these products became available. On June 9, 2017, Perrigo submitted additional comments along with oral and dermal LD50 toxicity studies for nicotine gums and lozenges manufactured by Perrigo.[40] The gums and lozenges tested contain 5% nicotine polacrilex. Nicotine polacrilex is a nicotine-containing resin which contains 15% nicotine. With 5% nicotine polacrilex in the gums and lozenges, the total nicotine in these products is less than 1%. The Perrigo LD50 studies reported oral and dermal rat LD50 toxicity values of greater than 5000 mg/kg for both nicotine gum and lozenge products. Based on their data, Perrigo asked the Agency to exempt

[37] *http://pediatrics.aappublications.org/content/early/2016/05/05/peds.2016-0041?utm_source=TrendMD&utm_medium=TrendMD&utm_campaign=Pediatrics_TrendMD_1.*

[38] *https://www.healthychildren.org/English/safety-prevention/at-home/Pages/Liquid-Nicotine-Used-in-E-Cigarettes-Can-Kill-Children.aspx.*

[39] *https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143547.htm.*

[40] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0398.

from the P075 listing nicotine at concentrations below 5%.

EPA's review of the Perrigo LD50 studies revealed several critical flaws in the way these studies were conducted. First, the studies were conducted using nicotine polacrilex instead of nicotine itself. A concentration-based listing for nicotine would require toxicity data for nicotine itself. The amount of nicotine in gums and lozenges with 5% nicotine polacrilex, as stated above, is less than 1% and it is in a form that is not readily available when ingested or applied (nicotine is designed to be released slowly when it is in the form of nicotine polacrilex). In fact, the nicotine will not release from the nicotine-containing resin (nicotine polacrilex) until it is exposed to an aqueous solution or proper pH, such as found in saliva. Therefore, nicotine polacrilex would not be expected to be absorbed dermally. In contrast, nicotine is readily absorbed dermally, as indicated by nicotine patches. To support a concentration-based exemption of nicotine, Perrigo should have conducted the toxicity studies for nicotine using the percent of nicotine (not nicotine polacrilex) in the gums and lozenges, since this would have provided data on toxicity of nicotine (the P075 listed chemical). Second, for acute oral testing, a single bolus dose of nicotine should have been administered to the test animals all at once (or over a short period of time) instead of over a period of 24 hours. Third, in EPA's listing regulations under § 261.11(a)(2), the dermal LD50 toxicity value is based on studies with rabbits, but Perrigo's studies used rats. Fourth, Perrigo did not provide LD50 toxicity data for nicotine patches (this could be because Perrigo does not manufacture nicotine patches). Finally, no explanation or justification was included for using their toxicity data which was for nicotine polacrilex with concentrations of nicotine at less than 1%, to extrapolate to exempting all nicotine with a concentration below 5%.

EPA, for the reasons previously stated, has already determined that FDA-approved OTC NRTs are not acutely toxic and is exempting them from the P075 listing. The toxicological data submitted by Perrigo are for nicotine polacrilex, instead of nicotine, and are not considered to be adequate to support a concentration-based exemption for nicotine-containing products. Therefore, the Agency has no other information to conclude that a particular nicotine concentration can be exempt from the P075 listing.

VI. Reverse Distribution and Reverse Logistics

A. Summary

Based on information collected from outreach efforts and comments received on the proposed rulemaking, EPA is finalizing regulations for the reverse distribution of prescription hazardous waste pharmaceuticals, codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals,[41] and establishing a policy for the reverse logistics of other unsold retail items.[42] In the case of prescription pharmaceuticals, EPA maintains its position as stated in the proposed rulemaking preamble that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility (*e.g.,* retail store).[43] In contrast, EPA is codifying our existing interpretation that nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the retail store[44] if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose)[45] or reclaimed.[46] Additionally, EPA is establishing a policy that other retail items that are sent through reverse logistics are not solid waste at the retail store if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed. The remainder of this section proceeds as follows. First, EPA provides a brief background on the Agency's work to better understand the retail sector and provide guidance on RCRA's applicability to the retail sector. EPA then describes the proposal to revise the Agency's position regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors under the pharmaceuticals proposed rulemaking. Finally, EPA provides the rationale for finalizing distinct regulations and policies for the reverse distribution of prescription hazardous waste pharmaceuticals and the reverse logistics of other unsold retail items and nonprescription pharmaceuticals and describes new information received in comments on the proposed rulemaking.

B. Background

In 2008, EPA initiated a review of RCRA's applicability to the retail sector in order to understand the challenges the retail sector faces in complying with RCRA. EPA's review consisted of discussions with various members of the retail community and states through meetings, conferences, and site visits. In 2014, EPA published a NODA for the Retail Sector in order to better understand the concerns from all stakeholders regarding RCRA's applicability to that sector.[47]

Subsequent to issuance of the NODA, EPA continued conducting outreach efforts (*e.g.,* meetings, conferences, site visits) with stakeholders to gather information regarding the management of unsold retail items. EPA's outreach efforts, combined with an analysis of comments received on the NODA, improved the Agency's understanding of the challenges that the retail sector faces when managing items that have become unsalable at stores for a variety of reasons. Unsold retail items include excess inventory, such as expired or outdated items, seasonal items,

[41] Under the final rule, the definition of pharmaceutical includes, but is not limited to, prescription drugs, over-the-counter drugs, dietary supplements, and homeopathic drugs. See the definition of pharmaceutical in § 266.500. For the remainder of this section, EPA refers to over-the-counter drugs, dietary supplements, and homeopathic drugs as nonprescription pharmaceuticals. Prescription pharmaceuticals are defined by 21 CFR 203.3(y).

[42] Under the final rule, other unsold retail items can include any non-pharmaceutical unsold retail item from a retail store that if discarded would otherwise meet the definition of hazardous waste. Examples include but are not limited to aerosol cans, pool chemicals, mercury-containing lightbulbs, some pesticides, certain cleaning products, paint thinner, ammunition, and fireworks.

[43] Under the final rule, the definition of healthcare facility includes, but is not limited to, retail facilities such as pharmacies and retailers of over-the-counter medications. See the definition of healthcare facility in § 266.500.

[44] Throughout this section, EPA uses the term ''retail store'' to describe facilities that send nonprescription pharmaceutical and other unsold retail items through reverse logistics. EPA's understanding is that the retail sector is the only industry that sends nonprescription pharmaceuticals and other unsold items through reverse logistics. However, EPA's final policy that nonprescription pharmaceuticals and other unsold retail items, excluding prescription pharmaceuticals, that are sent through reverse logistics are not solid wastes if they have a reasonable expectation of being legitimately used/reused or reclaimed, is not limited to the retail sector.

[45] Commenters from the retail industry commonly use the terms ''liquidation'' or ''donation'' to refer to legitimate methods of redistribution. For example, see comment numbers EPA–HQ–RCRA–2007–0932–0312 and EPA–HQ–RCRA–2007–0932–0340 in the docket. Under RCRA's definition of solid waste regulations in § 261.2(e), redistribution would be referred to as use/reuse.

[46] See § 261.1(b)(4) for the definition of reclamation and § 261.1(b)(5) for the definition of use/reuse.

[47] February 14, 2014 (79 FR 8926).

overstock, recalled items, and returned items that cannot be returned to stock/inventory. In the NODA, EPA used the terms ''reverse distribution'' and ''reverse logistics'' to describe the process or system employed by the retail sector to manage these unsold retail items.

Based on information gathered through outreach and comments to the Retail NODA, EPA developed a cohesive plan to address the unique challenges faced by the retail sector in complying with RCRA regulations. This plan is called the ''Strategy for Addressing the Retail Sector under the Resource Conservation and Recovery Act's Regulatory Framework'' (Retail Strategy) and was made publicly available on September 12, 2016.[48]

Throughout the Retail Strategy, EPA used the term ''reverse distribution'' to describe the system through which unsold retail items flow and the term ''reverse logistic center'' to describe the facilities managing the reverse flow of these items. In crafting the Retail Strategy, EPA recognized that the reverse distribution process that retail stores employ to send unsold retail items to reverse logistics centers is a well-established business practice in the retail sector and retail stores sometimes rely upon arrangements with manufacturers[49] to determine the ultimate disposition of these goods. EPA also noted that a number of questions have been raised by both retailers and regulators regarding how the reverse distribution process is regulated, or should be regulated, under RCRA. In addition, this issue becomes more complicated for national retailers with store locations in multiple states, as states have taken various positions on how RCRA regulations apply. The Agency's understanding when crafting the Retail Strategy was that ''reverse distribution'' is the term most commonly used for the return of all pharmaceuticals (both prescription and nonprescription) that have the potential to receive manufacturer credit, whereas ''reverse logistics'' is the term used for the reverse flow of retail items other than pharmaceuticals.[50]

Because of the challenges facing the retail sector in complying with RCRA, EPA stated in the Retail Strategy its intent to develop a policy addressing the reverse distribution process for the retail sector as a whole. In the Retail Strategy, EPA agreed to develop a comprehensive policy that applied to all unsold retail items, not just pharmaceuticals. In order to fulfill EPA's intent to address the reverse distribution process for the retail sector as a whole, EPA is establishing a policy for the reverse logistics of other unsold retail items in addition to finalizing regulations for the reverse distribution of prescription hazardous waste pharmaceuticals and codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals.

C. EPA's Proposed Regulations for Reverse Distribution of Pharmaceuticals

In the proposed Management Standards for Hazardous Waste Pharmaceuticals, EPA proposed to revise the Agency's position regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors to obtain manufacturer credit. EPA's original position was outlined in two RCRA policy memos released in 1981 and 1991.[51] In the first memo, EPA agreed that pharmaceuticals did not become wastes until the decision to discard was made at a manufacturing plant. EPA's interpretation was based on the understanding that the decision to either return goods for reclamation or dispose of them took place only at the manufacturing plant. In the second memo, EPA agreed that pharmaceuticals returned to a manufacturer, wholesaler, or third-party service company would not be considered wastes until a decision to discard has been made. In this 1991 memo, EPA specifically noted that, ''to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered waste until a determination to discard them is made.'' Although EPA made a statement in the preamble to the 2008 Pharmaceutical Universal Waste proposal that linked the value of these pharmaceuticals, in the form of manufacturers credit, to the idea that these pharmaceuticals would not be considered waste, EPA never finalized this universal waste rule or that interpretation. Thus, the 1991 memo describes EPA's interpretation regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors prior to this final rulemaking.

In the preamble to the proposed rulemaking, EPA indicated the Agency's intent to modify its position regarding the point of generation in circumstances where a pharmaceutical is sent to a reverse distributor. EPA proposed that the decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical. That is, EPA proposed that, once the decision is made to send a potentially creditable hazardous waste pharmaceutical[52] from a healthcare facility to a reverse distributor, a decision to discard has been made and the pharmaceutical is considered a solid waste. This proposed change of policy was based on the EPA's understanding that in almost all cases, pharmaceuticals returned to a reverse distributor for manufacturer credit are ultimately discarded.[53] Under the proposed rulemaking, the definition of ''pharmaceutical reverse distributor'' included any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Additionally, under the proposed rulemaking, the definition of ''pharmaceutical'' included not just prescription pharmaceuticals but also nonprescription pharmaceuticals. Therefore, under the proposal, potentially creditable prescription pharmaceuticals and nonprescription pharmaceuticals transported to a facility that facilitates or verifies manufacturer credit, even in cases where a credit determination is yet to be made, would be considered discarded and, therefore, solid wastes at the healthcare facility.

In proposing this shift, EPA specifically stated that, although a pharmaceutical may retain monetary value within the reverse distribution system (*i.e.,* potential exists for a manufacturer to issue credit), the

[48] EPA's Retail Strategy is available at *https://www.epa.gov/hwgenerators/strategy-addressing-retail-sector-under-resource-conservation-and-recovery-acts.*

[49] EPA has not distinguished among the terms ''supplier'' and ''vendor'' (the latter more commonly used in the retail industry) versus ''manufacturer'' and these terms are used interchangeably in this preamble, although the Agency realizes that the flow of goods/products more commonly occurs between retailers and suppliers/vendors (or agents thereof) and that suppliers themselves may also be manufacturers or product formulators.

[50] As discussed subsequently in this preamble, the distinction between ''reverse distribution'' and ''reverse logistics'' has become important in light of the Agency's response to comments received on the proposed rule.

[51] Refer to the preamble of the proposed rule (pages 58042 and 58043), which includes discussion of the two EPA policy memos, dated May 13, 1981 (RCRA Online #11012) and May 16, 1991 (RCRA Online #11606).

[52] Potentially creditable hazardous waste pharmaceutical in the proposal was generally defined as a hazardous waste pharmaceutical that has the potential to receive manufacturer credit and is (1) unused or un-administered; and (2) unexpired or less than one year past expiration date. See 80 FR 58014.

[53] See further discussion in the proposed rule preamble at 80 FR 58043.

pharmaceutical would still be considered a solid waste. The ''decision point'' on whether a pharmaceutical is a solid waste is when it has been discarded or when the decision has been made to discard the material. That is, when a pharmaceutical is discarded determines whether it is a solid waste, not whether the pharmaceutical has value. This interpretation is consistent with EPA's approach under RCRA that materials that are discarded are solid wastes, regardless of their monetary value or the economics of the system in which those discarded materials are handled. EPA has long maintained, and continues to maintain, the interpretation that value is not determinative of solid waste status.

In 1986, EPA released a memo on the regulation of hazardous wastes that are recycled, and wrote that ''persons transporting and storing hazardous wastes before recycling are similar to persons transporting and storing hazardous waste before disposal: There is nothing about the waste that makes it so valuable that safe handling is assured absent regulation.'' [54] EPA reaffirmed this interpretation in a 1989 memo on the regulatory status of solder skimmings (tin/lead alloy) purchased for reclamation, writing that even though the skimmings have value, they are still considered a solid waste.[55]

In a more recent application of this interpretation, EPA outlined its position on chlorofluorocarbons (CFCs) that are processed back into the refrigerant market or sent for destruction, but receive carbon offset credits and thus have value, in two memos signed in 2017.[56] Irrespective of whether facilities pay for hazardous CFCs or receive carbon offsets for the destruction of CFCs, the material is considered a solid waste. As another example of a material that is discarded as solid waste but has monetary value, EPA maintains that spent lead acid batteries being reclaimed are regulated as hazardous waste under part 266 subpart G or under universal waste irrespective of the fact that the batteries may have value and that reclamation facilities sometimes buy batteries due to the monetary value of the lead.[57] This finding was upheld in *United States* v. *Ilco Inc.,* 996 F. 2d 1126, where the court found that the fact that the batteries were discarded ''does not change just because a reclaimer has purchased or finds value in the components.'' EPA also maintains that recyclable materials that are reclaimed to recover economically significant amounts of gold, silver, and other various precious metals are still regulated as hazardous waste under part 266 subpart F despite the fact that the precious metals have monetary value. Additionally, the holdings of multiple court decisions is that simply because a hazardous waste has, or may have, monetary value does not mean the material loses its status as a solid waste. See *American Petroleum Institute* v. *EPA,* 906 F.2d 741 n.16 (D.C. Cir. 1990); *United States* v. *ILCO Inc.,* 996 F.2d 1126 1131–32 (11th Cir. 1993); *Owen Steel* v. *Browner,* 37 F.3d 146, 150 (4th Cir. 1994).

D. EPA's Final Reverse Distribution Regulation and Reverse Logistics Policy

1. Introduction

In light of comments received on the proposed rulemaking, along with EPA's understanding of current business practices, the Agency is making a clear distinction in the final rule between the reverse distribution of prescription pharmaceuticals and the reverse logistics of other unsold retail items, including nonprescription pharmaceuticals. In addition to receiving information from comments on the proposed rulemaking, EPA gathered information from site visits and by participating as an observer in the Retail Waste Working Group.[58] In the case of prescription pharmaceuticals, EPA is finalizing, as proposed, that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility. However, EPA notes that these tailored RCRA regulations for prescription pharmaceuticals going through reverse distribution are designed with existing business practices in mind. For more explanation, see section 4 below and section XVII of this preamble. EPA is also codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals. EPA makes it clear in § 266.501(g)(2) that nonprescription pharmaceuticals are not solid wastes because they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed (also see section IX of this preamble). Also in this preamble, EPA is establishing a policy that other unsold retail items that are sent through reverse logistics are not solid wastes at the retail store because they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed.

2. Comments on EPA's Proposed Reverse Distribution Regulation

EPA received numerous comments on the proposed position that the decision to send potentially creditable pharmaceuticals through reverse distribution is a decision to discard. States were generally supportive of the proposed change in position, while many comments from the retail industry objected to the Agency's proposed change in position.

EPA received many broad comments on EPAs proposed position regarding the waste status of pharmaceuticals going through reverse distribution and reverse logistics, which are discussed in further detail in section XVII. EPA also received many comments describing the potential burden that the revised interpretation would place on the retail industry, which are also discussed in further detail in section XVII. The remainder of this section focuses on comments received on the distinction between the reverse distribution of prescription pharmaceuticals and the reverse logistics of nonprescription pharmaceuticals and other unsold retail items.

EPA received numerous comments that described the key distinctions between reverse distribution and reverse logistics as they pertain to the waste status of pharmaceuticals and other unsold retail items going through these two processes. Multiple commenters argued that EPA mistakenly concluded that pharmaceuticals, including nonprescription pharmaceuticals, transported to facilities that facilitate or verify manufacturer credit are in most, if not all cases, discarded.[59] Commenters argued that the Agency failed to take into account the ability to donate, liquidate, or reclaim nonprescription pharmaceuticals that are sent through reverse logistics. However, commenters did confirm that prescription pharmaceuticals are in

[54] See RCRA Online #12762 for the October 8, 1986 letter from EPA to Senator John Glenn titled ''Hazardous Wastes that are Recycled, Handling.''

[55] See RCRA Online #11446 for the July 20, 1989 memo from EPA to Electrum Recovery Works, Inc.

[56] See docket number EPA–HQ–RCRA–2007–0932 for the January 30, 2017 letter from EPA Region 5 to Tradewater, LLC and the July 14, 2017 letter from EPA to A-Gas U.S. Holdings, Inc.

[57] See docket number EPA–HQ–RCRA–2007–0932 for notes from a November 19, 2013 site visit to a lead acid battery recycler.

[58] See the report prepared by the Retail Waste Working Group, ''Surplus Household Consumer Products and Wastes: Report to the Legislature.'' Available at: *http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

[59] See the preamble to the proposed rule for a discussion of the comments received on the 2008 Pharmaceutical Universal Waste proposal and the 2014 Retail Notice of Data Availability that argued that pharmaceuticals transported to reverse distributors to receive credit are rarely, if ever, repurposed, recycled, or reused (80 FR 58043).

most, if not all cases, discarded. Commenters argued that this fact contradicts EPA's rationale in proposing that all pharmaceuticals, including nonprescription pharmaceuticals, going through reverse distribution and reverse logistics are wastes at the healthcare facility.

Overall, commenters encouraged EPA to adopt the terminology used by industry where ''reverse distribution'' only refers to the process by which prescription pharmaceuticals are sent to a reverse distributor for the evaluation of manufacturers credit and ''reverse logistics'' refers to the process by which nonprescription pharmaceuticals and other unsold retail items are sent to a reverse logistics center and evaluated for legitimate use/reuse or reclamation. Commenters requested that if EPA intends to finalize that a decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical, that EPA also adopt separate and distinct policies regarding how RCRA applies to prescription pharmaceuticals going through ''reverse distribution'' and to nonprescription pharmaceuticals and other unsold retail items going through ''reverse logistics.'' [60] One commenter noted that reverse logistics is an integral component of inventory management, product recall confirmation, sale through liquidation, donation for use, and reclamation of commercial products—contributing billions of dollars to the retail industry annually.[61] Moreover, this commenter noted that the reverse logistics operations help maximize the amount of OTC pharmaceuticals and dietary supplements that can be reused or reclaimed. Another commenter made a similar argument, writing that the purpose of reverse distribution of prescription pharmaceuticals is to determinate creditworthiness while the primary purpose of reverse logistics of nonprescription pharmaceuticals is to aggregate and redirect viable products into another supply chain.[62]

One commenter honed in on the argument that EPA failed to take into account the ability to legitimately use/reuse or reclaim nonprescription pharmaceuticals that are sent through reverse logistics.[63] This commenter pointed out that stringent chain-of-custody documentation and disposal requirements under DEA regulations and state Board of Pharmacy Requirements only apply to prescription pharmaceuticals. In contrast, most nonprescription pharmaceuticals are not susceptible to the same diversion risks as prescription pharmaceuticals and do not face the same documentation and disposal requirements. This makes it possible to use/reuse or reclaim nonprescription pharmaceuticals.

Walmart Stores Inc. commented that pharmaceuticals going through reverse distribution that are ultimately discarded are likely prescription pharmaceuticals.[64] Walmart wrote that only a small percentage of the consumer goods [65] managed at Walmart's six Return Centers, which will be considered reverse logistics centers under EPA's final policy, are discarded. According to Walmart's data, only 2% of the consumer goods managed at Walmart's Return Centers are discarded by Walmart, while 28% are donated, recycled, or liquidated and 70% are returned to the vendor.[66] Further, for the consumer products that are considered RCRA hazardous waste when discarded, only 1% are discarded, 33% are liquidated or donated, and 66% are returned to the vendor.[67] Inmar, Inc. also argued that only a small percentage of the OTC pharmaceuticals returned to a reverse logistics center are disposed rather than liquidated, donated, or returned to the vendor.[68] Inmar does not maintain specific data on this issue, but wrote that it would not be unusual for one of their subsidiary reverse logistics centers handling nonprescription pharmaceuticals and other consumer goods to send as little as 5% of the products for destruction.

Retail Industry Leaders Association (RILA) et al. pointed out that nonprescription pharmaceuticals do not face the same restrictions that preclude the redistribution or donation of prescription pharmaceuticals.[69] RILA et al. added that nonprescription pharmaceuticals are regularly donated and liquidated and cited data from two retailers.

Inmar Inc. also noted that when an item is returned because an expiration date has been exceeded, disposal is more often the required disposition, but the products may be returned to the manufacturer for further evaluation for potential liquidation.[70] Inmar also wrote that nonprescription pharmaceuticals with ''best by'' dates (as opposed to expiration dates) can still be donated or liquidated after the date has passed.

Overall, these comments help to underscore the differences between how prescription pharmaceuticals and other unsold retail items, including nonprescription pharmaceuticals, are managed within the reverse supply chain. These comments led EPA to make a clear distinction in the final rule between the reverse distribution of prescription pharmaceuticals and the reverse logistics of all other unsold retail items, including nonprescription pharmaceuticals.

3. Distinction Between Reverse Distribution and Reverse Logistics

EPA acknowledges that reverse distribution and reverse logistics processes share common elements in terms of the role each plays in the management of pharmaceuticals. However, based on the comments received on the proposal, especially those summarized above, the Agency recognizes that there is a key distinction between how prescription pharmaceuticals and nonprescription pharmaceuticals (see definition of pharmaceutical in § 266.500) are managed in the reverse supply chain. The key distinction is that there is not a reasonable expectation of legitimate use/reuse (*e.g.,* lawful redistribution for its intended purpose) or reclamation for prescription pharmaceuticals, except in very limited circumstances, but there is for other retail items, including nonprescription pharmaceuticals.

Prescription pharmaceuticals shipped from healthcare facilities to reverse distributors for the evaluation of manufacturer credit are almost always discarded. EPA is aware that prescription pharmaceuticals are sometimes lawfully donated, in which case the pharmaceuticals would not be

[60] For example, see comment number EPA–HQ–RCRA–2007–0932–0377.

[61] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket.

[62] See comment number EPA–HQ–RCRA–2007–0932–0312 in the docket.

[63] Ibid.

[64] See comment number EPA–HQ–RCRA–2007–0932–0340 in the docket.

[65] EPA uses the term ''unsold retail items'' to refer to excess inventory, such as expired or outdated items, seasonal items, overstock, recalled products, and returned items that cannot be returned to stock/inventory. Walmart and other commenters from the retail industry use the term ''consumer goods'' to refer to similar items.

[66] EPA has not distinguished among the terms ''supplier'' and ''vendor'' verses ''manufacturer'' and the terms are used interchangeably throughout the preamble. The Agency more frequently used the term ''manufacturer'' while retail industry commenters more frequently used the term ''vendor.''

[67] EPA did not receive data on the ultimate disposition of consumer products returned to the vendor. EPA further discusses our policy on unsold retail items that are returned to the vendor in section ''e.) Nonprescription Pharmaceuticals and Other Retail Items Going through Reverse Logistics Are Not Wastes.''

[68] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket.

[69] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket.

[70] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket.

a solid waste.[71] In the case of nonprescription pharmaceuticals and other unsold retail items that are sent to a reverse logistics center, there is often a reasonable expectation that they will be legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

EPA recognizes that the awarding of credit for unsold pharmaceuticals is a critical element of both the reverse distribution and reverse logistics processes as it provides a healthcare facility financial incentive to not only stock a particular pharmaceutical but also to defray costs associated with transporting a pharmaceutical to a reverse distributor or reverse logistics center. However, it is EPA's position that the inherent monetary ''value'' conferred on any pharmaceutical due to the potential to receive manufacturer credit is not a proper indicator of waste status. Rather, the decision to discard is determinative of when an unsold product becomes a solid waste. Under EPA's final rule and preamble, if a nonprescription pharmaceutical or other retail item becomes unsalable at a retail store it can continue to be considered a product until a reverse logistics center or other subsequent entity makes the decision to discard it, as long as there is a reasonable expectation of it being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed.

4. Prescription Pharmaceuticals Going Through Reverse Distribution Are Wastes at the Healthcare Facility

In the case of prescription pharmaceuticals, EPA maintains its position, as stated in the proposed rulemaking preamble and reflected in the regulatory text, that prescription pharmaceuticals moving through reverse distribution are solid wastes starting at the healthcare facility. This includes prescription pharmaceuticals that, as potentially creditable hazardous waste pharmaceuticals, are sent from a retail facility or healthcare facility to a reverse distributor for manufacturer credit evaluation (see definition of potentially creditable hazardous waste pharmaceutical in § 266.500). Although the potential exists for a manufacturer to issue credit for a prescription pharmaceutical, the ''decision point'' on when a pharmaceutical is a solid waste is when the decision has been made to discard the item. That is, a pharmaceutical is a solid waste when the decision has been made to discard regardless of whether the pharmaceutical has value. Although prescription pharmaceuticals are evaluated for, and in many cases ultimately receive, manufacturer credit, it remains apparent to EPA that these pharmaceuticals will seldom, if ever, be legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed after they are sent to a reverse distributor. Thus, a decision to send prescription pharmaceuticals to a reverse distributor is a decision to discard the material. None of the comments on the proposed rule alter EPA's position regarding the likelihood of redistribution or reclamation of prescription pharmaceuticals being managed through reverse distribution. Rather, EPA received many comments that agreed with EPA's proposed interpretation that the decision to send a pharmaceutical to a reverse distributor is a decision to discard as it pertains to prescription pharmaceuticals because there are limited opportunities to legitimately use/reuse or reclaim prescription pharmaceuticals. In circumstances when prescription pharmaceuticals are lawfully donated for their intended purpose, they would not be considered a solid waste and we have specifically noted this in the regulations (see § 266.501(g)(1) and the definition of hazardous waste pharmaceutical in § 266.500).

Many of the broad comments in support of the proposed reinterpretation provided examples but did not distinguish between prescription pharmaceuticals and nonprescription pharmaceuticals. For example, multiple commenters argued that pharmaceuticals transported to a reverse distributor are rarely redistributed or reclaimed, and are usually destroyed, but did not explain if this applied only to prescription pharmaceuticals. One commenter observed that many manufacturers contract with reverse distributors to dispose of unsold pharmaceuticals after review for credit eligibility is complete, suggesting that use/reuse or reclamation does not generally occur. This commenter was only aware of one instance of potential reuse of a pharmaceutical after being sent through reverse distribution.[72] That being said, based on what EPA has learned from retail industry commenters, site visits, and discussions with retailers about prescription pharmaceuticals verses nonprescription pharmaceuticals, EPA can infer that these comments likely refer to the reverse distribution of prescription pharmaceuticals.[73] EPA's inference is supported by other comments received on the proposal. For example, Walmart argued that the comments EPA received on the 2008 Pharmaceutical Universal Waste proposal (where pharmaceuticals were defined only as prescription pharmaceuticals) and the 2014 Retail Notice of Data Availability that pharmaceuticals going through reverse distribution are ultimately discarded were likely talking about prescription pharmaceuticals.[74]

In conclusion, a material is considered a solid waste if it is accumulated or stored before or in lieu of being disposed of, burned, or incinerated (§ 261.2(b)(3)). Even if the healthcare facility intends to receive credit for the prescription pharmaceutical and the reverse distributor intends to evaluate the prescription pharmaceutical for credit, the pharmaceutical is still considered a discarded material (§ 261.2(a)(2)(i)) because it is being accumulated and stored prior to being sent for treatment (rather than being accumulated or stored prior to being used/reused or reclaimed). Although the healthcare facility or reverse distributor intends to elicit credit from the prescription pharmaceutical in the interim period before it is sent for treatment, the pharmaceutical is still considered a discarded material. An intent to receive credit does not preclude the pharmaceuticals from being discarded; they are not mutually exclusive.

Although EPA maintains its position that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility, this final rule establishes streamlined, practical standards for managing potentially creditable hazardous waste pharmaceuticals that will reduce regulatory burden on retailers and align with the existing practices of the retail sector. Thus, EPA's position that prescription pharmaceuticals moving

[71] EPA is aware of one non-profit organization that facilitates donations of prescription pharmaceuticals. See comment from SIRUM in the docket (EPA–HQ–RCRA–2007–0932–0353). EPA is also aware of multiple states, including Iowa, Wyoming, and Oklahoma, that run prescription pharmaceutical return and reuse programs. For more information, see ''State Prescription Drug Return, Reuse and Recycling Laws'' at *http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx.*

[72] The example cited was an unconfirmed claim that a rodent poison manufacturer could use discarded pharmaceutical warfarin tablets as feedstock in its process. See comment number EPA–HQ–RCRA–2007–0932–0358 in the docket.

[73] See docket number EPA–HQ–RCRA–2007–0932 for reverse distributor responses to EPA's questions about reverse distribution of pharmaceuticals, notes from Agency meetings with retail industry representatives, and notes from site visits to reverse distribution facilities.

[74] See comment number EPA–HQ-RCRA-2007-0932-0340 in the docket.

through reverse distribution are solid wastes at the healthcare facility only subjects these hazardous waste pharmaceuticals to the streamlined part 266 subpart P standards versus the full RCRA Subtitle C regulations. For example, EPA does not require healthcare facilities to use a hazardous waste manifest or a hazardous waste transporter when shipping potentially creditable hazardous waste pharmaceutical to a reverse distributor. See section XVI.D for a discussion of the shipping standards for potentially creditable hazardous waste pharmaceuticals.

Because the point of generation of potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, EPA can impose the RCRA Subtitle C cradle-to-grave management of hazardous wastes. Specifically, it allows us to impose consistent and enforceable tracking of hazardous waste pharmaceuticals from healthcare facilities en route to reverse distributors. Lack of tracking was identified as a regulatory gap by many commenters on our 2008 proposal to add pharmaceuticals to the Universal Waste program. The tracking provides the benefit of reducing the risk of diversion of these unused hazardous waste pharmaceuticals onto the black market, thus fulfilling our statutory mandate of protecting human health.

5. Nonprescription Pharmaceuticals and Other Retail Items Going Through Reverse Logistics Are Not Wastes if They Have a Reasonable Expectation of Being Legitimately Used/Reused or Reclaimed

Although EPA includes nonprescription pharmaceuticals in the definition of ''pharmaceutical'' under the final rule, the Agency makes it clear in the definition of ''hazardous waste pharmaceutical'' that nonprescription pharmaceuticals are not solid wastes, and therefore not hazardous waste pharmaceuticals, if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. The applicability of the final rule also has a new provision in § 266.501(g)(2) making it clear that a nonprescription pharmaceutical that is not a solid waste because it has a reasonable expectation of being legitimately used/reused or reclaimed is not subject to parts 260–273. Additionally, the final definition of reverse distributor has been revised so that it applies only to the reverse distribution of prescription pharmaceuticals.

In the final rule, EPA is reaffirming the Agency's previous policies on redistribution expressed in memos in 1981 and 1991 with respect to nonprescription pharmaceuticals and other retail items that have become unsalable at the retail store and are being managed by a reverse logistics center through the reverse logistics process. That is, EPA is maintaining a policy that nonprescription pharmaceuticals and other retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. EPA recognizes that reverse logistics centers are designed to evaluate unsold retail items, analyze secondary markets, and assess the suitability of the unsold retail items for reuse in those secondary markets. These services promote the donation, liquidation, and reuse of unsold retail items and reduce overall waste. Importantly, these activities are distinct from the activities of reverse distributors of prescription pharmaceuticals. Reverse distributors of prescription pharmaceuticals are not designed to evaluate unsold prescription pharmaceuticals and assess the suitability of the prescription pharmaceuticals for reuse in secondary markets. As mentioned previously, commenters pointed out that the purpose of reverse distribution of prescription pharmaceuticals is to determinate creditworthiness while the primary purpose of reverse logistics of nonprescription pharmaceuticals is to aggregate and redirect viable products into another supply chain.

Although EPA is reaffirming this policy, EPA remains concerned about the potential for overuse of reverse logistics centers, a concern we originally raised in a 1991 memo related to reverse distribution: ''a reverse distribution system cannot be used as a waste management service to customers/generators without the applicable regulatory controls on waste management being in place . . . to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered as wastes until a determination has been made to discard them.'' [75] To reiterate, in order to avoid being considered solid waste, items, including nonprescription pharmaceuticals, sent through reverse logistics, must have some reasonable expectation of being legitimately used/reused or reclaimed. The 199l guidance allowing pharmaceuticals to go through reverse distribution without being considered solid waste was based on the notion that they had the potential for recycling by use/reuse. Over the years, however, many have come to disregard the intent behind this guidance and erroneously believed that it was a blanket statement that pharmaceuticals going through reverse distribution were not solid wastes, even if they did not have a reasonable expectation of being redistributed or recycled. We strongly encourage the use of reverse logistics centers to facilitate redistribution and legitimate recycling to the fullest extent possible, and thus, reduce the amount of waste being generated. But we also caution reverse logistic centers not to become *de facto* waste management facilities for their customers. If this were to occur, it could be the case that the decision to discard for nonprescription pharmaceuticals and other retail items would have occurred at the retail store or healthcare facility.

Of course, once a reverse logistics center makes a decision to discard an item, it becomes a solid waste and, if it is listed or exhibits a characteristic, a hazardous waste. The reverse logistics center is subject to the applicable RCRA regulations, such as part 262, for the generation and accumulation of hazardous waste, including hazardous waste pharmaceuticals, but not part 266 subpart P.

EPA notes that although nonprescription pharmaceuticals and other retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused or reclaimed, the items must be shipped in accordance will all applicable Department of Transportation (DOT) regulations. For example, DOT promulgated a final rule in March 2016 on the reverse logistics of hazardous materials. This rule includes provisions to help ensure that items, including consumer grade fireworks, are in original packaging when shipped from a retail store to a manufacturer, supplier, or distribution facility.[76]

There are six issues that came to EPA's attention when shaping this final reverse logistics policy. The first issue regards the ultimate disposition of unsold retail items moving through reverse logistics. The second issue regards unsold retail items that have expired. The third issue involves instances when retail items cannot be

[75] See memo dated May 16, 1991, From Lowrance to Schulz, RCRA Online #11606.

[76] See 81 FR 18527; March 31, 2016.

legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) because the items are subject to a ''destroy disposition.'' The fourth issue regards the crediting process for unsold retail items. The fifth issue involves instances when nonprescription pharmaceuticals and other unsold retail items become subject to a voluntary, federally mandated, or state mandated recall. The final issue involves instances when nonprescription pharmaceuticals and other unsold retail items cannot be sent through reverse logistics because they are broken, damaged, or leaking.

a. *Unsold retail items returned to the manufacturer or vendor.* The first issue regards the ultimate disposition of unsold retail items moving through reverse logistics. As noted previously, data from commenters suggests a majority of unsold retail items moving through reverse logistics are returned to the manufacturer or vendor.[77] EPA did not receive data on the ultimate disposition of retail items that are returned to a manufacturer or vendor from a reverse logistics center. For this final action, EPA assumes the items are not wastes if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. However, if nonprescription pharmaceuticals or other retail items do not have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed after they are returned to a manufacturer or vendor, then the nonprescription pharmaceutical or other unsold retail item would be a solid and potentially hazardous waste at the reverse logistics center.

b. *Unsold retail items that have expired.* The second issue regards unsold retail items that have expired.[78] As mentioned previously, commenters noted that when an item is sent to a reverse logistics center because an expiration date has been exceeded, disposal is most often the required disposition, however the items may be returned to the manufacturer for further evaluation for potential liquidation.[79] Furthermore, nonprescription pharmaceuticals with ''best by'' dates (as opposed to expiration dates) often can still be donated or liquidated after the date has passed. In addition to information received from commenters suggesting that expired products might be considered eligible for redistribution, FDA occasionally allows the donation of drugs that are past the expiration date shown on the label when provided sufficient information to show the expired pharmaceuticals are safe and effective and other specific criteria have been met.[80] Thus, for this final action, EPA assumes that nonprescription pharmaceuticals and other unsold retail items that have expired are not wastes if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. These items are in their original, intact packaging and do not pose a high risk of release to the environment. Further, this position is consistent with the goal of the RCRA statute to reduce waste, as EPA is concerned that considering unsold retail items that have expired to be wastes at the retail store could introduce an unintended incentive for retailers to remove those items from shelves in advance of expiration dates, resulting in an unnecessary increase in overall waste generation.

c. *Unsold retail items subject to a destroy disposition.* The third issue involves instances when retail items cannot be legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) because the items are subject to a ''destroy disposition.'' A destroy disposition is when a manufacturer has established ''business rules'' that prohibit unsold retail items from being redistributed for their intended purpose (*i.e.,* liquidated or donated). The term ''business rules'' (*i.e.,* manufacturer return policies) refers to the rules that govern the disposition of retail items agreed to by the manufacturer, retailer, and reverse distributor or reverse logistics center.[81] The Agency's understanding is that manufacturers adopt destroy dispositions over concerns related to liability and brand protection and that assigning a destroy disposition is not a common practice because it precludes income from potential redistribution and results in disposal costs.[82] For this final action, if a manufacturer has established business rules that prohibit unsold retail items from being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) because the items are subject to a ''destroy disposition,'' *and* that prohibit the unsold retail items from being reclaimed, the items are considered solid waste at the retail store or healthcare facility. However, if a manufacturer has established business rules that do not imply that disposal is the ultimate disposition for unsold retail items, and there is a reasonable expectation the items will be reclaimed, these items would not be solid wastes at the retail store when they are sent through reverse logistics. Thus, a manufacturer can adopt business rules that prohibit the lawful redistribution of retail items for their intended purpose (*i.e.,* liquidation or donation), but allow for the items to be sent through reverse logistics for reclamation. These items would not be wastes at the retail store if there is a reasonable expectation the items will be reclaimed.

d. *Crediting process for unsold retail items.* The fourth issue regards the crediting process for unsold retail items. It is the Agency's understanding that there are two primary credit models. The first is the ''traditional approach'' whereby credit is awarded after unsold retail items are returned to a reverse logistics center for processing. The second is the adjustable rate policy, which is also commonly referred to as a ''swell allowance,'' whereby credit is awarded up-front based on an assumption that a certain percentage of items will become unsalable for various reasons at the primary retailer.[83] EPA's understanding is that one of the goals of the adjustable rate policy is to reduce the amount of unsold items sent through to reverse logistics centers and to encourage sale at the primary retailer—even if this means discounting those items. EPA's understanding is that under such an approach, retailers are responsible for managing unsold retail items and determining the ultimate disposition since the manufacturer is not involved in the disposition decision. That being said, retailers can utilize reverse logistics to assist in the management and disposition of unsold retail items sold under an adjustable rate policy. More importantly, under EPA's final policy, although the

[77] See comment number EPA–HQ–RCRA–2007–0932–0340 in the docket.

[78] EPA uses the term ''expired'' consistent with Food and Drug Administration regulations. See 21 CFR part 201.66, part 201.17, and 211.137.

[79] See comment number EPA-HQ-RCRA-2007-0932-0377 in the docket.

[80] See U.S. Food and Drug Administration ''Question and Answers for the Public: Donating Drugs to International Humanitarian Relief Efforts'' available at: *https://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM249617.pdf.*

[81] This definition is derived from the definition of ''business rules'' in the ''Surplus Household Consumer Products and Wastes: Report to the Legislature.'' Available at: *http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

[82] See discussion of ''destroy dispositions'' in the ''Surplus Household Consumer Products and Wastes: Report to the Legislature.'' Available at: *http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

[83] Additional information on the Adjustable Rate Policy and other reimbursement policies for unsalable items can be found in the publication entitled, 2008 Joint Industry Unsaleables Management Study: The Real Causes and Actionable Solutions. This publication is available at *http://www.gmaonline.org/downloads/research-and-reports/UnsaleablesFINAL091108.pdf.*

potential exists for a manufacturer to issue credit for an unsold retail item, the ''decision point'' on whether a retail item is a solid waste is when the decision has been made to discard the material. In other words, a pharmaceutical is a solid waste when the decision has been made to discard regardless of whether the pharmaceutical has value. Thus, for this final action, the credit model is not relevant to the waste status of unsold retail items. EPA assumes that nonprescription pharmaceuticals and other unsold retail items that receive credit up-front through an adjustable rate policy are not wastes if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

e. *Unsold retail items subject to a recall.* The fifth issue involves instances when nonprescription pharmaceuticals and other unsold retail items become subject to a voluntary, federally mandated, or state mandated recall. Almost all pharmaceutical recalls are overseen by FDA. However, under the Poison Prevention Packaging Act, the U.S. Consumer Product Safety Commission (CPSC) has authority regarding special packaging (sometimes called child resistant packaging) of certain household products, including drugs (as that term is defined in the Federal Food, Drug, and Cosmetic Act).[84] Similarly, under the child Nicotine Poisoning Prevention Act of 2015, CPSC has authority for administering special packaging requirements for liquid nicotine containers.[85] Thus, CPSC oversees a recall if there is a problem with a pharmaceutical's special packaging or containers for liquid nicotine. Additionally, CPSC has jurisdiction over recalls of many other consumer products sold at retail stores.[86] EPA is choosing not to apply RCRA regulations to nonprescription pharmaceuticals and other unsold retail items while they are subject to a recall, provided the recall is regulated and overseen by FDA or CPSC. This is true whether they become subject to a recall at a reverse logistics center, healthcare facility, or retail store. It is possible that recalled nonprescription pharmaceuticals and other unsold retail items are not a solid waste if they are legitimately used/reused or reclaimed. For example, if CPSC oversees a recall if there is a problem with a pharmaceutical's packaging (*e.g.,* an item's packaging poses a threat because it is not sufficiently child resistant), it is possible the pharmaceutical could still be sent for reclamation. Although it is difficult for EPA to make a blanket determination on whether all recalled nonprescription pharmaceuticals and other unsold retail items are or are not solid wastes, EPA is choosing not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items provided the recall is overseen by FDA or CPSC. When FDA directs the destruction of some or all of the recalled retail items, or CPSC grants permission to dispose or destroy some or all of the recalled items, the materials that are hazardous waste must be managed in accordance with RCRA, including the hazardous waste generator regulations standards in 40 CFR part 262.

Although FDA and CPSC are the federal agencies that primarily regulate recalled nonprescription pharmaceuticals and other unsold retail items, other federal agencies regulate some recalled retail items. For example, the National Highway Traffic Safety Administration oversees motor vehicle defects and safety recalls. Although other federal agencies may occasionally regulate recalled retail items, EPA is only choosing not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items when the recall is overseen by FDA or CPSC. CPSC requires manufacturers to develop a recall strategy that outlines all of the actions to be taken on behalf of the manufacturer from start to finish. FDA requires firms that initiate a recall to develop a recall strategy and recommends that firms that initiate a FDA-requested recall develop a recall strategy.[87] Included as a required component of a comprehensive recall strategy is a requirement that FDA or CPSC approves a manufacturer's decision to take the action to discard some or all of the recalled items. Thus, EPA believes it is reasonable not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items when the recall is overseen by FDA or CPSC. However, the Agency will continue to evaluate recalled nonprescription pharmaceuticals and other unsold retail items managed by other federal agencies on a case-by-case basis. As an example, see the memo that EPA released in 2017 that describes how RCRA regulations apply to recalled Takata airbag inflators while they are being held under the 2015 DOT preservation order.[88] EPA's policy does not apply to unused pesticides that are suspended or canceled under the Federal Insecticide, Fungicide, and Rodenticide Act and recalled, as these can be managed as universal waste under 40 CFR part 273. Finally, while EPA is not applying RCRA regulations in these situations, we note that if recalled nonprescription pharmaceuticals and other unsold retail items are not managed and stored in a manner that prevents release to the environment, they may be considered a solid waste and a hazardous waste under sections 3007, 3013, and 7003 of RCRA.

f. *Unsold retail items that are broken, damaged, or leaking.* The sixth issue involves instances when nonprescription pharmaceuticals and other unsold retail items cannot be sent through reverse logistics because they are broken, damaged, or leaking. In recent years, EPA took multiple enforcement actions against national retailers for sending hazardous waste, in the form of broken and/or leaking items with hazardous contents, to unpermitted TSDFs (in the form of reverse distributors and reverse logistics centers), among other RCRA violations.[89] The resulting settlements specify that unsold retail items with broken and/or leaking packaging are waste at the retailer and, if they are hazardous, cannot be sent to a reverse distributor or reverse logistics center. CVS commented on the proposed rulemaking and asked that EPA clarify that when pharmaceutical packaging is in sufficiently poor condition that it is broken, leaking, or otherwise unable to be used for its intended purpose, that those pharmaceuticals become solid waste at the healthcare facility.[90] CVS noted that this is consistent with their current practice, whereby broken and leaking items are managed as waste at their facilities and are not sent through reverse distribution or reverse logistics.

Although EPA affirms the resulting settlements and agrees that nonprescription pharmaceuticals and other retail items cannot be sent through reverse logistics when they are broken, damaged, or leaking, the Agency is aware that there is inherent uncertainty

[84] See 15 U.S.C. 1471–1477 for the Poison Prevention Packaging Act.

[85] Public Law 114–116 (January 28, 2016).

[86] The CPSC has jurisdiction over more than 15,000 kinds of consumer products used in and around the home, in sports, recreation and schools. See *https://www.recalls.gov/cpsc.html* for more information.

[87] See 21 CFR 7.46(a)(8) and 21 CFR 7.45(b), respectively.

[88] See RCRA Online #14893 for the June 23, 2017 memo titled ''Recalled Takata Airbag Inflators.''

[89] Walmart Consent Agreement and Final Order, Docket Nos. RCRA–HQ–2013–4001 and FIFRA–HQ–2013–5056.

[90] See comment number EPA–HQ–RCRA–2007–0932–0312 in the docket.

surrounding when these items are considered broken, damaged, or leaking. For example, a nonprescription pharmaceutical could experience damage to the outer packaging while the inner container remains intact. For this final action, unsold retail items, including nonprescription pharmaceuticals, are not considered waste at the retail store if their packaging is in good condition, with no leaks or other continuing or intermittent unpermitted releases of the materials to the environment,[91] and they are contained to prevent releases to the environment,[92] and they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. Thus, the Agency intends that nonprescription pharmaceuticals and other unsold retail items can be sent to a reverse logistics center and are not considered wastes at the retail store if they meet this standard. For example, if an outer cardboard box containing vials of nonprescription pharmaceuticals is damaged, but the vials are intact and not damaged or leaking, EPA does not consider the item to be damaged such that it cannot go through reverse logistics.

In order to prevent exposures to personnel, the public, and the environment, if items are not in good condition, or are leaking or releasing to the environment, these items must be managed as wastes at the stores in accordance with the applicable hazardous waste regulations. Specifically, if the broken, damaged, or leaking item is a hazardous waste pharmaceutical, the retail store must manage it under the streamlined standards of part 266 subpart P (unless it is a VSQG for all its hazardous waste). Otherwise, the retail store would manage hazardous wastes under the applicable RCRA regulations, including part 262 generator regulations.

E. Applicability of the Household Hazardous Waste Exemption to Retail Items

One commenter suggested that the ''household hazardous waste'' exclusion at 40 CFR 261.4(b)(1) apply to retail items purchased by a customer and subsequently returned to the retailer.[93] The Agency has already addressed the issue of retail wastes as part of a previous rulemaking that responded to a petition from the American Retail Federation. As explained in a November 13, 1984, final rule[94], EPA excluded household hazardous waste because the legislative history of RCRA indicated an intent to exclude such wastes and not because these wastes can never pose the risks associated with hazardous wastes. Additionally, consistent with legislative history, when evaluating the American Retail Federation's petition, EPA determined that it was necessary to establish two criteria that must be met to qualify for this exclusion. First, the waste must be generated by individuals on the premises of a temporary or permanent residence and, second, the waste stream must be composed primarily of materials found in wastes generated by consumers in their homes. In this final rule, EPA denied the American Retail Federation's petition to exempt consumer household hazardous waste generated by retail sources because these wastes fail to meet both criteria. The Agency reaffirmed this position in the Retail Strategy, arguing that retail goods, including those that could become wastes when discarded, do not satisfy the criteria for this exclusion.

The Agency believes that this interpretation extends to retail items purchased by a customer and subsequently returned to a retail store. Hazardous waste generated at retail stores, including retail items purchased by a customer that are subsequently returned, does not meet the first criterion for the household hazardous waste exemption. Specifically, the decision to discard does not occur at the residence, it occurs at the retail store. In fact, many retail items that are returned are restocked and sold at the store (*e.g.* lawfully redistributed for their intended purpose) and are not solid wastes.

On the other hand, the Agency notes that a household pharmaceutical that is collected from individuals by a healthcare facility (*e.g.,* retail store) as part of a DEA pharmaceutical take-back program maintains the household hazardous waste exemption as long as it is not sewered, and is destroyed by a method that DEA has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the types of combustors identified in § 266.506(b). For more discussion on DEA take-backs of household pharmaceuticals, please see section XIV of this preamble.

VII. Scope of the Final Rule

A. What facilities are subject to the final rule?

This final rule is a sector-based rule that applies to the management of hazardous waste pharmaceuticals that are generated and managed by healthcare facilities and reverse distributors. Subsequent sections of the preamble will discuss in detail the definitions of these terms, as well as what provisions of the rule apply to each type of facility (see section VIII for a discussion of each definition and section IX for Applicability). Healthcare facilities and reverse distributors will use the regulations finalized under 40 CFR part 266 subpart P in lieu of the RCRA generator regulations in 40 CFR part 262 to which they were previously subject.

B. What facilities are not subject to the final rule?

1. Pharmaceutical Manufacturers

Part 266 subpart P does not apply to the management of hazardous waste pharmaceuticals that are generated by pharmaceutical manufacturers. A pharmaceutical manufacturer remains subject to part 262 and all applicable RCRA subtitle C regulations for the management of its hazardous waste, including its hazardous waste pharmaceuticals. Pharmaceutical manufacturers do not face the same challenges that healthcare facilities experience when managing hazardous waste pharmaceuticals in accordance with the federal RCRA subtitle C regulations (for an explanation of the challenges healthcare facilities face, see discussion in section III of the preamble). The types of hazardous waste pharmaceuticals generated by manufacturers are less variable and therefore more predictable, and the staff have the necessary expertise to determine which pharmaceutical waste is hazardous waste. However, when any facility, including a pharmaceutical manufacturer, meets the definition found in this proposal for a reverse distributor, it would be subject to the final regulations for reverse distributors with respect to those operations.

2. Households

The Agency emphasizes that the regulatory requirements in this final rule do not apply to households that discard pharmaceuticals. Pharmaceuticals that are discarded by households are not regulated as hazardous waste and are generally considered municipal solid waste. While a small percentage of these

[91] As defined in § 260.10, unpermitted releases are releases that are not covered by a permit (such as a permit to discharge to water or air) and may include, but are not limited to, releases through surface transport by precipitation runoff, releases to soil and groundwater, wind-blown dust, fugitive air emissions, and catastrophic unit failures.

[92] These conditions are derived from the definition of contained as defined in § 260.10.

[93] See comment number EPA–HQ–RCRA–2007–0932–0277 in the docket for this rulemaking.

[94] See 49 FR 44978; November 13, 1984.

household waste pharmaceuticals meet the definition of hazardous waste under RCRA, the federal RCRA hazardous waste regulations include an exclusion for all hazardous wastes generated by households.[95] Thus household hazardous waste pharmaceuticals—like other household hazardous wastes—are not subject to the federal RCRA hazardous waste regulations.

Despite the fact that household hazardous wastes are not regulated as hazardous wastes, it is important to note that ''EPA excluded household wastes because the legislative history of RCRA indicated an intent to exclude such wastes, though *not* because they necessarily pose no hazard.'' [96] Some household products, including pharmaceuticals, contain ignitable, corrosive, reactive, or toxic ingredients. As a result, for household hazardous waste collected at a household hazardous waste collection program, the Agency has historically recommended that communities operating the collection programs manage the collected household hazardous waste as hazardous waste, even though it is not required by RCRA.[97]

Similarly, the Agency recommends that, whenever possible, households utilize pharmaceutical collection events as the preferred disposal option for their unwanted pharmaceuticals.[98] For consumers without access to a pharmaceutical take-back event, FDA provides information on the disposal of unused pharmaceuticals and step-by-step guidance for disposing of pharmaceuticals in the household trash.[99]

In a 2012 memo, the Agency recommended that collected household waste pharmaceuticals be incinerated—preferably at a permitted hazardous waste incinerator, but when that is not feasible, at a large or small municipal waste combustor.[100] The Agency believes that this practice is already common among collection programs since one goal of many collection programs is to divert pharmaceuticals from municipal landfills. Additionally, incineration is commonly used to meet the non-retrievable standard of destruction required by DEA for controlled substances collected from consumers (''ultimate users,'' as DEA refers to them). The Agency included this recommendation as a requirement for household waste pharmaceuticals that have been collected (see § 266.506).[101] See section XIV of this preamble for a detailed discussion of this provision.

3. Farmers, Ranchers and Fisheries

This final rule is a sector-specific rulemaking that applies to healthcare facilities and reverse distributors. As such, this final rule does not apply other generators of hazardous waste pharmaceuticals such as farmers, ranchers, and fisheries. Although these businesses might administer pharmaceuticals to their animals in the regular course of their business, they would not fall within the definition of a healthcare facility or a reverse distributor. The Agency designed this final rule to address the unique needs of the healthcare sector and concluded that it would not be appropriate to apply it to all sectors that generate hazardous waste pharmaceuticals. Other generators of hazardous waste pharmaceuticals, such as farmers, ranchers and fisheries, remain subject to the part 262 generator regulations. As discussed in detail in section VIII of this preamble, the definition of healthcare facility does include veterinary clinics and veterinary hospitals.

4. RCRA-Permitted or Interim Status Treatment, Storage and Disposal Facilities

This final rule does not affect how RCRA-permitted or interim status TSDFs manage hazardous waste pharmaceuticals at their facilities, except indirectly when they treat hazardous waste pharmaceuticals to meet the land disposal restrictions (LDRs). See section X.H. of this preamble for additional detail.

C. Scope of Hazardous Wastes Addressed by This Final Rule

1. Hazardous Waste Pharmaceuticals

These final regulations pertain only to those pharmaceutical wastes that are RCRA hazardous wastes that are generated by healthcare facilities or managed by reverse distributors. Under this rulemaking, EPA has not added additional pharmaceuticals to the hazardous waste listings or expanded the hazardous waste characteristics to include additional pharmaceuticals. Although we solicited ideas from commenters for possible methods or approaches for regulating additional pharmaceuticals as hazardous waste, any action taken to address the comments we received in response to this request would be a separate action taken by the Agency in the future and is not part of this final rulemaking.

2. Related Federal or State Regulations

The generation, accumulation, transportation, treatment, storage, and disposal of hazardous waste pharmaceuticals are regulated under RCRA Subtitle C. However, hazardous waste pharmaceuticals may also be subject to a number of other statutes and implementing regulations administered by state or other federal agencies. Examples include pharmaceuticals that are subject to the Controlled Substances Act and DEA regulations; infectious pharmaceutical wastes that are subject to state and local medical waste regulations; pharmaceuticals with a radioactive component that are subject to the Atomic Energy Act (AEA) and pharmaceuticals that are hazardous waste as defined in 40 CFR 261.3 that are subject to OSHA's Hazardous Waste Operations and Emergency Response standard. These potentially overlapping requirements make the appropriate management of pharmaceutical wastes a complex matter. The following discusses the impact of this final rule on various dually regulated hazardous waste pharmaceuticals.

a. *Controlled substances.* Under prior regulations, any healthcare facility generating or managing a RCRA hazardous waste pharmaceutical that is also a DEA controlled substance listed in Schedule II–V[102] had to comply with the RCRA hazardous waste requirements, as well as the requirements of the Controlled Substances Act and DEA regulations. DEA regulations from 2014 to implement the Secure and Responsible Drug Disposal Act of 2010 require that

[95] See the household waste exclusion at § 261.4(b)(1), which is often referred to as the household hazardous waste or HHW exclusion.

[96] See 49 FR 44978; November 13, 1984.

[97] See memo November 1, 1988, from Porter to Regions (RCRA Online #11377).

[98] For pharmaceuticals, these collection events are often referred to as pharmaceutical take-back events. As used in this preamble, a take-back event refers to one-day collection events, such as the DEA bi-annual pharmaceutical take back days, while a take-back program refers to an ongoing collection program, such as a DEA-approved collection receptacle at a retail store.

[99] For more information on the safe disposal of household waste pharmaceuticals, please see: *http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm.*

[100] See memo September 26, 2012, Rudzinski to the Regional RCRA Division Directors (RCRA Online# 14833).

[101] Since pharmaceutical collection programs typically commingle DEA controlled substances with non-controlled substances, this requirement is included in a section of the regulations that pertains to controlled substances.

[102] See 21 CFR part 1308 for a complete list of controlled substances.

controlled substances be destroyed so that they are ''non-retrievable.''[103] In the preamble to both the proposed and final DEA rules, DEA stated that flushing alone will not meet DEA's new non-retrievable standard.[104] Due to difficulties associated with managing these hazardous waste pharmaceuticals that are also controlled substances, the Agency is finalizing a conditional exemption from the RCRA regulatory requirements for the handful of pharmaceuticals that are both a RCRA hazardous waste and a DEA controlled substance. That is, this final rule eliminates the dual regulation for RCRA hazardous waste pharmaceuticals that are also DEA controlled substances. A more detailed discussion of this conditional exemption is found in section XIV of this final rule.

b. *Medical wastes.* There are instances when a hazardous waste pharmaceutical will also pose a biological hazard. The healthcare industry often refers to pharmaceutical wastes that are both RCRA hazardous and a biological hazard as ''dual wastes,'' and such wastes must be managed in accordance with RCRA and state and/or local medical waste regulations. As a result, the healthcare facility must send these dual wastes to a hazardous waste TSDF that is also permitted by their state to accept medical wastes. Some examples of dual wastes include partially administered syringes containing hazardous waste pharmaceuticals (*e.g.,* physostigmine) or intravenous (IV) bags containing residues of a hazardous waste pharmaceutical that are attached to the tubing and needles used to administer the pharmaceutical. The RCRA hazardous waste pharmaceutical component of these dual wastes are included within these final subpart P management standards so that healthcare facilities can obtain the benefits of this new subpart, while ensuring the hazardous waste component of the waste is managed appropriately and ultimately delivered to RCRA-permitted TSDFs. Healthcare facilities must still manage the biological hazard in accordance with state and/or local medical waste requirements. EPA notes that autoclaving alone is not an acceptable method of treating hazardous wastes (pharmaceutical or non-pharmaceutical) that are also medical waste. In addition, as discussed in section XV of this preamble, EPA is exempting from RCRA regulation the residues of hazardous waste pharmaceuticals remaining in empty (*i.e.,* fully administered) syringes.

c. *Hazardous waste pharmaceuticals with a radioactive component.* Hazardous waste pharmaceuticals that also contain a radioactive component subject to the Atomic Energy Act of 1954 (AEA) (which are often referred to as ''mixed waste'') are also regulated by multiple agencies. The hazardous waste component is regulated under EPA or the authorized state RCRA Subtitle C programs, while either the Nuclear Regulatory Commission (NRC) or the Department of Energy (DOE) regulates the radioactive component of the waste under the AEA.[105] Healthcare facilities can use this final rule to meet the obligation of complying with the RCRA Subtitle C hazardous waste regulations for hazardous waste pharmaceuticals while also complying with the appropriate AEA regulations. Although we do not believe that anything in this subpart is inconsistent with the AEA, § 1006(a) of RCRA states that if the RCRA requirements are inconsistent with the AEA requirements, then the RCRA requirements do not apply. Therefore, if a healthcare facility that manages hazardous waste pharmaceuticals encounters specific RCRA requirements that are inconsistent with specific AEA requirements, only the AEA requirements would apply.

As is discussed in the Joint NRC/EPA Guidance on Testing Requirements for Mixed Radioactive and Hazardous Waste an inconsistency occurs when compliance with one statute or set of regulations would necessarily cause non-compliance with the other statute or set of regulations.[106] Relief from the regulatory inconsistency would be provided by the AEA requirement overriding the specific RCRA requirement. It is important to note, however, that the determination of an inconsistency would relieve the healthcare facility only from compliance with the specific RCRA requirement(s) that is deemed inconsistent with the AEA requirement(s); the healthcare facility would still be required to comply with all of the other hazardous waste pharmaceutical management standards.

d. *Clean Air Act.* The combustion of hazardous waste pharmaceuticals is subject to both RCRA and to § 112 of the Clean Air Act. In general, the Clean Air Act protects human health and the environment from the harmful effects of air pollution by requiring reductions in the emissions of air pollutants. These pollutants, which are known or suspected to cause serious health problems, such as cancer or birth defects, are referred to as hazardous air pollutants (HAPs) and include several metals that are found in pharmaceuticals, such as selenium, mercury, and chromium compounds. Under § 112 of the Clean Air Act, EPA is required to list categories of major and area sources of HAPs; EPA has listed Hazardous Waste Combustors as one of these categories.

EPA is also required to establish National Emission Standards for Hazardous Air Pollutants (NESHAPs) for the control of HAP emissions from listed sources. The NESHAPs are to reflect the maximum degree of reduction in emissions of HAPs that is achievable. This is known as ''maximum achievable control technology'' (MACT) and is based on emission levels that are achieved by the best-performing sources within a source category. On October 12, 2005, EPA promulgated NESHAP for Hazardous Waste Combustors that set MACT standards for HAPs from this source category.[107] The owner or operator of a hazardous waste combustor is required to comply with specific emission standards that control HAPs to levels that reflect MACT. These standards vary based on the type of hazardous waste combustion source (*e.g.,* incinerator, cement kiln, boiler), and in some instances based on the amount of HAPs that are emitted by the facility (*e.g.,* boilers that are area sources can elect to comply with fewer HAP emission standards). Generally speaking; however, hazardous waste combustors are required to comply with emission standards for chlorinated dioxins and furans, mercury, lead, cadmium, arsenic, beryllium, chromium, hydrochloric acid/chlorine gas, as well as particulate matter as a surrogate to control five additional metals, and carbon monoxide, hydrocarbon, and destruction removal efficiency as surrogates to control nondioxin/furan organic HAPs.

Hazardous waste combustors may be subject to more stringent emission limitations issued under the RCRA omnibus authority provisions (§ 3005(c)(3)). This is usually where site-specific circumstances indicate that a MACT standard is not protective of health and the environment. In other words, some hazardous waste combustors also have a RCRA permit

[103] Final rule: September 9, 2014; 79 FR 53520.

[104] Proposed rule: December 21, 2012; 77 FR 75784, see page 75803; and final rule: September 9, 2014; 79 FR 53520, see page 53548).

[105] The NRC regulates radioactive wastes generated by commercial or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

[106] 62 FR 62079, 62085; November 20, 1997.

[107] 70 FR 59402; October 12, 2005.

limit that further reduces emissions of certain HAPs (*e.g.,* mercury) beyond that which is required by the Clean Air Act MACT standard.

The combustion of pharmaceuticals that meet the definition of a RCRA solid waste but do not meet the definition of RCRA hazardous waste (*i.e.,* non-hazardous waste pharmaceuticals) is regulated by § 129 of the Clean Air Act and implementing regulations. These regulations established emission limits for nine substances or mixtures (*i.e.,* particulate matter, carbon monoxide, dioxins/furans, sulfur dioxide, nitrogen oxides, hydrogen chloride, lead, mercury, and cadmium, as well as opacity where appropriate) from several categories incineration units, including: municipal waste combustors (MWCs); hospital, medical and infectious waste incinerators (HMIWIs); commercial and industrial solid waste incinerators (CISWIs); and other solid waste incinerators (OSWIs). The emission limits are based on the application of MACT and reflect the emission levels achieved by the best performers in each category.

3. Drug Supply Chain Security Act

On November 27, 2013, the Drug Quality and Security Act was signed into law, amending the Federal Food, Drug and Cosmetic Act (FD&C Act).[108] The Drug Quality and Security Act consists of two titles: Title I is known as the Compounding Quality Act and Title II is known as the Drug Supply Chain Security Act (DSCSA). The FDA was given the responsibility of developing the implementing regulations for both titles of the Drug Quality and Security Act. In a summary of the DSCSA written by the Congressional Research Service, a nonpartisan division of the Library of Congress, it states that the Act ''Establishes requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain.'' [109] Prior to enactment of this federal law, several states had passed similar laws to ensure the pedigree of the drug supply chain. Because each state law was slightly different, it made compliance difficult for companies operating in multiple states. As a result, Congress amended the FD&C Act to add § 585, entitled Uniform National Policy, which moots the pedigree laws already in effect (to the extent they are inconsistent with the DSCSA) and prevents states (and others) from enacting inconsistent pedigree laws in the future. This section, which was added by the DSCSA, includes sub-sections that are sometimes referred to as ''preemption clauses.'' [110]

Since the DSCSA was signed into law, some have argued to EPA and RCRA-authorized states that § 585 of the FD&C Act (as amended by the DSCSA) preempts all state hazardous waste regulatory authority as it may relate to the documentation of the disposition of hazardous waste pharmaceuticals. EPA disagrees with this interpretation of the DSCSA. Section 585 specifically avoids preempting state requirements, such as RCRA hazardous waste laws, that are unrelated to the tracing of products within the prescription drug distribution supply chain and other issues expressly addressed by the DSCSA. As stated in § 585(c), ''Nothing in this section shall be construed to preempt State Requirements related to the distribution of prescription drugs *if such requirements are not related to product tracing* as described in subsection (a) or wholesale distributor and third-party logistics provider licensure as described in subsection (b) applicable under § 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter (or regulations issued thereunder)'' (emphasis added).

This provision makes clear that § 585 applies only to state requirements related to distribution of prescription drugs and only to the extent that these requirements are related to product tracing or other issues specifically addressed by the DSCSA, such as licensure. Thus, as EPA interprets § 585, it would not apply to state requirements related to documentation of RCRA hazardous waste management activities, including disposal, because those activities are distinct and unrelated to the product tracing and other requirements of the DSCSA.

And indeed, in EPA's consultation with FDA on this issue, FDA agreed with EPA's conclusion that § 585 does not preempt state hazardous waste regulations related to the documentation of the management of hazardous waste pharmaceuticals. EPA's position is based upon our review of both the direct language and intent of the statute.[111]

To understand the connection between state hazardous waste regulations and the DSCSA, it is important to understand the relationship between the federal and state hazardous waste regulations. The federal RCRA program is implemented by state RCRA programs that are authorized by EPA under RCRA section 3006, 42 U.S.C. 6926. Authorized state hazardous waste regulations must, at a minimum, be equivalent to federal RCRA hazardous waste regulations. Under RCRA, EPA authorizes state hazardous waste programs to operate in lieu of the federal hazardous waste program.[112] Authorized state requirements are federally enforceable as requirements under RCRA Subtitle C.

Nothing in the DSCSA indicates that Congress intended to impliedly repeal federal RCRA requirements. Such an implied repeal would leave gaps in RCRA coverage and result in no hazardous waste regulations of any kind—federal or state—applying to the documentation of the management of hazardous waste pharmaceuticals. Given that (i) there is no indication of Congressional intent to repeal hazardous waste documentation regulations via the DSCSA (indeed, there is no mention of hazardous waste in the DSCSA at all), and (ii) § 585(c) of the FD&C Act, as added by the DSCSA, expressly notes the limits of the statute's preemptive effect, we believe it is clear that Congress did not intend to impliedly repeal RCRA authorized state hazardous waste requirements as they apply to the documentation of the management, including disposal, of hazardous waste pharmaceuticals. The general rule enunciated by the U.S. Supreme Court is that ''when two [federal] statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.'' [113] Here, both RCRA and the DSCSA coexist easily, because neither the language nor the purpose of the DSCSA is in conflict with RCRA.

In addition, some commenters have argued that, in the case of nonsaleable pharmaceutical products, DSCSA requirements preempt RCRA requirements and that nonsaleable pharmaceutical products are regulated exclusively by the FDA pursuant to the provisions of the DSCSA.[114] Commenters have also argued that under the DSCSA, nonsaleable pharmaceutical products that are sent from wholesale distributors, dispensers, and repackagers as nonsaleable may be sent to a returns processor reverse

[108] Public Law 113–54.

[109] *https://www.congress.gov/bill/113th-congress/house-bill/3204/summary/49;* accessed September 13, 2017.

[110] See sections 585(a) and 585(b)(1) of the FD&C Act, as amended by the DSCSA.

[111] For a more thorough legal analysis of this issue, see EPA's letter to the Minnesota Pollution Control Agency, dated April 9, 2015, in the docket for this rulemaking EPA–HQ–RCRA–2007–0932. EPA consulted with FDA in the development of this letter and FDA agrees with the analysis and conclusions set forth in the letter.

[112] RCRA section 3006(b), 42 U.S.C. 6926(b).

[113] Morton v. Macari, 417 U.S. 535, 551(1974).

[114] The DSCSA uses the term ''drug product.''

logistics provider for handling as products. These commenters believed that, at a minimum, the mere fact that a pharmaceutical product becomes nonsaleable does not mean that such pharmaceutical product is now a solid waste under the RCRA hazardous waste regulations.

EPA does not agree with these comments. The preemption provisions added to the FD&C Act by the DSCSA—both § 585(a) and § 585(b)—only apply to the protection of the drug supply chain and do not apply to waste management requirements under RCRA.[115] Under RCRA, EPA regulates pharmaceuticals differently than FDA does under the DSCSA since the goals of the statutes serve different purposes. The purpose of the DSCSA is to protect the security, pedigree, and quality of pharmaceutical products in the drug supply chain. One of the many purposes of RCRA is to ensure that any waste that is generated is ''treated, stored or disposed of so as to minimize the present and future threat to human health and the environment.'' [116] In addition, we note that the DSCSA applies only to prescription drug products (not to OTC drug products), so there can be no conflict between DSCSA and RCRA for nonsaleable OTC drug products.

As explained in further detail throughout this preamble, whether a pharmaceutical has monetary value (such as when it receives manufacturer credit) is not determinative of whether it is a waste under RCRA. Under RCRA, one considers whether a material is discarded—and not whether it receives credit, or holds value or no value—to determine whether it is waste. Thus, prescription pharmaceuticals that are sent by healthcare facilities to reverse distributors and that will be discarded (even if these pharmaceuticals receive credit) will first be considered wastes at the healthcare facility when the decision is made by the healthcare facility to send them to a reverse distributor.

Furthermore, EPA disagrees with commenters that a nonsaleable pharmaceutical product sent to reverse distributors should not be considered a waste. Nonsaleable pharmaceutical products sent to reverse distributors are not sent for reuse or donation, but are sent for disposal, and thus would be considered wastes at the healthcare facility. In its comments to the FDA on the Draft Guidance for Industry, Identifying Trading Partners Under the Drug Supply Chain Security Act,[117] an industry trade association appears to confirm this point when it says, ''Most fundamentally, returns processors are unlike the trading partners described in the DSCSA. Trading partners are dedicated to moving products forward for dispensing and administration to patients. Returns processors' activities come at the end, when the product is no longer retained for distribution or dispensing and is safely removed from the supply chain.''[118] The commenter goes on to say that ''the assumptions that product is being distributed for further use, rather than only for credit assessment and/or disposition'' do not appear to apply to returns processors (known as reverse distributors in this final rule.[119] Similarly, a reverse distributor also submitted comments to the FDA on the same draft guidance, stating that ''once these products reach the returns processors for creditability assessment and final disposition management, they are forever removed from commerce.'' [120] Furthermore, during a site visit to a large reverse distributor, EPA was told that none of the pharmaceuticals on site would be donated or redistributed or otherwise returned to commerce.[121] After they are evaluated for manufacturer credit, the pharmaceuticals are sent for incineration. Under § 261.2(b)(3) of the RCRA regulations, ''Materials are solid waste if they are abandoned by being . . . Accumulated, stored, or treated (but not recycled) before or in lieu of being abandoned by being disposed of, burned, or incinerated.'' The pharmaceuticals at reverse distributors are being accumulated prior to being incinerated and therefore are solid wastes. Additionally, in a 2013 memo EPA includes a series of questions to help determine whether a commercial chemical product is a solid and hazardous waste. One set of questions relates to whether the facility appears to be selling into commerce the material being evaluated. If the facility has no customers or market for the material, it can be an indication that the material is a solid waste.[122]

As explained elsewhere in the preamble, EPA distinguishes between reverse distributors (as defined in this rule) and reverse logistics centers. Reverse distributors do not reuse or donate, but in fact, dispose of the pharmaceuticals they receive. In sum, what DSCSA would consider to be a nonsaleable product is still considered to be a solid waste under RCRA when it is discarded according to the RCRA regulations, and the DSCSA does not preclude pharmaceuticals from being waste under RCRA.

EPA notes that many of the implementing regulations for the DSCSA are still under development by the FDA and the FDA has announced that it is delaying enforcement of certain requirements.[123] Section 584(d) of the FD&C Act, as added by the DSCSA, directs the FDA to issue licensing regulations for third party logistics providers (3PLs) within two years of the date of enactment of the DSCSA.[124] Draft FDA guidance issued in August 2017 indicates that FDA plans to consider a returns processor or reverse logistics provider to be a type of 3PL.[125] However, FDA has not yet finalized this guidance or issued proposed or final regulations for licensing 3PLs. The listing for the relevant regulation in the most recent version of the public list of planned federal rulemaking (the Unified Agenda of Regulatory and Deregulatory Actions, or ''Unified Agenda'') indicates that FDA plans to issue a *proposed* DSCSA licensing regulation within the next year.[126]

Furthermore, since 3PLs, such as reverse logistics providers, do not take ownership of the drugs that they manage at their facilities, the DSCSA requirements related to tracing drugs

[115] Section 585(a) of the DSCSA contains a preemption provision for state requirements for tracing drug products through the distribution system. Section 585(b) of the DSCSA contains a preemption provision for state requirements for wholesale prescription drug distributors and third-party logistics providers.

[116] See 42 U.S.C. 6902(b).

[117] August 2017, docket number FDA–2017–D–1956.

[118] See page 6 of comment FDA–2017–D–1956–0013.

[119] See page 7 of comment FDA–2017–D–1956–0013.

[120] See page 14 of comment FDA–2017–D–1956–0011.

[121] See notes from site visit to Med-Turn, October 10, 2017 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932. Med-Turn is a subsidiary of Inmar.

[122] See Section 3 of Attachment A of memo entitled Checklist to Assist in Evaluating Whether Commercial Chemical Products or Solid and Hazardous Waste Under the Resource Conservation and Recovery Act, May 14, 2013, Devlin to RCRA Division Directors, RCRA Online #14837.

[123] On June 30, 2017, FDA issued a draft guidance, Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy. *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf.*

[124] The DSCSA was enacted on November 27, 2013; therefore, the 3PL licensing regulations were scheduled to be issued by FDA by November 27, 2015.

[125] August 2017, Identifying Trading Partners Under the Drug Supply Chain Security Act—Guidance for Industry. *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572252.pdf.*

[126] See the Spring 2018 Unified Agenda, available at *https://www.reginfo.gov/public/do/eAgendaMain.*

through the supply chain, including transaction information (TI), transaction history (TH), and transaction statements (TS), do not apply to them. In the absence of relevant FDA regulations, it is difficult for EPA to consider the possibility of deferring to FDA for the regulation of reverse distributors, who we consider to be managing hazardous wastes. In the future, if there are duplicative regulations, EPA may need to revisit the regulation of reverse distributors after the FDA issues proposed and final licensing regulations for 3PLs in accordance with the DSCSA.

D. Wastes Generated at Healthcare Facilities That Are Not Included in the Scope of This Final Rule

Wastes that are not included in the scope of this proposed rulemaking include non-hazardous wastes and non-pharmaceutical hazardous wastes. Pharmaceutical wastes that are not listed or characteristic hazardous wastes under RCRA Subtitle C may nonetheless pose some risks to public health and the environment. These wastes are discussed further below.

1. How should non-hazardous waste pharmaceuticals be disposed?

A large portion of the pharmaceutical wastes generated at healthcare facilities will not meet the definition of a RCRA hazardous waste under RCRA Subtitle C. This final rule, therefore, does not require that healthcare facilities manage these waste pharmaceuticals under the RCRA Subtitle C hazardous waste regulations, including this final rule. However, a healthcare facility may choose to manage its non-hazardous and hazardous waste pharmaceuticals together (as hazardous waste pharmaceuticals) under the new subpart P regulations. Because all healthcare facilities operating under this subpart are regulated in the same way regardless of quantity of hazardous waste pharmaceuticals generated, managing non-hazardous waste pharmaceuticals as hazardous waste under this subpart would not affect the facility's hazardous waste generator category. While not regulated by the federal RCRA hazardous waste requirements, non-hazardous waste pharmaceuticals that are not managed under subpart P are still considered solid wastes under the federal regulations and must be managed in accordance with applicable federal, state, and/or local regulatory requirements. Moreover, some waste pharmaceuticals that do not qualify as ''hazardous wastes'' under RCRA can nonetheless be extraordinarily hazardous thus, extreme care may be warranted.[127] These are discussed below in section VII.D.1.a.

If a healthcare facility decides to segregate its hazardous and non-hazardous waste pharmaceuticals, EPA recommends that healthcare facilities follow the best management practices (BMPs) outlined in ''Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States,'' (Blueprint) [128] an EPA guidance document for the management, treatment, storage and disposal of non-hazardous waste pharmaceuticals. The following summarizes the recommended BMPs found in the Blueprint for various categories of pharmaceutical wastes, including those wastes that possess hazardous waste-like qualities yet are not regulated as hazardous waste under RCRA Subtitle C.

a. *Recommended best management practices for healthcare facilities managing non-hazardous waste pharmaceuticals possessing hazardous waste-like qualities.* Currently, most pharmaceuticals are not regulated as RCRA hazardous wastes when discarded by healthcare facilities. These ''non-RCRA-hazardous'' pharmaceuticals can be divided into two categories: Those that possess hazardous waste-like qualities and those that do not. As outlined in the Blueprint, there are pharmaceuticals that possess hazardous waste-like qualities, but for various reasons, are not regulated by the RCRA Subtitle C hazardous waste regulations. The Agency supports the Blueprint's recommendation of hazardous waste incineration as the BMP for healthcare facilities and reverse distributors discarding pharmaceuticals that may possess hazardous waste-like qualities, but are not regulated as RCRA hazardous waste. This recommendation would apply to pharmaceuticals with more than one active ingredient listed on the P- or U-lists,[129] chemotherapeutic agents characterized as bulk wastes,[130] pharmaceuticals which meet the hazardous drug criteria set by the National Institute for Occupational Safety and Health (NIOSH),[131] pharmaceuticals with LD50s ≤ 50 mg/kg, pharmaceuticals that are carcinogenic or endocrine disrupting compounds, and vitamin/mineral preparations containing heavy metals.

b. *Recommended best management practices for other non-hazardous waste pharmaceuticals (not possessing hazardous waste-like qualities).* As far as other non-hazardous waste pharmaceuticals (*i.e.,* those not possessing hazardous waste-like qualities), disposing of non-hazardous waste pharmaceuticals at healthcare facilities via drain disposal is strongly discouraged and not recommended by EPA. Therefore, EPA endorses the Blueprint's recommendation of municipal solid waste incineration or medical waste incineration for any non-hazardous waste pharmaceuticals, even when they do not possess hazardous waste-like qualities. The potential risk remains for active pharmaceutical ingredients (APIs) to be released into the environment if medical waste autoclaves or municipal solid waste landfills are used for the purposes of pharmaceutical waste treatment and disposal. For example, autoclaves are designed to kill pathogens and do not achieve the temperatures required to destroy most APIs during the autoclaving process. As a result, when wastewater is generated either by cleaning an autoclave, or during automatic blow down from autoclaves equipped with steam generators, there is the potential for wastewater containing APIs to be generated and discharged into the sewer. In addition, some limited studies have shown APIs present in landfill leachate collected in municipal solid waste landfill leachate

[127] See, for example, *https://www.cdc.gov/niosh/review/peer/isi/hazdrug2018-pr.html* or NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016–161 (Supersedes 2014–138). *https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf.*

[128] Practice Greenhealth, Revised August 2008. Published in 2006, the development of the original Blueprint was funded by the Office of Solid Waste and Emergency Response and managed by EPA Region 1. The 2008 revision of the Blueprint was funded by the Healthcare Environmental Resource Center. *http://practicegreenhealth.org/sites/default/files/upload-files/pharmwasteblueprint.pdf.*

[129] As noted in the comment after § 261.33(d), the phrase ''commercial chemical product'' includes formulations in which the P- or U-listed chemical is the sole active ingredient. Therefore, formulations with more than one active ingredient do not meet the specifications of the P- and U-listings even if one, two or all of the active ingredients are listed on the P- and/or U-lists.

[130] The descriptions ''bulk'' and ''trace'' when applied to chemotherapeutic wastes are industry terms and are not defined by the federal RCRA regulations.

[131] See NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016–161 (Supersedes 2014–138). *https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf.*

systems.[132] [133] Typically, the collected landfill leachate is subsequently sent to wastewater treatment plants for treatment, but their treatment technologies are not designed to remove all APIs from the wastewater (See section XIII for more information regarding the prohibition on sewering hazardous waste pharmaceuticals).

2. How should non-pharmaceutical hazardous waste be disposed?

These newly promulgated subpart P regulations will pertain only to hazardous waste pharmaceuticals. Therefore, other types of hazardous wastes generated at healthcare facilities and reverse distributors that do not meet the definition of a hazardous waste pharmaceutical cannot be managed in accordance with this new subpart (as previously discussed, non-hazardous waste pharmaceuticals may be managed under this new subpart). For example, hazardous wastes generated in hospital laboratories or during cleaning and maintenance of the facility are not considered hazardous waste pharmaceuticals and are not included within the scope of this final rule. The generation of non-pharmaceutical hazardous wastes is often more routine and does not trigger the same concerns that healthcare facilities experience when managing hazardous waste pharmaceuticals. Also note that the 2016 Hazardous Waste Generator Improvements final rule added new flexibility for episodic generators of non-pharmaceutical hazardous waste under part 262 subpart L.

VIII. What terms are defined in this final rule? (§ 266.500)

A. Definition of Pharmaceutical

1. Summary of Proposal

EPA proposed to define ''pharmaceutical'' as any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition included, but was not limited to dietary supplements as defined by the Federal Food, Drug, and Cosmetic Act (FD&C Act), prescription drugs, OTC drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from the spills of pharmaceuticals. This proposed definition of ''pharmaceutical'' was intended to include all dose forms, including, but not limited to, tablets, capsules, medicinal gums or lozenges, medicinal liquids, ointments and lotions, IV or other compound solutions, chemotherapy pharmaceuticals, vaccines, allergenics, medicinal shampoos, antiseptics, and any delivery device, including medicinal dermal patches, with the primary purpose to deliver or dispense the pharmaceutical.

EPA relied on the FD&C Act's definition of ''drug'' to develop the proposed definition of ''pharmaceutical'' but expanded on the definition based on comments to the 2008 Universal Waste proposed rulemaking. In particular, stakeholders requested that the Agency take a broad view in delineating what items are included in the definition of pharmaceutical so that the proposed standards applied broadly. Thus, the proposed definition of ''pharmaceutical'' did not exclude pharmaceuticals with a radioactive component and included items not specifically recognized by the FDA as drugs, such as dietary supplements, pharmaceutical residues in non-empty containers (including delivery devices), personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from spills of pharmaceuticals.

2. Summary of Comments

The most frequent comment EPA received on the definition of ''pharmaceutical'' was on the inclusion of personal protective equipment and clean-up material in the definition of pharmaceutical. Many commenters argued that personal protective equipment and clean-up material should not be included in the final definition. One commenter suggested that loose tablets be included in the definition of pharmaceutical but that personal protective equipment should not be included. Waste Management National Services, Inc. suggested that only ''overtly contaminated'' personal protective equipment or clean-up materials be included in the definition, but not personal protective equipment and clean-up materials with trace contamination.[134] Two commenters asked EPA to clarify which personal protective equipment is included in the definition of ''pharmaceutical.''

One state expressed concern that EPA proposed to take a broad view in delineating what items are included in the definition of ''pharmaceutical.'' The New Jersey Department of Environmental Protection pointed out that although ''sharps'' did not meet the proposed definition of ''pharmaceutical'' that IV bags, tubing and syringes that come in contact with blood or pathogens could fall under the definition of ''pharmaceutical.'' They asked that EPA exclude these items from the definition.[135]

EPA requested comment on the Agency's decision to include dietary supplements in the definition of ''pharmaceutical'' under the final rule. Four states and one industry association supported the Agency's proposal to include dietary supplements under the definition of ''pharmaceutical.'' One state and five industry associations did not support including dietary supplements in the definition of ''pharmaceutical.'' Multiple commenters requested that EPA only include dietary supplements that are regulated as drugs and exclude supplements regulated as foods.

EPA requested comment on the possibility of including low-concentration nicotine products, such as electronic nicotine delivery systems (e-cigarettes), in the definition of ''pharmaceuticals'' under the final rule. EPA received multiple comments on whether to include e-cigarettes and liquid nicotine (e-liquids) in the final definition. Hawaii State Department of Health and the Hematology/Oncology Pharmacy Association did not support including e-cigarettes or e-liquids in the final definition of ''pharmaceutical.''[136] RILA requested that EPA exempt all low-concentration nicotine products from the P075 listing, including e-cigarettes and e-liquids, but agreed that if EPA did not exempt these products from the P075 listing, that e-cigarette products should fall under the definition of ''pharmaceutical.''[137]

The American Dental Association asked that EPA specifically exclude

[132] Barnes, K.K., Christenson, S.C., Kolpin, D.W., Focazio, M.J., Furlong, E.T., Zaugg, S.D., Meyer, M.T. and Barber, L.B. (2004), Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill. Groundwater Monitoring & Remediation, 24: 119–126

[133] Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (June 2009), Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. Bulletin of Environmental Contamination and Toxicology, V82.6:635–659.

[134] See comment number 0257 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[135] See comment number 0235 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[136] See comment numbers 0238 and 0264 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[137] See comment number 0295 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

dental amalgam from the final definition of ''pharmaceutical.'' [138]

Multiple commenters pointed out that the same chemical may have a pharmaceutical and non-pharmaceutical use (*e.g.,* isopropyl alcohol is used to clean wounds and to clean instruments and surfaces). [139] Commenters asked EPA to clarify that they are regulated differently.

Stericycle, Inc. requested that investigational or research drugs be considered pharmaceuticals because they are difficult to characterize.[140]

3. Final Rule Provisions

In this final rule, ''pharmaceutical'' means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (*e.g.,* electronic cigarette or vaping pen), or any liquid nicotine (e-liquid) packaged for retail for use in electronic nicotine delivery systems (*e.g.,* pre-filled cartridges or vials). This definition includes, but is not limited to dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 203.3(y); OTC drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

The final definition of pharmaceutical includes both prescription drugs, as defined by 21 CFR 203.3(y) and OTC drugs. As previously mentioned, commenters pointed out that the same chemical may have a pharmaceutical and non-pharmaceutical use.[141] If an OTC product is required by the FDA to include ''Drug Facts'' on the label, it would be considered a pharmaceutical for the purposes of this rule.[142] In rare cases, some items that are OTC pharmaceuticals may not be labeled appropriately with a ''Drug Facts'' label. It is the Agency's understanding, however, that all OTC drugs must contain a Drug Facts label. Therefore, if an item meets the criteria to be considered a pharmaceutical under subpart P but is not labeled with Drug Facts, it should still be managed as a pharmaceutical. Any non-pharmaceutical hazardous wastes must be managed pursuant to all other applicable RCRA regulations. The final definition of ''pharmaceutical'' also includes any pharmaceutical residuals remaining in non-empty containers, such as the pharmaceutical residuals remaining in dispensing bottles, IV bags and tubing, vials, unit dose packages, and delivery devises, such as syringes and patches. However, the final definition does not include sharps (*e.g.,* needles from IV bags or syringes). Used sharps, such as needles or syringes with needles, are not included under the final definition of pharmaceutical because sharps are considered medical wastes, presently regulated at both the state and local level. Further, as discussed in section XV of this preamble, EPA is finalizing regulations for when pharmaceutical containers are considered empty.

The final definition of ''pharmaceutical'' also includes items contaminated with or containing pharmaceuticals, such as personal protective equipment contaminated with pharmaceuticals or related spill clean-up materials (including loose tablets accumulated during pharmacy floor sweepings). EPA's decision to include contaminated personal protective equipment under the definition of ''pharmaceutical'' reflects the Agency's interest in promoting a similar management scheme for the personal protective equipment containing pharmaceuticals and other types of pharmaceuticals. Only personal protective equipment that is already considered hazardous waste under the ''contained in'' policy because it is contaminated with pharmaceuticals will fall under the definition of pharmaceutical.[143] These items are included in the definition so that facilities can manage more types of hazardous waste commonly found in healthcare settings under the same standards. For example, the contained in policy would not apply to gloves that have touched a warfarin pill during the course of patient care. However, if a healthcare worker spills a hazardous waste pharmaceutical on their personal protective equipment and it cannot be removed from the personal protective equipment, the personal protective equipment would be considered a hazardous waste pharmaceutical. If the personal protective equipment only has trace amounts of contamination it would not be considered a hazardous waste and therefore not be considered a hazardous waste pharmaceutical.

The final definition of ''pharmaceutical'' includes dietary supplements for the same reason—in order to promote a consistent management scheme for similar waste streams. Dietary supplements are commonly found in various healthcare settings because they are recommended or prescribed by healthcare providers to patients.[144] Further, retail pharmacies routinely sell vitamins and other medicinal minerals and supplements. When EPA uses the term ''dietary supplements'' in the definition of ''pharmaceutical,'' EPA is referencing the definition for dietary supplement used by the FD&C Act, as amended by the Dietary Supplement Health and Education Act of 1994 (21 U.S.C. 321 (ff)).[145] If a dietary supplement is required by the FDA to include a ''Supplement Facts'' panel on the label, it would be considered a pharmaceutical for the purposes of this rule.[146] The FD&C Act categorizes dietary ingredients and dietary supplements under the general umbrella of foods and therefore does not review them before being marketed. In fact, several commenters suggested that because the FD&C Act does not regulate supplements as drugs, EPA does not have the authority to regulate them as pharmaceuticals under RCRA. EPA disagrees with the commenters, noting that any waste that is listed or exhibits a characteristic is regulated as a hazardous waste when discarded, including supplements. This final rule does not newly apply RCRA to the disposal of supplements that meet the definition of hazardous waste, as some commenters suggest; it changes which regulations apply when discarding supplements that are hazardous waste. EPA recognizes that healthcare facilities may benefit from managing dietary supplements along with drugs under the

[138] See comment number 0294 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[139] See comment numbers 0246, 0280, 0296 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[140] See comment number 0280 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[141] See comment numbers 0246, 0280, 0296 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[142] See 21 CFR 201.66

[143] See memo from Lowrance to Fields, January 3, 1989 (RCRA Online #11387).

[144] Including dietary supplements under the definition of ''pharmaceutical'' does not supersede the requirements of the Dietary Supplement Health and Education Act of 1994, the Federal Food, Drug and Cosmetic Act, or FDA regulations.

[145] The substance of the definition is: A Product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A): A vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); For the complete definition of dietary supplement, please see: *https://www.gpo.gov/fdsys/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21-chap9-subchapII.pdf.*

[146] See 21 CFR 101.36.

final regulation, and thus, is including it in the final definition of ''pharmaceutical.'' Although dietary supplements are considered pharmaceuticals under this definition, only the dietary supplements that meet the definition of hazardous waste (*e.g.,* exhibits the toxicity characteristic for metal content) would be regulated under part 266 subpart P as hazardous waste pharmaceuticals (see the definition of ''hazardous waste pharmaceutical'').

The final rule specifically excludes dental amalgam from the final definition of pharmaceutical. EPA promulgated new pretreatment standards in June 2017 to reduce discharges of mercury from dental offices into publicly owned treatment works.[147] If EPA included dental amalgam in the final definition of pharmaceutical, it would subject dentists to duplicative regulatory requirements.

The final definition of ''pharmaceutical'' includes electronic nicotine delivery systems and liquid nicotine (e-liquid) packaged for retail for use in electronic nicotine delivery systems. These items are included in the definition ''pharmaceutical'' so that facilities can manage more types of hazardous waste commonly found in healthcare settings under part 266 subpart P. The final definition of ''pharmaceutical'' applies to finished product electronic nicotine delivery systems, including components and parts, sealed in final packaging intended for consumer use (*e.g.,* electronic cigarettes and vaping pens) and e-liquid that is packaged for retail for use in the electronic nicotine delivery systems (*e.g.,* pre-filled cartridges and vials that are sold separately to consumers or as part of kits). EPA intends that e-liquid used by manufacturers of tobacco products (as defined by the FD&C Act) not be included in the final definition of ''pharmaceutical.'' [148] That is, a pre-filled e-liquid cartridge sealed in final packaging that is to be sold or distributed to a consumer for use is included in the definition, but in contrast, an e-liquid that is sold or distributed for further manufacturing, mixing, or packaging into a finished electronic nicotine delivery system is not included.[149] EPA believes that finished products sealed in packaging intended for consumer use pose a lower risk for leaks and other releases to the environment than e-liquid that is sold or distributed for further manufacturing. E-liquid that is packaged for retail for use in electronic nicotine delivery systems, such as e-liquid that is in pre-filled cartridges and vials, is typically sold at lower concentrations and smaller quantities than e-liquid that is sold or distributed for further manufacturing.

The final definition of ''pharmaceutical'' includes investigational drugs. One commenter asked EPA to include investigational drugs in the definition because these drugs are difficult to characterize. The investigational drugs might have proprietary ingredients that the manufacturer might not be willing to divulge during trials. The final definition includes investigational drugs in order to provide clarity on how to manage these items when discarded. See section IX.B.2.e regarding the applicability of subpart P to discarded investigational drugs.

B. Definition of Hazardous Waste Pharmaceutical

1. Summary of Proposal

EPA proposed to define ''hazardous waste pharmaceutical'' as a pharmaceutical that is a solid waste, as defined in § 261.2, and is listed in part 261 subpart D, or exhibits one or more characteristics identified in part 261 subpart C. The Agency proposed to define the term ''hazardous waste pharmaceutical'' in order to clarify its intent that only pharmaceuticals that meet the definition of hazardous waste when disposed or discarded need to be managed under the new subpart P management standards.

2. Summary of Comments

EPA requested comment on the proposed definition of ''hazardous waste pharmaceutical'' and specifically on whether any dietary supplements currently on the market meet or could potentially meet RCRA's definition of hazardous waste.

The New Mexico Environment Department requested that EPA broaden the definition of ''hazardous waste pharmaceutical'' to include antineoplastic agents. The New Mexico Environment Department argued that EPA has not updated the P- and U-hazardous waste lists even though new pharmaceuticals have been developed that should be considered hazardous waste.[150] Public Employees for Environmental Responsibility also argued that the definition of ''hazardous waste pharmaceutical'' is too narrow because not enough pharmaceuticals meet the definition.[151] American Pharmacists Association expressed concern that the definition is difficult to understand because the P- and U-hazardous waste lists are not comprehensive.[152]

Waste Management National Services Inc., supported the proposed definition of ''hazardous waste pharmaceutical'' and pointed out that there are dietary supplements on the market that meet the RCRA definition of hazardous waste because the supplements contain selenium or chromium.[153]

3. Final Rule Provisions and Response to Comments

In this final rule, ''hazardous waste pharmaceutical'' means a pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C, or is listed in part 261 subpart D. A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (*e.g.,* lawfully donated for its intended purpose) or reclaimed. An OTC pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed.

The Agency is including in the final definition of ''hazardous waste pharmaceutical'' that a pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical if it is lawfully donated. The Agency included this language to clarify that pharmaceuticals are not solid waste if they are donated for use (see section IX.B for more discussion).

The Agency is defining the term ''hazardous waste pharmaceutical'' in order to clarify its intent that only pharmaceuticals (as defined in this final rule) that are hazardous waste when disposed or discarded need to be managed under the final subpart P management standards. For example, warfarin (brand name Coumadin) is a listed hazardous waste and when discarded meets the definition of hazardous waste pharmaceutical. The Agency notes that hazardous waste pharmaceuticals are hazardous wastes; more specifically, they are a subset of

[147] 82 FR 27154; June 14, 2017.

[148] 26 U.S.C. 5702 (d)

[149] This distinction is adapted from the term ''finished tobacco product'' used by FDA in its regulations for e-cigarettes, cigars, and all other tobacco products. 81 FR 28973; May 10, 2016.

[150] See comment number 0211 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[151] See comment number 0247 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[152] See comment number 0321 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[153] See comment number 0257 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

hazardous waste. The term hazardous waste is defined in § 260.10 as ''a hazardous waste as defined in § 261.3.'' Therefore, even though we do not reference § 261.3 in the definition of hazardous waste pharmaceutical, a hazardous waste pharmaceutical is also hazardous waste as defined in § 261.3. This is relevant to the OSHA Hazardous Waste Operations and Emergency Response standard (29 CFR 1910.120), which apply to hazardous wastes, as defined by § 261.3. This final rule does not impact the applicability of the OSHA Hazardous Waste Operations and Emergency Response standards.

Multiple commenters suggested that the proposed definition of ''hazardous waste pharmaceutical'' was too narrow because the P- and U-hazardous waste lists have not been updated even though new pharmaceuticals have been developed. Although we solicited ideas from commenters for possible methods or approaches for regulating additional pharmaceuticals as hazardous waste, any action taken to address the comments we received in response to this request would have to be a separate action taken by the Agency in the future and is not part of this final rulemaking. Therefore, these comments are considered to be out of the scope of this final action and we do not plan to address them at this time. That said, we do anticipate that because subpart P lowers regulatory barriers to over-managing non-hazardous waste pharmaceuticals, some healthcare facilities will choose to over-manage non-hazardous waste pharmaceuticals as hazardous waste pharmaceuticals even if they do not meet a current listing or exhibit a hazardous waste characteristic.

C. Definition of Reverse Distributor [154]

1. Summary of Proposal

EPA proposed to define reverse distributor as any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. EPA proposed that any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer credit would be considered a reverse distributor. Pharmaceutical manufacturers often offer credit to healthcare facilities for unused and/or expired pharmaceuticals.[155] Manufacturers issue credit for a variety of reasons: it can be a marketing incentive tool, it helps protect against illicit diversion [156] or improper disposal, and it allows manufacturers to collect data on the returned items, which then can be used to help plan for future pharmaceutical production. Reverse distributors contract with both manufacturers and healthcare facilities to act as an intermediary to facilitate the crediting process.

EPA proposed new standards for shipping potentially creditable hazardous waste pharmaceuticals to reverse distributors and management standards of potentially creditable hazardous waste pharmaceuticals by reverse distributors. Thus, EPA proposed to define ''reverse distributor'' to clearly delineate which types of facilities were subject to the proposed rulemaking. The agency solicited public comment on its proposed definition of ''reverse distributor.'' Specifically, EPA asked for comment on whether the definition of ''reverse distributor'' captures the universe of facilities acting as reverse distributors for pharmaceuticals.

2. Summary of Comments

Commenters requested that EPA clarify who would be considered a reverse distributor and what the functions of a reverse distributor are. States and industry, including manufacturers, wholesalers, and waste management companies, wanted to know if any facility that performed reverse distribution functions would be encompassed in this definition. Reverse distributors asked for clarification in how 3PLs fit into the definition of reverse distributor and whether all functions performed by their business would fall under the definition.

3. Final Rule Provision

Under the final rule, reverse distributor means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

In response to comments, EPA made two changes to the definition of ''reverse distributor'' for the final rule. First, EPA proposed to use the term ''pharmaceutical reverse distributor'' but the final rule uses the term ''reverse distributor.'' EPA dropped the word ''pharmaceutical'' from reverse distributor because the definition of pharmaceutical is overly broad given that it refers to both prescription and nonprescription pharmaceuticals. EPA received comments from stakeholders pointing out that in the terminology of the industry, reverse distributors receive prescription pharmaceuticals, while reverse logistics centers receive nonprescription pharmaceuticals and other unsold retail items. This distinction is useful to EPA in making the same distinction in these regulations and EPA has adopted it.

The second change EPA made was to add the word prescription to the definition to further clarify that the definition does not include reverse logistics centers that receive nonprescription pharmaceuticals or other unsold retail items that are evaluated for legitimate use/reuse or reclamation. EPA's definition of ''reverse distributor'' only includes prescription hazardous waste pharmaceuticals that are evaluated for credit and then disposed. EPA made this clarification to be consistent with the policy for the reverse logistics of nonprescription pharmaceuticals and other unsold retail items. See section VI of this preamble for discussion of the regulations for the reverse distribution of prescription hazardous waste pharmaceuticals and the policy for the reverse logistics of other unsold retail items, including nonprescription pharmaceuticals.

EPA incorporated the changes to the final definition of ''reverse distributor'' in response to the comments summarized below.

4. Comments and Responses

EPA received comments from states and industry, including manufacturers, wholesalers and waste management companies, asking for clarification on who would be considered a reverse distributor. For example, commenters asked whether wholesalers, forward distributors and 3PLs meet the definition of ''reverse distributor'' even if reverse distribution is only a part of their business. For example, a facility

[154] The proposed rule used the term ''pharmaceutical reverse distributor'' but the final rule uses the term ''reverse distributor.'' To avoid confusion, we use the term ''reverse distributor'' in this preamble, even when discussing the proposed rulemaking.

[155] As noted in the definition of ''potentially creditable hazardous waste pharmaceutical,'' manufacturers provide credit for those pharmaceuticals that are less than one year past the expiration date.

[156] Through the return of pharmaceuticals by a pharmacy for manufacturer credit, manufacturers are able to maintain control of the pharmaceutical up to the point of its disposal, thereby, decreasing the risk of diversion of the pharmaceutical.

might act as a sorting and shipping facility or a pharmacy might act as a consolidation center but not evaluate for manufacturer credit. The definition of ''reverse distributor'' specifically states that any person, including forward distributors (*e.g.,* wholesalers), 3PLs, or pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor. Any person that is performing the function of a reverse distributor, even if it is a small part of their business, would need to operate under the reverse distributor standards. If a facility is not processing any hazardous waste prescription pharmaceuticals for facilitating or verifying manufacturer credit, then it would not meet the definition of ''reverse distributor.''

The retail industry was especially concerned with need to differentiate between reverse distributors and reverse logistics centers. Reverse logistics centers that receive nonprescription pharmaceuticals (such as OTC pharmaceuticals) would not fall under this definition. Likewise, wholesale distributors receiving returns from their customers would not be considered reverse distributors. This is because wholesale distributors do not facilitate manufacturer credit. Further, according to comments received from Healthcare Distribution Management Association, in 2013, approximately 94% of the returns to wholesale distributors, were saleable.[157] [158] As saleable products, the pharmaceuticals returned to wholesale distributors would remain subject to the track and trace requirements of the DSCSA. Reverse logistics centers, which evaluate nonprescription pharmaceuticals for legitimate use/reuse and reclamation do not fit this definition.

EPA is also finalizing the definitions for potentially creditable and non-creditable hazardous waste pharmaceuticals (in parts D and E of this section) to differentiate between reverse distributors' function in evaluation of credit versus the traditional TSDF role in waste disposal. It is the Agency's intent that potentially creditable hazardous waste pharmaceuticals can be sent to reverse distributors for the determination of credit under subpart P. It is not the Agency's intent, however, for reverse distributors to serve in the capacity as storage facilities or TSDFs for other hazardous waste.

Multiple state commenters asked EPA to clarify what is meant by ''facilitate.'' The facilitation of credit encompasses the role that reverse distributors serve between healthcare facilities and manufacturers. A reverse distributor receives potentially creditable hazardous waste pharmaceuticals for evaluation of manufacturer credit. Once the evaluation is complete and it is determined that credit can be given, reverse distributors will issue the manufacturer credit on behalf of the manufacturer to the healthcare facility.

Reverse distributors wanted to add all the other functions performed by reverse distributors to the regulatory definition to more fully define their role. EPA did not add reverse distributors' other functions to the definition of ''reverse distributor'' in the final rule. While a reverse distributor may continue to perform other lawful activities, they are not relevant for the purpose of defining a reverse distributor under this final rule. EPA's definition of reverse distribution focuses on issuing of manufacturer credit because although the pharmaceuticals are hazardous waste, they have value to the healthcare facility and the reverse distributor. Since these hazardous waste pharmaceuticals have value, there is a greater economic incentive to manage them with more care than typical hazardous waste. The final definition captures the handling of prescription hazardous waste pharmaceuticals that fall under RCRA and the rest of the functions can be regulated, as needed, under local, state and other federal regulations.

The waste management industry requested clarification on the intersection of DEA reverse distributors and RCRA reverse distributors and how a reverse distributor that receives a DEA controlled substance as a waste would determine if they are also subject to subpart P. A hazardous waste pharmaceutical that is also a DEA controlled substance is not subject to subpart P, provided they meet the terms of the conditional exemption in § 266.506. The conditional exemption for DEA controlled substances that are also RCRA hazardous waste is covered in section XIV of the preamble.

The Agency also wants to clarify the difference between what is defined as a reverse distributor under this final rule and how DEA regulations define ''reverse distribute.'' The recently amended DEA regulatory definition of ''reverse distribute'' is to ''acquire controlled substances from another registrant or law enforcement for the purposes of: (1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or (2) Destruction.'' [159]

Under DEA's definition, a reverse distributor does not necessarily process pharmaceuticals for the purpose of determining manufacturer credit: Often a reverse distributor's main function under DEA's definition is to destroy the controlled substances. Under EPA's definition, however, a reverse distributor is defined as a facility that accepts potentially creditable pharmaceuticals for the purposes of evaluating manufacturer credit. These potentially creditable hazardous waste pharmaceuticals may or may not be identified as controlled substances by DEA.[160] Therefore, a DEA-registered reverse distributor may or may not meet EPA's definition of a reverse distributor and vice versa. For example, a reverse distributor that accepts DEA controlled substances that are also hazardous waste pharmaceuticals for the purpose of destruction (*e.g.,* incineration) would be regulated as a DEA-registered reverse distributor and as a RCRA TSDF (or other regulated incinerator, depending on what other wastes it combusts), but not as a reverse distributor under part 266 subpart P. Conversely, a reverse distributor that processes pharmaceuticals for manufacturer credit, but is not a DEA registrant and therefore, cannot accept controlled substances, would meet the subpart P reverse distributor definition, but not DEA's reverse distributor definition. However, EPA has heard from stakeholders that most, if not all, entities that facilitate manufacturer credit are also DEA-registered reverse distributors. Therefore, such reverse distributors would meet both EPA's definition of reverse distributor and the DEA's definition of reverse distributor. Lastly, EPA's definition for reverse distribution does not alter or supersede the requirements of the Controlled Substances Act and DEA regulations.

In addition, the DOT's Pipeline and Hazardous Materials Safety Administration has defined the closely related term, ''reverse logistics,'' in a

[157] Healthcare Distribution Management Association has since been renamed Healthcare Distribution Alliance.

[158] See comment #EPA–HQ–RCRA–2007–0932–0276.

[159] See 21 CFR 1300.01. On September 9, 2014, DEA finalized new definitions for ''reverse distribute'' and ''reverse distributor.'' Please see 79 FR 53520. The term ''reverse distributor'' is defined as ''a person registered with the Administration [DEA] as a reverse distributor.''

[160] In order for a reverse distributor to be able to accept controlled substances, the reverse distributor must be a DEA registrant. See 21 CFR part 1308 for a complete list of controlled substances.

recent rulemaking.[161] EPA coordinated with the Pipeline and Hazardous Materials Safety Administration to ensure that our rules are compatible, even if the definitions differ. It is important to note that their final rule does not supersede EPA's RCRA Subtitle C regulations for solid or hazardous waste determinations or hazardous waste management.

D. Definition of Potentially Creditable Hazardous Waste Pharmaceutical

1. Summary of Proposal

In order to distinguish hazardous waste pharmaceuticals that are sent by a healthcare facility to RCRA TSDFs from those hazardous waste pharmaceuticals that are sent by a healthcare facility to a reverse distributor for a determination or verification of manufacturer credit, the Agency proposed a definition for ''potentially creditable hazardous waste pharmaceutical.''

EPA proposed to define ''potentially creditable hazardous waste pharmaceutical'' to mean a hazardous waste pharmaceutical that has the potential to receive manufacturer credit and is

(1) unused or un-administered; and

(2) unexpired or less than one year past expiration date.

The proposed term did not include evaluated hazardous waste pharmaceuticals, residues of pharmaceuticals remaining in containers, contaminated personal protective equipment, and clean-up material from the spills of pharmaceuticals. These pharmaceuticals are typically unopened and in their original packaging and include both generic and name brand pharmaceuticals.

Whether a pharmaceutical is eligible for manufacturer credit is determined solely by the manufacturer's return policy. Based on comments received for the 2008 Universal Waste proposed rulemaking and through discussions with various stakeholders, the Agency understands that the return policies of manufacturers change regularly. As a result, healthcare facilities are not always aware if a particular pharmaceutical will be creditable at the time that it is pulled from the shelves. However, the Agency also understands that there are instances where it is well known that a pharmaceutical will not be creditable. Examples of these instances include the following: If the pharmaceutical has been removed from the original container and repackaged for dispensing purposes; if an attempt was made to administer a pharmaceutical, but the patient refused to take it; if the hazardous waste pharmaceutical was generated during patient care; if the pharmacy receives a return of a dispensed pharmaceutical for which they had already received compensation by a third-party payer; or if the pharmaceutical is more than one year past its expiration date. In these instances, as well as others, the healthcare facility knows that it will not receive manufacturer credit. It is the Agency's intent for the proposed definition of ''potentially creditable hazardous waste pharmaceutical'' to allow the return of hazardous waste pharmaceuticals to reverse distributors for the determination of credit. It is not the Agency's intent, however, for reverse distributors to serve in the capacity as TSDFs when it is well known that the manufacturer will not give credit for those hazardous waste pharmaceuticals.

Also, based on communication with stakeholders and the public comments received on the 2008 Universal Pharmaceutical Waste proposal, EPA understands that pharmaceutical manufacturers' policies often allow for credit to be issued on the return of ''partials.'' ''Partials'' is a term used in the industry to refer to opened containers that have had some contents removed. Under the proposed definition, the Agency considered partials to be potentially creditable hazardous waste pharmaceuticals.

2. Summary of Comments

States, manufacturers and waste management companies commented that word changes to this definition would clarify which hazardous waste pharmaceuticals could or could not be returned to reverse distributors. Manufacturers, some states and healthcare facilities argued that all pharmaceuticals should go to reverse distributors to relieve the burden on healthcare facilities to make these individual determinations. Pharmacists and reverse distributors wanted further clarification on what distinguishes a potentially creditable hazardous waste pharmaceutical and how it relates to credit.

3. Final Rule Provision

In response to comments, EPA has made five changes to the definition of ''potentially creditable hazardous waste pharmaceutical'' from the proposal. First, the final definition specifically includes prescription pharmaceuticals only. Second, we added the phrase ''reasonable expectation'' to clarify that the healthcare facility does not have to definitively know whether something will receive manufacturer credit but rather indicates that they should have a reasonable expectation that it will. We also note that EPA could have proposed to use the term ''creditable hazardous waste pharmaceuticals,'' but chose to use the term ''potentially creditable hazardous waste pharmaceutical'' to convey the same concept (*i.e.,* that a healthcare facility does not have to definitively know whether a specific item will receive manufacturer credit.) Third, we replaced ''unadministered'' with the term ''undispensed'' to make clear that it is not just that a patient refused to take a prescription pharmaceutical, but rather that it was never dispensed to a patient at all. Fourth, we removed the word ''unused'' from the definition since the use of this term could introduce some confusion given that ''partials'' can get manufacturer credit. Fifth, we specified that the pharmaceuticals be in the ''original manufacturer's packaging'' since repackaged prescription pharmaceuticals are not typically eligible for credit.[162]

For the final rule, a potentially creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is (1) in original manufacturer's packaging (except pharmaceuticals that were subject to recall); (2) undispensed; and (3) unexpired or less than one year past expiration date. The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, OTC drugs, homeopathic drugs, and dietary supplements.

4. Comments and Responses

a. Definitional Wording. EPA received many comments from states and industry on revising the definition to clarify which hazardous waste pharmaceuticals could and could not be returned to reverse distributors. States especially stressed that ''potentially creditable'' should be changed to ''reasonable expectation of credit'' or that EPA should define potentially creditable hazardous waste pharmaceuticals as those that are

[161] 79 FR 46748; August 11, 2014. The Pipeline and Hazardous Material Safety Administration's definition of reverse logistics ''is the process of moving goods from their final destination for the purpose of capturing value, recall, replacement, proper disposal, or similar reason.''

[162] See email correspondence from Nicole Wilkinson of CVS dated February 21, 2018 and Erica Burwell of Inmar dated February 22, 2018, both in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

accepted by reverse distributors for evaluation, as compared to those that are not. Manufacturers and states asked us to clarify whether we mean ''unadministered'' or ''undispensed'' or whether the term ''unopened'' should be added to the definition. The waste management industry had some concern that adding expiration dates to the definition might prevent potentially creditable hazardous waste pharmaceuticals from being returned to the reverse distributor.

In the final definition of potentially creditable hazardous waste pharmaceuticals, EPA has added some new phrases such as ''reasonable expectation of credit'' to the definition to be clear that not all hazardous waste pharmaceuticals should be going back to reverse distributors. We have also changed words like ''unadministered'' to ''undispensed'' since the expectation of credit ends once a pharmaceutical has been dispensed to a patient regardless of whether the patient takes the pharmaceutical and deleted ''unused'' since that could imply it has been dispensed but not used and/or that it was never opened.

We are specifically not adding the word ''unopened'' to the definition as some commenters had suggested, since it is EPA's understanding that ''partials'' can be given credit under certain circumstances and some pharmaceuticals may be repackaged. Although the definition does not include the word ''intact'' when describing original manufacturer's packaging, the definition of ''potentially creditable hazardous waste pharmaceutical'' does not include anything that is leaking or damaged.

Some commenters also argued that EPA was limiting manufacturers from changing policies by defining potentially creditable hazardous waste pharmaceuticals and giving examples of what those are. EPA recognizes that special circumstances may arise where a prescription hazardous waste pharmaceutical may be given credit but not fit squarely within this definition. We have added an example of this in our definition by noting that a recalled pharmaceutical may be given credit although it is not in original packaging. This definition is meant to give examples of what is commonly done and to aid healthcare facilities in being able to more easily identify a potentially creditable from a non-creditable hazardous waste pharmaceutical. It is not intended to prevent a manufacturer from changing its credit policies.

b. Evaluation of Hazardous Waste Pharmaceuticals and Credit. In their comments regarding potentially creditable hazardous waste pharmaceuticals received by reverse distributors, manufacturers and reverse distributors expressed concern about the burden being added to healthcare facilities by not allowing them to send all the hazardous waste pharmaceuticals together and putting the onus on them to determine if something is ''potentially creditable''. Healthcare facilities were concerned that credit policies are frequently updated by manufacturers and that a healthcare facility would not know if credit would be issued for any given pharmaceutical or not.

Commenters also addressed the question of a bright line as to what is and what is not potentially creditable hazardous waste pharmaceuticals. Commenters asked whether generics were considered ''potentially creditable.'' The waste management industry commenters asked how many times credit must be rejected before a type of pharmaceutical is no longer considered potentially creditable.

It is the Agency's intent in our definition of ''potentially creditable hazardous waste pharmaceutical'' to allow the return of hazardous waste pharmaceuticals to reverse distributors for the determination of manufacturer credit. It is not the Agency's intent, however, for reverse distributors to serve in the capacity as TSDFs when it is well known that the manufacturer will not give credit for certain hazardous waste pharmaceuticals.

EPA recognizes that in some cases a healthcare facility may not know if the hazardous waste pharmaceuticals will be given credit. We do not want to deter healthcare facilities from sending their hazardous waste pharmaceuticals to a reverse distributor if there is a reasonable expectation of credit. Whether or not credit is actually given is not a defining factor and it is not within EPA's expertise to know how many times a potentially creditable hazardous waste pharmaceutical needs to be rejected before it is considered ''non-creditable.'' Each pharmaceutical is different and is or is not creditable for various reasons as dictated by the manufacturer. EPA has learned since the proposal that generic prescription drugs can have a reasonable expectation of receiving manufacturer credit. EPA also agrees with commenters that ''partials'' can be given credit.

EPA's intent is to prevent hazardous waste pharmaceuticals that are clearly ineligible for credit and are ready for disposal, due to their condition, previous use with a patient, or other reason, from being sent to the reverse distributor. Hazardous waste pharmaceuticals that are in original packaging and have not been dispensed to a patient would fit under this definition of ''potentially creditable hazardous waste pharmaceutical.''

E. Definition of Non-Creditable Hazardous Waste Pharmaceutical

1. Summary of Proposal

In order to distinguish hazardous waste pharmaceuticals that have the potential for credit from those that have no expectation of receiving credit, the Agency proposed to define the term ''non-creditable hazardous waste pharmaceutical.'' The proposed definition of a ''non-creditable hazardous waste pharmaceutical'' is a hazardous waste pharmaceutical that is not expected to be eligible for manufacturer credit. Examples include, but are not limited to pharmaceuticals that have been removed from the original container and repackaged for dispensing purposes; a pharmaceutical refused by a patient after an attempt to administer it; hazardous waste pharmaceuticals generated during patient care; dispensed pharmaceuticals returned to a pharmacy after the pharmacy had already received compensation by a third-party payer (*e.g.,* health insurance company); or pharmaceuticals that are more than one year past their expiration dates. Non-creditable hazardous waste pharmaceuticals are typically opened and not in their original packaging and have been dispensed (though not administered) to a patient. These conditions of the non-creditable pharmaceutical are what makes them not creditable rather than the manufacturer's policy on the specific type of pharmaceutical.

2. Summary of Comments

Commenters expressed a variety of opinions on EPA's proposed definition of ''non-creditable hazardous waste pharmaceutical.'' Some states, manufacturers and the waste management industry stated that they were satisfied with the proposed definition of ''non-creditable hazardous waste pharmaceutical.'' Wholesalers argued that the definition should be struck and the regulations should allow all intact hazardous waste pharmaceuticals to go back to a reverse distributor. Pharmacists, some states, and the retail industry argued that EPA should define ''non-creditable hazardous waste pharmaceuticals'' as those hazardous waste pharmaceuticals that are not accepted by reverse distributors for manufacturer credit.

3. Final Rule Provision

For the final rule, EPA made three major changes to the definition of ''non-creditable hazardous waste pharmaceutical'' to address comments. First, EPA has added the word ''prescription'' to the first portion of the definition to be consistent with the use of terminology in the final rule that reverse distribution is the reverse flow of prescription hazardous waste pharmaceuticals. Second, the Agency has added new language to the definition to reflect the fact that nonprescription hazardous waste pharmaceuticals can also be considered non-creditable hazardous waste pharmaceuticals that must be managed under the healthcare facility standards in § 266.502 when they do not have a reasonable expectation to be legitimately used/reused or reclaimed. For purposes of this definition, the determination is being made that at the healthcare facility, prescriptions that have already been dispensed to a patient, and free samples given to healthcare facilities do not have a reasonable expectation of receiving manufacturers credit. Third, EPA has also added examples of non-creditable hazardous waste pharmaceuticals.

Under the final rule, non-creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

While not specifically laid out in the definition, other examples of non-creditable hazardous waste pharmaceuticals can be pharmaceuticals that have been removed from the original container and repackaged for dispensing purposes; pharmaceuticals in their original packaging when the packaging is leaking or otherwise damaged; a pharmaceutical refused by a patient after an attempt was made to administer it; pharmaceuticals generated during patient care; dispensed pharmaceuticals returned to a pharmacy after the pharmacy already received compensation by a third-party payer (*e.g.,* health insurance company); or pharmaceuticals at are more than one year past their expiration date.

4. Comments and Responses

Wholesalers and some reverse distributors recommended that we do not differentiate between potentially creditable and non-creditable hazardous waste pharmaceuticals and allow all hazardous waste pharmaceuticals that are intact and in original packaging to go to the reverse distributors. EPA disagrees with the commenters. EPA proposed this differentiation between potentially creditable and non-creditable hazardous waste pharmaceuticals to distinguish between a traditional TSDF and the function served by a reverse distributor. A reverse distributor should not act as a hazardous waste disposal facility for healthcare facilities. It is serving as the manufacturer's agent for determination of credit. If a reverse distributor is not determining credit, EPA views it as managing hazardous waste pharmaceuticals that do not have monetary value and thus would be subject to TSDF regulations. If a reverse distributor begins to routinely receive non-creditable hazardous waste pharmaceuticals, then it is serving as a TSDF. EPA has made this differentiation to correctly represent the reverse distributor role as a manufacturer's agent for facilitating credit and not like a more traditional hazardous waste management facility.

Pharmacists, the retail industry and some states recommended that we define non-creditable hazardous waste pharmaceuticals as those hazardous waste pharmaceuticals that do not receive credit. There are some situations in which pharmaceuticals are well known to not be eligible for credit, such as leaky containers, samples or when pharmaceuticals were already dispensed to patients. The Agency did not finalize the commenters' recommendation, however, because it could potentially lead to situations where a healthcare facility sends a hazardous waste pharmaceutical to a reverse distributor in good faith that manufacturer credit is forthcoming, but credit is not issued. If EPA accepted this recommendation, the reverse distributor could be determined to unlawfully be in possession of non-creditable hazardous waste pharmaceuticals. For this reason, the Agency added into the definition that non-creditable hazardous waste pharmaceuticals are prescription pharmaceuticals that do not have a reasonable expectation of receiving manufacture credit, or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. It should be clear to healthcare personnel that leaking containers, for example, are not eligible for credit and should be sent to a designated facility for disposal (*e.g.,* a TSDF). However, it is often not clear to the healthcare facility personnel making the determination which hazardous waste pharmaceuticals will receive manufacturer credit if they were not dispensed and/or are in their original packaging (*i.e.,* potentially creditable). The Agency does find it reasonable that healthcare personnel may not know if a manufacturer credit policy for a particular pharmaceutical has changed.

Because it is not always clear that all hazardous waste pharmaceuticals will be eligible for credit due to frequent changes in manufacturers' policies, it is inappropriate to create a bright line in the definition solely based on whether the hazardous waste pharmaceutical would or would not receive manufacturer credit. Instead, this final definition takes into account this uncertainty and the difficulty it poses for healthcare facilities and allows for instances where a potentially creditable hazardous waste pharmaceutical can be correctly sent to a reverse distributor under the subpart P regulations despite not actually receiving manufacturer credit.

F. Definition of Evaluated Hazardous Waste Pharmaceutical

1. Summary of Proposal

EPA proposed a definition for evaluated hazardous waste pharmaceuticals. After potentially creditable hazardous waste pharmaceuticals arrive at a reverse distributor, they are evaluated by the reverse distributor to determine whether they are eligible for manufacturer credit or whether they need to be transferred to another reverse distributor for additional verification of manufacturer credit. Hazardous waste pharmaceuticals that need to be transferred to another reverse distributor for additional verification of manufacturer credit will continue to be considered potentially creditable hazardous waste pharmaceuticals. EPA proposed that hazardous waste pharmaceuticals for which manufacturer credit has been issued (and no further verification of credit is required), as well as those that do not receive credit, be referred to as ''evaluated hazardous waste pharmaceuticals.''

EPA proposed to define an ''evaluated hazardous waste pharmaceutical'' as a hazardous waste pharmaceutical that

was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a reverse distributor to establish whether it is eligible for manufacturer credit and will not be sent to another reverse distributor for further evaluation or verification.

It is important to define this term since the proposed management and shipping standards for potentially creditable hazardous waste pharmaceuticals differ from the proposed management and shipping standards for evaluated hazardous waste pharmaceuticals and the regulations must therefore distinguish between them. For a discussion of the proposed shipping and management standards for potentially creditable hazardous waste pharmaceuticals, see section XVI.D. and for a discussion of the proposed shipping and management standards for evaluated hazardous waste pharmaceuticals, see section XVI.B.

2. Summary of Comments

There were few comments pertaining to this definition. One state sought clarification on whether under this definition, an evaluated pharmaceutical could be sent on to another reverse distributor. Pharmacists wanted further clarification that evaluated hazardous waste pharmaceuticals are not eligible for credit.

3. Final Rule Provision

For the final rule, EPA made two changes to the definition of ''evaluated hazardous waste pharmaceuticals'': (1) Adding the word ''prescription'' to be consistent with our decision to distinguish between reverse distribution and reverse logistics and (2) focusing the definition on the evaluation process and does not rely as heavily on manufacturer credit.

EPA is finalizing that ''evaluated hazardous waste pharmaceutical'' means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

Under the definition of evaluated hazardous waste pharmaceutical, if credit has been determined and no other verification is needed, then the waste would be considered evaluated. If the prescription hazardous waste pharmaceutical needs further evaluation for credit, it can be sent on to another reverse distributor for that determination. It will not be considered evaluated until the credit is verified.

The Agency notes that an evaluated pharmaceutical still at the reverse distributor is not precluded from ever being awarded manufacturer credit. A manufacturer may change a credit policy while an evaluated pharmaceutical is being accumulated at a reverse distributor. However, as an evaluated pharmaceutical, it is no longer managed as a potentially creditable pharmaceutical at the reverse distributor, then it must be managed as an evaluated hazardous waste pharmaceutical even if credit is awarded after the initial evaluation. Please refer to section XVII.C of this preamble for a detailed discussion of the reverse distributor standards.

G. Definition of Household Waste Pharmaceutical

1. Summary of Proposal

EPA proposed to define the term ''household waste pharmaceutical'' as a solid waste, as defined in § 261.2, that also meets the definition of pharmaceutical, but is not a hazardous waste because it is exempt from RCRA Subtitle C regulation by the household waste exclusion in § 261.4(b)(1).

We proposed this term to distinguish this type of waste pharmaceutical from the hazardous waste pharmaceuticals that are proposed to be regulated under this new subpart.

2. Summary of Comments

Commenters generally agreed with EPA's definition of ''household waste pharmaceutical'' as proposed but were concerned with applicability of this definition and where the household waste exclusion can be used. For example, one commenter asked if it extended to schools. A few commenters wanted to know if this applied to all DEA take back programs and requested that the words ''including those generated by DEA regulations'' be added. Lastly, commenters asked us to clarify the significance of the household waste pharmaceutical definition with respect to long-term care facilities (LTCFs).

3. Final Rule Provisions

EPA is finalizing the definition of ''household waste pharmaceutical'' as proposed with one minor change. EPA changed the word ''exempt'' to ''excluded'' to be consistent with the title of § 261.4(b). In the final rule, ''household waste pharmaceutical'' means a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1).

4. Comments and Responses

In response to some of the commenters' concerns, EPA is defining the term ''household waste pharmaceutical'' as a matter of convenience in crafting the regulatory language as well as the preamble. By defining the term, we do not alter the criteria we have consistently relied on for determining whether a waste is considered a household hazardous waste. The two criteria that must be met to be a household hazardous waste are (1) the waste must be generated by individuals on the premise of a temporary or permanent residence and (2) the waste stream must be composed primarily of materials found in wastes generated by consumers in their homes. Section 261.4(b)(1) defines household to include single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds and day-use recreation areas. This exclusion does not include schools. Schools generate hazardous waste from various sources throughout the school grounds such as chemicals from labs, cleaning supplies and hazardous waste pharmaceuticals from medical clinics. These wastes are not being generated at a temporary or permanent residence and are not the types of wastes that would ordinarily be generated by a consumer at their home. Pharmaceuticals generated at schools would not be considered household waste pharmaceuticals. However, hazardous waste pharmaceuticals generated at dormitories at schools would be considered household waste pharmaceuticals and thus excluded, because the dormitories are residences.

Some types of healthcare facilities could be considered households. This final rule defines the term LTCF in § 266.500. LTCF means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities. The types of healthcare facilities listed at the end of this definition that are not considered to be LTCFs are not subject to subpart P requirements and hazardous waste pharmaceuticals generated there continue to be excluded from RCRA as household hazardous wastes. For a more thorough discussion of the applicability

of the household hazardous waste exclusion at LTCFs, see section VIII.K of this preamble.

While DEA controlled substances can sometimes be household waste pharmaceuticals, once these wastes are collected at a take back event or by law enforcement, DEA regulations require that any proper disposal must meet the DEA non-retrievable standards of destruction. Furthermore, this EPA rule finalizes specific requirements for the destruction of collected household waste pharmaceuticals, see section XIV of this preamble for details. Therefore, it could have been confusing to add ''including waste under DEA regulations'' to the definition of household waste pharmaceutical.

H. Definition of Non-Hazardous Waste Pharmaceutical

1. Summary of Proposal

EPA proposed to define the term ''non-hazardous waste pharmaceutical.'' While hazardous waste pharmaceuticals are regulated under this new subpart, non-hazardous waste pharmaceuticals are not regulated under RCRA Subtitle C, including this new subpart. The Agency proposed this definition since we believed it was important to clearly delineate what is and is not regulated under this new subpart.

The Agency proposed to define the term ''non-hazardous waste pharmaceutical'' as a pharmaceutical that is a solid waste, as defined in § 261.2, but is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C. The characteristics of hazardous waste are ignitability, corrosivity, reactivity, and toxicity.

2. Summary of Comments

Most commenters agreed with the definition of ''non-hazardous waste pharmaceutical'' as proposed. There were some comments concerning commingling of hazardous and non-hazardous waste. These comments are addressed in detail in section X.C. and XI.A. of this preamble.

3. Final Rule Provision

The Agency is finalizing the definition of ''non-hazardous waste pharmaceutical'' as proposed, with no changes. In this rule, a ''non-hazardous waste pharmaceutical'' is a pharmaceutical that is a solid waste, as defined in § 261.2, but is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C.

I. Definition of Non-Pharmaceutical Hazardous Waste

1. Summary of Proposal

Like the previous definition, we proposed to define non-pharmaceutical hazardous waste to help delineate what is and what is not regulated under this new subpart. We proposed to define the term ''non-pharmaceutical hazardous waste'' as a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical as defined in this section.

The proposed definition was needed because the management of non-pharmaceutical hazardous wastes is not regulated under subpart P; rather, generators of non-pharmaceutical hazardous wastes, including healthcare facilities and reverse distributors, remain subject to part 262 and other applicable Subtitle C hazardous waste regulations for the management of those hazardous wastes.

2. Summary of Comments

There were only a few comments on the proposed definition of ''non-pharmaceutical hazardous waste.'' Commenters generally agreed with the definition, but two commenters wanted EPA to clarify how to classify a waste with an ingredient that is used in both pharmaceutical and non-pharmaceutical items.

3. Final Rule Provisions

EPA is finalizing the definition of non-pharmaceutical hazardous waste, as proposed, with no changes. In this final rule, ''non-pharmaceutical hazardous waste'' is a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical as defined in § 266.500.

4. Comments and Responses

Multiple commenters asked EPA to clarify how a hazardous waste should be managed when it is used as an ingredient in both pharmaceuticals and non-pharmaceutical, *e.g.,* isopropyl alcohol, which can be used both as an antiseptic and a degreaser. Please see the definition in section VIII.A. for discussion about what meets the definition of pharmaceutical, including how to apply the definition in this type of scenario. Any hazardous waste not meeting the definition of pharmaceutical is considered a non-pharmaceutical hazardous waste and should be managed under all applicable RCRA standards.

J. Definition of Healthcare Facility

1. Summary of Proposal

EPA proposed to define ''healthcare facility'' as any person that provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or sells or dispenses OTC or prescription pharmaceuticals. The proposed definition was adapted from the definition of ''health care'' that the Department of Health and Human Services promulgated as a result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 CFR part 160.103).[163] The proposed definition of ''healthcare facility'' included, but was not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, LTCFs, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of OTC medications; and veterinary clinics and hospitals.

EPA proposed to include coroners and medical examiners in the definition of ''healthcare facility'' despite the fact that the services coroners provide occur after life. Coroners will often inventory, and then dispose of, any pharmaceuticals that may be found at the scene of a death, and commonly sewer dispose of pharmaceuticals by putting them down the drain.[164] In order to reduce sewer disposal of pharmaceuticals and provide these facilities with the same management options that are available to other healthcare facilities, EPA included coroners in the proposed definition of healthcare facility.

The proposed definition of healthcare facility did not include pharmaceutical manufacturers and their representatives, wholesalers, or any other entity that is involved in the manufacturing, processing, or wholesale distribution of pharmaceuticals. EPA proposed to

[163] 45 CFR part 160 *http://aspe.hhs.gov/admnsimp/final/pvctxt01.htm.*

[164] For more information on the disposal process, please see: Ruhoy, I.S. and Daughton, C.G. ''Types and Quantities of Leftover Drugs Entering the Environment via Disposal to Sewage—Revealed by Coroner Records,'' Sci. Total Environ., 2007, 388(1–3):137–148. *https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryID=168384.*

exclude manufacturing facilities from the definition of healthcare facility because the Agency did not anticipate that manufacturing facilities, which predictably generate a known range of hazardous wastes, face the same issues as healthcare facilities.

2. Summary of Comments

EPA requested comment on including coroners in the definition of ''healthcare facility.'' EPA received three comments supporting the inclusion of coroners in the definition of ''healthcare facility.'' One stakeholder was aware of coroner facilities that sewer dispose of pharmaceuticals and argued to include them in the definition in order to reduce the sewer disposal of pharmaceuticals. Two commenters expressed concern about including coroners in the definition of ''healthcare facility.'' One commenter stated that including coroners in the definition could discourage coroners from promoting take-back programs.

EPA also took comment on including compounding pharmacies in the definition of ''healthcare facility.'' Three commenters supported the inclusion of compounding pharmacies in the definition. One commenter stated that compounding pharmacies should be included because they do not predictably generate a known range of hazardous wastes and face problems similar to that of a healthcare facility.

The most frequent comment the Agency received on the definition of ''healthcare facility'' was that EPA should define wholesale distributors and third-party logistics providers as healthcare facilities or to create a separate definition for wholesale distributors and third-party logistics providers, but allow them to operate under the same standards as healthcare facilities.

3. Final Rule Provisions

EPA is finalizing a definition for ''healthcare facility'' so that it is clear to whom these final regulations apply. EPA is finalizing that ''healthcare facility'' means any person that is lawfully authorized to (1) provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) distribute, sell, or dispense pharmaceuticals, including OTC pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, LTCFs, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, and veterinary clinics and hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Although EPA uses the term ''person,'' in the definition of healthcare facility, the definition of healthcare facility does not necessarily apply to individual healthcare providers at a site. As defined in § 260.10, ''person'' means ''an individual, trust, firm, joint stock company, Federal Agency, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or any interstate body.'' Accordingly, a healthcare facility can have multiple healthcare providers or a sole healthcare provider. For example, an individual healthcare provider who works at a hospital with multiple healthcare providers is not considered a healthcare facility, but the hospital is considered a healthcare facility, under the final definition. Additionally, a doctor's office with a sole healthcare provider would also be considered a healthcare facility under this final rule.

The proposed definition of ''healthcare facility'' did not apply to pharmaceutical manufacturers' representatives, wholesale distributors, third-party logistics providers, or any other entity that is involved in the wholesale distribution of prescription or OTC pharmaceuticals. Commenters argued that excluding wholesale distributors and third-party logistics providers from the definition of ''healthcare facility,'' in combination with the revised interpretation that the point of generation for potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, could hinder wholesale distributors' and third-party logistics providers' ability to send potentially creditable pharmaceuticals through reverse distribution. These commenters were concerned that if they were not included in the definition of ''healthcare facility'' they would be precluded from using reverse distributors. Commenters also pointed out that wholesale distributors and third-party logistics facilities are likely to generate hazardous waste pharmaceuticals unpredictably and that their workers typically do not have the expertise to make hazardous waste determinations. Due to these comments, the Agency anticipates that wholesale distributors and third-party logistics facilities face similar issues as healthcare facilities and therefore is including them in the final definition of ''healthcare facility.''

The final definition of ''healthcare facility'' includes wholesale distributors, third-party logistics providers that engage in forward distribution, and military medical logistics facilities. Including wholesale distributors and third-party logistics facilities in the definition of ''healthcare facility'' ensures that these facilities can continue sending potentially creditable hazardous waste pharmaceuticals through reverse distribution. EPA recognizes that wholesale distributors and third-part logistics providers are not accustomed to referring to themselves as healthcare facilities. However, it is helpful to have a single, umbrella term when discussing who is subject to this subpart.

The final definition of ''healthcare facility'' does not apply to pharmaceutical manufacturers or any other entity that is involved in the manufacturing of OTC or prescription pharmaceuticals. The purpose for these sector-based regulations is to address the various issues that healthcare facilities and reverse distributors face when managing hazardous waste pharmaceuticals. The Agency does not anticipate that manufacturing facilities, which predictably generate a known range of hazardous wastes, face the same issues as healthcare facilities, and therefore are excluded from the definition of ''healthcare facility'' under this rule.

The final definition of ''healthcare facility'' includes locations that sell pharmaceuticals over the internet, through the mail, or through other distribution mechanisms. A pharmacy does not necessarily have to have a ''brick and mortar'' or ''store front'' presence to be considered a healthcare facility for the purposes of this final rule. The final definition of a ''healthcare facility'' also applies to entities that engage in drug compounding. In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. EPA solicited comment on including compounding

pharmacies in the definition of healthcare facility and received three comments supporting and no comments opposing the inclusion of compounders in the definition. The final definition of ''healthcare facility'' applies to state-licensed pharmacies, federal facilities, and licensed physicians that compound drugs in accordance with section 503A of the FD&C Act, and to outsourcing facilities that compound drugs in accordance with section 503B of the FD&C Act.

4. Comments and Responses

The final definition does not include independently located coroners and medical examiners. EPA made this change in response to commenter concern that including coroners and medical examiners in the definition could discourage coroners and medical examiners from promoting take-back programs for household pharmaceuticals. However, coroners and medical examiners that are co-located with healthcare facilities, such as hospitals, will fall under the definition of ''healthcare facility,'' because they are physically part the healthcare facility.

K. Definition of Long-Term Care Facility

1. Summary of Proposal

The proposed definition of healthcare facility specifically included LTCFs as an example of a type of healthcare facility. Since the term ''long-term care facility'' does not have a standardized, industry definition, EPA proposed to define the term for purposes of this rule. We proposed to define a LTCF as a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, assisted living, hospices, nursing homes, skilled nursing facilities, and the assisted living and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, and the independent living portions of continuing care retirement communities.

The facilities we proposed to include as LTCFs are licensed care facilities that are more similar to hospitals than to standard residences. Although group homes may be licensed care facilities, they are typically very small (fewer than 10 beds) and therefore were not included within the proposed definition. Similarly, independent living communities are not licensed care facilities, but rather are residences made up of individual units such as townhomes or apartments and therefore were not included within the proposed definition. Finally, we clarified in the preamble to the proposed rulemaking that private residences with visiting nurses would not be considered long-term care facilities.

By proposing to define a LTCF as a type of healthcare facility, EPA was proposing to revise its policy regarding the regulatory status of hazardous waste from long-term care facilities. We proposed that hazardous waste from LTCFs would no longer be excluded as household hazardous waste; rather, it would be regulated as hazardous waste, subject to the appropriate RCRA Subtitle C management standards, including the standards proposed for hazardous waste pharmaceuticals under part 266 subpart P. In other words, the proposed revision to our policy regarding long-term care facilities pertained to all of the facilities' hazardous waste, not just the hazardous waste pharmaceuticals.

The Agency proposed revising its interpretation with regard to hazardous wastes generated at LTCFs based on a reevaluation of how such facilities operate. Specifically, in order to qualify for the household hazardous waste exclusion of § 261.4(b)(1), waste must meet two criteria: (1) The hazardous waste must be generated by individuals on the premises of a household, and (2) the hazardous waste must be composed primarily of materials found in the wastes generated by consumers in their homes.[165] In the preamble to the proposed rulemaking, EPA explained that hazardous waste generated at LTCFs, even those pharmaceuticals that are under the control of the patient or resident, does not meet either criterion for the household hazardous waste exemption.

In brief, the explanation provided in the preamble to the proposed rulemaking was two-fold. First, a LTCF is more similar to a hospital than it is a typical residence and EPA does not consider a hospital to be a household. LTCFs are licensed, residential care settings that offer their residents a wide range of services, many of which are centered on administering medications and providing healthcare by various professional healthcare providers, such as medical technicians, nurse's aides, nurses, and doctors. Other services provided involve assistance in performing activities of daily living, such as bathing and eating. Given that LTCFs are licensed settings for the care of their residents and routinely provide healthcare services, EPA believes that LTCFs more closely resemble hospitals than typical residences.

Second, we explained, the hazardous wastes generated by LTCFs do not meet the second criteria for the waste to be considered household hazardous waste. This is primarily due to the quantity and breadth of pharmaceutical wastes that are often generated on the premises of LTCFs when compared to a typical residence. This distinction about volume and breadth of waste is analogous to the distinction that EPA has made in the past about contractor or do-it-yourself waste from households: Waste from ''routine residential maintenance'' is exempt as household hazardous waste, while waste from ''building construction, renovation, demolition'' is not excluded.[166]

2. Summary of Comments

EPA received a number of comments requesting changes to the proposed definition of ''LTCF'' that were instrumental in the final definition in the rule. We also received a number of comments related to whether hazardous waste from LTCFs should be excluded from RCRA Subtitle C regulations as household hazardous waste.

3. Final Rule Provisions

Based on comments, we have made some changes to the proposed definition of LTCF. The final definition retains the descriptive portion of the definition, but the list of types of facilities included as a LTCF has been revised to be more consistent with how the term is used by DEA and the Centers for Medicare and Medicaid Services (CMS). This final rule defines ''LTCF'' as a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

The primary change we have made to the proposed definition relates to assisted living facilities. Under the proposed definition, an assisted living facility was considered a type of LTCF.

[165] See November 13, 1984; 49 FR 44978.

[166] Memo from Petruska to McNally, February 28, 1995; RCRA Online #11897 that discusses the distinction about what renovation waste is household hazardous waste and what is not.

Under the final definition, an assisted living facility is not considered a type of LTCF. This change is responsive to commenter's concerns and will make EPA's definition more consistent with how the term is used by both DEA and CMS. The DEA's definition of ''long term care facility'' is ''a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.'' [167] DEA does not consider assisted living facilities to be long-term care facilities. CMS also does not consider assisted living facilities to be long-term care facilities. One commenter pointed out that ''As primary regulatory oversight of [assisted living] resides at the state level, regulatory requirements and applicable definitions differ state by state. This is why the Centers for Medicare and Medicaid Services (CMS) excluded [assisted living] in its definition of Long Term Care Facilities.'' [168]

Furthermore, commenters argued, and EPA agrees, that assisted living facilities differ from LTCFs in at least two ways. First, some assisted living facilities do not provide medication management.[169] In some cases, assisted living facilities are actually prohibited from managing medications.[170] Second, many assisted living facilities do not have on-site nursing or other medical staff.[171] EPA believes it is easier for implementation of this rule, to make a determination about assisted living facilities as a category, rather than on the basis of whether they provide medication management of have on-site medical staff. Therefore, for ease of implementation as well as consistency with DEA and CMS, EPA is not considering assisted living facilities to be long-term care facilities for purposes of subpart P.

4. Comments and Responses

a. *Long-term care facilities and the household hazardous waste exclusion.* Aside from the comments about what types of facilities should and should not be considered LTCFs, we received many comments about whether LTCFs should be eligible to use the household hazardous waste exclusion of § 261.4(b)(1). Three states, the Hematology/Oncology Pharmacy Association, Stericycle, Inc., Healthcare Waste Institute, National Waste and Recycling Association, and Public Employees for Environmental Responsibility agreed that LTCFs should be considered healthcare facilities and therefore not eligible to use the household hazardous waste exemption. The American Society of Consultant Pharmacists and the National Community Pharmacists Association disagreed with EPA's proposed change of interpretation that hazardous waste (including pharmaceuticals) generated at LTCFs will no longer be considered exempt as household hazardous waste. The American Society of Consultant Pharmacists expressed concern that this change would be a substantial learning curve for LTCFs and the costs may be significant. Covanta Energy LLC expressed concern that the impacted facilities do not have robust financials and would pass the costs on to consumers. An assisted living community commented that the facility does not have the authority to compel residents to surrender their medications for disposal and therefore the new requirement would cause the assisted living community to be perpetually in noncompliance. One state opposed classifying group homes as healthcare facilities rather than as households. Waste Management National Services, Inc. suggested that self-administered pharmaceuticals that are under residents' control should be considered household waste.

EPA is finalizing that LTCFs are included within the final definition of healthcare facility. Accordingly, EPA is also finalizing that hazardous waste (including pharmaceuticals) generated at LTCFs will no longer be excluded as household hazardous waste: It will be regulated as hazardous waste, subject to the appropriate RCRA Subtitle C management standards, including the final subpart P management standards for hazardous waste pharmaceuticals. EPA is revising its interpretation with regard to hazardous wastes generated at LTCFs based on a reevaluation of how such facilities operate. Specifically, in order for hazardous waste to qualify for the household hazardous waste exclusion of § 261.4(b)(1), it must meet the two criteria. EPA continues to believe that hazardous waste generated at LTCFs, does not meet either criterion for the household waste exclusion.

In summary, EPA is finalizing that LTCFs may no longer use the household hazardous waste exclusion. LTCFs need to manage their hazardous waste pharmaceuticals in accordance with the healthcare facility specific management standards in this final rule and their non-pharmaceutical hazardous wastes in accordance with the applicable RCRA hazardous waste generator regulations in § 262.14 (for VSQGs), § 262.16 (for SQGs), or § 262.17 (for LQGs), as well as § 262.15 (for satellite accumulation areas (SAAs)). However, even though LTCFs will no longer be eligible to use the household hazardous waste exclusion, EPA estimates that there are between 2,875 and 4,770 LTCFs that generate hazardous waste and that 98–99 percent of the facilities are VSQGs regulated under § 262.14 and therefore not subject to part 266 subpart P (except the sewer prohibition, the empty container provisions and the optional provisions of § 266.504).[172] This means that this change in policy will primarily affect the larger long-term care facilities, which are far fewer in number (1–2 percent of LTCFs).

It is also important to note that, because of the change to the definition of LTCF, this change in policy regarding the household hazardous waste exclusion and LTCFs will not impact residents in assisted living facilities. As discussed previously, assisted living facilities will not be considered healthcare facilities and therefore will continue to be considered residences that are eligible to use the household hazardous waste exclusion in 40 CFR 261.4(b)(1). Under the household hazardous waste exclusion, assisted living facilities are not required to manage their residents' hazardous waste, including their hazardous waste pharmaceuticals, under the RCRA regulations. Commenters confirmed our data that two-thirds of assisted living facilities are small facilities with 25 residents or less, many of whom would presumably be VSQGs.[173] Therefore, we believe that this revised interpretation will have minimal environmental impact: instead of assisted living facilities being exempt as VSQGs, residential waste from assisted living facilities will be exempt as household hazardous waste. That said, under RCRA, states may be more stringent than the federal government and we are aware that some states already have a more stringent interpretation and do not consider assisted living facilities to be exempt from RCRA as households.

[167] See 21 CFR 1300.01.

[168] Medicare Prescription Drug Benefit Manual—Chapter 5, § 10.2, as cited by commenter EPA–HQ–RCRA–2007–0932–0289.

[169] See comment EPA–HQ–RCRA–2007–0932–0242.

[170] See comment EPA–HQ–RCRA–2007–0932–0289.

[171] Overview of Assisted Living, 2009, A collaborative research project of American Association of Homes and Services for the Aging (AAHSA), American Seniors Housing Association (ASHA), Assisted Living Federation of American (ALFA), National Center for Assisted Living (NCAL), and National Investment Center for the Seniors Housing and Care Industry (NIC).

[172] Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[173] See commenter EPA–HQ–RCRA–2007–0932–0289.

As noted previously, EPA's household hazardous waste exclusion in 40 CFR 261.4(b)(1) exempts hazardous waste that meets two criteria: (1) It is generated on the premises of a temporary or permanent residence for individuals and (2) the waste stream is composed primarily of materials found in the waste generated by consumers in their homes.[174] Therefore, only hazardous wastes that are generated in the residential areas of an assisted living facility would be excluded as household hazardous waste. On the other hand, hazardous wastes that are generated by an assisted living facility outside of the residential areas would not be considered excluded as household hazardous waste. This interpretation regarding non-residential hazardous waste generated at assisted living is consistent with our interpretation regarding dry cleaning wastes generated at hotels. Specifically, our interpretation has been that while hazardous waste generated in hotel rooms is excluded as household waste, ''dry cleaning wastes produced by the hotel do not meet both criteria for household waste and will not qualify for the household waste exclusion.'' [175] Similarly, when it comes to assisted living facilities, this final rule will rely on the interpretation that we initially expressed in the preamble to the proposed rulemaking to add pharmaceuticals to Universal Waste: ''the [long-term care] facility itself may generate hazardous waste as a result of its central management of pharmaceuticals in its pharmacy or pharmacy-like area. These hazardous pharmaceutical wastes would be subject to the RCRA hazardous waste generator regulations since the pharmaceuticals are under the control of the facility, and thus, the resulting wastes are generated by the facility. However, patients and residents in long-term care facilities may generate hazardous wastes. Those pharmaceuticals that are under the control of the patient or resident of this LTCF, when discarded, would be subject to RCRA's household hazardous waste exclusion (§ 261.4(b)(1)). Hazardous pharmaceutical wastes generated by the resident are excluded from regulation because they are considered to be derived from the household.'' [176]

Under the final rule, group homes and independent living communities are also not defined as LTCFs but rather are considered residences that are eligible to use the household hazardous waste exclusion. An assisted living facility, group home and independent living facility are eligible for the household hazardous waste exclusion whether they are stand-alone facilities, or whether they are part of a continuing care retirement community. Conversely, a nursing facility or skilled nursing facility is considered a LTCF, and hence a healthcare facility, whether it is a stand-alone facility or part of a continuing care retirement community. Therefore, a continuing care retirement community will likely have portions of the facility that are excluded from RCRA regulation as households, while other portions of the facility will be regulated under RCRA for their hazardous waste generation and management, including hazardous waste pharmaceuticals.

b. *Other comments.* Commenters asked us to clarify the difference in regulatory status between in-home hospice care and in-patient hospice facilities. One commenter points out that ''Most hospice care is provided in the private residence of a patient.'' [177] Hazardous waste pharmaceuticals that are generated by in-home medical care, such as in-home hospice care, would be eligible for the household hazardous waste exclusion. On the other hand, hospice *facilities* are not considered residences and are not eligible for the household hazardous waste exclusion. Nevertheless, as discussed in section XII.D. of this preamble, long-term care facilities, including hospice facilities, that have 20 beds or fewer will be presumed to be VSQGs. Healthcare facilities that are VSQGs are subject to the sewer prohibition for hazardous waste pharmaceuticals under this final rule, the empty container standards in § 266.507, and the optional provisions of § 266.504, but otherwise are regulated by the reduced regulations of 40 CFR 262.14 for the generation and accumulation of hazardous waste, including hazardous waste pharmaceuticals.

IX. Applicability (§ 266.501)

Part 266 subpart P was proposed to replace the standard RCRA generator regulations in part 262 for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. We proposed separate regulations for healthcare facilities and reverse distributors. Further, we proposed separate regulations for the management of the two types of hazardous waste pharmaceuticals—potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals. When a healthcare facility disposes hazardous waste pharmaceuticals directly by sending it to a hazardous waste treatment, storage, or disposal facility, we proposed that these would be considered non-creditable hazardous waste pharmaceuticals. On the other hand, when a healthcare facility disposes of hazardous waste pharmaceuticals indirectly through a reverse distributor that facilitates manufacturer credit, we proposed that these would be considered potentially creditable hazardous waste pharmaceuticals. We proposed that when a reverse distributor receives the potentially creditable pharmaceuticals, it must evaluate them to determine whether they need to go onto another reverse distributor, in which case the pharmaceuticals would still be considered potentially creditable, or whether they will go to a TSDF, in which case they will be considered evaluated hazardous waste pharmaceuticals. Although EPA proposed that potentially creditable pharmaceuticals destined for reverse distributors would be considered hazardous wastes, we also recognized that due to the considerable value they retain in the form of potential credit from manufacturers, there was a strong incentive to manage them appropriately and we did not need to apply the standard RCRA regulations to them or to the reverse distributors that manage them. In contrast, once the credit has been established for the evaluated hazardous waste pharmaceuticals, the incentive to manage them appropriately no longer exists and we needed to apply more rigorous regulations. This section of the preamble discusses the types of facilities and pharmaceuticals that are and are not subject to this rulemaking. Subsequent sections of the preamble discuss the details of the regulations for healthcare facilities managing non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals as well as the regulations that pertain to reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated pharmaceuticals.

A. What facilities are subject to the final rule?

1. Healthcare Facilities (§§ 262.10(n) and 266.501(d))

a. *Summary of proposal.* The Agency proposed that healthcare facilities that

[174] 49 FR 44978; November 13, 1984.

[175] See RCRA Online #13736, March 1995.

[176] See 73 FR 73525, December 2, 2008. Note that while the Universal Waste proposal used the term ''hazardous pharmaceutical wastes,'' this final rule uses the term ''hazardous waste pharmaceuticals''.

[177] CareFirst, Commenter EPA–HQ–RCRA–2007–0932–0239.

are not VSQGs will be required to manage all hazardous waste pharmaceuticals generated at their facilities in accordance with the new part 266 subpart P (see § 262.10(n)) in lieu of the part 262 generator regulations. In other words, we proposed that these new management standards apply to any healthcare facility that generates more than 100 kg of hazardous waste per calendar month *or* more than 1 kg of acute hazardous waste per calendar month (*e.g.,* P-listed hazardous waste) *or* more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31, or 261.33(e) per calendar month. We proposed that part 266 subpart P applies to all healthcare facilities that generate above the VSQG monthly quantity limits, including LTCFs.

Further, we proposed that subpart P is not optional for healthcare facilities that generate above the VSQG monthly quantity limits. EPA proposed to make subpart P mandatory to promote national consistency, a goal championed by stakeholder comments as well as EPA. We reasoned that having one set of standards applicable to hazardous waste pharmaceuticals would be less confusing to the regulated community, which should lead to better compliance.

We also proposed that any healthcare facility that generates hazardous waste above VSQG limits is subject to the same set of standards for the management of its hazardous waste pharmaceuticals. That is, unlike under part 262, the stringency of the proposed regulations for healthcare facilities operating under part 266 subpart P does not increase as the amount of hazardous waste generated increases. Put another way, we proposed that there is no generator category for hazardous waste pharmaceuticals under part 266 subpart P. The SQG and LQG categories under the part 262 RCRA requirements will only be relevant for the healthcare facilities' non-pharmaceutical hazardous waste because non-pharmaceutical hazardous waste remains subject to those 40 CFR part 262 generator regulations (along with other applicable sections of the subtitle C regulations).

We proposed that healthcare facilities generating non-creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.502, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.508.

We proposed that healthcare facilities generating potentially creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.503, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.509.

We expect that most potentially creditable hazardous waste pharmaceuticals will be sent to reverse distributors; however, that may not always be the case. For example, in some cases, manufacturer credit can get awarded without having to physically send the potentially creditable hazardous waste pharmaceuticals to a reverse distributor. In such cases, we proposed that if they are not destined for a reverse distributor, then they must be managed by the healthcare facility as non-creditable hazardous waste pharmaceuticals.

b. *Summary of comments.* Comments on the applicability section addressed several main areas of concern. First, commenters weighed in on whether the VSQGs should be subject to part 266 subpart P in its entirety, as opposed to just the sewer prohibition. Second, commenters weighed in on whether the new subpart should be mandatory. Third, commenters weighed in on our proposed revision to our policy related to the reverse distribution of pharmaceuticals. While some commenters agreed with our proposed revised position that pharmaceuticals going through reverse distribution would be considered solid waste, many commenters strongly objected to our proposed revised position. We have made several changes to the final regulations that affect applicability, although several of these changes are to definitions, rather than to the applicability section of § 266.501. The primary focus of this section is to discuss changes made to the applicability section of § 266.501, although changes to definitions that affect applicability are also noted.

c. *Final rule provisions.* The final rule applies to all healthcare facilities that generate above any of the VSQG monthly quantity thresholds. Healthcare facilities that are not VSQGs do not have the choice of opting into part 266 subpart P in lieu of part 262. Further, all healthcare facilities that are subject to part 266 subpart P are regulated the same with respect to their hazardous waste pharmaceuticals, regardless of how much hazardous waste pharmaceuticals they generate. Note that we have made two changes to § 262.10(n). First, we have revised the regulations so that only a healthcare facility that *generates* above the VSQG quantity thresholds are subject to part 266 subpart P. A healthcare facility that *accumulates* above the VSQG quantity thresholds would not be subject to part 266 subpart P; it would remain subject to part 262 (although as with any VSQG, it would be allowed to opt into subpart P). The 2016 Hazardous Waste Generator Improvements final rule amended the part 262 regulations to make it clear that a VSQG that accumulates above the quantity thresholds must manage its hazardous waste in accordance with the conditions of either the SQG or LQG regulations, but the generator would remain a VSQG.[178] Second, in response to comments, we have added the following clarifying sentence at the end of the paragraph: A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is not subject to part 266 subpart P, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.[179]

We have made four changes to the proposed regulatory language of § 266.501(d). First, we have made a conforming change to reflect the change in terminology in this final rule. That is, in § 266.501(d)(1)(ii), ''pharmaceutical reverse distributor'' has now been replaced by ''reverse distributor.'' The second change we made is to omit the reference to § 266.504 in both § 266.501(d)(1) and (2). Section 266.504 only applies to healthcare facilities that are VSQGs and should not have been referenced when discussing the requirements for other healthcare facilities. The third change is to clarify in § 266.501(d)(2), that healthcare facilities managing potentially creditable hazardous waste pharmaceuticals are also subject to the notification and withdrawal standards of § 266.502(a). While EPA believes it is extremely unlikely that a healthcare facility would only manage potentially creditable hazardous waste pharmaceuticals, as proposed, in this situation a healthcare facility would not need to notify as a healthcare facility. EPA is clarifying in the final rule, that

[178] See § 262.14(a)(3) for accumulating >1 kg of acute hazardous waste and § 262.14(a)(4) for accumulating >1000 kg non-acute hazardous waste.

[179] See comment number EPA–HQ–RCRA–2007–0932–0341.

should this situation arise, a healthcare facility only managing potentially creditable hazardous waste pharmaceuticals and no non-creditable hazardous waste pharmaceuticals is subject to notification.

The fourth, and far more substantive change we made is to § 266.501(d)(2). This paragraph has been revised to reflect our decision that healthcare facilities are regulated under part 266 subpart P for the management of prescription hazardous waste pharmaceuticals going through reverse distribution but healthcare facilities are not regulated under part 266 subpart P for the management of nonprescription pharmaceuticals, such as OTCs, homeopathic drugs, and dietary supplements, going through reverse logistics because they are not considered solid or hazardous wastes, provided they have the potential to be lawfully redistributed or legitimately reused or reclaimed. To summarize, part 266 subpart P applies to healthcare facilities managing *non-creditable* hazardous waste pharmaceuticals, whether the pharmaceuticals are prescription or nonprescription. But part 266 subpart P applies to healthcare facilities managing *potentially creditable* hazardous waste pharmaceuticals only if they are prescription hazardous waste pharmaceuticals. The comments we received in this area and the reasoning for our decision have been discussed at length in section VI of the preamble to this final rule.

Due to changes in the definition of healthcare facility and LTCF, there are effectively additional substantial changes to the applicability of the final rule. These two definitional changes have already been discussed, but are summarized here. In short, due to changes to the definition of ''healthcare facility,'' wholesale distributors will now be regulated under part 266 subpart P as healthcare facilities for the management of their hazardous waste pharmaceuticals. This includes 3PLs when they perform the function of a wholesale distributor. Unlike wholesale distributors, 3PLs do not take ownership of the pharmaceuticals; however, both wholesale distributors and 3PLs take physical custody of pharmaceuticals. Under RCRA, a 3PL would meet the definition of a hazardous waste generator, regardless of whether they own the hazardous waste pharmaceuticals.

The final rule still applies to long-term care facilities, because they are still considered healthcare facilities. However, we have amended the proposed definition of LTCF such that assisted living facilities will not be considered long-term care facilities. Further, we have finalized a rebuttable presumption that long-term care facilities with 20 beds or fewer will be presumed to be VSQGs. The combined impact of these changes is that this final rule will apply to far fewer long-term care facilities than the when the rule was proposed.

In other respects, § 266.501(d) of the final rule remains the same as the proposal. That is, healthcare facilities generating non-creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.502, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.508. And healthcare facilities generating potentially creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.503, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.509. Finally, if potentially creditable hazardous wastes are not destined for a reverse distributor, then they must be managed by the healthcare facility as non-creditable hazardous waste pharmaceuticals. For example, if a healthcare facility receives manufacturer credit for a prescription pharmaceutical without shipping it to a reverse distributor, then the healthcare facility is required to manage the hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals.

d. *Comments and responses.* Several commenters asked us to consider making part 266 subpart P an optional alternative to part 262, instead of mandatory. They argued that EPA's previous sector- or waste-specific regulations, such as the Academic Laboratories Rule or Universal Waste, are not mandatory and that generators have the option to use them in lieu of the standard RCRA generator regulations under part 262. On the other hand, several states agreed that having ''one set of standards will be less confusing to the regulated community.'' [180]

As discussed previously, part 266 subpart P will be mandatory for all healthcare facilities generating above VSQG monthly quantity thresholds. Previous sector or waste specific regulations have all been considered either less stringent (Universal Waste) or equally stringent (Academic Laboratories rule) as the standard RCRA generator regulations. In contrast, part 266 subpart P is considered, on the whole, more stringent than the standard RCRA regulations. EPA has never made a more stringent RCRA regulation optional. In part, this is because it seems unlikely that anyone would opt into a more stringent regulatory scheme. If healthcare facilities chose to remain operating under part 262, they would not be subject to the sewer prohibition, which is a cornerstone of this new subpart.

Further, if part 266 subpart P were not mandatory, another result would be that healthcare facilities would not be able to use the new provisions for empty containers or the conditional exemptions for hazardous waste pharmaceuticals that are also DEA controlled substances. But the most important consideration is that this final rule revises our previous policy regarding pharmaceuticals being sent to reverse distributors for manufacturer credit such that they are now considered solid, and possibly hazardous, wastes. Under part 262, a generator can only send its hazardous waste to an off-site facility that has a RCRA permit or interim status. This would require reverse distributors to get RCRA storage permits to be able to accept hazardous waste from off-site. In light of all these considerations, with the exception of VSQG healthcare facilities, EPA has concluded that it is not feasible to make part 266 subpart P an optional alternative to part 262.

That said, we recognize that some commenters are concerned that this final rule will impact their established programs for managing hazardous waste pharmaceuticals. In response, we would point out that, in some cases, compliant practices by healthcare facilities under part 262 would also meet the standards under part 266 subpart P. For example, the training provisions for SQGs (§ 262.16(a)(9)(iii)) and LQGs (§ 262.17(a)(7)) would meet the training provisions for healthcare facilities under part 266 subpart P (§ 266.502(b)). In fact, the subpart P regulatory language for training personnel at healthcare facilities in managing non-creditable hazardous waste pharmaceuticals is identical to the regulatory language in part 262 for SQGs. For labeling, under part 266 subpart P, containers of non-creditable hazardous waste pharmaceuticals part 266 subpart must

[180] See comment numbers: EPA–HQ–RCRA–2007–0932–0242 and EPA–HQ–RCRA–2007–0932–0304.

be labeled with the words ''hazardous waste pharmaceuticals,'' but nothing would prohibit additional labeling by the healthcare facility. Likewise, under part 266 subpart P, healthcare facilities are not required to accumulate their non-creditable hazardous waste pharmaceuticals in a central accumulation area (CAA), but nothing would prohibit them from being accumulated in a CAA. Furthermore, healthcare facilities have up to one year to accumulate non-creditable hazardous waste pharmaceuticals on site under part 266 subpart P, but nothing would prohibit a healthcare facility from accumulating for the shorter time-frames dictated by the SQG (180 days) or LQG (90 days) regulations in part 262.

2. Reverse Distributors (§§ 262.10(m), 264.1, 265.1, 266.501(e), and 270.1)

a. *Summary of proposal.* The proposed rulemaking responded to stakeholders who have asked EPA to clarify how reverse distributors are regulated under RCRA, as states have applied varied hazardous waste regulatory approaches to reverse distributors.[181] EPA proposed specific standards in 40 CFR part 266 subpart P for reverse distributors (as defined in this proposed rulemaking) that incorporated various generator standards, as well as some TSDF standards. EPA proposed that reverse distributors that accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals are subject to this new subpart. We proposed that reverse distributors are only subject to part 266 subpart P for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals; if a reverse distributor also treats and/or disposes of hazardous waste pharmaceuticals, we proposed that it would be subject to the applicable RCRA Subtitle C TSDF regulations, including the requirement to have a permit or interim status. We proposed that all reverse distributors would be regulated the same for the accumulation of hazardous waste pharmaceuticals under part 266 subpart P, including any reverse distributors that would be considered VSQGs under part 262 (see § 262.10(m)). Under the applicability section in § 266.501(e), we proposed that reverse distributors would be subject to the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, the shipping standards in § 266.508 and § 266.509, and the reverse distributor standards in § 266.510, for the management of hazardous waste pharmaceuticals. As with healthcare facilities, if a reverse distributor generates other, non-pharmaceutical hazardous waste, it remains subject to part 262 and all other applicable portions of the Subtitle C regulations (see § 266.501(c)).

b. *Summary of comments.* We received a large number of comments regarding the foundational question of whether the pharmaceuticals going through reverse distribution should be considered solid or hazardous wastes. In section VI of the preamble we have responded thoroughly to that threshold question; therefore, we do not elaborate here. We received a few comments on other areas related to the applicability of part 266 subpart P to reverse distributors, which have led to some conforming changes in the final rule.

c. *Final rule provisions.* Other than changing the term ''pharmaceutical reverse distributor'' to ''reverse distributor,'' we are finalizing the regulatory text of § 262.10(m) and § 266.501(e), as proposed. As a result, all reverse distributors will be subject to part 266 subpart P for the management of their hazardous waste pharmaceuticals instead of part 262. This includes any reverse distributors that would have been considered VSQGs under part 262. This also includes third-party logistics providers (3PLs) when they perform the function of a reverse distributor. Reverse distributors and 3PLs acting as reverse distributors do not take ownership of the pharmaceuticals; however, both take physical custody of hazardous waste pharmaceuticals from off-site healthcare facilities and both facilitate the awarding of manufacturer credit for potentially creditable hazardous waste pharmaceuticals.

Under part 266 subpart P, there are no generator categories for the accumulation of hazardous waste pharmaceuticals; all reverse distributors will be regulated the same with respect to the management of their hazardous waste pharmaceuticals, regardless of the quantity. All reverse distributors will be subject to the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, the shipping standards in § 266.508 and § 266.509, and the reverse distributor standards in § 266.510, for the management of hazardous waste pharmaceuticals.

d. *Comments and responses.* It is important to note that, although we have not made any substantive changes to the applicability section of the regulations pertaining to reverse distributors, a change we have made to the definition of reverse distributor has effectively made a change to the applicability of the final rule. Under the final rule, the term ''reverse distributor'' has been narrowed considerably, so that it only includes reverse distributors of prescription pharmaceuticals. This change has been described and explained thoroughly in previous sections of the preamble and will be discussed here only briefly. In short, under the proposed rulemaking, the term ''pharmaceutical reverse distributor'' included facilities that facilitated manufacturer credit for both prescription and nonprescription pharmaceuticals (*e.g.,* OTCs and dietary supplements). In this final rule, we have adopted the distinction drawn by commenters between reverse distributors, who manage prescription pharmaceuticals, and reverse logistics centers, who manage nonprescription pharmaceuticals (and all other, non-pharmaceutical retail items). While reverse distributors are regulated by part 266 subpart P, reverse logistics centers are not regulated by part 266 subpart P.

Additionally, we have made several conforming changes to §§ 264.1, 265.1 and 270.1. Specifically, we added paragraphs §§ 264.1(g)(13), 265.1(c)(16), and 270.1(c)(2)(x). Together, these paragraphs make it clear that reverse distributors complying with the conditions for accumulating hazardous waste pharmaceuticals under part 266 subpart P are not required to operate under the regulations for permitted TSDFs in part 264 or interim status TSDFs in part 265; nor are they required to get a RCRA permit under part 270.

3. Very Small Quantity Generators (§§ 266.501(a) and (b))

a. *Summary of proposal.* VSQGs are subject to a limited set of federal RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 262.14.[182] We proposed that subpart P would preserve

[181] Note that the proposed rule used the term ''pharmaceutical reverse distributor'' but final rule uses the term ''reverse distributor;'' therefore, the preamble will use the term ''reverse distributor,'' even when discussing the proposed rule.

[182] Not all authorized states recognize the VSQG (or CESGQ) category and may have more stringent regulatory requirements for VSQGs. Therefore, as noted previously, EPA recommends that facilities that qualify as VSQGs under the federal regulations contact their state and/or local environmental regulatory agencies to determine whether more stringent regulatory requirements apply to VSQGs in their state.

this current regulatory structure for the most part, such that healthcare facilities that generate hazardous waste pharmaceuticals and qualify as VSQGs would maintain their conditional exemption under § 262.14 and would not be subject to *most* aspects of the proposal. However, as part of this rulemaking, EPA proposed a prohibition on sewer disposal of hazardous waste pharmaceuticals by all healthcare facilities, including VSQG healthcare facilities (and all reverse distributors). (See section XIII of this preamble for a more detailed discussion on the sewer prohibition.) We also proposed that healthcare facilities that are VSQGs would be able to use the standards in § 266.504 for the management of their hazardous waste pharmaceuticals, as well as the standards in § 266.507 for determining when their containers of pharmaceutical are considered empty (See sections XII and XV for detailed discussion of those sections of the regulations). We also proposed that VSQG healthcare facilities would have the ability to opt into using part 266 subpart P in lieu of the conditional exemption in § 262.14.

b. *Summary of comments.* Many of the comments on the applicability section for VSQG healthcare facilities were related to whether EPA should maintain the conditional exemption for VSQG healthcare facilities or whether we should make them fully subject to subpart P. Several commenters urged us to be clearer in our regulatory language and preamble about how a healthcare facility determines whether it is a VSQG or not. Although this section will address this area of confusion, see section IX.C of the preamble for additional information about not counting hazardous waste pharmaceuticals toward generator category when they are managed under subpart P.

c. *Final rule provisions.* In the final rule, healthcare facilities that are VSQGs (when counting all their hazardous waste, both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste) remain mostly exempt from part 266 subpart P. Note that all healthcare facilities, including healthcare facilities that are VSQGs, and all reverse distributors are subject to the sewer prohibition of § 266.505.

Healthcare facilities that are VSQGs are also subject to § 266.504 which includes optional provisions specifically for healthcare facilities that are VSQGs for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste. We note that although § 266.501(a) states that VSQGs are subject to § 266.504, all of the provisions in § 266.504 are optional. For example, a healthcare facility that is a VSQG operating under § 262.14 for all of its hazardous waste is not required to send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Rather, we are providing a regulatory mechanism that allows a VSQG healthcare facility to use a reverse distributor to obtain manufacturer credit. Nor is a VSQG healthcare facility required to send its hazardous waste pharmaceuticals off site to be consolidated at another healthcare facility that is operating under subpart P. Again, subpart P provides a regulatory mechanism for those VSQG healthcare facilities that wish to manage their hazardous waste pharmaceuticals in a more environmentally protective manner. A VSQG that elects to use any of the optional provisions of § 266.504 will not be considered to be opting into subpart P. See section XII of the preamble for a further discussion of § 266.504.

Several states asked us to expand the applicability of the final rule so that all of the healthcare facility standards in part 266 subpart P would be mandatory for all healthcare facilities, including VSQGs. For example, Colorado wrote that " . . . healthcare professionals can be highly mobile across the healthcare industry. As a result, professionals that leave a hospital setting and move to the [long-term care] setting have to relearn a new process for waste management, adding opportunity for more confusion and mismanagement. Colorado strongly encourages EPA to consider regulating all healthcare facilities (including CESQGs) that generate hazardous waste pharmaceuticals under the proposed regulations to minimize confusion and promote consistency across the entire spectrum of the healthcare industry settings." [183] Although we agree with Colorado, we also believe that it would pose a burden on the large number of small healthcare facilities and divert resources from regulatory agencies to expand the applicability of the final rule to include healthcare facilities that are VSQGs. We have concluded that it would be best to let the individual states that adopt this new subpart to decide whether to expand the applicability to healthcare facilities that are VSQGs.

Additionally, in the final rule we have retained the ability for healthcare facilities that are VSQGs to opt into part 266 subpart P in lieu of operating under § 262.14. A VSQG healthcare facility may choose this option if it does not want to have to keep track of how much hazardous waste pharmaceuticals and acute hazardous waste pharmaceuticals it is generating on a monthly basis or if it generates an unpredictable or fluctuating amount of hazardous waste pharmaceuticals each month that might exceed one or more of the VSGQ monthly quantity thresholds. If a healthcare facility that is a VSQG (counting all of its hazardous waste, including pharmaceuticals and non-pharmaceuticals) chooses to opt into subpart P, it must comply with all the standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals, including notification as a healthcare facility.[184] The VSQG healthcare facility may not selectively pick which provisions of part 266 subpart P it chooses to comply with; it would be treated the same as any other healthcare facility that is subject to part 266 subpart P. More specifically, if a VSQG healthcare facility chooses to opt into subpart P, then it would be subject to all the provisions identified in § 266.501(d) rather than the optional provisions of § 266.504 for VSQGs or § 262.14. The final regulatory language has been amended to be more specific in this regard. That is, rather than saying a healthcare facility has the option of complying with "this subpart," we have changed the regulations to say that a healthcare facility has the option of complying with "§ 266.501(d)," which identifies the specific sections of the regulations that non-VSQG healthcare facilities must comply with. Further, the final regulatory language clarifies that a VSQG healthcare facility that opts into part 266 subpart P would no longer be able to use the optional provisions for VSQG healthcare facilities in § 266.504.

We have made four additional changes to the applicability section of the regulations pertaining to healthcare facilities that are VSQGs. The first two changes are conforming changes to reflect the 2016 Hazardous Waste Generator Improvements final rule; this includes changing the term "conditionally exempt small quantity generator" to "very small quantity generator" and changing the regulatory citation for VSQGs from § 261.5 to § 262.14.

[183] See comment number: EPA–RCRA–HQ–2007–0932–0242.

[184] A VSQG healthcare facility that opts into part 266 subpart P for managing its hazardous waste pharmaceuticals would still have to keep track of its monthly generation of non-pharmaceutical hazardous waste to verify that it is, in fact, a VSQG. Assuming it is a VSQG, the healthcare facility could manage its non-pharmaceutical hazardous waste under § 262.14.

The third change was made to address commenters' concerns that the use of the term VSQG in § 266.501(a) and (b) was confusing. The Generator Improvements final rule has now defined the term VSQG in 260.10, which should help reduce confusion. Nevertheless, in response to the comments, we also have added language to § 266.501(a) and (b) to make it clearer that we are referring to VSQGs that are below the VSQG quantity thresholds for all of their hazardous waste combined—including both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste. Such VSQGs are VSQGs for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste. In large part, VSQGs are not subject to subpart P for the management of their hazardous waste pharmaceuticals (except the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional standards of § 266.504). This type of VSQG stands in contrast to what might be referred to as a ''subpart P VSQG,'' meaning a healthcare facility that generates over one or more of the VSQG quantity thresholds and is therefore subject to subpart P for its hazardous waste pharmaceuticals but becomes a VSQG for its non-pharmaceutical hazardous waste after complying with subpart P because it is no longer required to count its hazardous waste pharmaceuticals toward its generator category.

The fourth change to § 266.501(a) is to the reference to the new empty container regulations of § 266.507. We proposed in § 266.501(a) that a VSQG would be subject to § 266.507(a) and (b). In both the proposed and final rules, these two paragraphs of § 266.507 define when unit dose containers and dispensing vials, and syringes, respectively, are empty. The purpose of the reference was to allow a healthcare facility to use the new empty container provisions in determining how much hazardous waste pharmaceuticals it generates and therefore whether it is subject to subpart P. Under the final rule, a healthcare facility is still able to use the new empty container provisions in § 266.507 when determining how much hazardous waste pharmaceuticals it generates, but we have concluded that this reference should include all of § 266.507, rather than just paragraphs (a) and (b) because § 266.507 (c) and (d) include provisions for determining whether IV bags and other types of containers of hazardous waste pharmaceuticals are empty. Additionally, we have also amended the associated language in § 261.7 which defines when a container of hazardous waste is considered empty. We had already proposed to add a new paragraph (c) to § 261.7 to direct healthcare facilities and reverse distributors to § 266.507. The final rule modifies the proposed paragraph such that the new empty container regulations in § 266.507 are no longer limited to healthcare facilities and reverse distributors operating under part 266 subpart P. Section 266.507 defines when containers of hazardous waste pharmaceuticals are empty and apply regardless of whether they are being managed by a healthcare facility, a reverse distributor, or another entity. Generators, including healthcare facilities, can use the new provisions in § 266.507 in determining when the containers of hazardous waste pharmaceuticals are empty and the residues are no longer regulated as hazardous waste. In turn, this will help generators determine how much hazardous waste they generate and; therefore, whether they are subject to part 266 subpart P and/or part 262. See section XV of this preamble for further information about § 266.507.

d. *Comments and responses.* A few commenters had suggestions for alternative organization or placement of the applicability section pertaining to healthcare facilities that are VSQGs. One commenter suggested that we combine all of the subpart P regulations that pertain to VSQG healthcare facilities in one place, under § 266.504, rather than have some in § 266.501 and others in § 266.504.[185] We generally agree with the commenter and have included all substantive standards for VSQG healthcare facilities in § 266.504 (see section XII of the preamble for a further discussion of § 266.504). However, we believe that, when discussing the central question of who the subpart applies to, it is best to keep together in § 266.501 all the regulations that address applicability. And since the applicability section of § 266.501 appears before the VSQG healthcare facility standards of § 266.504, we believe that it is more helpful to the reader to know, up front in the regulations, whether the subpart applies. Another commenter thought we should move the entire applicability section so that it appears before the definitions section in the regulations, in order to allow ''the reader to determine if [s]ubpart P applies to his facility before reviewing any of its requirements.''[186] Although we agree that the applicability section is critical to the reader, we believe that the reader must have a full understanding of terms used in the applicability section in order to accurately determine whether the subpart applies. As a result, we have declined to make this suggested change. We requested comment on whether the applicability section for VSQG healthcare facilities should appear in § 262.14 (formerly § 261.5) rather than in subpart P and a couple of commenters responded that we should.[187] Although that would have been an acceptable option for crafting the new regulations, we have concluded that we prefer the option of keeping the regulatory language related to hazardous waste pharmaceuticals contained within the same subpart when possible. As a result, we have declined to make this suggested change, as well.

B. What facilities or pharmaceuticals are not subject to the final rule? (§§ 266.501(c) and 266.501(f) and 266.501(g))

1. Summary of Proposal

EPA proposed that the new part 266 subpart P management standards would apply only to hazardous waste pharmaceuticals generated or managed by healthcare facilities and reverse distributors. This new subpart was designed as a sector-specific rulemaking to address the unique circumstances of the healthcare sector and the reverse distribution of their hazardous waste pharmaceuticals. In § 266.501(f), we proposed that other entities that generate or manage hazardous waste pharmaceuticals would not be subject to part 266 subpart P, but would remain subject to the standard generator regulations in part 262, along with other applicable Subtitle C regulations. For example, in the preamble to the proposed rulemaking we stated that pharmaceutical manufacturers and wholesalers would remain subject to part 262 generator regulations because they do not face the same challenges that healthcare facilities experience when managing hazardous waste pharmaceuticals. We reasoned that manufacturers and wholesalers generate hazardous waste pharmaceuticals that are more predictable and the staff have the necessary expertise to determine which pharmaceuticals are considered hazardous waste. However, we noted in the proposal that when any facility, including a pharmaceutical

[185] See comment number: EPA–HQ–RCRA–2007–0932–0280.

[186] See comment number: EPA–HQ–RCRA–2007–0932–0231.

[187] See comment numbers: EPA–HQ–RCRA–2007–0932–0231 and 0280.

manufacturer, meets the definition of a reverse distributor, it would be subject to the new regulations for reverse distributors with respect to those operations.

In § 266.501(c), we also proposed that this new subpart would only apply to the management of hazardous waste pharmaceuticals. The proposed new subpart was sector-specific as well as waste stream-specific. We proposed that other, non-pharmaceutical hazardous wastes generated or managed by healthcare facilities and reverse distributors would remain subject to all applicable hazardous waste regulations.

2. Final Rule Provisions and Comments and Responses

This final rule remains a sector-specific rule as well as a waste stream-specific rule. Accordingly, § 266.501(c) of the final rule remains as proposed. That is, a healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste. Likewise, as discussed previously, a number of commenters requested that we include wholesale distributors in part 266 subpart P as healthcare facilities and in response we have amended the definition of healthcare facility to include wholesale distributors. This, of course, affects which entities are subject to the rule, but as we have made this change through amending the definition of healthcare facility, it does not necessitate a change to § 266.501 of the regulations, which is entitled Applicability. Therefore, the final rule applies to the generation and management of hazardous waste pharmaceuticals only by healthcare facilities and reverse distributors and not to others that might generate or manage hazardous waste pharmaceuticals, such as pharmaceutical manufacturers.

We have added paragraph (g) to § 266.501 of the final rule, substantially expanding the list of types of wastes that are not subject to part 266 subpart P or to RCRA regulation in general. In some cases, the additions grew out of comments and in some cases, the additions grew out the need for additional clarity. Each of the types of waste that are not subject to this subpart are discussed individually below.

a. *Donations.* As discussed previously, we have amended the definition of hazardous waste pharmaceutical to make it clear that a pharmaceutical is not a solid waste, as defined in § 261.2, and therefore, not a hazardous waste, if it is lawfully donated for its intended purpose. We have made the same change to the applicability section of this subpart to similarly indicate that pharmaceuticals are not subject to subpart P when they are lawfully donated for their intended purpose.[188] In fact, because pharmaceuticals that are lawfully donated or are otherwise legitimately used/reused or reclaimed are not solid wastes, as defined by § 261.2, they would not be subject to RCRA at all. Although this is common for nonprescription pharmaceuticals, it is rare for prescription pharmaceuticals. Sirum, a commenter that is a non-profit organization that ''helps implement State-based programs to recycle unused medication to indigent patients'' in four states, concurred that ''repurposing pharmaceuticals happens under narrow circumstances'' and that ''in most cases, pharmaceuticals transported back to a reverse distributor are discarded by the reverse distributor.'' [189] State donation and repository laws dictate the conditions under which pharmaceuticals may be donated. These laws are tracked by the National Conference of State Legislatures.[190] EPA would note that, in addition to the state regulations, the FDA has guidelines for the donation of pharmaceuticals for international relief efforts,[191] as does the World Health Organization (WHO).[192]

Sirum is providing a valuable and commendable service and EPA does not wish to impede their operations, which support the waste minimization goal of RCRA. We have amended both the definition of hazardous waste pharmaceutical and the applicability section to clarify that pharmaceuticals that are lawfully donated are not solid or hazardous wastes and therefore are not subject to RCRA, including this subpart. This would include donations to a charity, non-governmental organization, or to a healthcare facility that is participating in a donation or repository program that is authorized by the state. EPA concurs with Sirum that this should act ''as an incentive and path forward for socially responsible reverse distributors [and others] to donate rather than destroy pharmaceuticals within the safety of existing state laws that allow for these practices.'' [193]

b. *Over-the-counter pharmaceuticals going through reverse logistics.* As discussed at length in section VI of the preamble, OTC pharmaceuticals, and other items meeting our definition of pharmaceutical that do not require a prescription, such as dietary supplements, or homeopathic drugs, will only be subject to this subpart when they are discarded by a healthcare facility. OTCs and other nonprescription pharmaceuticals are not considered solid or hazardous wastes when they are sent through reverse logistics for the purpose of determining whether they can be redistributed for their intended purpose or legitimately reused or reclaimed. We have added § 266.501(g)(2) to the applicability section to codify this position regarding OTC pharmaceuticals, dietary supplements and homeopathic drugs.

c. *Recalled hazardous waste pharmaceuticals.* The Agency initially proposed standards for recalled non-creditable hazardous waste pharmaceuticals at healthcare facilities in § 266.502(g)(3), and for potentially creditable and evaluated hazardous waste pharmaceuticals at reverse distributors in § 266.510(a)(5). The finalized recall provisions for all hazardous waste pharmaceuticals are now in the applicability section in § 266.501(g)(3) and (4).

The Agency proposed that healthcare facilities managing recalled non-creditable hazardous waste pharmaceuticals could request an extension from the EPA Regional Administrator should they need to accumulate them for longer than the allotted one-year period. Likewise, the Agency proposed that reverse distributors managing recalled potentially creditable hazardous waste pharmaceuticals could request an extension from the EPA Regional Administrator should they need to accumulate them for longer than the allotted 90-day period. In the proposed regulations, the reasons for requesting an extension were characterized as ''any unforeseen circumstances beyond the control'' of the healthcare facility or reverse distributor. In the proposed preamble, we gave the specific examples of recalls and litigation as circumstances that are the beyond the control of the healthcare facility or reverse distributor, which could require longer accumulation than the proposed time frames. The proposed provision in both sections required that an extension

[188] See 40 CFR 266.501(g)(1).

[189] See comment number EPA–HQ–RCRA–2007–0932–0353.

[190] *http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx.*

[191] See Questions and Answers for the Public Donating Drugs to International Humanitarian Relief Efforts *https://www.fda.gov/downloads/newsevents/publichealthfocus/ucm249617.pdf.*

[192] *http://www.who.int/selection_medicines/emergencies/guidelines_medicine_donations/en/.*

[193] See comment number EPA–HQ–RCRA–2007–0932–0353.

request be sent in writing (electronic or paper) to the EPA Regional Administrator explaining the need for the extension, the approximate amount of hazardous waste pharmaceuticals accumulated beyond the corresponding time period, and the amount of extra time requested. The Agency also proposed to allow the Regional Administrator discretion to grant, modify, or deny extension requests on a case-by-case basis. Lastly, the Agency solicited comment on the proposed mechanism to request a time extension.

The proposed recall provisions only applied to hazardous waste pharmaceuticals that had limited accumulation times, *i.e.,* non-creditable hazardous waste pharmaceuticals at healthcare facilities, and potentially creditable and evaluated hazardous waste pharmaceuticals at reverse distributors. The finalized recall provisions, however, apply to all recalled hazardous waste pharmaceuticals.

These proposed extension provisions were opposed by many commenters from both industry and state governments. Industry commenters were concerned about the additional burden that would arise from having to generate, transmit, and maintain an additional set of records every time they would need to request an extension of the accumulation time period. The commenters suggested that these situations occur more often than EPA indicated in the proposal. Similarly, many state agencies were concerned about the added burden imposed on them by requiring notifications that must be processed, analyzed, afforded appropriate consideration, and responded to. In addition, many commenters mentioned the possibility that these provisions would conflict with other federal oversight authorities, in particular, recalls overseen by the FDA and CPSC. Commenters were also wary of the discretion these proposed provisions afforded the Regional Administrator to grant extensions, primarily due to the lack of a mechanism to coordinate those extensions with other agencies that might require longer accumulation times. Commenters were concerned this would likely lead to a scenario in which the EPA Regional Administrator does not grant sufficient accumulation time needed to comply with other federal requirements for recalls.

To address these adverse comments, the Agency has modified the final rule. The modifications also address the fact that the duration of a recall is highly variable, making it unreasonable to prescribe a specific time frame for accumulation. The Agency is finalizing provisions to ensure that recalled hazardous waste pharmaceuticals are properly managed without imposing requirements that are superfluous or conflict with other federal regulations and procedures.

In an effort to avoid overreach and potentially overlapping regulations, the Agency consulted with FDA and CPSC to better understand their procedures and policies in regulating and overseeing recalls of OTC and prescription pharmaceuticals. We learned that almost all pharmaceutical recalls are overseen by FDA, however, CPSC occasionally oversees a recall if an item's packaging does not comply with special (also called child resistant) packaging requirements. We also learned that third-party companies (typically reverse distributors, as defined in subpart P) serve as recall facilitators contracted by the manufacturer of the recalled item, to provide recall logistics such as aggregating recalled items, tracking recall progress, and making disposition determinations. Nearly all pharmaceuticals sent to a recall facilitator as part of a recall are ultimately destroyed. However, in some cases, the content of a recalled item is reclaimed and put back into commerce. For example, if the outer packaging has incorrect information, the manufacturer may choose to place the contents in updated packaging so they can be lawfully sold.

Although retailers are not permitted to sell a pharmaceutical that is subject to a CPSC recall, participation in a recall is not compulsory on the part of every consignee (entity that has purchased those items), which means that there is no way to compel participation, whether the recall is voluntary or federally mandated. The Agency had considered taking the position that all pharmaceuticals subject to a recall are waste when the recall is issued. However, because some recalled pharmaceuticals have the potential to be legitimately used/reused or reclaimed, combined with the fact that they sometimes can be lawfully dispensed by the consignee (but not sold by a retailer), we concluded that pharmaceuticals subject to a recall do not necessarily become waste simply by virtue of being subject to that recall.

Although many pharmaceuticals being sent by a healthcare facility to a recall facilitator as part of a recall could be considered solid waste, the Agency has determined that the combination of regulations, guidance and/or oversight provided by FDA and CPSC is sufficiently protective of human health and the environment while pharmaceuticals are subject to a recall. Therefore, EPA is choosing not to apply RCRA regulations on hazardous waste pharmaceuticals that are subject to a voluntary or federally-mandated recall until the decision is made to send some or all items for destruction (see below for further discussion).

EPA is not attaching any requirements to recalled hazardous waste pharmaceuticals while subject to a recall. In the final rule, healthcare facilities and reverse distributors will not be required to request an extension of the accumulation time period for recalled non-creditable hazardous waste pharmaceuticals or potentially creditable hazardous waste pharmaceuticals as proposed. This decision is also responsive to commenters who were concerned about having to operate under multiple and possibly conflicting federal regulatory schemes. It is also worth noting again that FDA and CPSC are the only federal agencies that regulate recalled pharmaceuticals and special packaging for pharmaceuticals, respectively.

When a pharmaceutical recall is initiated, the manufacturer must develop, and the corresponding agency must accept, a recall strategy which outlines all of the actions to be taken on behalf of the manufacturer from start to finish. A disposition determination is a required component of a comprehensive recall strategy. It is EPA's understanding that items being managed under an FDA or CPSC recall may be periodically sent for destruction as part of the disposition strategy (other disposition options allowed by FDA and CPSC can include redirection, and in rare circumstances, reconditioning). It is at this point (upon the decision to send some or all of the recalled pharmaceuticals for destruction) that the Agency will apply RCRA regulations these hazardous waste pharmaceuticals.

Any recalled pharmaceutical that is sent for destruction as part of the disposition strategy and is a RCRA hazardous waste, must be managed according to RCRA Subtitle C and any applicable provisions of this new subpart. This strategy is also in line with FDA and CPSC recall procedures in that they both specify that items being sent for destruction must comply with other applicable state, local and federal regulations, which may include DOT's Hazardous Material Regulations (HMR) and RCRA. In other words, this rule maintains the framework that any entity sending recalled items for destruction under a FDA or CPSC recall must comply with RCRA regulations but imposes these new subpart P regulations

at the point at which RCRA regulations already applied in lieu of the generator regulations in 40 CFR part 262.

d. *Preservation orders, investigations, and judicial proceedings.* In addition to recalls, the proposed rulemaking included litigation holds as an example of a circumstance that is beyond the control of a healthcare facility or reverse distributor, which would be a valid reason to request an extension of the accumulation period. Similar to the proposed standards for recalled hazardous waste pharmaceuticals, the standards for hazardous waste pharmaceuticals under litigation holds were also included in § 266.502(f)(3) for non-creditable hazardous waste pharmaceuticals at healthcare facilities, and in § 266.510(a)(5) for potentially creditable and evaluated hazardous waste pharmaceuticals at reverse distributors. As with recalls, we have moved the section of the regulations that addressed accumulation time extensions for litigation holds out of the healthcare facility standards and reverse distributor standards and into the applicability section of § 266.501(g)(5). The final rule also uses terminology that is more encompassing than just litigation holds, such that we are choosing not to apply RCRA regulations on hazardous waste pharmaceuticals that are being held pursuant to preservation orders, investigations, and judicial proceedings (which would include litigation holds).[194] Accordingly, the hazardous waste pharmaceuticals under a preservation order, investigation, or judicial proceeding are not subject to part 266 subpart P until after the preservation order, investigation or judicial proceeding has concluded and/or a decision is made to discard the hazardous waste pharmaceuticals. As with recalled hazardous waste pharmaceuticals, the final rule no longer requires healthcare facilities and reverse distributors to request an extension of the accumulation time period for hazardous waste pharmaceuticals under a preservation order, investigation, or judicial proceeding, as was originally proposed.

Some commenters were concerned that the Agency had proposed that any item under a preservation order, investigation, or judicial proceeding would be considered waste. We would like to emphasize that non-waste hazardous pharmaceuticals do not automatically become a waste upon being directed to participate in a preservation order.

The Agency has determined that any pharmaceuticals that were, prior to a preservation order, investigation, or judicial proceeding, determined to be waste, are not subject to RCRA when under the preservation order, investigation, or judicial proceeding. The Agency believes that sufficient protections are in place to be duly protective of human health and the environment while the preservation order, investigation, or judicial proceeding is ongoing. In addition, the extreme variability and multijurisdictional nature of judicial actions and Agency investigations make it impractical to impose RCRA standards while a corresponding preservation order, investigation, or judicial proceeding is ongoing. When lifted—for any portion or the entire complement of items—a new waste determination must be made. The location at which the waste determination is made will be the new point of generation. If the items are ultimately determined to be hazardous waste pharmaceuticals, all applicable standards in this subpart apply and the time frames for accumulation, inventory, etc., begin anew.

e. *Investigational drugs.* Similar to recalls, FDA has specific regulations pertaining to investigational new drugs, including that an investigational new drug application must be developed and approved by FDA, in accordance with 21 CFR part 312. These regulations include a requirement that ''The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. The sponsor may authorize alternative disposition of unused supplies of the investigational drug provided this alternative disposition does not expose humans to risks from the drug.'' [195] Because FDA requires these investigational drugs to be returned to the sponsor of the new drug application, EPA would not consider these returned investigational new drugs to be solid wastes and therefore, they would not be subject to RCRA, including this subpart. However, when a decision is made to discard the investigational new drug, or when the FDA approves the destruction of the investigational new drug, at that point it would be considered a solid waste, and if it is a hazardous waste, then it would be subject to subpart P, if the investigational new drug is discarded by a healthcare facility or a reverse distributor. However, typically, investigational new drugs that are part of a clinical trial are returned to the manufacturer at the conclusion of the clinical trial. In that case, if the investigational new drug is discarded by a manufacturer, then it would be subject to part 262, not part 266 subpart P. We have added § 266.501(g)(6) to carve out investigational new drugs for which an investigational new drug application is in effect in accordance with the FDA regulations in 21 CFR part 312. But we have also included a sentence to make it clear that, when the decision of discard has been made, the investigational new drug is subject to subpart P, if it meets the definition of hazardous waste and it is discarded by a healthcare facility or a reverse distributor.

f. *Household pharmaceuticals.* In the proposed rulemaking, we indicated that pharmaceuticals from households would continue to be excluded as household hazardous waste under § 261.4(b)(1). However, this was only a discussion in the preamble, we did not include regulatory language in part 266 subpart P. Additionally, we proposed a conditional exemption for collected household pharmaceuticals in § 266.507. For added clarity in the final rule, we have included in the applicability section a new paragraph § 266.501(g)(7). This paragraph indicates that household waste pharmaceuticals are not regulated under part 266 subpart P or other RCRA regulations. A household waste pharmaceutical is defined as a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1). This exclusion is for the residential generator of the household waste pharmaceuticals, as well as the collection and disposal of the residential trash as municipal solid waste.

As discussed later in this preamble, we are finalizing a conditional exemption in § 266.506(a)(2) for household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration). To remain exempt as household waste pharmaceuticals, these collected pharmaceuticals may not be sewered and have to be destroyed by a method that the Drug Enforcement

[194] See the following three memos: (1) June 23, 2017, from Johnson to Regional RCRA Division Directors, RCRA Online #14893; (2) August 11, 1988, from Lowrance to McGuire, RCRA Online #11363; and (3) January 6, 2014, from Devlin to Mitlo, RCRA Online #14881.

[195] See 21 CFR 312.59.

Administration has publicly deemed in writing to meet their non-retrievable standard of destruction, or combusted at one of the types of combustors identified in § 266.506(b). We have included in the applicability section in § 266.501(g)(7) references to the conditional exemption in § 266.506(a)(2) and the conditions in § 266.506(b) to clarify that household waste pharmaceuticals that are collected as part of a take-back event or program are distinct and different from those that are not part of a collection program. That is, when discarded directly at a residence, the household waste pharmaceuticals remain excluded as household hazardous waste, without any conditions; however, when the household waste pharmaceuticals are collected in a take-back event or program, they must be destroyed in accordance with the conditions in § 266.506 to remain exempt. See section XIV of this preamble for a more detailed discussion of the conditional exemption for household waste pharmaceuticals that are collected in a take-back event or program.

C. Do Not Count Hazardous Waste Pharmaceuticals Managed Under Subpart P Toward Determining Generator Category (§§ 262.13(c)(9))

1. Summary of Proposal

EPA proposed that hazardous waste pharmaceuticals that are managed under part 266 subpart P are not required to be counted in determining a facility's hazardous waste generator category under part 262. There were two primary reasons this provision was proposed. First, we received support for this provision when we initially proposed it as part of the 2008 proposal to add pharmaceuticals to the Universal Waste program. Second, and more importantly, under part 266 subpart P, there are no generator categories; therefore, it is not necessary to know the quantity of hazardous waste pharmaceuticals being generated. EPA emphasized that a healthcare facility must be managing its hazardous waste pharmaceuticals under subpart P in order to have the benefit of not counting them towards its generator category (see section XIX for further discussion).

2. Summary of Comments

There was widespread support among commenters for this proposed provision. However, a number of the commenters expressed some confusion and asked for further explanation and clarity regarding the effect this may have on determining a facility's hazardous waste generator category.

3. Final Rule Provisions

We are finalizing this provision with a minor edit. Additionally, the provision is now in a different place in the final regulations. First, the minor edit was made in response to Connecticut Depart of Energy and Environmental Protection's (CT DEEP) objection to the phrasing of the proposed regulatory language. Specifically, CT DEEP thought the phrase ''managed under 40 CFR part 266 subpart P'' could lead to confusion if a healthcare facility was operating under part 266 subpart P, but was not in full compliance with part 266 subpart P and whether that would be considered to be ''managed under 40 CFR part 266 subpart P.'' [196] In response, and to avoid this potential area of confusion, we have changed the regulatory language so that ''a hazardous waste pharmaceutical *subject to* or managed in accordance with 40 CFR part 266 subpart P'' does not have to be counted toward determining a facility's generator category. The second change is a conforming change necessitated by the reorganization of the generator regulations in the 2016 Hazardous Waste Generator Improvements final rule. The list of hazardous wastes that do not have to be counted toward generator category had been listed in § 261.5(c), but when the Hazardous Waste Generator Improvements final rule reorganized the generator regulations, this list was moved to § 262.13(c). Under this final rule, hazardous waste pharmaceuticals that are subject to part 266 subpart P do not have to be counted toward determining a facility's generator category. This provision now appears in § 262.13(c)(9). Finally, for clarity we have added that the hazardous waste pharmaceuticals that are also DEA controlled substances and are conditionally exempt under § 266.506, do not have to be counted toward determining generator category.

4. Comments and Responses

Several commenters asked us to clarify when a healthcare facility does and does not count its hazardous waste pharmaceuticals toward determining a facility's generator category. A healthcare facility must count all of its hazardous waste—including hazardous waste pharmaceuticals—to determine whether it is subject to part 266 subpart P. If a healthcare facility generates below all of the VSQG monthly quantity limits, then it remains subject to § 262.14 for all of its hazardous waste and it is not subject to subpart P for its hazardous waste pharmaceutical, except for the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional provisions of § 266.504. On the other hand, if a healthcare facility generates above any of the VSQG monthly quantity limits, then the healthcare facility is subject to subpart P for its hazardous waste pharmaceuticals. But since subpart P is only for the management of hazardous waste pharmaceuticals, the healthcare facility remains subject to part 262 for its non-pharmaceutical hazardous waste.

The next step is for the healthcare facility to determine its new generator category under part 262 so it knows how to manage its non-pharmaceutical hazardous waste. At this point, a healthcare facility does not need to count its hazardous waste pharmaceuticals in determining its generator category for its non-pharmaceutical hazardous waste. EPA continues to emphasize that a healthcare facility must be managing its hazardous waste pharmaceuticals under subpart P in order to have the benefit of not counting them towards its generator category. Put another way, a healthcare facility managing its hazardous waste pharmaceuticals under subpart P does not have a generator category for the hazardous waste pharmaceuticals, but it will be a VSQG, SQG or LQG for its non-pharmaceutical hazardous waste.

When a healthcare facility that manages its hazardous waste pharmaceuticals under subpart P no longer counts the hazardous waste pharmaceuticals to determine its part 262 generator category, the healthcare facility may experience a change in RCRA generator category for its non-pharmaceutical hazardous waste. For example, a healthcare facility may shift from being an LQG to an SQG or even VSQG by not counting its hazardous waste pharmaceuticals toward its generator category, especially when acute hazardous waste pharmaceuticals such as warfarin (brand name: Coumadin) no longer need to be counted. A shift in generator category, should it occur, would allow a healthcare facility to manage its non-pharmaceutical hazardous waste, such as hazardous waste from laboratories, according to the reduced part 262 generator regulations for a smaller category.

For reverse distributors, it works somewhat differently than with healthcare facilities, because all reverse distributors are subject to part 266 subpart P for the management of their hazardous waste pharmaceuticals, including reverse distributors that are

[196] See comment number: EPA–HQ–RCRA–2007–0932–0341.

VSQGs. In other respects, the regulations work the same, because reverse distributors also are not required to count their hazardous waste pharmaceuticals when determining their part 262 generator category for their non-pharmaceutical hazardous waste.

Again, we emphasize, such dropping down in generator category only pertains to non-pharmaceutical hazardous waste and is only possible when the hazardous waste pharmaceuticals are being managed under subpart P. Further, EPA points out that universal wastes also are not counted toward a facility's generator category and what we are finalizing for hazardous waste pharmaceuticals has been implemented successfully for years within the universal waste program for facilities that generate both universal waste and other hazardous waste.

Below are a diagram and a table to help summarize the preceding sections of the preamble related to the applicability of the final rule and the provision that allows a healthcare facility or a reverse distributor to not count hazardous waste pharmaceuticals when determining the facility's generator category for its non-pharmaceutical hazardous waste.

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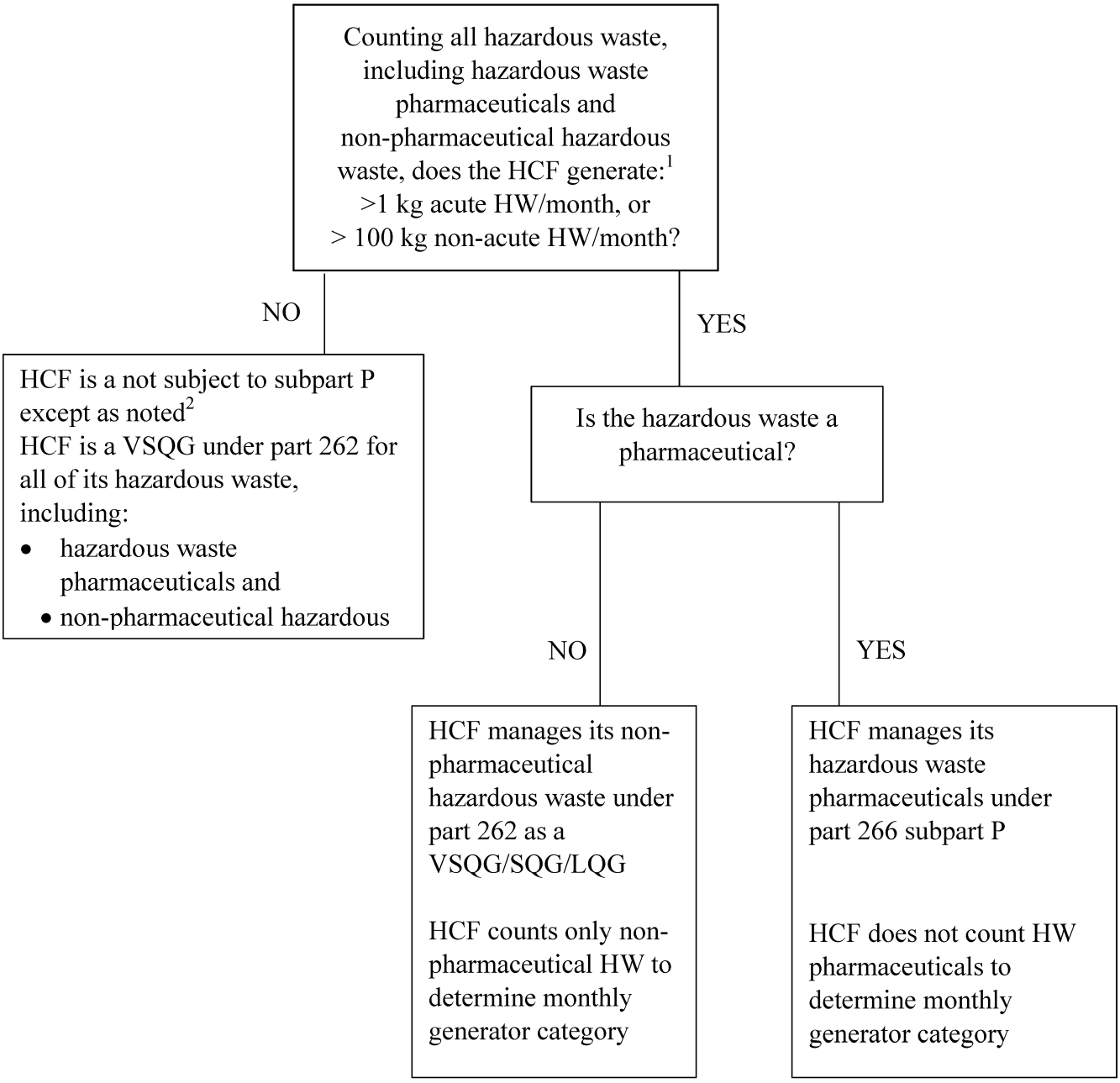
Diagram 1: When is a Healthcare Facility Subject to Part 266 Subpart P?



HW = Hazardous Waste HCF = Healthcare Facility RD = Reverse Distributor Rx = Prescription

[1] Non-Rx pharmaceuticals are not solid or hazardous waste if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed. Reverse logistics facilities are subject to the generator standards in part 262.

[2] All VSQGs are subject to the sewer prohibition of § 266.505 and the empty container standards of § 266.507, and can use the optional provisions of § 266.504.

Table 2: Applicability of Subpart P and Part 262 Generator Category for Healthcare Facilities

Hazardous Waste Pharmaceutical			Non-Pharmaceutical Hazardous Waste		Total Hazardous Waste		Part 266 Subpart P?	Part 262 Generator Category of Healthcare Facility		
Acute	Non-Acute		Acute	Non-Acute	Acute	Non-Acute		LQG	SQG	VSQG
Any amount		and	>1 kg and/or	≥1000 kg	>1 kg and/or	≥1000 kg	Yes	✓		
Any amount		and	≤1 kg and	>100 and <1000 kg	≤1 kg and	>100 and <1000 kg	Yes		✓	
>1 kg and/or >100 kg		and	≤1 kg and	≤100 kg	>1 kg and/or >100 kg		Yes			✓[2]
≤1 kg and	≤100 kg	and	≤1 kg and	≤100 kg	>1 kg and/or	>100 kg	Yes			✓[2]
≤1 kg and	≤100 kg	and	≤1 kg and	≤100 kg	≤1 kg and	≤100 kg	No[1]			✓[3]
Long-Term Care Facilities with ≤ 20 beds							No[1]			✓[4]

[1] All VSQGs healthcare facilities are subject to the sewer prohibition of § 266.505, and the empty container standards of § 266.507, and can use the optional provisions in § 266.504

[2] VSQGs for non-pharmaceutical hazardous waste only ("subpart P VSQG")

[3] VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste

[4] Presumed to be a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste

BILLING CODE 6560–50–C

X. Standards for Healthcare Facilities That Manage Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502)

A. Notification/Withdrawal Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(a))

1. Summary of Proposal

To address commenters' concerns from the 2008 Pharmaceutical Universal Waste proposal that regulatory agencies are unaware of hazardous waste pharmaceutical management activities, EPA proposed to require that a healthcare facility that does not qualify as a VSQG to submit a one-time notification as a ''healthcare facility'' to the appropriate EPA Regional Administrator. EPA proposed that healthcare facilities subject to 40 CFR part 266 subpart P will have to submit a notification even if the healthcare facility has previously obtained an EPA identification number. The required notification was meant to enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals subject to the 40 CFR part 266 subpart P requirements.

At any point, a healthcare facility's hazardous waste pharmaceutical generation may change due to waste minimization efforts or other reasons, causing the facility to legitimately decrease its total monthly hazardous waste generation enough to qualify as a VSQG. In this case, if the healthcare facility withdraws from the 40 CFR part 266 subpart P requirements due to qualifying as a VSQG, EPA proposed that the healthcare facility must re-notify EPA of its choice to withdraw.

Alternatively, if a healthcare facility determines that it is a VSQG, but does not want to keep track of the amount of hazardous waste pharmaceuticals it generates and whether it is above or below the VSQG threshold, we proposed that it can choose to operate under subpart P. By choosing to operate under subpart P, the VSQG healthcare facility must comply with all of the requirements, including the one-time notification that it is operating under 40 CFR part 266 subpart P. We proposed that healthcare facilities that are not VSQGs, however, are required to operate under 40 CFR part 266 subpart P for the management of their hazardous waste pharmaceuticals.

The Agency proposed that this notification occur using the RCRA Subtitle C Site Identification Form (EPA Form 8700–12; or Site Identification Form). EPA believes that notification via the Site Identification Form is the preferred approach for notification purposes for several reasons. First, both state environmental regulatory agencies and hazardous waste generators are familiar with the form, as it is the form currently used by hazardous waste generators to notify regulators of their RCRA Subtitle C activities. Second, as stated previously, the use of the Site Identification Form will allow for EPA and state regulatory agencies to monitor the healthcare facilities utilizing the new regulatory requirements. Lastly, public comments received on previous EPA actions (*e.g.,* Academic Laboratories Rulemaking (73 FR 72912; December 1, 2008)) have indicated that notification via the Site Identification Form is the notification approach typically preferred by the regulated community. We proposed that healthcare facilities can submit their notification as part of the Biennial Report, if the healthcare facility will be required to submit a Biennial Report due to its non-pharmaceutical hazardous waste. This was intended to take advantage of an existing reporting mechanism for LQGs or other generators already required to submit the Biennial Report and avoid duplicative notification requirements. Otherwise, healthcare facilities are required to notify within 60 days of this new subpart becoming effective, or within 60 days of becoming subject to this new subpart. We also proposed that a healthcare facility would have to keep a record of its notification as long as it is subject to this subpart.

The Agency did not anticipate that the proposed notification requirement would place any undue economic burden upon healthcare facilities or the environmental regulatory agencies that process these notifications (see the Regulatory Impact Analysis for the proposed rulemaking in the rulemaking docket EPA–HQ–RCRA–2007–0932). In fact, under the proposed regulations, healthcare facilities would no longer need to count the hazardous waste pharmaceuticals managed under 40 CFR part 266 subpart P towards a healthcare facility's generator category. As a result, EPA anticipates that many healthcare facilities will reduce their generator category to either an SQG or VSQG for their other non-pharmaceutical hazardous wastes. So, while the notification requirement ensures that the environmental regulatory agencies are informed of all hazardous waste pharmaceutical management activities subject to the 40 CFR part 266 subpart P requirements, the fact that some healthcare facilities will no longer qualify as LQGs will reduce the number of healthcare facilities in the LQG universe.

The Agency solicited comment on the notification requirement for healthcare facilities, the method of notification via the Site Identification Form, and whether this notification requirement will result in any undue burden to either healthcare facilities or state environmental regulatory agencies.

2. Summary of Comments

While there was general support for requiring healthcare facilities to notify the EPA Regional Administrator that they are operating under this subpart, a number of states and industry commenters provided opposition to the proposed 60-day time frame. States supported notification but were concerned that they would not be able to process all of the notifications in a timely manner given that all VSQG and SQG facilities operating under subpart P would have to notify within 60 days of the effective date of this rule. One suggestion was to instead require notification on a rolling or staggered basis to give resource-limited states enough time to process the notices within a timely manner.

States also voiced concern about the provision allowing healthcare facilities that are LQGs because of their non-pharmaceutical waste to notify as part of their normal Biennial Reporting schedule.[197] Depending on the timing of the Final Rule, states were concerned about the possibility that LQGs would not have to notify that they are operating under this subpart for up to two years, during the course of which they could be generating large amounts of pharmaceutical waste and managing it under the reduced restrictions of this subpart unbeknownst to the state or EPA. Meanwhile VSQGs and SQGs would have to notify within 60 days.[198] Another state recommended that healthcare facilities be required to list on the notification what their generator category would be if they were to count their pharmaceutical waste. The state was concerned that a healthcare facility could be generating LQG amounts of pharmaceutical waste but because they are now VSQGs, would be a much lower inspection priority.[199]

There was, however, no opposition to the provision that a healthcare facility

[197] § 262.18(d)(2) requires LQGs to renotify EPA by March 1 of each even-numbered year thereafter using EPA Form 8700–12. An LQG may submit this renotification as part of its Biennial Report required under § 262.41.

[198] EPA–HQ–RCRA–2007–0932–0341.

[199] EPA–HQ–RCRA–2007–0932–0235.

be required to maintain a copy of its notification on file as long as it is subject to this subpart.

3. Final Rule Provisions

EPA is finalizing the notification provisions for healthcare facilities managing non-creditable hazardous waste pharmaceuticals as proposed, with no changes.

All healthcare facilities as defined in § 266.500 that are subject to the requirements of this subpart (all healthcare facilities that generate above the VSQG thresholds and healthcare facilities that are VSQGs choosing to operate under this subpart) will have to submit a notification to the EPA Regional Administrator using the Site ID Form (EPA Form 8700–12) stating that they are a healthcare facility and will be operating under this subpart. A healthcare facility that already has an EPA Identification Number must re-notify the EPA Regional Administrator that it will be operating under this subpart within 60 days of becoming subject to subpart P. Healthcare facilities that do not have an EPA Identification Number will be required to obtain one by submitting the Site Identification Form (EPA Form 8700–12) within 60 days from the effective date of this rule if they are not otherwise required to submit Biennial Reports. A healthcare facility that undergoes a change in generator category causing them to become subject to the requirements of this subpart must notify the EPA Regional Administrator within 60 days of the event that triggered the change in generator category.

Healthcare facilities that are LQGs for their non-pharmaceutical hazardous waste, and therefore must submit a Biennial Report, may notify the EPA Regional Administrator according to their normal reporting cycle. SQGs that are required by their state to submit a Biennial Report may also notify EPA that they are operating under subpart P on their normal reporting cycle. Healthcare facilities that are required to submit a Biennial Report are not, however, required to wait to notify EPA that they are operating under subpart P on their Biennial Report, and may notify EPA at any point prior to submitting the Biennial Report. The Agency notes that any healthcare facility that is required to operate under subpart P must begin complying with its requirements as soon as the final rule becomes effective. VSQGs that opt into subpart P may notify the EPA whenever they choose, but they become subject to the requirements of this subpart on the date they submit the notification. All healthcare facilities must retain a copy of the notification as long as they are operating under this subpart.

4. Comments and Responses

Some states were concerned about their ability to process notifications in a timely manner given the 60-day time frame after the effective date of this rule within which all non-LQG healthcare facilities must notify EPA that they are operating under this subpart. The Agency reasserts, however, that the added burden is reasonable and necessary for the Agency and implementing states to gain a timely understanding of the facilities within the universe of this rule.

The Agency also notes that this final rule goes into effect six months from the date it is published in the **Federal Register** in EPA Territories and states that do not have an authorized RCRA program. That time frame could be even longer in authorized states which must first adopt this rule for it to become effective. Therefore, healthcare facilities in all states have a minimum of six months from the day this rule is published in the **Federal Register**, plus the 60 days in this requirement, to notify their state that they are operating under this subpart.

One commenter suggested that the agency implement a staggered roll-out of this notification provision to prevent them from becoming inundated with incoming notifications, preventing them from processing notifications in a timely manner. The Agency would note, however, that there is no provision requiring a healthcare facility to receive approval before it can operate under this subpart and states and regions can process the notifications by whatever time frames and methods they choose. All healthcare facilities must operate under this subpart immediately upon becoming subject to this rule. Therefore, as long as a healthcare facility that does not submit a BR notifies its state within 60 days that it is operating under this subpart, it will be in compliance. In addition, we did not propose and are not finalizing any time frames within which regional or state offices must process notifications, therefore, we defer to those agencies to develop their own best practices.

Another state suggested that EPA develop a ''smart-form'' tool for RCRAInfo—EPA's database of RCRA-related information from required reporting— that would allow healthcare facilities to notify the state electronically that they are operating under subpart P, directly input their own information, and update their information on a regular basis. EPA notes that it has developed an online tool called myRCRAid which allows generators to complete and submit the Site Identification Form electronically, which the Agency expects will reduce states' administrative burden by reducing the number of notifications that have to be manually input, while simultaneously reducing the potential for error while transferring data.

In addition, the Site Identification Form will be modified by EPA in a separate action to add a section for a healthcare facility to indicate that it generates hazardous waste pharmaceuticals. The healthcare facility will no longer be required to identify on the Site Identification Form the specific types of hazardous waste pharmaceuticals it generates. The Agency also intends to add a checkbox to the new section which will allow a healthcare facility to indicate that its generator category is changing to a VSQG and it is no longer managing its hazardous waste pharmaceuticals according to 40 CFR part 266 subpart P.

Some states disagreed with the provision that allows healthcare facilities that file a BR to notify EPA that they are operating under subpart P on their normal reporting schedule, as opposed to notifying within 60 days of this rule becoming effective, or becoming subject to subpart P. This means that healthcare facilities that file a BR could potentially operate under this subpart for up to two years without having to notifying the Agency, depending on when their normal BR date falls in relation to the effective date of this rule. They recommended that all facilities, regardless of generator category, be required to notify within 60 days. While the Agency agrees that the possibility for a healthcare facility to operate for up to two years under this subpart without notifying EPA does, in fact, exist, we do not wish to impose duplicative notification requirements.

One state requested that a healthcare facility be required to list on the notification what its generator category would be if it were required to count its hazardous waste pharmaceuticals. They were concerned that some facilities that are LQGs because of their hazardous waste pharmaceuticals would reduce their generator category as a result of this rule, making them a low priority for inspections, even though they could still be generating LQG quantities of pharmaceutical waste. We understand the state's concern, however, making a change like this would not be in line with the goals of this rule to provide streamlined standards. However, options available to the states with similar concerns are adopting more stringent requirements or using

historical notifications and Biennial Report data.

B. Personnel Training Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(b))

1. Summary of Proposal

a. Performance-based training standards. EPA believes that the part 262 LQG training regulations are excessive for healthcare personnel who sporadically generate hazardous waste pharmaceuticals at healthcare facilities, but believes it is necessary to have some familiarity with the dangers that hazardous waste pharmaceuticals can pose, making the VSQG training standards insufficient. Therefore, the Agency proposed healthcare facility-specific personnel training requirements that are akin to the training requirements for SQGs and small quantity universal waste handlers, for all healthcare facilities subject to subpart P. Specifically, we proposed that healthcare facilities managing hazardous waste pharmaceuticals in accordance with subpart P must inform all employees that handle or have responsibility for generating and/or managing hazardous waste pharmaceuticals of the proper handling and emergency procedures appropriate to their responsibilities during normal facility operations and emergencies. We indicated in the preamble to the proposed rulemaking that this training information can be disseminated through verbal communication or through distribution of pamphlets or other documentation. However, a healthcare facility that is an LQG due to its non-pharmaceutical hazardous wastes may choose to continue to use its existing training program as an LQG so as not to have different training programs.

Under part 262 regulations, an LQG healthcare facility had to provide full RCRA training to its personnel involved in the generation and/or management of hazardous waste according to the standards in § 262.17(a)(7). These personnel training requirements include either classroom instruction, on-line training, or on-the-job training in RCRA and require the facility to maintain documentation of that training. On the other hand, before this rule was finalized, under the part 262 regulations, an SQG healthcare facility had to meet a performance-based standard when training personnel involved in the generation and/or management of hazardous waste pharmaceuticals. Specifically, this entailed ensuring ''that all employees are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.'' [200] For comparative purposes, healthcare facilities that are considered VSQGs did not have any personnel training requirements under the part 262 regulations. Similarly, SQGs and LQGs, including healthcare facilities, were not required to provide RCRA training to personnel that only work in SAAs regulated under § 262.15. That said, healthcare personnel that are involved in the generation of hazardous waste pharmaceuticals must be familiar enough with the pharmaceuticals with which they work to know when they have generated a hazardous waste so that it will be managed in accordance with the RCRA regulations.

b. Documentation of training. Although no regulations were proposed, EPA also sought comment in the preamble to the proposed rulemaking on whether documentation of training is necessary in order to verify compliance with the training requirement.

2. Summary of Comments

a. Performance-based training standards. There were a variety of comments on the proposed training standards, both in support and opposition. Although most states agreed with the assessment that standard LQG regulations would be excessive if applied to healthcare facilities, some wanted EPA to provide more stringent and prescriptive language. Commenters from the waste management industry were also opposed to the proposed performance-based standards for similar reasons.

Pharmacy trade groups generally agreed with the proposed standards, citing the same rationale provided in the preamble of the proposed rulemaking, which states that the variability in waste generated and turnover in employees warrants a performance-based standard, and any subsequent training should be left up the healthcare facility. They stated that most pharmacy staff are trained on proper handling and management of radiation and other pharmaceuticals that can pose significant risks as required by other accreditation and standard-setting agencies and any prescriptive training standards under subpart P would be duplicative.

b. Documentation of training. There were mixed comments on whether to require that a healthcare facility document that its personnel have been trained according to the standards set forth in 40 CFR 266.502(b). All of the states that commented on this issue were supportive of the requirement to document training. These states were mostly concerned with their ability to cite specific violations of the training provisions during inspections. Another state mentioned that many facilities already maintain documentation of training as a best management practice.

Waste management companies also wanted EPA to require healthcare facilities to document that employees have been trained. They argued that the training standards will not have their intended effect if there is no requirement for documentation because healthcare facilities will not feel compelled to comply with them.

Pharmacy trade groups were concerned that requiring documentation of training would result in added burden and generally opposed this provision. They argued that there are a number of standard-setting and accreditation agencies that already require documentation that employees have been trained, and as such, this requirement would be redundant and overly burdensome.

3. Final Rule Provisions

a. Performance-based training standards. EPA is finalizing the performance-based training standards as proposed. A healthcare facility must train employees to the extent that they are thoroughly familiar with the proper handling and emergency procedures relevant to their responsibilities during normal operations and emergencies. The information can be disseminated verbally, via printed materials, or other means. These standards are similar to the training standards for SQGs and small quantity handlers of universal waste.[201] [202] The agency feels that these standards provide consistency across generator types and do not impose any added burden on inspection and enforcement actions beyond what is already in place within the Universal Waste program.

b. Documentation of training. EPA has decided not to finalize a standard that would have required healthcare facilities to document that the performance-based training standards have been met. The Agency thinks this requirement would have resulted in an undue increase in the regulatory burden for healthcare facilities. Also, there is no such requirement in the part 262 SQG training requirements or for small quantity handlers of universal waste.

[200] § 262.16(b)(9)(iii)

[201] 40 CFR part 262.16 (a)(9)(iii).

[202] 40 CFR part 273.16.

The agency feels this approach is consistent with other RCRA regulations and would improve consistency with the Universal Waste program, especially since the requirements for healthcare facilities managing hazardous waste pharmaceuticals were purposefully modeled after the requirements for small quantity handlers of universal waste. The Agency ultimately concluded that, because this approach is sufficient for universal waste, it is also acceptable for hazardous waste pharmaceuticals.

4. Comments and Responses

a. Performance-based training standard. There were a number of commenters from states and the waste management industry that recommended more rigorous and prescriptive training standards such as more specific minimum requirements, recurring training, and that the Agency specify the job titles subject to the training requirements. The Agency is not finalizing any of these recommendations, however, because we believe that the proposed performance-based standards are protective of human health and the environment without imposing undue burden either on states or industry. These standards strike an appropriate balance between ensuring proper management of hazardous waste pharmaceuticals and reducing the regulatory burden on healthcare facilities and healthcare personnel in a manner that also encourages compliance with these new regulations.

One commenter mentioned that prescriptive RCRA training requirements would be duplicative given the training requirements of the various accreditation entities. The Agency responds that any waste management training for healthcare personnel would not be duplicative because accreditation training typically focusses on managing pharmaceuticals prior to becoming a waste, whereas the training required in subpart P is targeted specifically at management practices after the pharmaceuticals have become waste. As mentioned previously, the Agency is not finalizing prescriptive training standards in an effort to minimize regulatory burden and allow healthcare facilities to tailor their training programs in a way that best fits their circumstances.

These training standards apply only to healthcare personnel. Healthcare personnel includes any person that manages hazardous waste pharmaceuticals at a healthcare facility (*e.g.,* employees, volunteers, students). Environmental health and safety personnel are likely to manage hazardous wastes other than just hazardous waste pharmaceuticals at a healthcare facility, in which case, they would be subject to other RCRA Subtitle C training requirements.

The Agency acknowledges that there are many pharmaceuticals that pose significant risk to human health and the environment, yet are not RCRA hazardous when they become waste. We in no way intend to imply that these items pose any less of a risk by virtue of being considered non-hazardous under RCRA and encourage healthcare facilities to provide all relevant training to healthcare personnel and observe industry best management practices.

b. Documentation of training. After requesting comment on documentation of training, the Agency decided not to finalize any requirements for healthcare facilities to document and maintain records verifying that healthcare personnel have met the training requirements. We considered the many adverse comments and ultimately agreed that such requirements would be overly burdensome and more stringent than the training requirements in the Universal Waste rule, which were largely emulated in this rule. Many comments that advocated for a requirement to document training were from states. Although such a requirement is not being finalized at the federal level, any authorized state has the ability to impose more stringent regulations. If a state chooses to require documentation of training, that would be considered more stringent and permissible under RCRA.

C. Healthcare Facilities Making a Hazardous Waste Determination for Non-Creditable Pharmaceuticals (§ 266.502(c))

1. Summary of Proposal

EPA proposed that, similar to the current part 262 generator requirements, healthcare facilities operating under subpart P would be required to make hazardous waste determinations on pharmaceutical wastes in order to determine the applicable management standards. Specifically, we proposed that when a healthcare facility generates a solid waste pharmaceutical, the healthcare facility must determine if the discarded pharmaceutical is listed in 40 CFR part 261 subpart D and/or if it exhibits one or more of the four characteristics of hazardous waste identified in 40 CFR part 261 subpart C. We proposed that, if the non-creditable pharmaceutical waste is determined to be a hazardous waste, then the healthcare facility must manage the non-creditable hazardous waste pharmaceuticals in accordance with part 266 subpart P instead of 40 CFR part 262. Pharmaceutical wastes—both potentially creditable and non-creditable—not meeting the definition of a hazardous waste (*i.e.,* non-hazardous waste pharmaceuticals) must be managed in compliance with applicable federal, state and local regulations.

EPA understands that healthcare facilities utilize various approaches when making hazardous waste determinations. For example, healthcare facilities may hire consultants to review their formularies and identify those pharmaceuticals that are hazardous wastes when discarded. These facilities may then identify hazardous waste pharmaceuticals at the pharmacy level, marking these pharmaceuticals with a special label so that healthcare personnel know how to properly dispose of the pharmaceutical when it becomes a waste. Other healthcare facilities may instruct personnel to dispose of all pharmaceutical wastes into one RCRA hazardous waste collection container. These healthcare facilities may then choose to manage all of the contents of the container as hazardous waste or they may choose to sort the hazardous waste portion from the non-hazardous waste pharmaceutical portion in an on-site hazardous waste accumulation area, also known as a CAA. Due to the various ways that healthcare facilities make the hazardous waste determination, the Agency did not propose that a specific approach be utilized when making the hazardous waste determination, only that the facility performs the hazardous waste determination.

We also proposed that healthcare facilities have the option to manage all of their pharmaceutical wastes as hazardous, and thus, if a healthcare facility chooses this approach, they would not need to make individual hazardous waste determinations. Instead, they would have made a generic decision that all of their discarded pharmaceuticals are hazardous and manage them as hazardous waste pharmaceuticals in accordance with the requirements in 40 CFR part 266 subpart P. Accumulating all non-creditable waste pharmaceuticals in one container (except for those that are incompatible or cannot be incinerated according to the dilution prohibition) [203] and

[203] § 268.3(c) Dilution prohibited as a substitute for treatment. See appendix XI of part 268 for a full list of hazardous wastes that are prohibited from being combusted.

managing them under subpart P would relieve healthcare facilities from the burden associated with making individual hazardous waste determinations.

2. Summary of Comments

There were a wide variety of comments on this provision. Many in the regulated community requested some sort of a reference or compendium containing a comprehensive and up-to-date list of the waste pharmaceuticals that would be considered RCRA hazardous.

Commenters from states were generally supportive of the provision allowing all waste pharmaceuticals to be managed as hazardous waste pharmaceuticals. They believe the provision will encourage healthcare facilities to manage all of their waste pharmaceuticals in an environmentally protective manner. One commenter did suggest that healthcare facilities be required to choose whether they will make individual hazardous waste determinations for their waste pharmaceuticals or manage all of them as hazardous waste pharmaceuticals under this subpart and maintain documentation reflecting their decision.

Retail industry commenters were opposed to what they believe are contrary requirements, specifically, allowing a healthcare facility to manage all of its waste pharmaceuticals as hazardous but still require them to segregate incompatible hazardous waste and those prohibited from combustion as required by § 266.502(d)(4). They believe having to segregate incompatible and non-combustible waste significantly diminishes the intended relief.

3. Final Rule Provisions

EPA has finalized the provisions of this section with minor edits that further clarify that this section applies only to non-creditable pharmaceuticals. A healthcare facility that generates solid waste that is a non-creditable pharmaceutical has two options for hazardous waste determination. It may choose to either; (1) determine if each non-creditable pharmaceutical is a listed or characteristic hazardous waste to determine whether it is subject to the subpart P requirements, or (2) manage all of its non-creditable waste pharmaceuticals under the subpart P requirements as non-creditable hazardous waste pharmaceuticals. A healthcare facility that chooses the latter option, instead of making individual hazardous waste determinations at the point of generation, would have made a generic decision that all of their non-creditable pharmaceutical waste is hazardous and place it into a container or containers that are managed under part 266 subpart P.

The Agency wanted to provide maximum flexibility to healthcare facilities managing non-creditable waste pharmaceuticals while ensuring protection of human health and the environment, which is why we are finalizing the provision to allow healthcare facilities the option of managing all of their waste pharmaceuticals under subpart P. If a healthcare facility chooses to manage all of its non-creditable waste pharmaceuticals under the subpart P requirements, healthcare personnel are relieved from having to make individual hazardous waste determinations which might otherwise distract from their efforts in providing patient care.

4. Comments and Responses

A number of commenters asked if a third party can come on site and make individual hazardous waste determinations for commingled non-creditable waste pharmaceuticals. If a healthcare facility chooses to use a third party, typically a hazardous waste transport company, to come on site and make hazardous waste determinations at any time (typically in preparation for transport off site), that would also be permissible under this subpart.

Many comments were focused on the lack of an EPA-provided reference guide of which pharmaceuticals are hazardous waste when discarded. The RCRA generator regulations have always placed the onus on the generator of a waste to determine whether it is solid and hazardous waste. Nevertheless, EPA has made efforts to aid healthcare facilities in making hazardous waste determinations by developing the Hazardous Waste Pharmaceuticals wiki.[204] The website has served as a central location where users (*e.g.,* healthcare facilities, states) can share their knowledge about which pharmaceuticals are listed or characteristic hazardous waste, and other related information. EPA has also funded a compliance assistance center for healthcare facilities, which provides information on which pharmaceuticals are hazardous waste as well as other hazardous wastes found in a healthcare setting.[205] [206]

D. No Central Accumulation Area and Satellite Accumulation Area Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

1. Summary of Proposal

Hazardous waste pharmaceuticals are generated at numerous locations across a healthcare facility. Under the part 262 generator regulations, each location at the healthcare facility with a RCRA hazardous waste receptacle for the disposal of hazardous waste pharmaceuticals is considered an SAA and is subject to volume accumulation limits and other provisions. Of particular concern regarding the SAA regulations for healthcare facilities is the one-quart accumulation limit for acute hazardous wastes (*i.e.,* P-listed wastes) and the requirement that hazardous waste must be accumulated at or near the point of generation. In particular, hospitals have noted that their difficulties are with having an SAA in each hospital room. As a result, the proposed December 2008 Pharmaceutical Universal Waste rule did not require the establishment of any accumulation areas (neither central nor satellite) for hazardous waste pharmaceuticals. This proposed approach was consistent with the current federal universal waste program, since facilities are not required to designate a special centralized area for the accumulation of universal wastes, nor are they required to have SAAs for universal wastes. Nevertheless, EPA understands that healthcare facilities will often accumulate their universal wastes within their 90- or 180-day hazardous waste accumulation areas. The part 262 generator regulations, including the SAA and CAA regulations, were designed more for industrial and manufacturing operations. Part 266 subpart P is a sector-based regulatory approach designed to work better with how the healthcare sector operates. Therefore, consistent with the approach initially taken in the Universal Waste proposed rulemaking, the Agency designed the proposed standards for healthcare facilities accumulating hazardous waste pharmaceuticals under subpart P to operate in lieu of the SAA regulations or the CAA regulations (also sometimes called ‘‘ less than 90- or 180-day are as’’).

[204] Hazardous Waste Pharmaceuticals Wiki. *http://hwpharms.wikispaces.com.* Wiki spaces is phasing out its business of hosting wiki pages. The Agency plans to preserve the information that has been contributed to the wiki on EPA's website, but the content will be static.

[205] Healthcare Environmental Resource Center. *http://www.hercenter.org.*

[206] EPA makes no claims, promises, or guarantees about the accuracy, completeness, or adequacy of the contents of these sites.

2. Summary of Comments

The majority of commenters on this provision were states. All but one state and all other commenters agreed with the proposal to eliminate requirements for SAAs and CAAs for healthcare facilities managing non-creditable hazardous waste pharmaceuticals. The lone dissenting state agreed with eliminating requirements for SAAs but expressed concern about not requiring CAAs. They recommended that hazardous waste pharmaceuticals be accumulated in or near a 90-day or 180-day accumulation area for LQGs and SQGs respectively.

3. Final Rule Provisions

The agency is finalizing the approach for part 266 subpart P to operate in lieu of requiring CAAs and SAAs for healthcare facilities managing non-creditable hazardous waste pharmaceuticals. The SAA regulations, in particular, were not a good fit for how healthcare facilities operate. Additionally, there was near-unanimous agreement among commenters that SAAs and CAAs are not necessary to accumulate hazardous waste pharmaceuticals, further supporting the agency's decision.

Although there is no requirement that a healthcare facility accumulate its hazardous waste pharmaceuticals in a CAA, doing so is, nonetheless, acceptable. A healthcare facility may choose to accumulate hazardous waste pharmaceuticals within its 90-day or 180-day CAA if it has one established for its other hazardous wastes, as long as it maintains compliance with the accumulation time limit and container requirements of 40 CFR part 266 subpart P. If a healthcare facility chooses to accumulate its hazardous waste pharmaceuticals in a CAA, those hazardous waste pharmaceuticals will only be subject to the requirements of part 266 subpart P and not the part 262 hazardous waste generator standards.

E. Container Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(d))

1. Summary of Proposal

The container standards discussed in this section apply to those containers used by healthcare facilities to accumulate non-creditable hazardous waste pharmaceuticals. First, we would note that due to the relatively small quantities of hazardous waste pharmaceuticals that are typically accumulated and stored at a healthcare facility, the Agency understands that other types of waste management units, such as tanks, are not used for the management of waste pharmaceuticals. Therefore, we only proposed standards for containers as defined in 40 CFR 260.10. However, the Agency solicited comment as to whether other types of waste management units are also used by healthcare facilities to accumulate and store hazardous waste pharmaceuticals and whether EPA should establish technical standards for other types of waste management units.

The Agency proposed to require that healthcare facilities place hazardous waste pharmaceuticals into containers that are structurally sound and that are compatible with the hazardous waste pharmaceuticals that will be contained within them. EPA intends this requirement to mean that containers used for holding non-creditable hazardous waste pharmaceuticals must be in good condition, with no severe rusting, apparent structural defects, nor deterioration. EPA also proposed that containers also must not have any evidence of leakage, spillage, or damage that could result in the release of waste under reasonably foreseeable circumstances. Furthermore, the Agency proposed to require that incompatible wastes not be placed in the same container, unless the commingling of incompatible hazardous wastes is conducted in such a way that it does not have the potential to (1) generate extreme heat or pressure, fire or explosion, or violent reaction; (2) produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health; (3) produce uncontrollable flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions; (4) damage the structural integrity of the facility or container containing the hazardous waste pharmaceuticals; or (5) through other like means threaten human health or the environment. For example, the majority of a healthcare facility's non-creditable hazardous waste pharmaceuticals are likely organic in nature, and thus, compatible with each other and can be accumulated together, especially since they will most likely be incinerated once they are transported to a TSDF.

The Agency believes that these technical standards, like similar technical standards that EPA has promulgated in § 265.17(b) for interim status TSDFs,[207] would ensure that hazardous waste pharmaceuticals are properly managed and would not be released into the environment, while at the same time providing flexibility to the healthcare facility in selecting those containers that are most appropriate for their situation.

In addition to the proposed container standards, the Agency also proposed that accumulation containers for hazardous waste pharmaceuticals be secured in a manner that prevents unauthorized access to the contents in order to prevent the diversion of hazardous waste pharmaceuticals or inadvertent exposures to them. Unlike most other hazardous wastes, some hazardous waste pharmaceuticals might still retain considerable value to individuals or on the black market, which can increase the likelihood of diversion for illicit purposes.

Some non-creditable hazardous waste pharmaceuticals, such as metal-bearing wastes not containing sufficient organics (*e.g.,* P012, arsenic trioxide), are prohibited from being incinerated under the dilution prohibition.[208] Dilution is not a substitute for treatment of certain restricted wastes because the hazardous constituents are not destroyed, removed, or immobilized before being disposed of on the land.[209] EPA proposed that the hazardous waste pharmaceuticals that cannot be incinerated must be accumulated separately from organic wastes destined for incineration.

2. Summary of Comments

There was considerable interest in this section with a broad range of comments in support, in opposition, and suggesting modifications. While some states were in support of the proposed standards, others were concerned that they would not be easily understood by healthcare facility workers, and that we should provide more detail about what constitutes a closed container. There was also a comment that recommended we clarify that hazardous waste pharmaceuticals can only be accumulated in containers, and not tanks or other accumulation units, and also what would constitute an acceptable container. For example, the commenter asked if re-sealable plastic storage bags or plastic pill bottles are considered a container under this subpart.

[207] § 265.17 General requirements for ignitable, reactive, or incompatible wastes is available. *https://www.gpo.gov/fdsys/pkg/CFR-2017-title40-vol28/pdf/CFR-2017-title40-vol28-part265.pdf.*

[208] § 268.3(c) Dilution prohibited as a substitute for treatment. See appendix XI of part 268 for a full list of hazardous wastes that are prohibited from being combusted.

[209] See RCRA Policy Statement: Clarification of the Land Disposal Restrictions' Dilution Prohibition and the Combustion of Inorganic Metal-Bearing Hazardous Waste. *https://www.epa.gov/hw/policy-statement-clarification-dilution-prohibition-and-combustion-inorganic-metal-bearing.*

Commenters from the waste management industry were generally in support of the proposed container standards although one commenter took issue with the security standards in 40 CFR 266.502(d)(3), stating that they are not adequate and recommending that we incorporate existing DEA guidance on container security standards. The commenter also suggested the final regulations incorporate an additional security provision stating that hazardous waste pharmaceuticals be put into a ''product or container that is specifically designed to render them inaccessible, non-consumable, and/or irretrievable prior to final disposal.'' A different waste management company echoed the concerns shared by the previously mentioned state that the final rule should specify that hazardous waste pharmaceuticals can only be accumulated in containers and not in other types of waste accumulation units.[210] No commenters indicated that any other types of waste management units are used to accumulate hazardous waste pharmaceuticals.

Trade associations representing a range of stakeholders also generally supported the proposed provisions but were concerned about the requirements to segregate hazardous waste pharmaceuticals that cannot be incinerated. One waste treatment trade association recommended that the regulatory language that allows the incineration of certain mercury-bearing hazardous waste pharmaceuticals be changed to discourage the incineration of such wastes even though it is permissible. They believe that the proposed language may be interpreted as advocating for their incineration. A state association was concerned about the possible subjectivity of the language in 40 CFR 262.502(d)(2), which contains standards for facilities that manage ignitable or hazardous waste pharmaceuticals or that mix or commingle incompatible wastes in the same container. They recommend instead, that the final rule employ the ''traditional prohibition'' on incompatibility.[211]

3. Final Rule Provisions

The Agency is finalizing the container standards for non-creditable hazardous waste pharmaceuticals as proposed. A healthcare facility must place its non-creditable hazardous waste pharmaceuticals in containers that are structurally sound, compatible with the contents, and that would prevent any leaks or spills under reasonably foreseeable conditions. If incompatible hazardous waste pharmaceuticals are commingled in a container, the healthcare facility must manage the container such that it does not have the potential to generate dangerous heat and/or pressure, emit any toxic substances (*e.g.,* mists, fumes, dust), produce flammable fumes or gases, damage the structural integrity of the container, or otherwise endanger human health and the environment.

To address the concerns of commenters, EPA would like to emphasize that, while it is permissible for hazardous waste pharmaceuticals containing metals such as mercury to be incinerated if the total organic carbon is greater than 1%,[212] we strongly recommend that they be segregated out and treated via other acceptable methods that comply with the land disposal restrictions.

EPA is clarifying that the container standards like the other standards for non-creditable hazardous waste pharmaceuticals do not apply to hazardous waste pharmaceuticals that are also DEA controlled substances because these DEA controlled substances are conditionally exempt from RCRA.[213] Section XIV further discusses hazardous waste pharmaceuticals that are also DEA controlled substances.

To reduce the risk of illicit diversion, the Agency is finalizing the requirement preventing unauthorized access to the contents of containers used to accumulate non-creditable hazardous waste pharmaceuticals. EPA intended this requirement to be performance-based and did not finalize prescriptive regulatory requirements for this standard. Healthcare facilities may choose to utilize containers that are designed to prevent unauthorized access to their contents when located in areas with uncontrolled access or store containers in areas with controlled access, such as locked storage lockers, locked closets, or locked rooms, to prevent unauthorized access to the contents of the containers. Containers used to accumulate non-creditable hazardous waste pharmaceuticals may also be kept behind a pharmacy counter because of the restricted access to those areas.

The Agency received no comments indicating that non-creditable hazardous waste pharmaceuticals are accumulated in any waste management units other than containers. Therefore, these standards apply only to containers used to accumulate non-creditable hazardous waste pharmaceuticals. Other types of hazardous waste accumulation units are not permitted for the accumulation of non-creditable hazardous waste pharmaceuticals.

4. Comments and Responses

Section (d)(4) of this provision regarding the requirement to segregate certain metal-bearing non-creditable hazardous waste pharmaceuticals was added as a reminder that, due to existing LDR regulations, a few hazardous waste pharmaceuticals cannot be incinerated and therefore must be segregated. This is not a new requirement for healthcare facilities and does not represent a change in the regulatory burden.

One commenter asked if plastic bags are considered a container as defined in § 260.10. If hazardous waste is placed inside a plastic bag, it meets the definition of a RCRA container and is subject to all applicable standards in 40 CFR 264 subpart I and 40 CFR 265 subpart I. Specifically, to be in compliance, a plastic bag must be compatible with the waste, able to prevent the contents from leaking, kept closed during storage except when it is necessary to add or remove waste, and handled or stored in a manner that prevents rupture and/or causes leaking. EPA would also note that, even though this commenter did not mention other types of containers, that cups, pill bottles, vials, etc. are also considered a container under RCRA.[214]

Regarding the state association that suggested EPA apply the ''traditional prohibition'' on mixing or commingling incompatible wastes in the same container because they were concerned about the possible subjectivity of the five specified conditions in 40 CFR 262.502(d)(2), that regulatory language was taken directly from the general requirements for ignitable, reactive, or incompatible wastes, in the General Facility Standards at 40 CFR 265.17(b). This is not a newly designed requirement. Healthcare facilities that manage hazardous waste pharmaceuticals are already required to comply with this provision.

[210] See comment number EPA–HQ–RCRA–2007–0932–0257.

[211] See comment number EPA–HQ–RCRA–2007–0932–0216.

[212] § 268.3 (c) Dilution prohibited as a substitute for treatment.

[213] § 266.506.

[214] See memo November 11, 2011, Rudzinski to the Regional RCRA Division Directors (RCRA Online #14827).

F. Labeling Standards on Containers for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(e))

1. Summary of Proposal

During the period of accumulation, the Agency proposed that containers of hazardous waste pharmaceuticals be marked with the words ''Hazardous Waste Pharmaceuticals.'' The Agency did not propose to require that the hazardous waste numbers (often referred to as hazardous waste codes) of the container's contents be listed on the label. Healthcare personnel (*e.g.,* nurses) typically generate the hazardous waste pharmaceuticals. Healthcare personnel are not usually intimately familiar with RCRA and its regulations and are primarily focused on patients and their health. In addition, while a healthcare facility may have an environmental compliance manager or environmental consultant that is knowledgeable about RCRA and its regulations and can make hazardous waste determinations, this individual cannot be present to assign a hazardous waste code and label the collection receptacle each time a hazardous waste pharmaceutical is generated. For these reasons, EPA did not believe it would be practical to require individual hazardous waste codes on the hazardous waste pharmaceutical collection container at the healthcare facility.

The Agency solicited comment on the appropriateness of the proposed general labeling requirement. The Agency also requested comment on security concerns regarding having the word ''pharmaceutical'' marked on the containers.

2. Summary of Comments

The issues of determining waste codes and whether they should be required on labels and/or manifests cuts across a number of provisions in this rule. Many commenters intertwined their opinions on container labeling standards with manifest requirements, waste code determinations by healthcare workers, and LDRs. While the Agency understands the inter-relatedness of these issues, this section pertains specifically to the proposed standards of requiring the words ''Hazardous Waste Pharmaceuticals'' on containers used to accumulate hazardous waste pharmaceuticals, and whether having the word ''Pharmaceutical'' displayed on those containers increases the risk of illicit diversion. Many of the comments alluded to these container labeling requirements during on-site accumulation, but did not address them directly, instead focusing on how the proposed labeling standards to not require hazardous waste codes on containers will affect the manifesting, shipping, and LDR processes. We will address those comments in subsequent sections as appropriate.

States had mixed views with a few voicing support for the proposed labeling standards, while another asked that the Agency provide more leeway in the required wording on the container label. Another state agreed with not requiring individual waste codes, but recommended that EPA require some sort of identification of potentially incompatible wastes to help prevent their inadvertent mixing. Two states were opposed to the proposed standards and recommended requiring individual hazardous waste codes on container labels to reduce the risk of mismanagement and incorrect treatment.

One reverse logistics company tacitly agreed with the proposal to not require hazardous waste codes on containers (or manifests) and instead, write ''Hazardous Waste Pharmaceuticals'' on the container and comply with DOT requirements. They expressed agreement with the agency's proposal to not require hazardous waste codes on the manifest, which leads the Agency to conclude that not requiring hazardous waste codes on containers is acceptable to them as well.

Comments from the waste treatment sector were mixed as well. One commenter agreed with the proposal to not require hazardous waste codes on container labels but wanted more flexibility in labeling. Other commenters from the waste treatment industry were wholly opposed to the proposed labeling requirements citing the need for waste codes by TSDFs to meet LDR standards.[215]

One medical waste trade association did not explicitly agree that hazardous waste codes should not be required on container labels, but they did request that, at a minimum, hazardous waste codes should be included on the manifest.

Stericycle initially disagreed with the proposal to require the word ''pharmaceutical'' on labels in addition to ''Hazardous Waste'' when it commented on the 2008 proposal to add pharmaceuticals to the Universal Waste rule. It has subsequently, through first-hand experience, determined that including the word ''pharmaceutical'' on containers does not increase the risk for illicit diversion. Therefore, in its comments to this proposed rulemaking, it is now in support of labeling containers of hazardous waste pharmaceuticals with the words ''Hazardous Waste Pharmaceuticals.''

Multiple commenters representing regional and national healthcare systems currently label their containers with the word ''pharmaceuticals'' and feel it is appropriate.[216] A commenter from the healthcare waste association also agrees that including the word ''pharmaceutical'' on containers is current practice and does not present any additional risk of diversion.[217]

3. Final Rule Provisions EPA is finalizing the container labeling requirements as proposed. Specifically, containers of non-creditable hazardous waste pharmaceuticals must be marked with the words ''Hazardous Waste Pharmaceuticals'' when accumulating on-site. This final rule provision is consistent with the container labeling requirements in the Hazardous Waste Generator Improvements rule,[218] in that generators are not required to label containers with hazardous waste codes during on-site accumulation. Previously, the regulations did not specify when hazardous waste codes needed to be added to container labels.

The Agency was concerned about increasing the risk of diversion resulting from displaying the word ''pharmaceutical'' on a container. However, given the general support from commenters, in this final rule, EPA is comfortable including the word ''pharmaceutical'' on the label of containers used to accumulate hazardous waste pharmaceuticals. There was no opposition from commenters representing healthcare systems and pharmacy trade groups. In fact, many commented that this is has been standard practice for some time and has not resulted in any increased diversion.

4. Comments and Responses

One state was concerned that allowing the commingling of hazardous waste pharmaceuticals could inadvertently lead to incompatible hazardous waste pharmaceuticals being mixed together, and suggested that EPA add a requirement to label containers with potentially incompatible wastes. It is the Agency's understanding that there are only a few pharmaceuticals that are incompatible according to DOT. Pressurized aerosols are the most common, although both DOT and EPA are considering relaxing their

[215] See comment numbers EPA–HQ–RCRA–2007–0932–0333 and EPA–HQ–RCRA–2007–0932–0297.

[216] See comment number EPA–HQ–RCRA–2007–0932–0297.

[217] See comment number EPA–HQ–RCRA–2007–0932–0296.

[218] Final rule: November 28, 2016; 81 FR 85808.

management requirements in the near future. Other DOT incompatible wastes include oxidizers, acids, and bases, yet they occur infrequently in dosage form.[219] In addition, there are a limited number of cases in which commingled incompatible pharmaceutical waste has caused a problem. Therefore, the Agency has determined that the risk does not rise to the level of requiring a specific provision and is not finalizing any additional labeling requirement for incompatible hazardous waste pharmaceuticals.

One commenter from the waste management industry suggested that EPA add the flexibility to label containers of hazardous waste pharmaceuticals with the words ''hazardous waste'' or other words that communicate the hazards per § 262.34(c)(1)(ii).[220] The Agency is not finalizing this suggestion. EPA recently revisited these provisions in the 2016 Hazardous Waste Generator Improvements rule to require that generators label containers with both the words ''hazardous waste'' and other words that indicate the nature of the hazard partially because the Agency felt that the previous requirements were too vague. In addition, § 262.34 applied only to containers in SAAs whereas there are no SAAs in a subpart P healthcare facility.

G. Accumulation Time Limits for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(f))

1. Summary of Proposal

a. One-year accumulation time limit. A few hazardous waste pharmaceuticals are P-listed acute hazardous wastes, the most common being warfarin. Under the part 262 generator regulations, if a generator generates more than 1 kg of acute hazardous waste per calendar month, the generator is regulated as an LQG and subject to a 90-day limit on accumulation. Due to this low generation/accumulation threshold associated with P-listed wastes, healthcare facilities are often LQGs. However, while healthcare facilities can generate enough P-listed waste to become LQGs, they often do not generate sufficient total amounts of hazardous waste pharmaceuticals within the allowed accumulation period of 90 days to make off-site shipments using a hazardous waste transporter cost-effective.

Under the 2008 proposed amendment to add pharmaceuticals to the Universal Waste program, handlers of pharmaceutical universal waste would have had one year to accumulate their hazardous waste pharmaceuticals in order to facilitate proper treatment and disposal. Commenters on the proposed 2008 Pharmaceutical Universal Waste rule indicated support for the one-year accumulation time limit. Thus, under part 266 subpart P, the Agency proposed to allow healthcare facilities to accumulate non-creditable hazardous waste pharmaceuticals for up to one year without triggering interim status or the need to obtain a RCRA permit. EPA proposed one year as an appropriate time frame because it strikes a balance between allowing healthcare facilities enough time to accumulate enough non-creditable hazardous waste pharmaceuticals to make it economically viable to transport their hazardous waste pharmaceuticals off site while ensuring that the hazardous wastes are not accumulated beyond the one-year storage limit under the LDR program (see § 268.50). Under the LDR storage prohibition, the Agency assumes that any accumulation for up to one year is for the purpose of facilitating proper treatment and disposal.

EPA proposed that healthcare facilities could use various approaches to demonstrate the length of time that non-creditable hazardous waste pharmaceuticals are accumulated on site. For example, EPA proposed that a healthcare facility can choose to mark the container label with the date that accumulation first began, maintain an inventory system that identifies dates when the hazardous waste pharmaceuticals were first accumulated, identify in the accumulation area the earliest date that a hazardous waste pharmaceutical became a hazardous waste, or any other method that clearly demonstrates the length of time that the hazardous waste pharmaceutical has been accumulated from the date it became a hazardous waste.

b. Extensions to accumulation time limits. In the proposed time frames to accumulate non-creditable hazardous waste pharmaceuticals, EPA included a provision that allowed any healthcare facility needing longer than the one-year accumulation time frame to request an extension from the appropriate EPA Regional Administrator. The Agency provided several examples of situations when a healthcare facility might request an extension. The reasons included litigation (now referred to as preservation orders, investigations or judicial proceedings),[221] recalls, and circumstances that are beyond the control of the healthcare facility. The proposed extension provision required that healthcare facilities send a request in writing (electronic or paper) to the Regional EPA Administrator explaining the need for the extension, the approximate amount of hazardous waste pharmaceuticals to be accumulated beyond the one year, and the amount of extra time requested. The Agency then proposed to allow the Regional Administrator the discretion to grant, modify, or deny the requested extension on a case-by-case basis. Lastly, the Agency solicited comment on the proposed mechanism to request a time extension.

2. Summary of Comments

a. One-year accumulation time limit. One commenter from industry agreed with the proposed time limits, but expressed concern about the ability of a healthcare facility to track accumulation times of their waste, and recommended that there be an additional requirement to inventory container contents in a manner that will ensure that the 1-year limit is not exceeded. Another state commenter also recommended that § 266.502(f)(2)(iv), which would have allowed containers to be marked in ''any other method which clearly demonstrates the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating from the date it first became a waste,'' be eliminated because it is too vague.

b. Extensions to accumulation time limits. The proposed extension provisions were opposed by a majority of commenters from both industry and state governments. Industry commenters were concerned about the additional burden that would likely arise from having to generate, transmit, and maintain an additional set of records for a scenario (the need to accumulate hazardous waste pharmaceuticals beyond the one-year allotment) that they say occurs more often than EPA seems to have been aware of at the time of proposal. Similarly, many state agencies were concerned about the added burden that would be imposed by a novel

[219] Smith, Charlotte A. ''Managing Pharmaceutical Waste: A New Implementation Blueprint.'' Pharmacy Practice News, Special Edition, 2011.

[220] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking. The regulation cited by the commenter has been since moved to 262.16(b)(6) as part of the 2016 Hazardous Waste Generator Improvements Final Rule.

[221] Subsequent to the proposal, the Agency became aware that the term ''litigation'' was not sufficiently broad to encompass all of the legal actions that might require a hazardous waste pharmaceutical to be preserved. To maintain consistency throughout the final rule, all instances where the term ''litigation'' or ''litigation holds'' appeared in the proposed rule have been changed to ''preservation order, investigation, or judicial proceeding,'' except in this section which discusses what was proposed.

source of administrative workload in the form of written requests that must be processed, analyzed, afforded appropriate consideration/discretion, and responded to. In addition, many commenters mentioned the possibility that these provisions would conflict with existing federal regulations, those of FDA for recalls, in particular. Other commenters brought up similar concerns about pharmaceuticals being stored pursuant to a litigation hold because of their protracted and unpredictable nature.

3. Final Rule Provisions

a. One-year accumulation time limit. The Agency is finalizing a one-year accumulation time limit for healthcare facilities accumulating non-creditable hazardous waste pharmaceuticals. Healthcare facilities may use one of three approaches to demonstrate the length of time that non-creditable hazardous waste pharmaceuticals are accumulated on site. A healthcare facility can choose to mark the container label with the date that accumulation first began, maintain an inventory system that identifies dates when the hazardous waste pharmaceuticals were first accumulated, or identify in the accumulation area the earliest date that a hazardous waste pharmaceutical became a hazardous waste.

The Agency reiterates that the one-year accumulation time limit only applies to a healthcare facility's non-creditable hazardous waste pharmaceuticals and does not apply to any other types of non-pharmaceutical hazardous waste generated on-site nor to potentially creditable hazardous waste pharmaceuticals.

The provision in § 266.502(f)(2)(iv) has been eliminated. It would have allowed for the accumulation start date to be labeled in any manner that clearly indicates the length of time that it first began accumulating non-creditable hazardous waste pharmaceuticals. One commenter argued that the provision was overly broad and EPA agreed.

b. Extensions to accumulation time limits. The Agency is not finalizing any of the proposed provisions in § 266.502(f)(3) that would have allowed a healthcare facility to request an extension of the one-year accumulation period for non-creditable hazardous waste pharmaceuticals and has addressed commenter concerns in other areas of the rule.

Recalls and preservation orders, investigations, or judicial proceedings (formerly referred to as litigation in the proposed rulemaking) were the two specific situations that the Agency attempted to address in the proposal as examples of unforeseen circumstances beyond the control of the healthcare facility. Pharmaceuticals that are subject to a voluntary or federally-mandated recall (most likely overseen by FDA, rarely CPSC) must be managed according to the requirements of either one or both agencies, as appropriate. Although many of these items could likely be considered RCRA solid waste, EPA is choosing not to apply RCRA regulations upon recalled pharmaceuticals that are managed under a voluntary or federally-mandated recall until a decision is made to destroy those items either in part or in whole. Similarly, the agency also determined that pharmaceuticals being stored pursuant to a preservation order, investigation, or judicial proceeding are not RCRA hazardous waste. Both scenarios are addressed in the Applicability section of the final rule in the preamble and regulations (see §§ 266.501(g)(4) and 266.501(g)(5)). Because pharmaceuticals that have been recalled and/or are being stored pursuant to a preservation order, investigation, or judicial proceeding are not subject to this subpart, the Agency does not see the need to include a provision for extending accumulation time. Recall managers (likely reverse distributors) and states will not be burdened by producing and responding to such requests.

The proposed rulemaking also discussed other unforeseen circumstances (other than a recall or preservation order, investigation, or judicial proceeding) as a legitimate reason for requesting an extension of the one-year period to accumulation of non-creditable hazardous waste pharmaceuticals. However, the only circumstances mentioned by commenters that would necessitate an extension were recalls and litigation (preservation orders, investigations, or judicial actions). Because both of those scenarios are now addressed individually in the finalized Applicability section of the preamble and regulations, and have no associated accumulation time limits, the Agency saw no need to codify a provision to allow a healthcare facility to request an extension of the accumulation time limit for other reasons beyond their control. Therefore, the EPA is not finalizing the proposal to allow healthcare facilities to request an extension of the one-year accumulation time frame from the Regional Administrator for any reason.

H. Land Disposal Restrictions for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(g) and § 266.502(d)(4))

1. Summary of Proposal

As required by HSWA and consistent with part 262 generator requirements, EPA proposed that healthcare facilities must comply with the LDR requirements prior to land disposal of the hazardous waste pharmaceuticals they generate. Since healthcare facilities are generators, even though they are not subject to the 40 CFR part 262 requirements for the management of hazardous waste pharmaceuticals, we proposed that they must comply with the LDR requirements found at 40 CFR part 268. The LDRs required by HSWA are in place to ensure that toxic constituents present in hazardous waste are properly treated to reduce their mobility or toxicity before hazardous waste is placed into or onto the land (*i.e.,* land disposed). With limited exceptions, hazardous waste must be treated by a RCRA-permitted or interim status TSDF.

In general, generators of hazardous waste assign the appropriate hazardous waste numbers (commonly called hazardous waste codes) to allow TSDFs to determine the specific treatment standard(s) for each prohibited waste. The Agency proposed that healthcare facilities generating non-creditable hazardous waste pharmaceuticals do not have to label the containers with the words ''hazardous waste'' or the hazardous waste codes when transporting them off site, but rather must label the containers with the words ''hazardous waste pharmaceuticals.'' Healthcare facilities do, however, need to make determinations as to whether wastes must be treated to meet LDR treatment standards. While most hazardous waste pharmaceuticals are likely organic in nature and may be incinerated, some hazardous waste pharmaceuticals may not be suitable for incineration and, therefore, must be segregated from the organic wastes. The hazardous waste pharmaceuticals not suitable for incineration include characteristic metal wastes (*i.e.,* D004–D043) prohibited from being combusted because of the dilution prohibition of § 268.3(c), as well as the listed wastes U151 (mercury), U205 (selenium sulfide), and P012 (arsenic trioxide), unless they contain greater than 1% total organic carbon. Put another way, hazardous waste pharmaceuticals with these metals that also contain greater than 1% total organic carbon may be incinerated.

In order to comply with the LDRs, healthcare facilities will need to segregate these wastes from the organic hazardous waste pharmaceuticals so that they can be properly treated by the TSDF. Although the Agency did include a requirement to segregate these metal-bearing low total organic carbon hazardous waste pharmaceuticals in proposed § 266.502(d)(4), the Agency requested comment on whether it is necessary to incorporate into the regulations at § 266.502(g) a requirement to segregate these wastes and whether additional labeling requirements are necessary to identify the hazardous waste pharmaceuticals that are not suitable for incineration.

Because EPA proposed that containers of non-creditable hazardous waste pharmaceuticals would not be required to list the hazardous waste codes on the label, we also proposed that waste codes are not required on the LDR notification.

2. Summary of Comments

There were a variety of comments on this provision, primarily regarding four issues: (1) The segregation of hazardous waste pharmaceuticals unsuitable for incineration, (2) the incineration of hazardous waste pharmaceuticals with numeric treatment standards, (3) the LDR notification, and (4) the need for hazardous waste pharmaceuticals-specific waste code and treatment standard.

Commenters from both states and the waste management industry requested that the agency add a requirement for healthcare facilities to segregate any hazardous waste pharmaceuticals that are unsuitable for incineration into separate containers and label them with the appropriate waste codes. They argued that there would be an increased likelihood that pharmaceuticals containing metals subject to the dilution prohibition would be inadvertently incinerated, resulting in noncompliance with LDR standards.

Many waste management companies expressed concern about their ability to meet LDR standards without knowing specific waste codes and the added burden they would incur from having to test their ash for the seven hazardous waste pharmaceuticals with numeric treatment standards—lindane, chloroform, m-cresol, dichlorodifluoromethane, trichloromonofluoromethane, phenacetin and phenol.[222] They did, however, agree that healthcare workers should not have to make hazardous waste determinations. They stated that they would have to alter or augment their testing protocols for residual ash which would add undue burden. One commenter suggested that, at a minimum, segregation be performed before a shipment of hazardous waste pharmaceuticals are transported off site for disposal, but having waste codes either on a label or the manifest would be preferable. They generally stated that they do not feel waste management should bear all of the added burden of LDR compliance under this rule.

Another common theme among commenters, from the waste management industry in particular, was a recommendation for a new, single hazardous waste code for all hazardous waste pharmaceuticals with a corresponding alternate treatment of standard of combustion (CMBST). One commenter representing the retail industry expressed concern that the relief provided by this rule will be negated by the requirement to list waste codes on the LDR notice.

3. Final Rule Provisions

The Agency is finalizing the LDRs for non-creditable hazardous waste pharmaceuticals as proposed. The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the LDRs of 40 CFR part 268. A healthcare facility that generates hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with § 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (*i.e.,* hazardous waste codes) on the LDR notification.

To address commenters' concerns about whether hazardous waste codes are required on the LDR notification, the Agency has added clarifying language to specify that waste codes are, in fact, not required on the LDR notification. The Agency would note, however, that the proposed regulatory language did, in fact, specify in § 266.502(g) that waste codes are not required on the LDR notice. Due to the number of commenters who were under the impression that waste codes would still be required on the LDR notice, we added an additional clarification to make it more obvious that waste codes are not required on the LDR notice.

The final rule requires healthcare facilities that generate non-creditable hazardous waste pharmaceuticals to comply with the LDRs. In response to comments, we have made one minor change for added clarity. The Agency has added a requirement to § 266.502(d)(4) for healthcare facilities that generate non-creditable hazardous waste pharmaceuticals that are unsuitable for incineration to segregate them into separate containers from those containing commingled non-creditable hazardous waste pharmaceuticals, and label them with the appropriate hazardous waste codes. We would note, however, that the dilution prohibition of § 268.3 already necessitates such segregation, therefore, this addition in § 266.502 (d)(4) is for the purposes of clarity and does not substantially change any of the proposed LDR requirements for hazardous waste pharmaceuticals.

4. Comments and Responses

Waste management companies opposed the provision to not require healthcare facilities to label containers with hazardous waste codes because of the added burden they argue would result from having to conduct additional testing for pharmaceuticals with numeric treatment standards. Nevertheless, the Agency is not finalizing a requirement for healthcare facilities to label containers of non-creditable hazardous waste pharmaceuticals with hazardous waste codes, nor is the Agency finalizing any additional requirements for healthcare facility personnel to segregate the seven pharmaceuticals that have numeric treatment standards, although a vendor could include such a requirement in its contract with a healthcare facility.

Unlike metal-bearing hazardous waste pharmaceuticals that may not be incinerated, the seven hazardous waste pharmaceuticals with numerical treatment standards may be incinerated or treated using any other treatment method to meet LDR values. Therefore, the Agency thinks it would cause confusion and add burden to require healthcare facilities to segregate the hazardous waste pharmaceuticals with numeric treatment standards. Further, the Agency has determined that several of the seven organics with numeric treatment standards also appear in non-pharmaceutical hazardous waste, which means that hazardous waste combustors are already required to test their ash to ensure compliance with LDRs for those constituents.

Because this rule does not require that healthcare facilities label their waste with the hazardous waste codes, TSDFs will now have to analyze their incinerator residue (ash) for the seven organics that have numerical treatment standards according to the conditions established in the facility waste analysis plan, as they could possibly be present in any shipment of organic hazardous

[222] See 40 CFR 268.40 table ''Treatment Standards for Hazardous Wastes,'' which identifies maximum concentration values for all hazardous constituents in the waste/treatment residue prior to land disposal.

waste pharmaceuticals or treatment residues. Organic hazardous waste pharmaceuticals (other than arsenic trioxide) may all be incinerated at RCRA-permitted or interim status hazardous waste combustors. Most organic wastes have a specified treatment standard of combustion (CMBST). The remaining seven organics have numerical treatment standards, such that no particular treatment technology is required to achieve the numerical LDR treatment standards. While these wastes may be incinerated, the ash must be analyzed for these seven organic constituents to demonstrate compliance with the LDR treatment standards before that ash can be land disposed. The Agency is not finalizing any standards that would affect the frequency of testing, simply that TSDFs test their ash for these seven constituents as part of their existing protocol.

EPA is not finalizing recommendations from commenters that the Agency implement a new waste code or alternative treatment standards specifically for hazardous waste pharmaceuticals. Because the Agency did not propose any new waste codes or treatment standards for hazardous waste pharmaceuticals, the recommendation is outside the scope of this rule. The Agency does agree that implementing an alternative treatment standard of combustion for hazardous waste pharmaceuticals that currently have numeric treatment standards would be a viable solution to mitigate any added burden imposed on TSDFs that will have to modify their testing protocol; however, we did not receive the necessary data to propose such a change prior to proposal, and therefore cannot finalize an alternative treatment standard in this rule. The Agency is, however, open to considering alternative treatment standards for hazardous waste pharmaceuticals in possible future rulemakings.

In their comments on this rule and the 2008 Universal Waste proposal, Environmental Technology Council (ETC) suggested revising the treatment standards for the organic hazardous waste pharmaceuticals that have numerical treatment standards to the specified treatment standard of combustion. Specifying combustion would relieve the TSDFs from demonstrating compliance with the numerical treatment standards.[223] EPA explored the feasibility of making combustion an alternative treatment standard for the seven organic hazardous waste pharmaceuticals that currently have numeric LDR treatment standards. In fact, EPA notes that the numerical treatment standards were developed based on levels achieved through combustion. However, EPA has indicated a preference for numerical treatment standards over specifying treatment standards whenever possible, to allow maximum flexibility. Furthermore, it is not clear that pharmaceuticals would be the sole source of the seven organic constituents in question. Therefore, even if we proposed an alternative treatment standard of combustion for the seven organic pharmaceuticals, hazardous waste combustors would still be required to test their ash for these constituents to demonstrate compliance with numeric treatment standards if they received the organics from another, non-pharmaceutical source.

Again, EPA notes that autoclaving is not an acceptable method of treating hazardous waste.[224]

I. Procedures for Healthcare Facilities Managing Rejected Shipments of Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(h))

1. Summary of Proposal

In rare circumstances, a healthcare facility may send its non-creditable hazardous waste pharmaceuticals to a designated facility that is unable to manage the hazardous waste. For such situations, we proposed that healthcare facilities follow the same procedures listed in 40 CFR part 262 (see § 262.23(f)). EPA believes that it is appropriate to continue current practices for rejected shipments that are part of the generator regulations of 40 CFR part 262 because rejected shipments are relatively rare and the procedures currently used for rejected shipments is relatively straightforward. In addition, healthcare facilities should be familiar with these procedures already.

2. Summary of Comments

There were relatively few comments on this section of the proposed rulemaking. One state and one waste management company agreed with the standards as proposed. Another state suggested that, as written, the regulatory language contradicts itself. Specifically, the commenter said that proposed § 266.502(h)(4) implies that a healthcare facility that receives a rejected shipment of non-creditable hazardous waste pharmaceuticals (a shipment that it initiated) must offer it for shipment to a new designated facility upon receipt, as opposed to the 90-day additional accumulation period mentioned in § 266.502(h). They reason that, because there are no time frames in the requirement, the Agency intended to mean upon receipt.

3. Final Rule Provisions

The agency is finalizing the provisions in this section as proposed with the added clarification that a healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility must have an understanding that the designated facility can accept and manage the waste. However, if the healthcare facility later receives the shipment back as a rejected load, the healthcare facility must sign the manifest that was used to return the shipment, provide the transporter a copy of the manifest, send a copy of the manifest within 30 days to the designated facility that returned the shipment and ship the non-creditable hazardous waste pharmaceuticals to a new designated facility. The Agency also added additional clarification to § 266.502(h)(4), to respond to comments, specifying that a healthcare facility has up to 90 days to ship the rejected shipment to a new designated facility.

J. Reporting Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(i))

1. Summary of Proposal

We proposed that healthcare facilities that are required to submit a BR would no longer be required to include their non-creditable hazardous waste pharmaceuticals in the report. In addition, the Agency proposed that healthcare facilities managing non-creditable hazardous waste pharmaceuticals have reporting requirements similar to generators regulated under 40 CFR part 262—that is, the exception reporting requirement under § 262.44(b) and the additional reporting requirement under § 262.44(c).

We proposed to incorporate and adapt the generator exception reporting procedures of 262.44(b) for this new subpart. Specifically, we proposed that if a healthcare facility does not receive a copy of the hazardous waste manifest from the designated facility within 60 days, the healthcare facility must submit to the EPA Regional Administrator a copy of the manifest with a statement that the healthcare facility did not

[223] Prohibited waste may be land disposed if it is treated using the technology specified in the table (*e.g.,* CMBST:''), which are described in detail in § 268.42, Table 1—Technology Codes and Description of Technology-Based Standards.

[224] See section VII.D.1.b for further discussion.

receive confirmation of the non-creditable hazardous waste pharmaceuticals' delivery, along with an explanation of the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts. Likewise, we proposed that if a shipment of non-creditable hazardous waste pharmaceuticals from a healthcare facility is rejected by the designated facility and it is shipped to an alternate facility and if the healthcare facility does not receive a signed copy of the hazardous waste manifest from the alternate facility within 60 days, it must submit to the EPA Regional Administrator a copy of the hazardous waste manifest with a statement that the healthcare facility did not receive confirmation of the non-creditable hazardous waste pharmaceuticals' delivery along with an explanation of the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

Finally, the Agency proposed that the Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of hazardous waste pharmaceuticals. This is already the case for generators operating under the 40 CFR part 262. As with 40 CFR part 262, it is a codification of statutory authority under §§ 2002(a) and 3002(a)(6) that provides the Agency some flexibility in what reports may be required.

2. Summary of Comments

The Agency received few comments on this subsection. Comments primarily addressed there being no requirement to include hazardous waste pharmaceuticals on the BR, and opinions were mixed. All pharmacy trade groups that commented were in favor of the proposal to not require hazardous waste pharmaceuticals managed under part 266 to be reported on the BR. States that commented were split. One state opposed the proposal and argued it would hinder the state's ability to reconcile what is treated at a TSDF with what is generated at a healthcare facility. Another state disagreed with the proposed provision and argued states will be forced to establish their own reporting requirements at the state level, leading to inconsistency in the way states determine their reporting fees. Another state was in agreement with the proposed provision, stating that information regarding amounts of non-creditable hazardous waste pharmaceuticals generated and treated can be captured from reverse distributor and TSDF reporting. One other state pointed out that the lack of a requirement for healthcare facilities to determine waste codes would make reporting in the BR difficult, if not impossible.

Regarding the exception reporting requirements, one state suggested that § 266.502(i)(2)(ii)(A) and (B) are unnecessary because the requirements in § 266.502 (i)(2)(i)(A) and (B) for a healthcare facility that does not receive a signed copy of the manifest within 60 days of being accepted by the initial transporter are the same, whether the shipment is lost or rejected and transferred to a new designated facility. The state suggested that § 266.502(i)(2) should be rewritten to simply state that an exception report is only necessary if the healthcare facility has not received the signed manifest from the TSDF within 60 days. One healthcare provider suggested that the proposed 60-day period for a healthcare facility to receive the manifest from the TSDF should be shortened to 45 days because shipments of other non-pharmaceutical hazardous waste require receipt of the manifest from the TSDF within 45 days.

3. Final Rule Provisions

The reporting requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals are being finalized as proposed. That is, non-creditable hazardous waste pharmaceuticals managed under this subpart at a healthcare facility are not required to be reported on the BR, healthcare facilities must submit an exception report to the Regional Administrator if they have not received a signed copy of the manifest within 60 days of the initial transporter accepting the shipment, and the Agency may require a healthcare facility to furnish additional reports regarding the quantity and disposition of non-creditable hazardous waste pharmaceuticals. When managing rejected shipments, the Agency believes it is advantageous to use established procedures that should be familiar to healthcare facilities, especially given that rejected shipments are relatively rare.

To clarify, the exception reporting regulations for healthcare facilities differ from the exception reporting regulations for reverse distributors because they were based on the differing § 262.42 exception reporting for LQGs and SQGs. The exception reporting regulations for healthcare facilities were based on the corresponding § 262.42(b) SQG regulations, whereas the reverse distributor exception reporting regulations were based on the § 262.42(a) LQG regulations.

Although commenters voiced some concern about not knowing the volume of non-creditable hazardous waste pharmaceuticals being generated at healthcare facilities, the Agency believes it is unnecessary to require healthcare facilities generating non-creditable hazardous waste pharmaceuticals to report this information. If a state or region wants to obtain such information, it can examine hazardous waste received forms in the BR submission from TSDFs. Further, one of the goals of this final rule is to reduce burden on healthcare facilities so that they will be encouraged to manage all of their waste pharmaceuticals under part 266 subpart P. Requiring a healthcare facility to report hazardous waste pharmaceuticals on its BR would discourage them from managing non-hazardous waste pharmaceuticals as hazardous. Finally, we would note that this approach is consistent with the Universal Waste program upon which the healthcare facility standards are based. Universal wastes managed under part 273 are not reported on the BR.

4. Comments and Responses

As part of the part 262 generator regulations, healthcare facilities that are LQGs must submit a BR to the Regional Administrator by March 1st of every even numbered year (see § 262.41). Among other requirements, the BR must include a description (EPA hazardous waste number and DOT hazard class) and quantity of each hazardous waste shipped off-site to a TSDF during each odd numbered year. If a healthcare facility is an LQG due to its non-pharmaceutical hazardous waste, it will continue to be required to submit a BR under part 262. However, it need not include in its BR hazardous waste pharmaceuticals managed under part 266. As discussed previously, the Agency is no longer requiring healthcare facilities to count hazardous waste pharmaceuticals managed under part 266 when determining their generator category under part 262. Instead, all healthcare facilities, with the exception of VSQGs, will be subject to this final rule for the management of hazardous waste pharmaceuticals. The Agency has determined that it does not need the information to be included in the BR because this final rule will bring a consistent approach to managing hazardous waste pharmaceuticals.

One commenter suggested that the time frame within which a healthcare facility must receive a signed manifest be shortened from 60 days to 45. The Agency did not finalize that request

because many standards in this final rule were based upon SQG and universal waste standards. Since no manifest is required for transport and there is no exception reporting standard in the Universal Waste program, the Agency used the 60-day time frame in the part 262 SQG standards. LQGs have a 45-day time frame to receive a signed manifest from a designated facility. Therefore, shortening the exception reporting time frame from 60 days to 45 would not be consistent with the goals of this rule to relieve the burden of LQG standards on healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

The Agency is not finalizing the suggestion to unify the language in § 266.502(i)(2) to cover both missing and rejected shipments. The proposed language was taken from the generator requirements in § 262.42, which addresses both situations separately. The Agency is not aware of the existing approach creating any problems for generators and is finalizing the regulatory language as proposed.

K. Recordkeeping Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(j))

1. Summary of Proposal

The Agency proposed that healthcare facilities managing non-creditable hazardous waste pharmaceuticals maintain records similar to the records that must be kept by generators regulated under 40 CFR part 262 (see § 262.40). Specifically, we proposed that healthcare facilities must keep a signed copy of each hazardous waste manifest as a record for three years from the date that the non-creditable hazardous waste pharmaceutical was accepted by the initial hazardous waste transporter. If the healthcare facility is required to file an exception report because it does not receive a signed copy of the manifest from the designated facility within 60 days of the date that the hazardous waste pharmaceutical was accepted by the initial transporter, then the healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report. In addition, EPA proposed that a healthcare facility must keep records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals regarding which pharmaceuticals are hazardous wastes for three years from the date of the test, analysis, or other determination. The Agency also proposed that any of the retention periods be automatically extended during the course of ongoing enforcement actions against any activity associated with hazardous waste pharmaceutical management or as requested by the Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

2. Summary of Comments

There were very few comments on this proposed provision. All but one of the commenters were states, all of which agreed with the proposed standard. One commenter suggested that we specify that all three types of records (manifest, exception reports, and test results/analysis/waste determinations) be kept on site.

3. Final Rule Provisions

The recordkeeping requirement is being finalized as proposed, with two changes. First, the Agency added a fifth provision in § 266.502(j)(5) to address comments requesting that all records be kept on site. The added provision also requires that all records must be readily available upon request by an inspector. The Agency understands that some records may be kept at off-site locations (*e.g.,* headquarters), which is acceptable as long as those records are able to be produced in a timely manner upon the request of an inspector.

The second change was an addition to § 266.502(j)(3) that relieves a healthcare facility from the requirement to retain documentation of hazardous waste determinations in § 266.502(c) if it chooses to manage all of its non-creditable waste pharmaceuticals as hazardous waste under subpart P. As discussed elsewhere, a goal of this rule is to encourage healthcare facilities to manage all of their waste pharmaceuticals under subpart P to reduce the amount of pharmaceuticals entering surface and groundwater via sewering and landfill leachate. The relief provided in § 266.502(j)(3) provides additional incentive for healthcare facilities to manage their non-creditable non-hazardous pharmaceutical waste under subpart P.

A healthcare facility must keep a copy of the signed manifest for a period of at least three years from the date the shipment was accepted by the initial transporter. A healthcare facility must also keep a copy of any exception report for a period of at least three years from the date of the report. To make the recordkeeping consistent with the 2016 Generator Improvements final rule, a healthcare facility must keep any information used to support its hazardous waste determination for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal, unless it chooses to manage all of its non-creditable pharmaceutical waste as hazardous waste under subpart P. The periods of retention will be automatically extended in the event of any enforcement activity or as requested by the Regional Administrator.

L. Response to Spills for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(k))

1. Summary of Proposal

For non-creditable hazardous waste pharmaceuticals generated and managed by healthcare facilities under this subpart, the Agency proposed basic spill response requirements, including the requirement that healthcare facilities immediately contain all spills of, and other residues from, hazardous waste pharmaceuticals. In addition, we proposed that healthcare facilities determine whether any material (*e.g.,* residue, contaminated clean-up materials, or debris resulting from the spill) is or contains a hazardous waste pharmaceutical and, if so, that the healthcare facility manage it under the management standards for non-creditable hazardous waste pharmaceuticals. Commenters to the original 1993 proposed rulemaking for establishing the Universal Waste program overwhelmingly supported these release response measures (60 FR 25528; May 11, 1995). Thus, we believe it was appropriate to include them again in this proposal for healthcare facilities managing non-creditable hazardous waste pharmaceuticals since it was based on the Universal Waste program.

2. Summary of Comments

One waste management company was in support of the proposed standards while another voiced its concern with the proposed preamble language discussing the requirement to report releases into the environment greater than the reportable quantity without knowing the waste codes of the wastes that had been spilled. They recommended that the Agency establish a reportable quantity for hazardous waste pharmaceuticals so large releases are appropriately reported to EPA. Similarly, one pharmacist trade association recommended that the Agency define what constitutes a release because the proposed regulatory language and preamble are unclear, and therefore it is also unclear when a release needs to be reported to the Agency.

One state commenter pointed out that these standards should also apply to healthcare facilities that accumulate potentially creditable hazardous waste pharmaceuticals. They recommend that this standard apply to all hazardous waste pharmaceuticals and that after a spill is cleaned up, the determination of credit potential must be made again. All other states agreed with the proposed standards for responding to spills.

3. Final Rule Provisions

The standards in this subsection are being substantially finalized as proposed with two changes.

First, we changed the word ''release'' to ''spill'' in the regulations in response to a commenter that expressed concern about having to comply with CERCLA requirements for spills of non-creditable hazardous waste pharmaceuticals. It was not the Agency's intent to imply that spills occurring inside a healthcare facility are automatically subject to CERCLA. The proposed preamble language was intended to differentiate between three scenarios: Spills that are cleaned up immediately, spills that are not cleaned up immediately, and releases to the environment. Spills that are cleaned up immediately must be managed under this subpart. Spills that are not cleaned up immediately would generally constitute illegal disposal, which may result in further action by EPA or an authorized state. The proposal also mentioned that hazardous waste is included in the definition of hazardous substance under CERCLA, and any release to the environment would trigger CERCLA authority in addition to RCRA. In many cases, a spill of a hazardous waste pharmaceuticals that occurs inside a healthcare facility does not constitute a release to the environment under CERCLA.[225] Therefore, this standard applies to spills that do not constitute a release to the environment, and there are no reporting requirements for spills unless they result in a release to the environment. This requirement makes no assertions about when or how CERCLA applies to spills of both non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals. The new terminology is also consistent with the term used in the definition of non-creditable hazardous waste pharmaceuticals in § 266.500, which refers to spills as opposed to releases.

Second, we addressed the comment from the state that requested a clarification regarding whether the spill response requirements apply to potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals. The Agency agrees that the applicability of this proposed provision—whether it applies only to non-creditable hazardous waste pharmaceuticals or to both potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals—was unclear. The regulatory language has been changed to reflect that the standards in this subsection apply only to spilled non-creditable hazardous waste pharmaceuticals. Further, the proposed regulations required that a healthcare facility determine whether, after being cleaned up, spilled non-creditable hazardous waste pharmaceuticals are potentially creditable or non-creditable, implying that non-creditable hazardous waste pharmaceuticals could become potentially creditable. The Agency did not intend to imply that spilled non-creditable hazardous waste pharmaceuticals could become potentially creditable. The regulatory language has been modified to simply require that spilled non-creditable hazardous waste pharmaceuticals and clean-up material be contained and managed as non-creditable hazardous waste pharmaceuticals. To address this regulatory gap that commenters identified regarding spilled potentially creditable hazardous waste pharmaceuticals, the Agency has added a corresponding subsection containing standards for response to spills of potentially creditable hazardous waste pharmaceuticals at a healthcare facility to the regulatory language at § 266.503(f).

M. Management of Non-Creditable Hazardous Waste Pharmaceuticals by Long-Term Care Facilities That Collect Them From Individuals Who Self-Administer

1. Summary of Proposal

The Agency proposed that a LTCF must collect hazardous waste pharmaceuticals from its residents that self-administer their medication and manage them under this subpart. This provision was proposed in order to require the proper management of all hazardous waste pharmaceuticals at LTCFs. LTCFs are similar to hospitals in that they are both healthcare providers, but they differ with respect to who owns the pharmaceuticals dispensed to patients. While hospitals own the pharmaceuticals they dispense, the pharmaceuticals dispensed at long-term care facilities belong to the residents of the facility. EPA understands that, while long-term care facilities often maintain each individual's pharmaceuticals in a centralized location, such as a pharmaceutical cart, there are instances where some individuals at some types of LTCFs may keep and self-administer their own pharmaceuticals. Under the proposal, long-term care facilities would have had to collect and manage all hazardous waste pharmaceuticals generated on site, regardless of ownership, in accordance with these same proposed subpart P management standards for healthcare facilities. EPA believed this approach would prohibit and prevent sewering of hazardous waste pharmaceuticals at these locations.

2. Summary of Comments

There was very little agreement with the proposed requirement for LTCFs to collect hazardous waste pharmaceuticals from patients that self-administer their medication. Most commenters argued that hazardous waste pharmaceuticals generated by residents who self-administer are household hazardous waste and that LTCFs are not allowed by law to perform any mandatory collection actions and have no authority to compel residents to surrender their unused medications. In addition, they commented that medication prescribed under Medicare Subpart D is considered the property of the resident. One commenter also pointed out that this provision would be unlawful and even dangerous to enforce because it would entail inspectors having to enter private residences, which is prohibited by many state statutes, and search through garbage bags and dumpsters to ensure that hazardous waste pharmaceuticals have not been illegally disposed.

Also, one commenter mentioned that this provision would add significant cost to the residents because waste management expenses are not covered under Medicare and pharmacies are not allowed to offer waste collection services for less than cost and would therefore be required to pass the full cost onto the residents.

3. Final Rule Provisions

The Agency is not finalizing the proposed provisions in this subsection. As discussed previously, after consideration of the comments, the Agency modified the definition of LTCF

[225] Spills are likely to occur upon impermeable surfaces both inside of and outside of a healthcare facility which limits the potential for release into the environment. Under CERCLA, a release to the environment also includes releases into the atmosphere. Since many pharmaceuticals are in pill form, spilled pharmaceuticals would rarely, constitute a release to the environment under CERCLA.

to specifically exclude assisted living facilities, group homes, independent living communities, and the independent/assisted living portions of continuing care retirement communities. The Agency agrees that the hazardous waste pharmaceuticals generated at these types of facilities meet the criteria for the household hazardous waste exclusion in § 261.4(b)(1) and are therefore not under the purview of RCRA regulations. Accordingly, we have also deleted proposed § 266.502(l) and the final rule does not require LTCFs to collect hazardous waste pharmaceuticals for their residents that have custody of and self-administer their medication. The Agency does, however, reiterate that this definition of LTCFs classified them as a type of healthcare facility. As such, LTCFs are subject to all the provisions being finalized for hazardous waste pharmaceuticals that are present in an LTCF's central pharmacy, because the hazardous waste being generated is not the property of the residents. Additionally, hazardous waste pharmaceuticals that are in the custody of the LTCF on behalf of the resident must be managed under this subpart. That said, the Agency expects that most LTCFs will be VSQGs and therefore only subject to a limited subset of the regulations in this rule, including the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional provisions of § 266.504. In fact, § 266.504(d) of the final rule includes a presumption that an LTCF with fewer than 20 beds is a VSQG.

Although not regulated under this subpart, the Agency recommends that assisted living facilities, group homes, independent living communities, and the independent and assisted living portions of continuing care retirement communities develop voluntary pharmaceutical collection programs for both hazardous and non-hazardous waste pharmaceuticals as a best management practice, as allowed by DEA regulations, to ensure proper management, avoid flushing, and minimize the potential for accidental poisonings, misuse or abuse.

N. Healthcare Facilities That Accept Hazardous Waste Pharmaceuticals From Off-Site Very Small Quantity Generator Healthcare Facilities (§ 266.502(l))

1. Summary of Proposal

Typically, hazardous waste pharmaceuticals from healthcare facilities are transported either to a reverse distributor, if it is potentially creditable, or to a permitted or interim status hazardous waste TSDF, if it is not. However, stakeholders have informed EPA that in some cases, hazardous waste pharmaceuticals are transported to another healthcare facility.

Until EPA finalized the Hazardous Waste Generator Improvements rule on November 28, 2016, CESQG regulations of § 261.5 did not allow a generator to send its hazardous waste off site to another generator, unless the receiving generator was one of the seven types of facilities listed in § 261.5(f)(3)(i)–(vii) or § 261.5(g)(i)–(vii), which included landfills permitted by state law.[226] The 2016 Hazardous Waste Generator Improvements final rule added a new provision for the consolidation of hazardous waste from VSQGs to LQGs under the control of the same person.[227] Person is defined under RCRA in § 260.10 and control is defined as ''the power to direct policies at the facility under RCRA in § 260.10.'' [228] [229] This provision now allows the same company to consolidate its VSQG hazardous waste at its LQG sites.

Specific to healthcare facilities, EPA is aware of two situations in which VSQGs would like to consolidate their hazardous waste pharmaceuticals at other healthcare facilities. The first situation is LTCFs that are VSQGs that return their hazardous waste pharmaceuticals to long-term care pharmacies that they contract with. The second situation involves military bases, where the off-post clinics that are generally VSQGs would like to send their hazardous waste pharmaceuticals back to the base clinics or pharmacies on the nearby base.[230]

Since long-term care pharmacies are not generally under the control of the same person as the LTCF, the proposed healthcare facility consolidation provision was broader than what was finalized in the 2016 Hazardous Waste Generator Improvements rule to accommodate the contractual relationship between long-term care facilities and long-term care pharmacies. The Agency proposed this consolidation provision to allow healthcare facilities that are VSQGs to send their hazardous waste pharmaceuticals to another healthcare facility rather than send it to a municipal solid waste landfill.

Specifically, EPA proposed to allow VSQG healthcare facilities to send their hazardous waste pharmaceuticals to an off-site healthcare facility without a hazardous waste manifest, provided the receiving healthcare facility meets four conditions. First, the receiving healthcare facility must be contracted to supply pharmaceutical products to the VSQG LTCF, or the VSQG healthcare facility and the receiving healthcare facility must both be under the control of the same person, as defined by § 260.10.[231] Second, the receiving healthcare facility must be managing its hazardous waste pharmaceuticals in accordance with subpart P. Third, the hazardous waste pharmaceuticals from the VSQG must be managed by the receiving healthcare facility as hazardous waste pharmaceuticals in accordance with subpart P once it arrives at the receiving healthcare facility. Fourth, the receiving healthcare facility must keep and maintain records of the hazardous waste pharmaceuticals received from the off-site VSQG healthcare facilities for three years from receipt of shipment.

As proposed, these conditions would ensure the proper management of the hazardous waste pharmaceuticals: Once they are received by the healthcare facility, they are subject to the same management standards EPA proposed for hazardous waste pharmaceuticals managed by healthcare facilities.

EPA took comment on two aspects of this exclusion: (1) Whether any additional conditions should be imposed in this provision and (2) whether to expand the scope of the provision to facilities that do not meet the proposed definition of a healthcare facility in this rule.

2. Summary of Comments

Overall, states, waste management and the healthcare industry were supportive of the proposal to allow VSQG healthcare facilities to consolidate their hazardous waste

[226] The Hazardous Waste Generator Improvements final rule renamed CESGGs as VSQGs, moved the regulations from § 261.5 to § 262.14 and added an eighth type of facility.

[227] 40 CFR 262.14(a)(5)(viii).

[228] *Person* means an individual, trust, firm, joint stock company, Federal Agency, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or any interstate body.

[229] For purposes of this provision, ''control'' means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate facilities on behalf of a different person shall not be deemed to control such healthcare facility.

[230] See notes from 11–28–12 meeting with U.S. Army Institute of Public Health in the docket for this rule (EPA–HQ–RCRA–2007–0932–0209).

[231] For purposes of this provision, ''control'' means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate facilities on behalf of a different person shall not be deemed to control such healthcare facility.

pharmaceuticals at another healthcare facility, provided the four conditions outlined above are met. One state, however, did oppose this provision unless the receiving healthcare facility is subject to all of the LQG requirements under part 262. They recommended that hazardous waste pharmaceuticals from VSQGs be consolidated at larger healthcare facilities under the 2016 Hazardous Waste Generator Improvements final rule to ensure more stringent standards are met by the receiving facility. Some states and pharmacists raised concerns that some of the language within the conditions was too narrow to serve the purpose that the language was trying to achieve.

3. Final Rule Provision

EPA is finalizing the provision to allow healthcare facilities that are operating under subpart P to receive hazardous waste pharmaceuticals from VSQGs with minor changes. Healthcare facilities that are VSQGs for their pharmaceutical and non-pharmaceutical waste may send their potentially creditable and non-creditable hazardous waste pharmaceuticals to an off-site healthcare facility operating under subpart P, without a hazardous waste manifest, provided the receiving healthcare facility meets the four conditions in § 266.502(l)(1)–(4) or § 266.503(b)(1)–(4), as applicable.

Several conforming changes were made to reflect the change in terminology from CESQG to VSQG and to reflect the reorganization of the VSQG regulations from § 261.5 to § 262.14. There are three more substantive changes from the proposal. First, under § 266.502(l)(1) where we proposed that one way a healthcare facility could receive hazardous waste pharmaceuticals from an off-site VSQG healthcare facility was to have a contractual relationship to provide the pharmaceutical products to the LTCF, we broadened the language to allow cases in which a ''business relationship'' between the LTCF and long-term care pharmacy exists.

Under the final rule, a healthcare facility under subpart P may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the VSQG healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility;

(2) Is operating under subpart P for the management of its non-creditable hazardous waste pharmaceuticals;

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with subpart P; and

(4) Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

It is important to note that a VSQG healthcare facility that chooses to send their waste for consolidation to an off-site healthcare facility is not considered to be operating under subpart P and does not need to notify as a VSQG operating under subpart P.

The second substantive change was to include a parallel provision in § 266.503 for potentially creditable hazardous waste pharmaceuticals. This addition allows healthcare facilities that are VSGQs two options for where to send their potentially creditable hazardous waste pharmaceuticals. The first option is to send them directly to a reverse distributor.[232] The second option is to send them to a healthcare facility operating under part 266 subpart P, provided the receiving facility meets the conditions of 266.503(b)(1)–(4).

The third change related to off-site consolidation of hazardous waste pharmaceuticals is to add paragraph § 262.14(a)(5)(x). Section 262.14(a)(5) of the VSQG regulations consists of a list of types of facilities to which VSQGs can send their hazardous waste. Section 262.14(a)(5)(viii) allows VSQGs to send their hazardous waste to large quantity generators under the control of the same person as the VSQG, provided certain conditions are met. This provision is similar to the provision we are finalizing in this rule for healthcare facilities that are VSQGs. Therefore, for consistency, we have added paragraph (x) to the list of facilities in § 262.14(a)(5) such that a healthcare facility that is a VSQG can send its non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals to an off-site healthcare facility (as defined in § 266.500) that meets the conditions in § 266.502(l) and § 266.503(b), as applicable.

4. Comments and Responses

Some states and pharmacists noted that language in the first condition may have the unintended consequence of prohibiting healthcare facilities from consolidating their hazardous waste pharmaceuticals due to their relationship with the consolidating facility. The first condition that a receiving healthcare facility must be under the control of the same person or contracted to supply pharmaceutical products to the VSQG's LTCF might prevent some long-term care facilities from taking advantage of this provision. Long-term care facilities that would otherwise be eligible to take advantage of this exclusion might not use it since CMS does not prevent long-term care facilities and/or their residents from using more than one long-term care pharmacy. This allows the long-term care facilities and the residents to shop for the ''best and most competitive'' pricing for medications and to change as needed.[233] Commenters believed that adding ''business relationship'' in addition to a contractual relationship for the healthcare facility and receiving facility to both be under the control of the same person would relieve this concern.

Furthermore, pharmacists raised the concern that a long-term care pharmacy would not want to take responsibility for returned pharmaceuticals under this condition as proposed unless they could confirm that they were the ones that distributed the pharmaceuticals in the first place (a receipt of purchase or similar documentation), since the management of these wastes is costly and may not be covered by the various healthcare programs. According to the CMS website, the managing of returned pharmaceuticals at long-term care pharmacies varies from state to state and is not a specific requirement of the Medicare/Medicaid program.[234] This consolidation provision was created so that VSQGs could consolidate their hazardous waste pharmaceuticals for proper management. If the provision as written is preventing long-term care facilities from potentially consolidating their hazardous waste, then it is thwarting the intended outcome of this provision and that is why EPA decided to add ''business relationship'' to the first condition for VSQG consolidation.

One state commenter recommended that the receiving healthcare facilities must either be an LQG or comply with the LQG requirements under part 262, since LQGs have more protective management standards during accumulation. First, under part 266 subpart P, healthcare facilities do not

[232] As allowed by 40 CFR 266.504(a).

[233] *https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html.*

[234] *https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html.*

have a generator category for their hazardous waste pharmaceuticals; all healthcare facilities are regulated the same under part 266 subpart P. Second, if EPA limited this consolidation provision to LQGs, then there would be a very small subset of receiving healthcare facilities that would be able to take advantage of this provision. Since subpart P allows healthcare facilities operating under this subpart to not count their hazardous waste pharmaceuticals towards their generator category, some healthcare facilities may no longer be LQGs for their other hazardous waste. It is highly unlikely that a long-term care pharmacy would remain an LQG under this rule since the majority of the hazardous waste that would be handled at these pharmacies would be pharmaceuticals. If we were to limit this provision to only LQG receiving facilities, then we would be preventing LTCFs from consolidating at long-term care pharmacies. Therefore, we determined that requiring the receiving facilities to be LQGs or to comply with LQG standards as a condition of the consolidation provision would severely limit the value of this provision.

In addition, the Agency is not finalizing a requirement for healthcare facilities that receive hazardous waste pharmaceuticals from VSQG healthcare facilities to manage the received pharmaceutical waste under the part 262 LQG standards. The Agency does not see the necessity in having more stringent management standards for healthcare facilities that receive pharmaceutical waste, because subpart P management standards are the same for all non-VSQG healthcare facilities, regardless of the amount of hazardous waste pharmaceuticals they generate. The Agency has determined that the subpart P standards are sufficiently protective of human health and the environment since all pharmaceuticals at a receiving healthcare facility must be managed under the same subpart P standards, regardless of whether they were generated on site or received from off site. If a state determines that the standards being finalized for healthcare facilities that receive hazardous waste pharmaceuticals from off-site are not adequate, that state may implement its own standards, provided they are more stringent.

The waste management industry, as well as some states, recommended that EPA require a notification when a facility was receiving hazardous waste pharmaceuticals and at least some minimal requirements for labeling, recordkeeping, and documentation of shipments. One state also recommended that we issue licenses to facilities that were receiving hazardous waste pharmaceuticals in order to track who was taking advantage of this provision. Consistent with our rationale for the limited shipping requirements for ''potentially creditable hazardous waste pharmaceuticals'' in this rule, the Agency believes that the shipping of hazardous waste pharmaceuticals poses a relatively low risk of release to the environment but a high risk for diversion of the pharmaceuticals when labeled ''pharmaceuticals.'' The hazardous waste that are being shipped often are in pill form or blister packs and not fifty-gallon drums of liquids that can be easily spilled. They are not likely to pose the same risks that typical hazardous waste could cause during shipping and transport, but there is a real risk to them being stolen if attention is brought to the contents of the containers. If the four conditions are met, the Agency believes this ensures the proper management of hazardous waste pharmaceuticals and adding new labeling and shipping requirements is unnecessary to accomplish that goal. Furthermore, the part 262 VSQG regulations do not require labeling or recordkeeping, and VSQGs might not take advantage of this consolidation provision if the requirements are too onerous, thus continuing to put their hazardous waste pharmaceuticals in municipal solid waste landfills.

The waste management industry asked for clarification on hazardous waste pharmaceuticals consolidation across state lines that have different requirements for VSQGs. There is nothing in this section that prevents a healthcare facility from sending their hazardous waste pharmaceuticals to a healthcare facility in another state provided both states have adopted this provision. Each state has their own requirements, so it would be prudent for VSQG healthcare facilities to make sure that the state in which they are consolidating has adopted this provision and does not impose any additional requirements on the receiving healthcare facility that accepts this waste.

EPA also received comments on what types of facilities could take advantage of this provision, specifically whether this provision will include wholesale drug distribution centers. In the final rule, EPA has defined wholesale distributors as a type of healthcare facility under § 266.500. Wholesale distributors were not an example that was given to us at proposal for this consolidation provision, but if all four conditions were met and there was a contractual or business relationship between the VSQG healthcare facility and the wholesale distributor, they would not be precluded from using this provision. However, we would note that when a wholesale distributor receives hazardous waste pharmaceutical return from a healthcare facility, the pharmaceuticals are usually restocked, which means they are pharmaceutical products and not hazardous waste pharmaceuticals.

Lastly, a non-profit organization asked us to clarify if these consolidated hazardous waste pharmaceuticals would be eligible for redistribution or evaluation for donation once consolidated to the receiving facility. In regard to redistribution or evaluation for donation, if the receiving healthcare facility can lawfully donate or redistribute the consolidated hazardous waste pharmaceuticals, there is nothing in this provision that prevents that from occurring, but those shipments would not fall under the consolidation provision in subpart P. If a VSQG is sending products to another facility, then the receiving facility should evaluate the received pharmaceuticals as they would any other products they receive for continued use, redistribution to secondary markets, donation and/or any other lawful possibilities. At this point, they are not a solid or hazardous waste and not subject to the requirements in § 266.502(l) or § 266.503(b).

EPA would also note that this provision is optional and it is not meant to impose undue burden on healthcare facilities. This section does not require a VSQG healthcare facility to ship their hazardous waste pharmaceuticals to a receiving healthcare facility. VSQG healthcare facilities continue to have the option, unless the state regulations are more stringent, of sending their hazardous waste pharmaceuticals to any of the types of facilities specified in § 262.14, including a municipal solid waste landfill.

XI. Standards for Healthcare Facilities That Accumulate Potentially Creditable Hazardous Waste Pharmaceuticals Prior to Shipment to Reverse Distributors (§ 266.503)

A. Healthcare Facilities Making a Hazardous Waste Determination for Potentially Creditable Pharmaceuticals (§ 266.503(a))

1. Summary of Proposal

EPA proposed standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals in § 266.503 of subpart P. As with non-creditable hazardous waste pharmaceuticals, a healthcare

facility must determine which potentially creditable pharmaceuticals are listed or characteristic hazardous wastes, in order to determine which potentially creditable pharmaceuticals are subject to regulation under this subpart.

Accordingly, we proposed that a healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable solid waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical (*i.e.,* is listed in 40 CFR part 261 subpart D or exhibits a characteristic identified in 40 CFR part 261 subpart C).

We also proposed that a healthcare facility may choose to manage all of its potentially creditable waste pharmaceuticals (both hazardous and non-hazardous) together as potentially creditable hazardous waste pharmaceuticals while accumulating on site and when shipping off site under § 266.509. If a healthcare facility chooses this approach of commingling its hazardous and non-hazardous potentially creditable waste pharmaceuticals, it would not need to make individual hazardous waste determinations, but would have made a generic decision that all of its potentially creditable waste pharmaceuticals are hazardous and would manage them as potentially creditable hazardous waste pharmaceuticals in accordance with the requirements in 40 CFR part 266 subpart P.

We proposed that healthcare facilities may choose to manage potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under the shipping standards of § 266.509. Additionally, EPA proposed that healthcare facilities would be prohibited from sending hazardous waste other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor. This was in keeping with our position that a reverse distributor's function in managing hazardous waste should be limited to managing hazardous waste pharmaceuticals that have a reasonable expectation of receiving manufacturer credit and not non-creditable hazardous waste pharmaceuticals or other non-pharmaceutical hazardous waste.

2. Summary of Comments

Pharmacists, some wholesalers, and manufacturers expressed concern that making hazardous waste determinations at their facilities would require additional staff, additional training on making hazardous waste determination, as well as more storage space in which to hold the hazardous waste as the determinations are being made.

We received mixed comments on commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals. Healthcare facilities and pharmacists were in favor of EPA allowing commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals, and the benefit it offers in handling their pharmaceutical waste or continuing the common practice of commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals when sent to reverse distributors. On the other hand, waste management and states raised concerns that commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals may prevent healthcare facilities from sending their waste across state lines or to certain reverse distributors, due to state regulations and/or reverse distributors' policies.

3. Final Rule Provisions

EPA is finalizing the standards as proposed, with some minor changes. Under this section, a healthcare facility has two choices: (1) Make a hazardous waste determination on each potentially creditable waste pharmaceutical and determine individually which are hazardous waste and thus subject to regulation under this subpart or, (2) commingle all potentially creditable pharmaceutical waste whether or not it is hazardous waste and manage the commingled pharmaceuticals under this subpart and thereby not have to make individual hazardous waste determinations.

EPA removed ''even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261 subpart C and are not listed in 40 CFR part 261 subpart D'' from the non-hazardous waste provision of this section since it was redundant with determinations of solid waste pharmaceuticals and whether they are potentially creditable or not.

EPA has also modified the regulatory language in the final rule to make clear that when a healthcare facility commingles potentially creditable non-hazardous and hazardous waste pharmaceuticals, the healthcare facility is choosing to subject the potentially creditable non-hazardous waste pharmaceuticals to all of subpart P while being managed at a healthcare facility and in preparation for shipping off-site. Once potentially creditable non-hazardous and hazardous waste pharmaceuticals are commingled they are subject to all applicable subpart P management standards while they remain commingled. As a practical matter, however, we expect that the primary impact to healthcare facilities will be that potentially creditable non-hazardous waste pharmaceuticals are subject to the shipping standards of § 266.509. Once potentially creditable non-hazardous waste pharmaceuticals are shipped off site to a reverse distributor, a reverse distributor may choose to segregate the non-hazardous waste pharmaceuticals from the hazardous waste pharmaceuticals. This process of segregation by the reverse distributor would require the reverse distributor to make new hazardous waste determinations on the commingled pharmaceuticals.

4. Comments and Responses

We received many comments on making hazardous waste determinations and commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals. While the commenters raised valid concerns on why making hazardous waste determinations can be burdensome on a healthcare facility, or why commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals may not work for all facilities, EPA made only minor editorial changes to this section of the final rule. The Agency determined that more substantive changes were unnecessary because this provision contains sufficient flexibility by providing healthcare facilities with two options.

a. *Making hazardous waste determinations.* Pharmacists, some wholesalers, and manufacturers expressed concern that being required to make hazardous waste determinations at their facilities would impose undue burden because they would have to hire additional staff and train them to make accurate waste determination. They argue that they would also need to allocate more space in which to store waste as the determinations are being made. Some commenters stated that making hazardous waste determinations may prevent healthcare facilities from sending their hazardous waste pharmaceuticals to reverse distributors at all. In support of the comments above, manufacturers and wholesalers argued that reverse distributors have the appropriate RCRA expertise to make accurate waste determinations, that they have served as a consolidation point for unused and hazardous waste pharmaceuticals for many years, and that the process has been effective and successful. The Agency notes, however, that allowing potentially creditable

pharmaceuticals to be sent to a reverse distributor without a hazardous waste determination being made at the point of generation violates a basic tenet of RCRA, because the decision to send them to a reverse distributor is effectively a decision to discard. In addition, the burden mentioned by commenters associated with making individual waste determinations would likely be significantly mitigated by exercising the option to manage all potentially creditable waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals.

b. *Commingled waste stream.* As previously noted, we received mixed comments on commingling potentially creditable non-hazardous hazardous waste pharmaceuticals.

EPA proposed the option of commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals to mitigate the burden of complying with the management standards, particularly for healthcare personnel making hazardous waste determinations. Given that many healthcare facilities currently commingle their potentially creditable non-hazardous and hazardous waste pharmaceuticals, we expect the practice to continue. However, if commingling causes undue burden on a facility due to state regulations, reverse distributor policies, or other reasons, then the healthcare facility does not have to utilize this option and can make individual hazardous waste determinations in accordance with § 266.503(a). This is an individual decision for each healthcare facility and each healthcare facility may choose what works best for managing its potentially creditable pharmaceutical waste.

Retailers and reverse distributors recommended that healthcare facilities should be allowed to make a determination about whether the item will be managed as hazardous when it becomes a waste at the time of arrival at the retail store or healthcare facility. They believe this practice would be impeded if all pharmaceuticals must be managed as potentially creditable hazardous waste pharmaceuticals when they become waste. If this is common practice among healthcare facilities, then the need to commingle their waste may not be something that is important. Allowing the commingling of all solid waste pharmaceuticals is meant to ease the burden on healthcare facilities that are not currently making hazardous waste determinations, or do not wish to make them, by allowing them to manage and ship all of their potentially creditable waste pharmaceuticals together.

B. Accepting Potentially Creditable Hazardous Waste Pharmaceuticals From an Off-Site Healthcare Facility That Is a Very Small Quantity Generator (§ 266.503(b))

1. Summary of Proposal

EPA proposed to allow healthcare facilities operating under subpart P to accept potentially creditable and non-creditable hazardous waste pharmaceuticals from an off-site VSQG healthcare facility without a hazardous waste manifest, provided four conditions are met. We proposed this provision in § 266.502(m) under the standards for managing non-creditable hazardous waste pharmaceuticals.[235] We proposed that healthcare facilities operating under subpart P could accept both potentially creditable and non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG. Previously, the part 262 VSQG regulations did not allow a healthcare facility to send its hazardous waste off-site to another healthcare facility, unless the receiving healthcare facility is one of the eight types of facilities listed in § 262.14(a)(5)(i–viii). For more detailed information on our proposal, please refer to section X.N.

2. Summary of Comments

EPA only received one comment in this section concerning changes to the generator category of the receiving facility. A trade association of pharmacists was concerned that allowing VSQG consolidation would affect the generator category of the receiving healthcare facility, and that it would need to report as an LQG.

3. Final Rule Provision

In the proposed rulemaking, EPA intended to allow healthcare facilities to accept both potentially creditable and non-creditable (including commingled) hazardous waste pharmaceuticals from an off-site VSQG healthcare facility, provided the receiving healthcare facility complies with the four conditions of § 266.502(m) (now in § 266.502(l)). In the final rule, we clarified our intention to allow healthcare facilities to accept both potentially creditable and non-creditable (including commingled) hazardous waste pharmaceuticals from an off-site VSQG healthcare facility by placing similar standards in § 266.503(b) under the standards for managing potentially creditable hazardous waste pharmaceuticals. This does not reflect a change from what was proposed, only that the consolidation standards apply to healthcare facilities receiving both non-creditable and potentially creditable hazardous waste pharmaceuticals.

Under the final rule, a healthcare facility that is a VSQG can send both its potentially creditable hazardous waste pharmaceuticals and non-creditable (including commingled) hazardous waste pharmaceuticals to an off-site healthcare facility operating under subpart P, provided the receiving healthcare facility complies with the four requirements of the respective sections. Regulations for the receiving healthcare facilities now appear in § 266.502(l) for non-creditable hazardous waste pharmaceuticals and in § 266.503(b) for potentially creditable hazardous waste pharmaceuticals. VSQG healthcare facilities that send their hazardous waste pharmaceuticals to an off-site healthcare facility are subject to the regulations in § 266.504(b), with further discussion in section XII.B of the preamble.

Under § 266.503(b) of the final rule, a healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the VSQG healthcare facility that is sending potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility;

(2) Is operating under subpart P for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with subpart P; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

It is important to note that a VSQG healthcare facility that chooses to consolidate its hazardous waste pharmaceuticals at an off-site healthcare facility is not considered to be operating under subpart P, and does not need to notify as a VSQG operating under subpart P.

[235] This provision is now found at § 266.502(l).

4. Comments and Responses

A pharmacists' association was concerned that allowing for VSQG consolidation would change the generator category of the receiving healthcare facilities and that the consolidating facility would need to report as an LQG. All healthcare facilities operating under part 266 subpart P are regulated the same, regardless of the amount of hazardous waste pharmaceuticals they generate. Further, healthcare facilities managing their hazardous waste pharmaceuticals under this subpart do not count their hazardous waste pharmaceuticals toward their generator category so consolidation of this additional hazardous waste pharmaceuticals at their facilities would not change the generator category of the receiving healthcare facility.

C. Accumulation Time, Container Management and Labeling for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals

Under the hazardous waste generator regulations in part 262, EPA requires specific management standards for containers that hold hazardous waste. However, potentially creditable hazardous waste pharmaceuticals pose a lower risk of release into the environment than traditional industrial hazardous waste. The risk of release is lower for several reasons.

First, potentially creditable hazardous waste pharmaceuticals must be in original manufacturers' packaging by definition and are often in their outer packaging as well, providing two layers of protection from leaks or spills.[236] Second, potentially creditable hazardous waste pharmaceuticals are typically generated in the pharmacy area of a healthcare facility where there is restricted access, creating a layer of security for these pharmaceuticals. Third, EPA has been informed that it is common practice at healthcare facilities for potentially creditable waste pharmaceuticals that are destined for a reverse distributor to be taken from the shelves of the pharmacy periodically and promptly boxed for off-site shipment.

For the reasons listed above, EPA did not propose specific standards for managing and labeling containers of potentially creditable hazardous waste pharmaceuticals at healthcare facilities. For the same reasons, we also did not propose a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals.

This is not to say that all potentially creditable hazardous waste pharmaceuticals waste pharmaceuticals are safe and pose no risk of spill or release into the environment. It is important to note that the accumulation of some potentially creditable hazardous waste pharmaceuticals, such as liquids and aerosols, may pose more of a risk due to possible spills or leaks than solid pills. However, EPA believes that the small quantities in which liquid and aerosol potentially creditable hazardous waste pharmaceuticals are generated, along with the DOT packaging requirements (49 CFR parts 173, 178, and 180), significantly reduces the risks of spills or releases to the environment.

In addition, to further mitigate the potential for spills or leaks, as a best management practice, EPA encourages healthcare facilities to place the original containers, and packaging containing liquids and aerosols pharmaceuticals, in separate individual containers (*e.g.,* sealed storage bag) before placing them in the accumulation container.

1. Accumulation Time and Container Management of Potentially Creditable Hazardous Waste Pharmaceuticals

a. Summary of proposal. EPA did not propose a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals or specific standards for how the containers must be managed during accumulation.

b. Summary of comments. Most commenters were in favor of adding some guidelines for accumulation time and container management. Some states commented that the proposed standards for non-creditable hazardous waste pharmaceuticals should be applied to both non-creditable and potentially creditable hazardous waste pharmaceuticals to prevent confusion from having multiple accumulation standards, and to provide extra protection of human health and the environment.

c. Final rule provisions. EPA is not finalizing a time limit for accumulating containers of potentially creditable hazardous waste pharmaceuticals. EPA is also not finalizing specific container management standards for healthcare facilities that accumulate containers of potentially creditable hazardous waste pharmaceuticals

d. Comments and responses. Several states expressed concern about the security of potentially creditable hazardous waste pharmaceuticals during accumulation. These commenters agreed that potentially creditable hazardous waste pharmaceuticals should be accumulated in a designated area that is labeled and kept locked or sealed according to best management practices for that facility as an additional deterrent to illicit diversion. Commenters also expressed concerned that not having designated accumulation areas could lead to situations where healthcare facility personnel may misplace or forget the locations of accumulation containers. States were concerned that the potential for healthcare facilities to receive manufacturer credit does not sufficiently encourage proper management.

As previously discussed, potentially creditable hazardous waste pharmaceuticals do not pose the same risks as other hazardous wastes. We received many comments, especially from the retail industry, about the condition of packages being important for being eligible and receiving manufacturer credit. For example, broken and/or leaking containers cannot be sent to a reverse distributor per the definition of ''potentially creditable hazardous waste pharmaceuticals,'' so there is an incentive to manage these items carefully. There is also an incentive to not overaccumulate wastes in healthcare facilities since manufacturer credit is only issued by reverse distributors and in many cases, cannot be collected by a healthcare facility until the reverse distributor receives them.

It is also important to note that many of these potentially creditable hazardous waste pharmaceuticals are already being generated and stored in secure areas, such as pharmacies, and being handled by personnel that have pharmaceutical expertise. EPA is also recommending that liquids and aerosols be put in sealed plastic bags, containers, or other management practices during accumulation to reduce the risk of spills and releases.

As for labeling the accumulation area with the words pharmaceutical waste, the concern still remains for increasing the potential for illicit diversion of these potentially creditable hazardous waste pharmaceuticals by bringing attention to the fact that it contains pharmaceuticals. Therefore, the Agency is not finalizing a requirement for healthcare facilities to label accumulation areas for potentially creditable hazardous waste pharmaceuticals.

Finally, if a state is uncomfortable with our approach to the accumulation of potentially creditable hazardous waste pharmaceuticals, it may choose to be more stringent in this regard when it adopts the rule.

[236] See 73 FR 73529; December 2, 2008.

2. Labeling Requirements for Containers of Potentially Creditable Hazardous Waste Pharmaceuticals

a. Summary of proposal. EPA did not propose specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals while they are accumulated on-site at a healthcare facility because they are in original manufacturer packaging, they are already labeled, and any additional labeling would be duplicative or apply to secondary containers, such as boxes used to ship to reverse distributors.

In addition, due to concerns regarding illicit diversion of pharmaceuticals, EPA believes that it is safer not to call attention to the fact that these containers hold pharmaceuticals. Unlike floor or patient care pharmaceutical waste, the potentially creditable hazardous waste pharmaceuticals returned to a reverse distributor often have high black-market value that makes them susceptible to diversion. Thus, EPA did not propose to require a label for containers used to accumulate potentially creditable hazardous waste pharmaceuticals.

b. Summary of comments. Many states believe that labeling should be required for all containers of hazardous waste to ensure proper management and disposal. Proper management, according to comments, includes accumulation in designated locations with individual containers labeled for inspection.

Other commenters expressed concerns that containers that are not labeled are subject to inaccurate waste determinations and will be mishandled and treated as non-creditable hazardous waste pharmaceuticals and sent to a TSDF rather than as potentially creditable which could ultimately be destined for a reverse distributor.

c. Final rule provision. EPA is not finalizing labeling standards for containers of potentially creditable hazardous waste pharmaceuticals accumulated by healthcare facilities.

d. Comments and responses. While the commenter's concerns apply to hazardous waste in general and for hazardous waste going to a TSDF, we do not believe they are equally applicable to containers of potentially creditable hazardous waste pharmaceuticals. First, containers of potentially creditable hazardous waste pharmaceuticals are in original manufacturer's packaging (or have been repackaged for use in a LTCF) and thus the contents are easily identifiable. Second, if a healthcare facility does not label an accumulation container on site and then forgets about it or misidentifies where it needs to go, then no manufacturer credit will be issued for those potentially creditable hazardous waste pharmaceuticals. Likewise, if a healthcare facility does label the containers on site and the contents are illicitly diverted, then the healthcare facility will not receive the manufacturer credit for those items. Healthcare facilities have a monetary incentive to keep track of what is in these containers, regardless of whether they are labeled, and to make sure they arrive unmolested at the reverse distributor.

Additionally, by imposing labeling requirements, EPA does not want to deter the practice of commingling potentially creditable hazardous waste pharmaceuticals with potentially creditable non-hazardous waste pharmaceuticals since both are typically transported together to a reverse distributor.

Therefore, EPA concludes that it is not necessary to require any labeling standards for potentially creditable hazardous waste pharmaceuticals.

D. No Biennial Reporting for Potentially Creditable Hazardous Waste Pharmaceuticals Generated at Healthcare Facilities (§ 266.503(d))

1. Summary of Proposal

The Agency proposed that healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

2. Summary of Comments

One state commented that it would prefer to be notified about who is handling this waste to ensure that healthcare facilities are adhering to the prohibition on sewering, since they will not know who is handling this waste.

3. Final Rule Provision

The Agency is finalizing as proposed that healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart. Potentially creditable hazardous waste pharmaceutical quantities will be captured by the reverse distributors' required biennial reports,[237] therefore, a requirement for healthcare facilities to report quantities of potentially creditable hazardous waste pharmaceuticals generated would be duplicative.

[237] This provision is found at § 266.510(c)(9)(i)

4. Comments and Responses

One state was concerned that they would not know which healthcare facilities are generating potentially creditable hazardous waste pharmaceuticals. All healthcare facilities operating under this subpart will be required to submit a one-time notification that they are subject to subpart P (§ 266.502(a)(1)). States will, therefore, be informed of what healthcare facilities are operating under subpart P and can inspect accordingly.

E. Recordkeeping Requirements for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.503(e))

1. Summary of Proposal

EPA proposed to require healthcare facilities to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors.

Specifically, we proposed that healthcare facilities that initiate a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor keep (1) records of advance notification, (2) shipping papers or bills of lading, and (3) records of delivery confirmation. We proposed that a healthcare facility must retain these records for three years after the shipment was initiated. These records document that shipments of potentially creditable hazardous waste pharmaceuticals have been taken into the control and custody of the receiving reverse distributor and have not been diverted. In most cases, retaining records for three years should be sufficient for inspection purposes; however, we proposed that the periods of retention are automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator.

2. Summary of Comments

One state agreed that three years was a sufficient retention period to enable inspectors to identify issues upon inspection. State and local governments requested clarification about what types of documentation (*e.g.,* shipping papers/bills of lading) satisfies the requirement. One commenter argued that the receiving facility should document efforts made to locate shipments that did not arrive.

3. Final Rule Provision

EPA is finalizing the proposed recordkeeping provision for potentially creditable hazardous waste pharmaceuticals for healthcare facilities and reverse distributors that initiate a

shipment to another reverse distributor with two changes. First, as we discuss later in the shipping standards, we have eliminated the requirement for healthcare facilities to provide advance notification of shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Thus, we have removed the requirement to keep a record of the advance notification. Second, EPA removed the reference to bills of lading from the recordkeeping requirement while keeping shipping papers since bills of lading are a type of shipping papers under DOT regulations. This is also responsive to comments asking for clarification. Healthcare facilities initiating shipments of potentially creditable hazardous waste pharmaceuticals must keep, (1) delivery confirmation for each shipment and (2) shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable. EPA is finalizing that these records must be retained for three years unless there is an unresolved enforcement activity or a request by the EPA Regional Administrator to keep them longer. In that case, the period of retention is automatically extended. EPA is finalizing this requirement as proposed despite input from commenters, as this is standard practice with enforcement activity. At the request of commenters, we have added a requirement that all records must be readily available upon request by an inspector.

F. Response to Spills for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.503(f))

1. Summary of Proposal

EPA proposed response requirements for spills of non-creditable hazardous waste pharmaceuticals but did not propose similar response requirements for releases of potentially creditable hazardous waste pharmaceuticals.

2. Summary of Comments

A commenter suggested that spills of potentially creditable hazardous waste pharmaceuticals should also be subject to the same containment and cleanup requirements as non-creditable hazardous waste pharmaceuticals. The commenter also asked whether EPA intended that all spills of potentially creditable hazardous waste pharmaceuticals render them non-creditable.

3. Final Rule Provision

EPA agrees with comments that all spills of hazardous waste pharmaceuticals, both potentially creditable and non-creditable, must be contained, and that all spills of potentially creditable hazardous waste pharmaceuticals renders them non-creditable. Therefore, in response to this comment, we have added a similar provision to the healthcare facility standards of § 266.503(f) for responding to releases of potentially creditable hazardous waste pharmaceuticals.

The standards in this section are based upon what is being finalized in the standards for response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities in § 266.502(k). The final rule requires that a healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with subpart P.

It is EPA's understanding that unused/undispensed pharmaceuticals that remain in original manufacturer's packaging often receive manufacturer credit even if the packaging has been opened. In the event of a spill, a healthcare facility should reevaluate whether any pharmaceuticals that remain in their containers (not spilled) are still eligible to receive manufacturer credit per the definition of potentially creditable hazardous waste pharmaceutical in § 266.500. The healthcare facility must determine whether the pharmaceuticals that remain in the containers are potentially creditable and manage them according to subpart P. Even if a healthcare facility determines that the remaining pharmaceuticals are potentially creditable, it must also ensure that the decision is consistent with the manufacturer's policies. It is important to note that this only applies to whatever might be left in the container and was not spilled.

XII. How does this rule apply to healthcare facilities that are very small quantity generators for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste? (§ 266.504)

A. Very Small Quantity Generators Using Reverse Distributors (§ 266.504(a))

1. Summary of Proposal

VSQGs are subject to a limited set of federal RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 262.14.[238] Under § 262.14, VSQGs are limited in where they may send their hazardous waste for treatment and disposal.[239] In § 266.504(a), we proposed to allow VSQG healthcare facilities to send their potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Without this change, VSQGs would have been required to send all their hazardous waste pharmaceuticals, including those that are potentially creditable, to one of the types of facilities in § 262.14, which does not include a reverse distributor. Although we proposed to make this change within part 266 subpart P, we requested comment on whether stakeholders would prefer this change to be made within the VSQG regulations in § 262.14 (formerly the CESQG regulations in § 261.5) instead. VSQGs are still required to send their non-pharmaceutical hazardous waste and their non-creditable hazardous waste pharmaceuticals to one of the types of facilities listed in § 262.14.[240]

2. Summary of Comments

States, waste management and reverse distributors supported allowing VSQG healthcare facilities to send their potentially creditable hazardous waste to reverse distributors. These same commenters were also in favor of including their change in both this rule and § 262.14 to ensure that all healthcare facilities that might have potentially creditable hazardous waste pharmaceuticals would be aware of this provision and be able to take advantage of it.

3. Final Rule Provision

We are finalizing this provision as proposed, with minor edits. In general, this final rulemaking will preserve the current regulatory scheme for VSQGs: healthcare facilities that qualify as VSQGs for their total count of hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste will maintain their conditional exemption under § 262.14 and will not be subject

[238] Since the hazardous waste pharmaceutical rule was proposed, § 261.5 has been renumbered to § 262.14 as part of the reorganization of the generator regulations in the Generator Improvements final rule and this will be referenced later in this section.

[239] Since the Pharmaceutical rule was proposed§ 261.5(f)(3)(i)–(vii) for acute hazardous waste and § 261.5(g)(3)(i)–(vii) for non-acute hazardous waste has been combined and renumbered to § 262.14(a)(5)(i)–(vii) for acute and non-acute hazardous waste in the Hazardous Waste Generator Improvements final rule.

[240] A VSQG healthcare facility may be able to send its hazardous waste pharmaceuticals for consolidation at another healthcare facility operating under subpart P as allowed by § 266.504(b), or a large quantity generator and 262.14(a)(5)(viii), see section X of the preamble for further discussion.

to most aspects of this proposal. Healthcare facilities that are VSQGs are subject to three provisions of part 266 subpart P: The sewer ban in § 266.505, the empty container standards in § 266.507, and the optional provisions in § 266.504.

In response to commenter's request for clarity, the final rule makes it clear that § 266.504 applies to VSQG healthcare facilities that are VSQGs when counting both its hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste. Section 266.504 does not apply to healthcare facilities that become VSQGs under this rule as a result of not having to count their hazardous waste pharmaceuticals. Such healthcare facilities are VSQGs with respect to their non-pharmaceutical hazardous waste only and must operate under subpart P for their hazardous waste pharmaceuticals.

Under the final rule, a healthcare facility that is a VSQG when counting both its hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may choose to send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor. In response to comments, EPA has added a conforming change to the VQSG generator provision in § 262.14(a)(5)(ix) for added clarity on this point. It is a restatement of § 266.504(a) which allows VSQG healthcare facilities to send their potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

A healthcare facility that is a VSQG for both their hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste is given a choice. The healthcare facility may

- Operate as a standard VSQG under part 262 rules, and can use the optional provisions in § 266.504, or
- Operate under as a healthcare facility under part 266 subpart P.

4. Comments and Responses

The waste management industry requested that EPA regulate all healthcare facilities under the proposed subpart P requirements regardless of generator category. While this rule's requirements are meant to create uniformity for healthcare facilities managing hazardous waste pharmaceuticals, we want to avoid creating undue burden on VSQGs and have declined to make them subject to part 266 subpart P except for the sewer prohibition in § 266.505, the empty container provisions in § 266.507 and the optional provisions in § 266.504..

B. Off-Site Collection of Hazardous Waste Pharmaceuticals Generated by Healthcare Facilities (§ 266.504(b))

1. Summary of Proposal

EPA proposed that a healthcare facility that is a VSQG may send its hazardous waste pharmaceuticals to another healthcare facility provided the receiving healthcare facility meets certain conditions. These conditions were proposed in § 266.502(m) of this subpart.

2. Summary of Comments

One state was concerned about how consolidation might affect the generator category of the receiving facility. The commenter also raised concerns about the receiving facility performing some functions of a reverse distributor.

3. Final Rule Provision

EPA is finalizing the proposed provision with conforming changes that correspond with other sections within this rule and one additional change. The first conforming change added the words ''hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste'' to clarify that only healthcare facilities that are VSQGs for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste may take advantage of this provision. The second conforming change converted the term CESQG to VSQG according to the 2016 Hazardous Waste Generator Improvements final rule. EPA notes that the consolidation provisions for healthcare facilities that receive both non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals from off-site were added to the regulations in §§ 266.502(l) and 266.503(b) (sections X.N and XI.B of the preamble), respectively. The final change added flexibility for VSQGs to meet the consolidation provisions that were added as part of the 2016 Hazardous Waste Generator Improvements final rule in lieu of the subpart P off-site consolidation provisions. In this case, the receiving LQG would have to meet the conditions in § 262.17(f) while the VSQG healthcare facility would have to meet the conditions in § 262.14(a)(5)(viii).

The final rule provision allows a healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste to send its hazardous waste pharmaceuticals off-site provided either of the following is met: (1) The receiving healthcare facility meets the conditions in § 266.502(1) and § 266.503(b) of this subpart, as applicable, or (2) the VSQG healthcare facility meets the conditions in § 262.14(a)(5)(viii), and the receiving large quantity generator meets the conditions in § 262.17(f).

4. Comments and Responses

One commenter asked for clarification about whether EPA will allow consolidation of a healthcare facility's potentially creditable or non-creditable hazardous waste pharmaceuticals at a reverse distributor. In response, the Agency is clarifying that subpart P does not allow healthcare facilities to consolidate any pharmaceutical waste at a reverse distributor. Healthcare facilities may only consolidate their waste at another facility that meets the definition of a healthcare facility as defined in § 266.500. See sections X.N and XI.B, respectively, for further discussion about healthcare facilities that receive non-creditable and potentially creditable hazardous waste pharmaceuticals from off-site healthcare facilities.

C. Long-Term Care Facilities That Are Very Small Quantity Generators Can Dispose Hazardous Waste Pharmaceuticals in Drug Enforcement Administration Collection Receptacles (§ 266.504(c))

1. Summary of Proposal

We proposed that a LTCF that is a VSQG that has an on-site DEA collection receptacle could use the collection receptacle for its hazardous waste pharmaceuticals, even if they are not controlled substances. We reasoned that since DEA already allows controlled substances to be commingled with non-controlled substances, it was consistent to allow VSQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA authorized collection receptacles along with controlled substances. Further, we reasoned that the management of VSQG hazardous waste pharmaceuticals as DEA controlled substances is preferable to management as municipal solid waste because it provides greater protection to patients, visitors, and workers at LTCFs to have the hazardous waste pharmaceuticals in DEA authorized collection receptacles than down the sewer or in the facility's regular trash.

2. Summary of Comments

The few comments we received on this specific provision of the proposed rulemaking were mostly supportive.

3. Final Rule Provisions

We are finalizing the provision that allows an LTCF that is a VSQG to use

a DEA authorized collection receptacle to dispose of its hazardous waste pharmaceuticals with three minor changes. The first change is to clarify again that this provision only applies to LTCFs that are VSQGs for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and are therefore not subject to subpart P (except the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional provisions of § 266.504). The second change is to clarify that the DEA authorized collection receptacle that the VSQG LTCF uses to dispose of its hazardous waste pharmaceuticals must be on-site. The third change is to exclude items such as contaminated personal protective equipment or clean-up residues from being placed into the DEA authorized collection receptacle. Although these items meet our new definition of pharmaceutical, a DEA authorized collection receptacle is designed for the collection of the pharmaceuticals themselves and not larger items that might be contaminated by the pharmaceuticals, such as contaminated PPE or clean-up residues. For instance, they are required to have small openings and limited volumes, making their use for contaminated PPE and clean-up residues impractical.

4. Comments and Responses

One commenter thought that this proposed provision was ''not feasible'' because ''take-back kiosks for controlled substances are intended to be used by end users and not the DEA registrant.'' [241] In many, if not most, cases at an LTCF, the hazardous waste pharmaceuticals will be from an ultimate user and the DEA regulations permit the collection receptacles to be used for collecting both controlled and non-controlled substances from ultimate users. There are more limited cases where an LTCF may have its own inventory of non-controlled hazardous waste pharmaceuticals.

Although EPA concurs with the commenters that the DEA authorized collection receptacles are only for controlled substances from ultimate users, EPA does not believe that the same limitation needs to be placed on the pharmaceuticals from VSQGs that are hazardous waste but not controlled substances. In fact, it could be argued that long-term care facilities that are VSQGs would be allowed to use DEA authorized collection receptacles for their hazardous waste pharmaceuticals even without this new provision, provided the waste from the DEA authorized collection receptacles is treated or disposed at one of the types of facilities identified in § 262.14(a)(5) (*e.g.,* facilities that are permitted or have interim status to manage hazardous waste and facilities that are permitted, licensed or registered by a state to manage hazardous waste, municipal waste or non-municipal waste). Nevertheless, we did propose, and are finalizing the provision in § 266.504(c) making it clear that an LTCF that is a VSQG can place its hazardous waste pharmaceuticals in an on-site DEA collection receptacle.

However, as the commenter pointed out, it is important to note that the DEA regulations for controlled substances are much narrower in what may be placed in a collection receptacle; DEA only allows controlled substances from ultimate users (patients) to be placed in collection receptacles that are at long-term care facilities. As a result, if a LTCF (or any other healthcare facility) is a DEA registrant, it may not place its inventory of controlled substances in a collection receptacle, even if it is a VSQG.

D. Long-Term Care Facilities With 20 Beds or Fewer Are Presumed To Be Very Small Quantity Generators (§ 266.504(d))

1. Summary of Proposal

EPA took comment on whether we should provide a rebuttable presumption that LTCFs with fewer than 10 beds are assumed to be VSQGs and thus would not be required to keep track of the amount of hazardous waste generated each month. The Agency did not propose regulatory language for this provision. EPA asked commenters to submit data to support a 10-bed cutoff to show that LTCFs with fewer than 10 beds are generally VSQGs. Alternatively, if commenters supported a different cutoff for the rebuttable assumption, EPA asked that the commenters submit information to support their suggested cutoff.

2. Summary of Comments

Comments on the rebuttable presumption for LTCFs with fewer than 10 beds varied. One state did not support providing a rebuttable presumption for LTCFs with fewer than 10 beds and argued that all generators should be required to count the hazardous waste they generate.[242] One state expressed support for providing a rebuttable presumption and requested that EPA keep the cutoff at 10 beds.[243] One state did not support providing the rebuttable presumption because most healthcare facilities in their state, including LTCFs, have more than 10 beds but generate only VSQG quantities of hazardous waste.[244]

Two healthcare industry commenters that supported the rebuttable presumption asked that EPA increase the cutoff from 10 beds to 20 beds.[245] One healthcare industry commenter supported the rebuttable presumption and asked that EPA increase the bed cutoff from 10 beds to 15 beds.[246]

3. Final Rule Provisions

Under the final rule, EPA is finalizing a rebuttable presumption in § 266.504(d) that LTCFs with 20 beds or fewer are assumed to be VSQGs and thus are not required to demonstrate the amount of hazardous waste generated each month. Under this presumption, LTCFs are only subject to the requirements for VSQG healthcare facilities as described elsewhere in this proposal, including the requirement not to sewer hazardous waste pharmaceuticals (§ 266.505), the empty container standards (§ 266.507), and the optional provisions of § 266.504. Under the final rule, the EPA Regional Administrator has the responsibility to demonstrate that a LTCF with 20 beds or fewer generates quantities of hazardous waste that are in excess of the VSQG limits as defined in § 260.10 if the EPA Regional Administrator wishes to mandate that the LTCF operate under subpart P. A LTCF with more than 20 beds that operates as a VSQG under § 262.14 must demonstrate that it generates quantities of hazardous waste that are within the VSQG limits as defined by § 260.10.

Based on available data, EPA believes it is reasonable to be responsive to the healthcare industry commenters who supported the rebuttable presumption and to increase the cutoff to 20 beds. The available information on hazardous waste generation at LTCFs suggests that LTCFs with 20 beds or fewer are generally VSQGs. Although EPA did not receive any data from the healthcare industry commenters, one state commented that most healthcare facilities in their state, including LTCFs, have many more than 10 beds but generate only VSQG quantities of

[241] See comment number EPA–HQ–RCRA–2007–0932–0280.

[242] See comment number EPA–HQ–RCRA–2007–0932–0238 in the docket for this rulemaking.

[243] See comment number EPA–HQ–RCRA–2007–0932–0242 in the docket for this rulemaking.

[244] See comment number EPA–HQ–RCRA–2007–0932–0332 in the docket for this rulemaking.

[245] See comment numbers EPA–HQ–RCRA–2007–0932–0239 and EPA–HQ–RCRA–2007–0932–0282 in the docket for this rulemaking.

[246] See comment number EPA–HQ–RCRA–2007–0932–0328 in the docket for this rulemaking.

hazardous waste.[247] Additionally, EPA estimates that there are between 2,875 and 4,770 long-term care facilities that generate hazardous waste and that 98 to 99 percent of the facilities are VSQGs.[248] Although EPA estimates that there are few LTCF hazardous waste generators that are SQGs or LQGs, EPA does not have data on the number of beds at each facility, making it difficult to estimate a facility size threshold at which a LTCF becomes an SQG or an LQG. EPA conducted additional analysis using data on the average size of LTCFs in the United States and data on the average volume of hazardous waste generated annually at LTCFs that submitted a biennial hazardous waste report between 2001 and 2015 in order to estimate the average size at which a LTCFs become SQGs or LQGs.[249] The estimates suggest that LTCFs with fewer than 20 beds will generally be VSQGs. Therefore, EPA concludes that it is reasonable to provide a rebuttable presumption that LTCFs with 20 beds or fewer are assumed to be VSQGs and thus are not required to demonstrate the amount of hazardous waste generated each month.

XIII. Sewer Disposal Prohibition (§ 266.505)

A. Regulatory Background on the Domestic Sewage Exclusion

Under RCRA and the Subtitle C hazardous wastes regulations, if a material is not a solid waste, then it cannot be considered a hazardous waste. Under § 261.4(a)(1)(ii) of the RCRA regulations, ''Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment'' is not a solid waste for purposes of Subtitle C regulation. This exclusion was finalized by EPA on May 19, 1980, based on the reasoning that ''Mixed waste streams that pass through sewer systems to publicly-owned treatment works (POTWs) will be subject to controls under the Clean Water Act (CWA). The Agency's construction grants program provides financial assistance for the proper treatment of these wastes. In addition, the Agency's pretreatment program provides a basis for EPA and the local communities to ensure that users of sewer and treatment systems do not dump wastes in the system that will present environmental problems.'' [250]

In 1984, Congress enacted the Hazardous and Solid Waste Amendments (HSWA) to the Solid Waste Disposal Act (SWDA), as amended by RCRA. HSWA included a new Section 3018, entitled Domestic Sewage. This section directed EPA to do two things with respect to the § 261.4(a)(1)(ii) exclusion for mixtures of domestic sewage and other wastes: (1) Submit a Report to Congress (RTC) that describes the types, size and number of generators which dispose of such wastes in this manner, the types and quantities of wastes disposed of in this manner, and identify significant generators, wastes and waste constituents not regulated under existing Federal law or regulated in a manner sufficient to protect human health and the environment; and (2) based on the report, revise the appropriate existing regulations to ''ensure that substances . . . which pass through a sewer system to a publicly owned treatment works are adequately controlled to protect human health and the environment.''

EPA submitted its Report to Congress on February 7, 1986 (Domestic Sewage Study). Subsequent to the Report to Congress, EPA issued an advance notice of proposed rulemaking on August 22, 1986; [251] a response to comments on the advanced notice of proposed rulemaking on June 22, 1987; [252] a notice of proposed rulemaking (NPR) on November 23, 1988; [253] and a final rule on July 24, 1990.[254] That final rule expanded an existing prohibition on the discharge of pollutants which create a fire or explosion hazard in the POTW, so that it included, but was not limited to, ''waste streams with a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Centigrade using the test methods specified in 40 CFR 261.21.'' [255] Although the RCRA characteristic of reactivity (D003) was not specifically mentioned in the CWA regulations, discharges of some D003 reactive hazardous wastes are also prohibited by this section of the CWA regulations: (1) Chemicals that react violently with water [256] and (2) chemicals that form potentially explosive mixtures with water.[257]

The 1990 CWA final rule added a new prohibition such that no discharge shall ''result in the presence of toxic gases, vapors or fumes within the POTW in a quantity that may cause acute worker health and safety problems.'' [258] Similarly, although the RCRA characteristic of reactivity (D003) was not specifically mentioned in this section of the CWA regulations, discharges of some D003 reactive hazardous wastes are also prohibited by this section: (1) Chemicals that, when mixed with water, generate toxic gases, vapors or fumes in quantity sufficient to present a danger to human health or the environment [259] or (2) cyanide or sulfide bearing waste which, when exposed to pH conditions between 2 and 12.5, can generate toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment.[260]

In addition, some D002 corrosive hazardous wastes were prohibited prior to the 1990 CWA final rule and remain prohibited. Under RCRA, a waste is considered D002 for corrosivity if it has a pH of less than or equal to 2 (strongly acidic) or greater than or equal to 12.5 (strongly basic). Section 403.5(b)(2) of the CWA regulations prohibits discharges with a pH of less than 5.0, except under limited circumstances. Therefore, acidic D002 hazardous waste is prohibited from being discharged under the CWA regulations.

Note that although the exclusion for mixtures of domestic sewage and other wastes is found under the RCRA regulations in § 261.4(a)(1)(ii), and it was HSWA, which is an amendment to RCRA, that directed the review of and amendments to that exclusion, the sewer ban of liquid ignitable D001 hazardous wastes and some D002 and D003 hazardous wastes was established under 40 CFR 403.5(b), which is under the CWA regulations. Also note that EPA left open the possibility of additional future action when it stated in the preamble to the July 24, 1990, final rule, its intent ''to carefully review the effect of this rule and promulgate in the future any additional regulations that experience reveals are necessary to improve control over hazardous waste and other industrial user discharges to POTWs.'' [261]

[247] See comment number EPA–HQ–RCRA–2007–0932–0332 in the docket for this rulemaking.

[248] Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[249] See memorandum ''Long-Term Care Facility Summary Data and Hazardous Waste Generation Data'' in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[250] May 19, 1980; 45 FR 33097.

[251] See the advance notice of proposed rulemaking in August 22, 1986; 51 FR 30166.

[252] See the response to comments in June 22, 1987; 52 FR 23477.

[253] See the proposed rule November 23, 1988; 53 FR 47632.

[254] See the final rule in July 24, 1990; 55 FR 30082.

[255] See the prohibition in 40 CFR 403.5(b)(1).

[256] See 40 CFR 261.23(a)(2).

[257] See 40 CFR 261.23(a)(3).

[258] See 40 CFR 403.5(b)(7).

[259] See 40 CFR 261.23(a)(4).

[260] See 40 CFR 261.23(a)(5).

[261] July 24, 1990 **Federal Register**; 55 FR 30084.

B. Summary of Proposal

In 2015, EPA proposed to impose a sewer ban on all hazardous waste pharmaceuticals managed by healthcare facilities and reverse distributors. That is, healthcare facilities and reverse distributors subject to part 266 subpart P would not be able to use the RCRA domestic sewage exclusion in § 261.4(a)(1)(ii) any longer for their hazardous waste pharmaceuticals. They would be prohibited from disposing of pharmaceuticals that are listed hazardous waste and/or exhibit one or more of the four hazardous waste characteristics (*i.e.,* ignitability, corrosivity, reactivity, or toxicity) by putting them down a drain (*e.g.,* sink, toilet, or floor drain).

EPA proposed this sewer prohibition of hazardous waste pharmaceuticals for several reasons. First, as described in detail in the preamble to the proposed rulemaking, a number of studies had shown that flushing of leftover medications had become a prevalent practice used in lieu of proper hazardous waste management and that experience had, indeed, revealed that additional regulations were ''necessary to improve control over hazardous waste and other industrial user discharges to POTWs.'' [262]

Second, although EPA establishes national regulations under the CWA (called effluent limitations guidelines and pretreatment standards) to reduce discharges of pollutants from industries to surface waters and POTWs, currently there are no national effluent limitations or pretreatment standards that apply to healthcare facilities discharging pharmaceuticals to POTWs. Furthermore, traditional wastewater treatment operations implemented at POTWs are designed to remove conventional pollutants, such as suspended solids and biodegradable organic compounds. They are not designed to remove pharmaceuticals that are present in discharges from medical and veterinary facilities. While some POTWs may have implemented advanced treatment technologies, these technologies are not designed to remove pharmaceuticals. EPA released a study in 2009 in which over 100 chemicals (including some pharmaceuticals) were analyzed in the influent and effluent at nine POTWs.[263] Although it was a limited study and difficult to generalize the results to all POTWs, it does indicate that the capabilities of treatment technologies currently employed by POTWs does not include treatment to remove active pharmaceutical ingredients (APIs).[264] In a more recent study, EPA measured concentrations of 56 APIs in effluent samples from 50 large POTWs across the country and discovered at least one API in each sample.[265] In addition, as stated in EPA's Health Services Industry study, ''synthetic compounds, such as pharmaceuticals, are often manufactured to be resistant to metabolic transformation. As a result, some pharmaceutical compounds that are present in the influent to POTWs may pass through treatment systems at conventional POTWs and discharge to receiving waters.'' [266]

Third, the pharmaceuticals entering the environment, through flushing or other means, are having a negative effect on aquatic ecosystems and on fish and animal populations. A recent article highlighted the scientific literature that examines the effect of pharmaceuticals on freshwater ecosystems, particularly the effect of pharmaceuticals on key ecological processes.[267] The RIA for the proposed rulemaking more fully summarized the scientific literature with regard to ecological effects.[268] The scientific research with regard to human health effects due to pharmaceuticals in the environment is still ongoing. Nevertheless, the important features and risks of the problem can be summarized as follows: [269]

(1) Pharmaceuticals are intrinsically bioactive compounds; therefore, they can potentially impact living systems.

(2) There is a continuous and worldwide increase in their use and, thus, on their subsequent input into the environment.

(3) Many of the hundreds of frequently prescribed pharmaceuticals are known for targeted effects and adverse off-target side effects, a problem that can be exacerbated by interactive effects during therapy involving co-administration and disposal.

While healthcare facilities that are VSQGs were generally not subject to the proposed rulemaking, EPA proposed that the sewer ban of hazardous waste pharmaceuticals also apply to healthcare facilities that are VSQGs. The RIA for the rule projects that the vast majority of healthcare facilities are VSQGs (81–86 percent).[270] Some particular types of healthcare facilities have an even larger proportion of VSQGs: For example, the RIA estimates that of the LTCFs that generate hazardous waste, 98–99 percent of LTCFs are VSQGs.[271] EPA was and remains concerned that these smaller healthcare facilities are more likely to dispose of their hazardous waste pharmaceuticals via the sewer. EPA estimates that there are between 50,900 and 84,800 healthcare facilities that are VSQGs.[272] Given this large number, the combined impact of sewer disposal by healthcare facilities that are VSQGs has an even greater potential to provide a substantial impact on the environment, as well as human health. EPA solicited comment on whether it was appropriate to apply the proposed ban on the sewer disposal of hazardous waste pharmaceuticals to all healthcare facilities, including healthcare facilities that are VSQGs. Comments submitted to the Agency in response to this request are discussed in the next section.

We note that EPA's proposed ban on sewering hazardous waste pharmaceuticals is consistent with other federal state, and local actions. For example, the DEA has finalized regulations to implement the Secure and Responsible Drug Disposal Act of 2010.[273] DEA's regulations require a ''non-retrievable'' method of destruction of controlled substances. The preamble to DEA's proposed and final rules state that flushing does not meet the non-retrievable standard for destruction.[274] According to the preamble of the DEA final rule, DEA received 20 comments supporting their position against

[262] July 24, 1990 **Federal Register**; 55 FR 30084.

[263] EPA, Occurrence of Contaminants of Emerging Concern in Wastewater from Nine Publicly Owned Treatment Works, August 2009; EPA–821–R–09–009.

[264] Eggen RI, Hollender J, Joss A, Schärer M, Stamm C, ''Reducing the Discharge of Micropollutants in the Aquatic Environment: The Benefits of Upgrading Wastewater Treatment Plant.'' Environmental Science and Technology 2014, 48(14) 7683–7689.

[265] Kostich MS, Batt AL, Lazorchak JM, ''Concentrations of prioritized pharmaceuticals in effluents from 50 large wastewater treatment plants in the US and implications for risk estimation.'' Environmental Pollution 2014, 184:354–9.

[266] Health Services Industry Study: Management and Disposal of Unused Pharmaceuticals (Interim Technical Report) August 2008; EPA–821–R–08–013.

[267] Richmond EK, Grace MR, Kelly JJ, Reisinger AJ, Rosi EJ, Walters, DM. ''Pharmaceuticals and personal care products (PPCPs) are ecological disrupting compounds (EcoDC).'' Elem Sci Anth 2017, 5:66.

[268] See page 147 of the Regulatory Impact Analysis for the proposed rule in the docket EPA–HQ–RCRA–2007–0932–0151.

[269] A. Ginebreda et al., Environmental risk assessment of pharmaceuticals in rivers: Relationships between hazard indexes and aquatic macroinvertebrate diversity indexes in the Llobregat River (NE Sapin). Environ Int. (2009), doi:10.1016/j.envint.2009.10.003.

[270] See the Regulatory Impact Analysis for the final rule in the docket EPA–HQ–RCRA–2007–0932.

[271] Ibid.

[272] Ibid.

[273] September 9, 2014; 79 FR 53520.

[274] Proposed rule: December 21, 2012; 77 FR 75784 (see page 75803); and Final rule: September 9, 2014; 79 FR 53520 (see page 53548).

flushing controlled substances.[275] The comments supporting the prohibition against sewering came from states, regional, and local hazardous waste management programs, recycling associations, non-governmental organizations (NGOs), trade associations and environmental organizations. Many of these commenters noted that wastewater treatment systems do not eliminate many of the drugs that are flushed into the sewers and requested that DEA clearly state in the regulatory language, not just preamble, that sewering is not allowable as a means of destruction.

In addition, four states, the District of Columbia, and local California jurisdictions have taken action to limit the sewering of pharmaceuticals and another state has introduced a bill. ''Colorado has prohibited the discharging of solid/hazardous waste down the drain since the adoption of RCRA in the 1980s.'' [276] In 2009, Illinois passed the Safe Pharmaceutical Disposal Act, which prohibits healthcare facilities from flushing any solid dosage form other than DEA schedule II drugs into public sewers or septic systems.[277] In 2012, New Jersey passed a similar law that prohibits healthcare facilities from discharging prescription medications into public sewers or septic systems.[278] In 2002, California banned the use of lindane in pharmaceuticals after it found that lindane was adversely impacting wastewater quality. The authors of the paper ''Outcomes of the California Ban on Pharmaceutical Lindane: Clinical and Ecologic Impacts state that ''This is the first time that a pharmaceutical has been outlawed to protect water quality.'' [279] After researching and documenting environmental benefits of the ban, the authors conclude, ''This ban serves as a model for governing bodies considering limits on the use of lindane or other pharmaceuticals.'' Also in California, some county departments, such as Sacramento County and Contra Costa County, prohibit sewering of hazardous waste pharmaceuticals.[280] And the District of Columbia has promulgated municipal regulations, effective January 1, 2011, that prohibits healthcare facilities from flushing pharmaceutical products.[281] The Connecticut legislature has also considered a bill to ban the discharge of medication into public or private wastewater collection systems or septic systems, although it has not yet become law.[282] Nevertheless, the Connecticut Department of Energy and Environmental Protection's (CT DEEP) ''current hazardous waste management regulations essentially ban sewer disposal of RCRA waste by requiring all generators in Connecticut, including [VSQGs], to ensure delivery by a licensed waste transporter with an EPA ID Number to a facility authorized to receive the waste.'' [283]

The Agency sought comment on several areas related to the prohibition on sewering hazardous waste pharmaceuticals. First, the Agency requested comment on whether the sewer ban should apply to healthcare facilities that are VSQGs. Second, we requested comment on the trade-offs inherent in prohibiting sewer disposal; that is, would the benefit of the reduction in aquatic risk be outweighed by additional opportunities for diversion and the possibility of inadvertent exposures for certain workers? Third, we sought comment on whether it would be appropriate to allow any exceptions to the sewer ban, such as for leftover portions of hazardous wastes that are also controlled substances.[284] Finally, the Agency sought comment on whether it would be helpful to incorporate in 40 CFR 261.4(a)(1)(ii), a cross-reference to the CWA regulations that prohibit the sewering of certain hazardous wastes.

C. Summary of Comments

Nearly a third of the commenters to the proposed rulemaking commented on the proposed prohibition of sewering hazardous waste pharmaceuticals. Commenters were nearly unanimous in their support for the prohibition on sewering of hazardous waste pharmaceuticals. Support was expressed by a broad and diverse set of commenters, including state and local governments, sewer districts, environmental groups, and waste management companies. Although some commenters had suggestions for minor exceptions, few commenters expressed complete opposition to the prohibition on sewering. Furthermore, there was widespread support from commenters for applying the prohibition on sewering hazardous waste pharmaceuticals to healthcare facilities that are VSQGs. As one commenter noted, ''given the large number of small generators . . . If each of these small generators were allowed to discharge even a small amount of pharmaceuticals, the overall volume would be significant.''[285]

D. Final Rule Provisions

Given the environmental concerns described above combined with the overwhelming support that we received from commenters, we are finalizing the prohibition of sewering hazardous waste pharmaceuticals. The prohibition on sewering hazardous waste pharmaceuticals applies to all reverse distributors and all healthcare facilities, including healthcare facilities that are VSQGs. Furthermore, EPA is not providing any exceptions to the prohibition on sewering. Therefore, the prohibition on sewering hazardous waste pharmaceuticals applies to all hazardous waste pharmaceuticals that are generated by any healthcare facilities and reverse distributors, including hazardous waste pharmaceuticals that are also controlled substances and any pharmaceutical wastage from partial administration of hazardous waste pharmaceuticals. How the sewer prohibition intersects with the disposal of pharmaceutical wastage will be discussed in greater detail in section XIV.D.2. rather than this section.

In response to commenters' suggestions, we are making some minor editorial changes, including adding two cross references to the CWA prohibitions on sewering hazardous wastes in § 403.5(b). One cross reference will be added to § 261.4(a)(1)(ii) and the other cross reference will be added to § 266.505. We also eliminated the second sentence of the proposed prohibition, which read: The exclusion in § 261.4(a)(1)(ii) for mixtures of domestic sewage and other wastes that pass through a sewer system to a publicly owned treatment works does not apply to hazardous waste pharmaceuticals.

[275] September 9, 2014; 79 FR 53520 (see page 53548).

[276] See comment number: EPA–HQ–RCRA–2007–0932–0242.

[277] Illinois Public Act 096–0221.

[278] Nicknamed Bateman's Law, after Senator Christopher ''Kip'' Bateman (R-Somerset) that sponsored the legislation.

[279] Humphreys, et al. Environmental Health Perspectives. 2008 March; 116(3) 297–302.

[280] See comment number: EPA–HQ–RCRA–2007–0932–0378.

[281] DCMR Title 22–B Chapter 5 Safe Disposal of Unused Pharmaceuticals in Health Care Facilities

[282] State of Connecticut General Assembly, January Session 2013, Raised Bill No. 6439. An Act Concerning the Disposal and Collection of Unused Medication.

[283] See comment number EPA–HQ–RCRA–2007–0932–0341.

[284] In a DEA letter dated October 17, 2014, DEA refers to leftover, partially administered drugs as ''pharmaceutical wastage.'' *https://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf*

[285] See comment number EPA–HQ–RCRA–2007–0932–0337.

Oklahoma Department of Environmental Quality (OK DEQ) expressed concern that this ''second sentence could be interpreted that EPA is exerting RCRA authority over domestic sewage if it contains [hazardous waste pharmaceuticals]—an area that has been exclusively under Clean Water Act jurisdiction since the first regulations were promulgated in 1980.'' [286] EPA had proposed the second sentence in an attempt to be abundantly clear that the proposed prohibition on sewering hazardous waste pharmaceuticals supersedes the exclusion in § 261.4(a)(1)(ii). We did not intend to assert RCRA jurisdiction over domestic sewage; therefore, we have concluded that it is better to remove the sentence in order to avoid the concern expressed by OK DEQ. Nevertheless, we wish to emphasize that the prohibition on sewering hazardous waste pharmaceuticals being finalized in § 266.505 does, in fact, supersede the exclusion in § 261.4(a)(1)(ii). To make that point clear, we are amending § 261.4(a)(1)(ii) to state that any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, *except as prohibited by §§ 266.505 and Clean Water Act requirements at 40 CFR 403.5(b),* is not a solid waste.

E. Comments and Responses

Many comments suggested various ways in which we should broaden the applicability of the prohibition on sewering hazardous waste pharmaceuticals. In some cases, commenters urged us to apply the prohibition to all pharmaceuticals, not just hazardous waste pharmaceuticals. Subtitle D of RCRA, which governs the management of non-hazardous (solid) waste, does not provide EPA the statutory authority to apply the prohibition to non-hazardous waste pharmaceuticals. Nevertheless, EPA strongly recommends against sewering any pharmaceuticals. The American Water Works Association asked us to extend the prohibition to prevent the sewering of pharmaceuticals that are radioactive and patient waste containing radioactive pharmaceuticals. As discussed previously, hazardous waste pharmaceuticals that also contain a radioactive component subject to the Atomic Energy Act of 1954 (*i.e.,* ''mixed waste'') are regulated by multiple agencies. The hazardous waste component is regulated under EPA or the authorized state RCRA programs, while either the NRC or the Department of Energy regulates the radioactive component of the waste under the Atomic Energy Act.[287] Therefore, a ''mixed waste'' pharmaceutical that is both radioactive and RCRA hazardous waste is prohibited from being discharged to the sewer. We strongly recommend against sewering other radioactive pharmaceuticals and patient waste containing radioactive pharmaceuticals.

Other commenters suggested that the prohibition should not be limited to discharges to POTWs; rather, it should also apply to discharges to septic tanks, privately owned treatment works and federally owned treatment works. Section 261.4(a)(1)(ii) allows the discharge of what would otherwise be a hazardous waste to POTWs, without being considered a solid or hazardous waste. The prohibition on discharges of hazardous waste pharmaceuticals being finalized today is intended to reduce the scope of that exclusion in the existing regulations. Discharges of hazardous waste to other types of sewage systems, such as septic tanks, privately owned treatment works and federally owned treatment works are not allowed by exclusion in § 261.4(a)(1)(ii). Therefore, the discharge of hazardous wastes to septic tanks, privately owned treatment works and federally owned treatment works is already prohibited, even though it is not explicitly stated.

We note that although our RCRA statutory authority limits us to apply the prohibition on sewering narrowly to pharmaceuticals that are RCRA hazardous wastes, EPA strongly recommends as a best management practice to not sewer any waste pharmaceutical (*i.e.,* hazardous or non-hazardous) from any source or location. This recommendation against sewering pharmaceuticals includes households and assisted living facilities, except in the relatively rare situation when households and assisted living facilities are specifically directed by FDA guidance to flush certain potentially dangerous drugs down the toilet (as noted on pharmaceutical packaging), when a drug take-back option is not readily available, to help ensure that they are not misused or accidentally ingested or touched.[288] In lieu of sewering, we recommend that households, including residents of assisted living facilities, follow the guidelines developed by the U.S. Office of National Drug Control Policy (ONDCP), the FDA, and EPA for the disposal of unwanted household pharmaceuticals. In summary, the guidelines for households disposing of pharmaceuticals are as follows (in order of preference):

(1) Use a drug take-back event or program, when available;

(2) Dispose in household trash, after mixing the unwanted medicines with an unpalatable substance such as dirt, cat litter, or used coffee grounds and placing in a sealed container; and

(3) Only if the drug label specifically instructs you to, flush the unwanted medicine down the toilet.[289]

We also note that the CWA prohibitions on discharges of hazardous waste in § 403.5(b) are broader than just pharmaceuticals and apply beyond healthcare facilities and reverse distributors. Like all of the prohibited discharges under the CWA regulations, the prohibitions of hazardous waste discharges apply to any industrial user. Additionally, the CWA prohibitions on hazardous waste discharges apply to all D001 ignitable liquids, acidic D002 hazardous wastes, and D003 reactive hazardous wastes that (1) react violently with water,[290] (2) form potentially explosive mixtures with water,[291] or (3) result in the presence of toxic gases, vapors or fumes within the POTW in a quantity that may cause acute worker health and safety problems,[292] not just pharmaceuticals that exhibit those characteristics.

Some commenters asked us to include some exceptions to the prohibition on discharges of hazardous waste pharmaceuticals. Specifically, one commenter who supported our proposed ban on sewering of hazardous waste pharmaceuticals, and even supported extending it to non-hazardous waste pharmaceuticals, suggested that we allow exceptions ''for those that do not contain active pharmaceutical ingredients, such as sterile water and 0.9% sodium chloride for injection and irrigation.'' [293] First, as a point of clarification, because sterile water and 0.9% sodium chloride are not hazardous waste, they would not be subject to the prohibition of discharging hazardous waste pharmaceuticals to the

[286] See commenter number EPA–HQ–RCRA–2007–0932–0231.

[287] The NRC regulates radioactive wastes generated by commercial or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

[288] *https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM337803.pdf.*

[289] *https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm.*

[290] See 40 CFR 261.23(a)(2).

[291] See 40 CFR 261.23(a)(3).

[292] See 40 CFR 403.5(b)(7).

[293] See comment number EPA–HQ–RCRA–2007–0932–0230.

sewer. And even though, as a general rule, we strongly recommend against sewering any pharmaceutical, regardless of whether it meets our definition of hazardous waste, we agree with the commenter that it seems unnecessary to prohibit the sewering of sterile water and 0.9% sodium chloride.

Other commenters asked us to make other exceptions to the prohibition on discharging hazardous waste pharmaceuticals. For example, the Healthcare Waste Institute suggested that we allow the discharge of hazardous waste pharmaceuticals that are specifically allowed by the local wastewater treatment agency or POTW.[294] CT DEEP made a similar suggestion, saying that we should allow discharges if they are ''explicitly authorized by a National Pollutant Discharge Elimination System (NPDES) or State pretreatment permit.'' [295] We have concluded that such an allowance is unnecessary because no known pretreatment standards or local limits have been established that specifically allow for the discharge of any pharmaceuticals. Note that 40 CFR part 439 separately regulates discharges from pharmaceutical manufacturers to POTWs and waters of the U.S. Furthermore, in the absence of water quality standards for specific drugs, we would like to avoid a situation where local wastewater treatment agencies might feel pressured to make judgments on which discharges would be acceptable without knowing the effects on aquatic life or the synergistic effects of multiple drugs.

We received few comments related to our inquiry about trade-offs inherent in prohibiting sewer disposal. Sharps Compliance did note that as ''our experience as a DEA authorized collector has shown, regulations that ban the sewering in conjunction with a proactive collection and destruction program offer the best protection against both environmental harm and the risk of diversion.'' [296] In addition, CT DEEP commented they do ''not believe there is an unfavorable risk trade-off inherent in prohibiting sewer disposal,'' indicating both risks are manageable.[297]

Eli Lilly was one of the few commenters that opposed the prohibition on sewering hazardous waste pharmaceuticals, even though, as a manufacturer, they are not subject to the prohibition.[298] They expressed two reasons for their opposition: (1) They do not believe that a total prohibition is based on sound risk management decisions and should be more flexible to exclude pharmaceuticals which FDA says should be disposed of down the drain, and (2) they believe that an effluent guideline under the CWA regulations is more appropriate and that EPA's Office of Water has decided not to promulgate an effluent guideline for the healthcare industry. As discussed previously, the prohibition on sewering hazardous waste pharmaceuticals and the FDA flush list do not conflict with one another. The prohibition applies to healthcare facilities (which does not include assisted living facilities) and reverse distributors, while the FDA flush list is directed to households and assisted living facilities and includes the caveat that flushing takes place only when a drug take-back option is not readily available. As to the commenter's second point, while it is true that the Office of Water has not yet promulgated an effluent guideline for the healthcare industry, this should not be taken as a sign that a decision has been made affirmatively that an effluent guideline is not appropriate at some time in the future. Rather, the Office of Water has preferred that the Office of Resource Conservation and Recovery (ORCR) first focus on preventing intentional discharges of hazardous waste pharmaceuticals. We firmly believe that the prohibition of sewering hazardous waste pharmaceuticals would complement any future action taken by the Office of Water to issue effluent guidelines for the healthcare industry.

XIV. Conditional Exemptions for Hazardous Waste Pharmaceuticals That Are Also Drug Enforcement Administration Controlled Substances and Household Waste Pharmaceuticals Collected in Take-Back Programs (§ 266.506)

A. Summary of Proposal

Prior to this final rulemaking, the management and disposal of a pharmaceutical that was both a RCRA hazardous waste and a DEA controlled substance was regulated under both the RCRA Subtitle C hazardous waste regulations, which is under EPA's or the authorized state's purview, and the Controlled Substances Act and its implementing regulations, which is under DEA's purview. At the time of the proposal, EPA was aware of only a handful of pharmaceuticals in common usage that are both hazardous waste and controlled substances and therefore subject to regulation by both EPA and the DEA. These are identified in Table 3:

TABLE 3—PHARMACEUTICALS STILL USED IN HEALTHCARE THAT ARE DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Chloral; chloral hydrate.	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes.	Sedative	U034, toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics.
Fentanyl sublingual spray.	Subsys	Analgesic	D001, ignitable	II	Ignitable due to alcohol content.
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001, ignitable	IV	Ignitable due to alcohol content.
Testosterone gels	Androgel, Fortesta, Testim	Hormone	D001, ignitable	III	Ignitable due to gel base.
Valium injectable	Diazepam	Anti-anxiety	D001, ignitable	IV	Ignitable due to alcohol content.

[294] See comment number EPA–HQ–RCRA–2007–0932–0296.

[295] See comment number EPA–HQ–RCRA–2007–0932–0341.

[296] See comment number EPA–HQ–RCRA–2007–0932–0248.

[297] See comment number EPA–HQ–RCRA–2007–0932–0341.

[298] See comment number EPA–HQ–RCRA–2007–0932–0249.

Chloral hydrate (U034), which is listed for toxicity, is the only dually regulated hazardous waste/controlled substance that is a listed hazardous waste.[299] The other four dually regulated hazardous wastes/controlled substances in common use are considered hazardous because they exhibit the characteristic of ignitibility (D001). While the active ingredient is not ignitable, these particular forms of the pharmaceuticals are ignitable because they are prepared in ignitable solutions, such as alcohol.

EPA is aware of three additional hazardous waste pharmaceuticals that are DEA controlled substances, but it is our understanding that they are no longer in common usage, although there may be legacy supplies remaining in healthcare facilities. See Table 4.

TABLE 4—DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES PHARMACEUTICALS THAT ARE NOT IN COMMON USE

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Paraldehyde	1,3,5-Trioxane, 2,4,6-trimethyl-; Paral	Anticonvulsant	U182 toxic	IV	No longer in common use.
Paregoric	camphorated tincture of opium	Analgesic, expectorant, antidiarrheal.	D001 ignitable	III	No longer in common use.
Opium Tincture	Laudanam	Analgesic, antidiarrheal	D001 ignitable	II	No longer in common use.

Similarly, as noted in Table 5, phentermine is a controlled substance, but the medical form is a phentermine salt, and the salts are no longer considered to be within the scope of the P046 listing.[300]

TABLE 5—PHARMACEUTICALS THAT ARE DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES SALT(S) NO LONGER CONSIDERED HAZARDOUS WASTE

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Phentermine	alpha, alpha-Dimethylphenethyl amine; Benzeneethanamine, alpha,alpha-dimethyl-; Adipex-P, Atti Plex P, Fastin, Ionamin, Kraftobese, Panshape M, Obe-Nix, Pentercot, Phentride, Pro-Fast, Raphtre, Supramine, Tara-8, Termene, Termine, Zantryl.	Appetite suppressant.	P046, Acutely toxic	IV	If in salt form, it does not meet the P046 listing and medical dosage forms are salts.

EPA requested comment on whether these are, indeed, the only pharmaceuticals in common usage that are regulated both as DEA controlled substances, and when discarded, as RCRA hazardous waste.

To eliminate duplicative regulation for these handful of hazardous wastes that are also controlled substances, EPA proposed to conditionally exempt from RCRA Subtitle C regulation those hazardous wastes that are also DEA controlled substances. Specifically, EPA proposed that hazardous wastes that are also controlled substances will be exempt from all RCRA Subtitle C requirements, including 40 CFR part 266 subpart P, provided they meet two conditions: (1) They are combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln) and (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances.

The first condition we proposed was to ensure that the controlled substances are destroyed in an environmentally protective manner by a high-temperature combustor, such as a large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln). At the time of proposal, DEA had not specified or endorsed a method by which the controlled substances should be destroyed to meet the non-retrievable standard. Although many hazardous wastes/controlled substances were being destroyed by incineration, it was not required by DEA. At the time, EPA was concerned that in the future DEA might allow a technology that lacks environmental controls and permits. Therefore, combustion of the hazardous wastes/controlled substances, which requires permitting, operating and monitoring standards, was proposed as a condition of the exemption. However, EPA requested comment on whether there are additional technologies that would be appropriate to include for the destruction of hazardous waste pharmaceuticals that are also controlled substances.

The second condition we proposed was to ensure that dually regulated hazardous wastes/controlled substances are managed under another rigorous regulatory program since they will not be managed in accordance with the RCRA Subtitle C regulations. Although developed for different reasons, both EPA's hazardous waste and DEA's controlled substance regulatory programs are designed to track the regulated material from cradle to grave. EPA requested comment on whether the tracking that DEA requires for controlled substances is sufficient to act in lieu of the RCRA manifest.

We considered proposing a third condition that the hazardous waste pharmaceuticals that are also DEA controlled substances would be subject

[299] Note that EPA's U034 listing includes chloral hydrate, see memo dated April 6, 1998; Brandes to Knauss, RCRA Online #14175

[300] See memo dated February 17, 2012; from Devlin to RCRA Division Directors, RCRA Online #14831.

to the sewer prohibition of § 266.505. At the time of proposal, however, we concluded that because combustion in specific units was a condition of the exemption, that it was unnecessary to state that the hazardous waste/controlled substances may not be sewered.

EPA also proposed a related conditional exemption for household pharmaceuticals, including those that are collected in DEA authorized collection receptacles and commingled with DEA controlled substances. Specifically, we proposed that collected household pharmaceuticals will continue to be excluded from RCRA regulation as household hazardous waste, provided they comply with the same two conditions. The Agency has a long-standing recommendation that household hazardous waste collection programs manage the collected waste as hazardous waste.[301] As such, the Agency recommends that collected household waste pharmaceuticals be incinerated—preferably at a permitted hazardous waste incinerator, but when that is not feasible, at a large or small municipal waste combustor.[302] The Agency believes that this practice is already common among collection programs since one goal of many collection programs is to divert pharmaceuticals from municipal landfills. Additionally, incineration is commonly used to meet the ''non-retrievable'' standard of destruction required by DEA for controlled substances collected from consumers (ultimate users, as DEA refers to them). Nevertheless, the Agency proposed to make this recommendation a requirement for collected household waste pharmaceuticals in § 266.506.[303] We strongly believe that if a program goes to the expense of collecting the waste, including waste pharmaceuticals, it should manage the waste as hazardous waste, rather than manage it as municipal solid waste, which the household could do absent the collection program. However, the current household waste exemption does not *require* an entity that hosts a household hazardous waste collection event to manage the collected waste as hazardous waste. Typically, the parties conducting household hazardous waste collection events have been government entities—municipalities and counties. It is relatively new that retail pharmacies and others are becoming interested in performing this function. To encourage this practice, while at the same time ensuring that collection programs are managing the collected waste properly, we proposed to codify our policy that pharmaceuticals that are household hazardous waste (*i.e.,* ''household waste pharmaceuticals'') and are collected in DEA authorized collection receptacles where they may be commingled[304] with controlled substances continue to be excluded from RCRA regulation, provided they are (1) combusted at a municipal solid waste or hazardous waste combustor, and (2) managed in accordance with all applicable DEA regulations.[305]

B. Summary of Comments

Many of the commenters, including states, healthcare facilities, and waste management companies, supported both conditional exemptions as a way to eliminate the duplicative regulation by DEA and EPA and commenters thought that the DEA tracking, shipping and recordkeeping are sufficient to operate in lieu of RCRA. Several commenters suggested that we expand the types of treatment that are allowed to destroy the hazardous waste pharmaceuticals that are also controlled substances. In some cases, commenters suggested that we allow additional combustion units such as hospital, medical, infectious waste incinerators (HMIWIs); commercial, industrial solid waste incinerators (CISWIs); and other solid waste incinerators (OSWIs) to combust hazardous waste pharmaceuticals that are also controlled substances. Other commenters suggested that we allow forms of destruction beyond combustion, such as oxidation treatment[306] or chemical digestion,[307] or any technology that achieves DEA's standard of non-retrievable.[308]

C. Final Rule Provisions

We are finalizing both conditional exemptions for hazardous wastes that are also controlled substances, with some changes. First, we have amended the regulatory language in § 266.506(a)(2) to be more consistent with the preamble to the proposed rulemaking and to be more consistent with how the conditional exemption in § 266.506(a)(1) was crafted. In the preamble to the proposed rulemaking, we discussed the conditional exemption in terms of the waste pharmaceuticals from take-back events and programs, while in the proposed regulatory language, the conditional exemption was focused on the collector of the waste pharmaceuticals. We revised the regulatory language in § 266.506(a)(2) to conditionally exempt the collected household waste pharmaceuticals, as opposed to the collector of the household waste pharmaceuticals. Additionally, one commenter pointed out that the proposed regulatory language could be read to mean that if the household waste pharmaceuticals were not commingled with DEA controlled substances, then the requirement to combust them would not apply.[309] EPA did not intend to make this distinction. Although we understand that most, if not all, take-back events and programs do, in fact, commingle controlled substances with non-controlled substances, EPA proposed to place conditions on collectors of household waste pharmaceuticals with the understanding that this proposed regulatory language would capture all pharmaceuticals collected at take-back events and programs. The revised regulatory language in this final rule makes it clearer that the household waste pharmaceuticals collected during a take-back event or program must be destroyed by combustion or other DEA-approved method, whether or not the household waste pharmaceuticals are commingled with DEA controlled substances.

Also in response to comments, we are expanding the types of combustors that are allowed to destroy the conditionally exempt hazardous waste pharmaceuticals. Under the final rule, five types of combustors will be allowed to destroy hazardous waste pharmaceuticals that are also DEA controlled substances and the pharmaceuticals from take-back events and programs: (1) Permitted large municipal waste combustors (MWCs), (2) permitted small MWCs, (3) permitted HMIWIs, (4) permitted CISWIs and (5) permitted hazardous waste combustors (either an incinerator or other combustor, such as a cement kiln).

In addition to the five types of permitted combustors allowed to destroy the conditionally exempt

[301] See memo from J. Winston Porter to Regions, dated November 1, 1988; RCRA Online #11377.

[302] See memo September 26, 2012, Rudzinski to the Regional RCRA Division Directors (RCRA Online#14833) and memo October 2, 2015, Johnson to RCRA Division Directors (RCRA Online #14853).

[303] Since pharmaceutical collection programs typically commingle DEA controlled substances with non-controlled substances, this requirement is included in a section of the regulations that pertains to controlled substances.

[304] DEA does not prohibit co-mingling of controlled substances with non-controlled substances provided they are all then managed as controlled substances.

[305] See 40 CFR 26.506(a)(2).

[306] See Comment number EPA–HQ–RCRA–2007–0932–0287.

[307] See Comment number EPA–HQ–RCRA–2007–0932–0375.

[308] See Comment number EPA–HQ–RCRA–2007–0932–0333.

[309] See comment number EPA–HQ–RCRA–2007–0932–0261.

pharmaceuticals, EPA is building in flexibility to the final regulation to allow for the possibility that future technologies might be developed that meet the DEA non-retrievable standard. Specifically, we are allowing any method of destruction for the conditional exemption that DEA has publicly approved in writing as able to meet its non-retrievable standard. While it is reasonable to defer to the DEA's judgement in this matter to approve methods of destruction that are environmentally protective, we feel it is necessary to limit future allowable destruction technologies for the conditionally exempt pharmaceuticals to those that are publicly approved by the DEA as meeting the non-retrievable standard. This is intended to avoid a situation where parties might make unsubstantiated claims that their product is capable of meeting the DEA non-retrievable standard in order to qualify for the conditional exemption. Furthermore, any method that DEA might specify must not conflict with federal environmental laws or regulations. Also, because combustion is no longer specified as the only allowable method of destruction, we have concluded that an additional change to the regulations is needed to make it clear that the hazardous waste pharmaceuticals that are also DEA controlled substances are subject to § 266.505, and therefore, may not be sewered.

Both types of conditionally exempt hazardous waste pharmaceuticals (*i.e.,* those that are DEA controlled substances and those that are collected household waste pharmaceuticals) will be able to take advantage of the expanded list of allowable types of combustors. For healthcare facilities and reverse distributors that generate and manage the handful of hazardous waste pharmaceuticals that are also controlled substances, we think it will be helpful to have additional destruction methods for these previously dually regulated wastes. Also, the expanded list of allowable types of combustors will be helpful for those operating take-back programs and events. The Agency is a strong supporter of take-back programs and events for household pharmaceuticals as an alternative to disposing of leftover, unwanted medications in the trash or in the toilet or down the sink (except in cases where the FDA-approved labeling instructs patients to immediately flush the unneeded medication down the toilet if a take-back option is not readily available). In expanding the types of combustors that are allowed to burn the pharmaceuticals from take-back events, we strive to strike a balance between maximizing flexibility while still being protective of human health and the environment. Under the revised list in the final rule, the universe of allowable combustors will substantially increase in number. There are 77 municipal solid waste combustion facilities (also referred to as waste-to-energy facilities) in 22 states,[310] and 21 commercial hazardous waste combustion facilities (*i.e.,* those that accept waste from off-site) in 12 states.[311] There are currently 33 HMIWIs units in the U.S.: 11 of the 33 are commercial HMIWIs, while the other 22 HMIWI units only combust their own waste.[312] There are approximately 75 CISWIs facilities in the U.S.[313] We note that the types of combustors we are allowing to accept the conditionally exempt pharmaceuticals are not obligated to accept the conditionally exempt pharmaceuticals. Of course, we strongly encourage all the various types of allowable combustors to work with their communities and regulators in developing viable options for destroying the pharmaceuticals from take-back events. In particular, we encourage the ''captive'' combustors that currently only combust their own waste to consider amending their permits to allow them to accept pharmaceuticals from take-back events and programs.

We have concluded that it is reasonable to expand the list of allowable combustors able to accept the conditionally exempt pharmaceuticals because the combustion of pharmaceuticals that meet the definition of a RCRA solid waste but do not meet the definition of RCRA hazardous waste (*i.e.,* non-hazardous waste pharmaceuticals) is regulated by § 129 of the Clean Air Act. The statute requires EPA to establish emission limits for nine air pollutants (*i.e.,* particulate matter, carbon monoxide, dioxins/furans, sulfur dioxide, nitrogen oxides, hydrogen chloride, lead, mercury, and cadmium) from several categories of solid waste incineration units, including MWCs; HMIWIs; and CISWIs. EPA has established emission limits for each of the categories based on the application of maximum available control technology (MACT) which reflect the emission levels achieved by the best performers in each category.

In addition to complying with emission limitations, solid waste incineration units are also subject to comprehensive operating, monitoring and reporting requirements. In light of the common framework used to develop emission limits and requirements for MWC, CISWI, and HMIWI units, we believe that it is appropriate to include HMIWIs and CISWIs as types of combustors that are allowed to burn the pharmaceuticals from take-back events.

While the Agency has expanded the list of allowable combustors to include HMIWIs and CISWIs, we have not expanded the list to include other solid waste incinerators (OSWIs). OSWIs are small units that have fewer emission controls than other types of combustors. Further, there are only a handful of new OSWIs in operation and the legal status of existing OSWIs is uncertain due to litigation. EPA is also not expanding the list of allowable combustors to include human and pet crematoriums. Crematoriums are not regulated under the Clean Air Act and typically do not use air pollution control devices to limit toxic air pollutants such as mercury and dioxins and furans. We believe that crematoriums would not provide adequate public health and environmental protection when burning non-hazardous waste pharmaceuticals. If solid or hazardous wastes are burned in a crematorium, it would make the crematorium subject to the Clean Air Act.

D. Comments and Responses

In its comment, Cardinal Health included a list of pharmaceuticals that it manages as both RCRA hazardous waste and DEA controlled substances.[314] In most cases, their comments reinforced the list that we included in the proposed rulemaking. In two cases, Cardinal Health identified additional forms of drugs that were included in the table of DEA controlled substances and hazardous wastes in the preamble to the proposed rulemaking. First, Cardinal Health identified Axiron as the brand name of an additional form of testosterone that is a solution applied to the underarms that is also ignitable. Second, Cardinal Health identified Diastat as the brand name of an additional form of valium that is a gel intended for rectal administration that is also ignitable. We have amended our list of DEA controlled substances and RCRA hazardous wastes by including Axiron and Diastat in Table 6 below to be more

[310] Energy Recovery Council, 2016 Directory of Waste-to-Energy Facilities; *http://energyrecoverycouncil.org/wp-content/uploads/2016/06/ERC-2016-directory.pdf.*

[311] Memo from Rudzinski to Regions, dated September 26, 2012; RCRA Online #14833.

[312] See comment number EPA–HQ–RCRA–2007–0932–0280.

[313] See CISWI inventory EPA–HQ–OAR–2016–0664–0002.

[314] See comment number EPA–HQ–RCRA–2007–0932–0250.

complete and accurate. However, there is no corresponding regulatory change being made. The regulations conditionally exempt all RCRA hazardous wastes that are also DEA controlled substances; the table identifying which drugs are both is included in the preamble for informational purposes:

TABLE 6—PHARMACEUTICALS STILL USED IN HEALTHCARE THAT ARE DEA CONTROLLED SUBSTANCES & RCRA HAZARDOUS WASTES

[Amendments in bold based on comments]

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Chloral; chloral hydrate.	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes.	Sedative	U034 toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics.
Fentanyl sublingual spray.	Subsys	Analgesic	D001 ignitable	II	Ignitable due to alcohol content.
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001 ignitable	IV	Ignitable due to alcohol content.
Testosterone gels/solutions.	Androgel, Axiron, Fortesta, Testim	Hormone	D001 ignitable	III	Ignitable due to alcohol content.
Valium injectable/gel	Diazepam, Diastat	Anti-anxiety	D001 ignitable	IV	Ignitable due to alcohol content.

Cardinal Health's comment also indicated that the company manages Somatropin (brand names Humatrope and Genotropin) as a DEA controlled substance and a RCRA hazardous waste. M-cresol, which is a contaminant identified on the toxicity characteristic list in § 261.24 (D024), is used as a preservative in Somatropin. Per legislations, all anabolic steroids are considered controlled substances; [315] however, Somatropin is considered a human growth hormone, not an anabolic steroid.[316] Therefore, although Somatropin may be a RCRA hazardous waste for its m-Cresol content, it is not a DEA controlled substance.

The two conditional exemptions we are finalizing in this rule are intended to eliminate any duplicative regulations for pharmaceuticals that are RCRA hazardous wastes and DEA controlled substances. Nevertheless, there are several remaining areas where DEA and EPA regulations intersect, even if they are not duplicative. The Agency would like to address these intersecting areas in effort to reduce confusion and aid compliance.

1. Only Household (Ultimate User) Waste May Be Collected in DEA Authorized Collection Receptacles

It is important to note that in order to qualify for the conditional exemption, a retail pharmacy (or other DEA authorized collector pharmacy) can use the DEA authorized collection receptacle to collect waste generated only at households (DEA refers to this as waste from ''ultimate users'') and brought to the store for collection. The hazardous waste generated by the retail pharmacy and store, including hazardous waste pharmaceuticals, are not excluded household wastes under RCRA and may not be placed in the DEA authorized receptacle.[317] Depending on the amount generated, the hazardous waste pharmaceuticals generated by the retail pharmacy and store must be managed under either § 262.14 (as a VSQG) or under part 266 subpart P. Furthermore, states generally regulate non-hazardous waste and it is possible that they may have licensing or permitting requirements for the collection of solid waste. Because EPA would like to see the use of DEA authorized collection receptacles become widespread, we encourage states to streamline any requirements that may create a barrier to the use of the DEA authorized collection receptacles.

2. Sewer Prohibition, Conditional Exemption and Pharmaceutical Wastage

In response to comments, EPA has decided against making any exceptions to the sewer prohibition. Some commenters suggested that EPA should allow RCRA hazardous wastes that are also DEA controlled substances to be sewered. On the other hand, many commenters suggested, and EPA agrees, that it would be inappropriate to make exceptions to the sewer prohibition, even for the handful of hazardous wastes that are also controlled substances. In part, commenters thought it was bad environmental policy to allow sewering of any hazardous waste pharmaceuticals. Commenters were also concerned that it would send a mixed message to the regulated community about our goals and lead to confusion about which hazardous waste pharmaceuticals could and could not be sewered. As a result, all hazardous waste pharmaceuticals are prohibited from being sewered, including the handful that are also DEA controlled substances.

Under the DEA regulations, a registrant's inventory of controlled substances is already prohibited from being sewered as a means of meeting the non-retrievable standard.[318] Likewise, under the CWA regulations, RCRA ignitable hazardous wastes (D001) are prohibited from being discharged to the sewer.[319] As noted in Table 6, four out of the five RCRA hazardous wastes that are also DEA controlled substances are hazardous waste due to being ignitable and hence are already prohibited from being sewered by the CWA regulations. In effect, this new RCRA regulation only prohibits the sewering of one additional DEA controlled substance that is also a RCRA hazardous waste: Chloral hydrate, which is listed for toxicity. In summary, a RCRA hazardous waste that is also DEA controlled substance that is part of a DEA registrant's inventory may not be sewered.

[315] The Anabolic Steroids Control Act of 1990 placed anabolic steroids into Schedule III of the Controlled Substances Act (CSA) as of February 27, 1991.

[316] *https://www.fda.gov/Drugs/DrugSafety/ucm237839.htm;* accessed 8/24/2017.

[317] DEA also prohibits retail pharmacy stock/inventory from being placed in the collection receptacle or mail-back envelopes (see 21 CFR 1317.05(a)).

[318] See the preamble to DEA's final rule 79 FR 53548; September 9, 2014 and the preamble to DEA's proposed rule 77 FR 75803; December 21, 2012.

[319] See the Clean Water Act regulations at 40 CFR 403.5(b)(1).

DEA does allow controlled substance ''pharmaceutical wastage'' to be disposed of in accordance with applicable federal, state, and local laws, regulations, and healthcare facility policies, including sewering or putting down the drain.[320] DEA uses the term ''pharmaceutical wastage'' to refer to leftover, unadministered pharmaceuticals (''*e.g.,* some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized'' [321]). While DEA allows pharmaceutical wastage of controlled substances to be sewered, the CWA regulations already prohibit the discharge of any RCRA ignitable hazardous waste and, under this RCRA rule, EPA is not creating any exceptions to the sewer prohibition. As a result, neither inventory nor pharmaceutical wastage of DEA controlled substances that are also RCRA hazardous wastes may be sewered.

Even though inventory and pharmaceutical wastage are prohibited from being sewered, both inventory and pharmaceutical wastage would be eligible for the conditional exemption being finalized in this rule in § 266.506 for RCRA hazardous wastes that are also DEA controlled substances. As discussed previously, EPA is finalizing the conditional exemption that the few RCRA hazardous waste pharmaceuticals that are also DEA controlled substances would be exempt from RCRA regulation, on the condition that they are (1) managed in accordance with DEA regulations and (2) incinerated by one of five types of permitted combustors or destroyed by another method that has been publicly approved by DEA, and (3) are not sewered.

Therefore, if inventory or pharmaceutical wastage is both a RCRA hazardous waste and a DEA controlled substance it would not be allowed to be sewered, it would have to be incinerated (or destroyed by another method publicly approved by DEA). Prior to incineration, however, the inventory and pharmaceutical wastage, both of which are conditionally exempt under RCRA, are regulated differently by DEA. The leftover inventory of DEA controlled substances remains fully subject to DEA regulations, which includes tracking and witnessed destruction. On the other hand, controlled substance pharmaceutical wastage is no longer regulated by DEA. Therefore, only pharmaceutical wastage could be collected in a container at the healthcare facility prior to incineration. If this container were used to collect only conditionally exempt pharmaceutical wastage prior to incineration, it would not be subject to the subpart P container standards. It is more likely, however, that a container used to collect the conditionally exempt pharmaceutical wastage would also be used to collect regulated hazardous waste, in which case the container would be subject to subpart P container standards. In either case, as DEA states in its guidance, ''Although Part 1317 does not apply to pharmaceutical wastage, the DEA strongly encourages all practitioners to continue to adhere to security controls and procedures that ensure pharmaceutical wastage is not diverted. For example, most institutional practitioners have implemented policies that require two persons to witness and record destruction of pharmaceutical wastage.'' [322] In support of DEA's guidance, EPA strongly recommends that any container that is used to collect pharmaceutical wastage that will include DEA controlled substances contain some sort of absorbent or chemical reactant in order to bind or chemically alter the contents and thus deter the diversion of the collection container for controlled substance recovery.

3. Long-Term Care Facilities and the DEA Regulations

This section will discuss the intersection of the DEA regulations and the RCRA hazardous waste regulations that pertain to LTCFs.

Under the DEA regulations, most LTCFs are not registrants and until recently have had few options for properly and securely disposing of the controlled substances from its patients (ultimate users). DEA's 2014 final regulations to implement the Secure and Responsible Drug Disposal Act of 2010 are designed to help alleviate the problem that LTCFs face when discarding their patients' controlled substances. DEA's 2014 final rule allows, but does not require, retail pharmacies and hospital/clinics with an on-site pharmacy that are DEA registrants to modify their registrations to become ''collectors'' and to place collection receptacles at LTCFs (or at the retail pharmacy or hospital/clinic with an on-site pharmacy) for the collection of controlled substances from ultimate users. Per the DEA regulations, if a DEA authorized collection receptacle is placed in a LTCF, only the ultimate users' controlled substances may be placed in the DEA collection receptacle. If an LTCF is a DEA registrant and discards DEA controlled substances from its inventory, they may not be placed in the DEA authorized collection receptacle and must be otherwise destroyed to meet the non-retrievable standard.

Under the 2014 DEA final rule, LTCFs now have three options for managing their patients' controlled substances. First, if a DEA registered retail pharmacy or hospital/clinic with an on-site pharmacy places a collection container at an LTCF, the staff from the LTCF may place the patients' controlled substances in the collection receptacles. Second, although LTCFs are not allowed to conduct a facility-wide collection event for their patients' controlled substances for mail-back programs, they are allowed to assist patients who choose to use a mail-back program for their own controlled substances, on an individual-by-individual basis. And third, law enforcement can pick up patients' controlled substances for disposal. With these changes to DEA's regulation, LTCFs can now dispose of patients' controlled substances in a more environmentally protective way and EPA strongly encourages the use of any of these three collection methods. It should be noted that the 2014 DEA regulations do not mandate the placement of collection receptacles at long-term care facilities or patient participation in mail-back programs or take-back events.

As for the RCRA regulations, this rule finalizes the provision that hazardous waste from LTCFs will no longer be considered exempt as household hazardous waste. Instead, it will need to be managed as regulated hazardous waste. This interpretation will apply to all the hazardous waste generated by a LTCF, not just its hazardous waste pharmaceuticals (although the Agency expects that much of the hazardous waste generated by LTCFs consists of hazardous waste pharmaceuticals). Notwithstanding this revised interpretation, there are four other regulatory provisions that might affect how a LTCF will actually have to manage its hazardous waste pharmaceuticals under this final rule

First, we have added to the final rule a presumption that LTCFs with 20 beds or fewer will be VSQGs.[323] And those LTCFs that have more than 20 beds may still qualify as VSQGs (for all of their hazardous waste) if they generate less than 100 kg of hazardous waste and less

[320] See DEA letter to registrants re: Clarifying disposal of pharmaceutical wastage dated Oct 17, 2014; *http://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf.*

[321] Ibid.

[322] Ibid.

[323] See 40 CFR 266.504(d).

than 1 kg of acute hazardous waste per calendar month. In fact, based on the RIA for the final rule, EPA estimates that 98–99 percent of LTCFs that generate hazardous waste are VSQGs.[324] As VSQGs, the long-term care facilities will be subject to the reduced regulatory provisions of 40 CFR 262.14 for all of their hazardous waste (including those that are controlled substances), and only the sewer prohibition provision of this new subpart for their hazardous waste pharmaceuticals. Only the other 1–2 percent of LTCFs that generate hazardous waste will be subject to part 266 subpart P.

Second, this final rule allows an LTCF that is a VSQG (for all of its hazardous waste) to send its hazardous waste pharmaceuticals to an off-site healthcare facility that either supplies the LTCF with its pharmaceuticals (*e.g.,* a long-term care pharmacy) or is under the control of the same person and that is operating under subpart P.[325] Note that this provision is limited to hazardous waste pharmaceuticals and not to those that are also controlled substances because the DEA allows controlled substances to be returned to a long-term care pharmacy only when they are subject to a recall.

Third, this final rule also allows a healthcare facility, including a LTCF that is a VSQG, to use an on-site DEA authorized collection receptacle to dispose of its hazardous waste pharmaceuticals (see § 266.504(c)). It could be argued that VSQGs would already be allowed to use DEA authorized collection receptacles for their hazardous waste pharmaceuticals even without this new provision, provided the waste from the DEA authorized collection receptacles is treated or disposed at one of the types of facilities identified in § 262.14(a)(5) (*e.g.,* facilities that are permitted or have interim status to manage hazardous waste and facilities that are permitted, licensed or registered by a state to manage hazardous waste, municipal waste or non-municipal waste). Nevertheless, we did propose, and are finalizing the provision in § 266.504(c) making it clear that healthcare facilities that are VSQGs can place their hazardous waste pharmaceuticals in an on-site DEA collection receptacle. DEA already allows controlled substances to be commingled with non-controlled substances. Therefore, EPA believes it is consistent to allow VSQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA collection receptacles with controlled substances. EPA believes that management of VSQGs' hazardous waste pharmaceuticals as DEA controlled substances is preferable because it provides greater protection to patients, visitors, and workers at healthcare facilities to have the hazardous waste pharmaceuticals accumulating in DEA-authorized collection receptacles rather than in the regular trash. However, it is important to note that the DEA regulations for controlled substances are much narrower in what may be placed in a collection receptacle; DEA only allows controlled substances from patients to be placed in collection receptacles that are at LTCFs. To reiterate, under the DEA regulations, if a LTCF, or any other healthcare facility, is a DEA registrant it may not place its own inventory of controlled substances in a collection receptacle, even if it is a VSQG under RCRA.

Fourth, for the LTCFs that are not VSQGs, the handful of RCRA hazardous waste pharmaceuticals that are also DEA controlled substances will not be subject to RCRA, provided they meet three conditions: (1) They are combusted at a small or large MWC, a HMIWI, a CISWI or a hazardous waste combustor (or destroyed by another method publicly approved by DEA), (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances, and (3) they are not sewered. DEA allows LTCFs to put their patients' controlled substances into an on-site collection receptacle; therefore, an LTCF could also place its patients' controlled substances that are also RCRA hazardous waste into a DEA authorized collection receptacle (alternatively, patients could use another allowable take-back method, such as mail-back envelopes) in order to meet the conditional exemption. However, we must stress that only LTCFs would be able to use collection receptacles (or another allowable take-back method) to meet the conditional exemption for RCRA hazardous wastes that are also DEA controlled substances, because they are the only type of facility that DEA allows to place their patients' wastes into an on-site collection container. Other healthcare facilities, such as hospitals, could not meet the conditional exemption by placing their DEA controlled substances that are also RCRA hazardous wastes in a collection receptacle because DEA does not allow patients at hospitals to use on-site collection receptacles. No registrant healthcare facility, including an LTCF, would be able to use the collection receptacle to meet the terms of the conditional exemption for any of its own inventory of DEA controlled substances that are also RCRA hazardous wastes because DEA does not allow registrants to use collection receptacles for their own inventory.

For those LTCFs that are not VSQGs, the hazardous waste pharmaceuticals that are not controlled substances (and therefore not conditionally exempt) will be subject to part 266 subpart P, while the other hazardous wastes will be subject to the SQG or LQG regulations, as applicable, in part 262.

See Table 7 for a summary of the intersection of RCRA and DEA regulations for the disposal of hazardous waste pharmaceuticals at LTCFs:

TABLE 7—INTERSECTION OF RCRA & DEA REGULATIONS AT LONG-TERM CARE FACILITIES

Types of pharmaceutical waste at long-term care facilities	RCRA regulatory requirements		
	How RCRA applies	DEA authorized collection methods allowed for HW pharmaceuticals?	Can be returned to an off-site HCF owned by the same person or LTC pharmacy?
Hazardous Waste Pharmaceuticals that are NOT Controlled Substances:			
if LTCF is a VSQG	§ 262.14 and sewer prohibition.	Yes. § 266.504(c)	Yes.
if LTCF is *not* a VSQG	part 266 subpart P	No	No.
Hazardous Waste Pharmaceuticals that are also Controlled Substances:			

[324] See the Regulatory Impact Analysis for this final rule in the docket EPA–HQ–RCRA–2007–0932.

[325] See 40 CFR 266.502(l) and 266.503(b) for non-creditable and creditable hazardous waste pharmaceuticals, respectively.

TABLE 7—INTERSECTION OF RCRA & DEA REGULATIONS AT LONG-TERM CARE FACILITIES—Continued

Types of pharmaceutical waste at long-term care facilities	RCRA regulatory requirements		
	How RCRA applies	DEA authorized collection methods allowed for HW pharmaceuticals?	Can be returned to an off-site HCF owned by the same person or LTC pharmacy?
if LTCF is a VSQG	§ 262.14 and sewer prohibition.	Yes. Only from patients	Only if subject to a recall.
if LTCF is *not* a VSQG	Conditionally exempt from RCRA (§ 266.506) if: • Combusted (or other DEA approved destruction method). • Comply with DEA regulations.	Yes. Only from patients (DEA collection methods meet the terms of the RCRA conditional exemption).	Only if subject to a recall.

XV. Management of Residues in Pharmaceutical Containers (§ 266.507)

A. Regulatory Background

Over the years, EPA has received numerous inquiries regarding the regulatory status of residues in various types of containers that once held pharmaceuticals that are considered hazardous waste when discarded. Stakeholders have been particularly concerned about residues in containers that once held pharmaceuticals that are on the ''P-list'' of acutely hazardous commercial chemical products in § 261.33(e) because a generator becomes an LQG if it generates more than 1 kg of acute hazardous waste per calendar month.[326] The regulatory status of acute and non-acute commercial chemical product residues remaining in a container are specifically addressed in § 261.33:

''The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded . . . (c) Any *residue* remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is *empty* as defined in § 261.7(b).''

In § 261.7(b)(1), there are two ways a container that held a non-acute hazardous waste can be considered ''empty.'' The container is considered empty if all wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, *e.g.,* pouring, pumping, aspirating, *and* (1) no more than 2.5 centimeters (one inch) of residue remain on the bottom of the container or inner liner, *or* (2) No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size; or no more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size.

Therefore, it is important to note that if the container that held the non-acute hazardous waste pharmaceutical does not have its contents removed by a commonly employed practice even though it has one inch or less of residue remaining or has 3 percent or less by weight of the total capacity of the container remaining,[327] the container is still *not* considered ''RCRA empty.'' If the container is not ''RCRA empty,'' then the residues are regulated as hazardous waste (since the residues are within the container, the container must be managed as hazardous waste, as well, even if it is not itself hazardous waste).

According to § 261.7(b)(3), there are three ways that a container that held an acute hazardous waste can be considered empty:

(1) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;

(2) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or

(3) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed.

According to these requirements, if the container that held the P-listed pharmaceutical is not triple rinsed, or cleaned by another method that has been demonstrated to achieve equivalent removal, or had the inner liner removed, the container is not considered ''RCRA empty,'' even though the pharmaceutical may have been fully removed. If the container is not ''RCRA empty,'' then the residues are regulated as acute hazardous waste.

In November 2011, EPA issued guidance about containers that once held P-listed pharmaceuticals[328] that provides three possible regulatory approaches for generators:

(1) Count only the weight of the hazardous waste residues toward generator category

(2) Demonstrate an equivalent removal method to render containers RCRA empty

(3) In the case of warfarin, show that the concentration in the residue is below the P-listed concentration

This guidance was intended as a short-term solution that worked within the confines of the existing RCRA hazardous waste regulations. In 2015, we proposed to amend the regulations that pertain to residues in containers that once held pharmaceuticals that are RCRA hazardous wastes. EPA proposed different regulatory solutions for different types of containers found in healthcare settings. Specifically, the proposal addressed the following three categories of containers: (1) Unit-dose containers (*e.g.,* packets, cups, wrappers, blister packs, and delivery devices) and dispensing bottles and vials; (2) dispensed syringes; and (3) other containers, including delivery devices. Generally, commenters were supportive of the need for these new empty container standards specifically developed for the types of small containers used in the healthcare setting, although they did have suggestions for changes. Each category

[326] Additionally, acute hazardous wastes are included on the F-list of § 261.31; however, none of those acute hazardous wastes are pharmaceuticals.

[327] We are assuming that containers that hold pharmaceuticals are in containers less than 119 gallons in size.

[328] Rudzinski to RCRA Division Directors, November 11, 2011, RCRA Online #14827.

of container is discussed separately below. Today's new ''empty container'' regulations in § 266.507 will replace the November 2011 guidance as it pertained to residues of hazardous waste pharmaceuticals in containers, although the memo will remain in effect for non-pharmaceutical hazardous wastes.

B. Stock, Dispensing and Unit-Dose Containers (§ 266.507(a))

1. Summary of Proposal

We proposed that a dispensing bottle, vial, or ampule (not to exceed 1 liter or 1,000 pills) or a unit-dose container (*e.g.,* a unit-dose packet, cup, wrapper, blister pack or delivery device) would be considered empty and the residues would not be regulated as hazardous waste if the hazardous waste pharmaceuticals have been removed from the dispensing or unit-dose container by commonly employed methods.

This proposal applied to containers that once held acute or non-acute hazardous waste pharmaceuticals. Under the proposal, for containers that once held non-acute hazardous waste pharmaceuticals, it would not be necessary to measure the remaining contents. Likewise, under the proposal, for containers that once held acute hazardous waste pharmaceuticals, it would not be necessary to triple rinse the containers or demonstrate an equivalent removal method. Rather, we proposed that a dispensing or unit-dose container would be considered empty if all pharmaceuticals have been removed using the practices commonly employed to remove materials from that type of container—thus, the residues (and therefore the container as well) may be disposed of as non-hazardous waste.

We proposed this new ''RCRA empty'' standard for containers used within a healthcare setting for two reasons. First, this approach will help eliminate the sewering of pharmaceuticals. In a healthcare setting, if containers are triple rinsed, the rinsate will likely be poured down the drain, which is not a good environmental practice. We think it is important that the residues be managed in a more controlled manner—such as in municipal solid waste landfills— rather than poured down the drain. Second, although the ''empty container'' regulations of § 261.7 apply to all sizes of containers, they were developed with larger, industrial-sized containers in mind. For the most part, the containers that hold pharmaceuticals are smaller in size than a 55-gallon drum; therefore, the amount of residue will likely be much less in these containers. In the preamble to the proposed rulemaking, we explained that we selected the 1,000-pill/1-liter limit because, in our observation, EPA had rarely seen dispensing bottles larger than that. We specifically sought comment on whether larger containers are used for dispensing pharmaceuticals and, if so, which pharmaceuticals they are used for and what RCRA hazardous waste codes would apply.

In the proposal, EPA presented data from three stakeholders helping to confirm the assumption that very little residue remains in containers after the pharmaceuticals (*e.g.,* pills) have been removed. In addition, EPA's Office of Research and Development conducted similar research.[329] A summary of the results is in the preamble to the proposed rulemaking, while the full results from each of the four sources are included in the docket for the proposed rulemaking.[330] [331]

EPA is aware that there are certain limitations with the data from the four sources. For instance, in one of the studies, no replicate samples were tested. In another study, only warfarin residues were tested. However, given the size of the containers involved and the nominal quantities of residues involved, the Agency proposed to allow the residues in dispensing bottles, vials and ampules, and single-unit dose containers that once held hazardous waste pharmaceuticals to be managed as non-hazardous waste provided the pharmaceutical product has been removed (*e.g.,* all pills have been removed).

As part of the proposal, EPA raised the concern of potential diversion of the pharmaceutical containers that may occur when the pharmaceutical residues and containers are discarded in the municipal waste stream. The Agency proposed that RCRA-empty pharmaceutical containers that are original pharmaceutical packages (and therefore susceptible to diversion) should be destroyed prior to placing them in the trash. These types of containers would include dispensing bottles, vials, or ampules typically used in pharmacies, but would not include paper or plastic cups, or blister packs used for dispensing singles doses to patients. In the preamble to the proposal, we explained that the means of destruction could include crushing or shredding the container.

2. Summary of Comments

The comments for this section can be broken into two major groups. One group of comments expressed concern with the 1,000-pill/1-liter size limit to pharmaceutical dispensing containers and commenters asked EPA to consider allowing the new RCRA-empty standard for pharmaceutical dispensing containers to apply to larger pharmaceutical containers or even to all dispensing containers, regardless of size.

As part of its comments, CVS Health included results from an analysis conducted on containers that held warfarin.[332] Their tests included brand name and generic warfarin stock bottles, testing the largest stock bottles with the highest prescription strength warfarin typically found in a CVS Health Pharmacy, although their comments do not specify the size of the largest stock bottle, nor do they specify the highest prescription strength of warfarin. That said, their results do offer similar results as the studies used in support of the proposal, indicating the range of total residues detected was 0.0–19.8 mg (excluding outliers).

Another group of comments objected to the proposed requirement to destroy the containers before disposing of them in municipal solid waste landfills. Commenters objected to this proposed provision for several reasons. First, the most common reason given by commenters that objected to this provision was they disagreed with EPA that diversion of these containers is occurring. Many states commented that this has never been a problem in their state and that the issues with these types of containers arise from purchase of empty vials on the internet and counterfeit labels made on home computers, not from dumpster diving. Second, there was concern that this would be a costly option since many healthcare facilities would now need to hire someone or buy equipment to destroy the containers. Many commenters thought the same goals could be reached through more cost-effective means such as defacing the label to render the containers unusable for illicit purposes. Third, a few commenters were also concerned with the release of the residues in these containers upon destruction and the effect that could have on the workers. This set of commenters included the one state that favored destruction of the containers. Finally, some commenters noted that these empty containers are already being disposed of in locked

[329] Tolaymat, T. and A. El Badawy. Evaluation of P-Listed Pharmaceutical Residues in Empty Pharmaceutical Containers. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R–14/167, 2015.

[330] September 25, 2018; 80 FR 58052.

[331] EPA–HQ–RCRA–2007–0932–0153 through 0156.

[332] See comment number EPA–HQ–RCRA–2007–0932–0312.

dumpsters and there are adequate institutional controls to address any public health risk from use of discarded containers in counterfeit drug sales.

3. Final Rule Provisions

In response to comments, we have made three substantive changes to the regulations proposed in § 266.507(a) that define when a dispensing or unit-dose container is empty. First, based on comments, we now recognize that we used the term ''dispensing'' bottle, vial, or ampule incorrectly. Dispensing bottles are those that are provided to patients when they get a prescription filled. Although a healthcare facility such as a pharmacy may dispose of some dispensing bottles, they are more likely to dispose of the stock bottles that they use to fill the dispensing bottles provided to the patients. As a result, we have modified the regulatory language to include stock bottles in addition to dispensing bottles, vials or ampules, and unit-dose containers.

Second, after reviewing comments and asking for additional support and clarification from commenters, including the Army Public Health Center, CVS Health and the Department of Veterans Affairs, the Agency has increased the size of the dispensing containers from 1,000 pills to 10,000 pills.[333] The Army Public Health Center states that they ''routinely procure containers containing 1K, 2K, and even 5K or 10K pill counts'' for refilling the automated dispensing machines at their facilities.[334] This exceeds the size of dispensing containers that we and others tested, but given that the contents are solid pills, capsules and tablets, and that the residues we and others detected are very small, we determined that it is appropriate to increase the size of the stock or dispensing container to 10,000 pills.

However, we have kept the maximum volume for stock and dispensing containers at a maximum of 1 liter since this volume limit would apply to liquids (and other non-pill formulations), which are harder to fully remove, and commenters did not provide sufficient information to support increasing the volume limit. Further, it is not clear from comments or subsequent correspondence whether any containers larger than 1 liter are in use for pharmaceuticals that would be hazardous waste when discarded. Stock or dispensing containers that exceed 1 liter would be considered ''other containers'' under § 266.507(d). As such, under the final rule, if they held pharmaceuticals that are non-acute hazardous waste, then they would be able to use § 261.7(b)(1) to show that they are empty.

The third substantive change is that we have removed the proposed requirement to destroy the empty pharmaceutical containers prior to disposal. We share commenters' concerns about possible worker exposure during the process of crushing or shredding the containers. However, EPA remains concerned about the diversion of the empty containers for illicit purposes. Therefore, we strongly encourage healthcare facilities to use best management practices, such as locked dumpsters and defacing labels, to prevent the diversion of these containers, but the extra step of destroying these containers will not be required.

Thus, under the final rule, a stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (*e.g.,* a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

In § 261.33(c), we have also added a reference to the new empty container provisions for hazardous waste pharmaceuticals in § 266.507 as a conforming change. Previously, § 261.33(c) referenced only the empty container provisions of § 261.7(b).

4. Comments and Responses

One commenter asked us to add an explicit reference to acute/P-listed hazardous waste in this section of the regulations. We believe this is unnecessary since § 261.7(c) indicates that containers of hazardous waste pharmaceuticals (which includes acute and non-acute hazardous waste pharmaceuticals) are subject to § 266.507 in lieu of § 261.7 for determining when they are empty. Nevertheless, we agree with the commenter that all of the new empty container provisions in § 266.507 apply to containers that held either non-acute or acute hazardous waste pharmaceuticals. Under the new subpart P provisions, for containers that once held non-acute waste pharmaceuticals to be considered empty, it will not be necessary to measure the remaining contents, and for containers that once held acute hazardous waste pharmaceuticals, it will not be necessary to triple-rinse the containers or demonstrate an equivalent removal method.

C. Syringes (§ 266.507(b))

1. Summary of Proposal

EPA proposed that the residues remaining in a syringe would not be regulated as hazardous waste provided the syringe had been used to administer a pharmaceutical to a patient, the syringe is placed in a sharps container (if appropriate), and is managed in accordance with all applicable federal, state, and local medical waste or regulated waste regulations. As with all of the new empty container standards proposed in § 266.507, this proposed provision applied to syringes used to administer pharmaceuticals that are acute or non-acute hazardous waste when discarded.

Prior to the proposal, EPA issued guidance regarding the regulatory status of residues in syringes in December 1994 and April 2008.[335] [336] In the December 1994 RCRA/Superfund Hotline Q&A about whether epinephrine residues in a discarded syringe would be P042, EPA stated, ''Drug residues often remain in a dispensing instrument after the instrument is used to administer medication. EPA considers such residues remaining in a dispensing instrument to have been used for their intended purpose. The epinephrine remaining in the syringe, therefore, is not a commercial chemical product and not a P042 hazardous waste. The epinephrine could be a RCRA hazardous waste, however, if it exhibits a characteristic of hazardous waste.'' [337] In the April 2008 memo, EPA clarified that the 1994 interpretation extends to other P- and U-listed pharmaceuticals that have been used to administer the pharmaceutical by syringe.

EPA thinks that it is important to clarify in regulation when syringes are considered RCRA empty as this has been a source of many questions over the years. As part of the decision making, EPA is aware of the need to

[333] See the email correspondence from Lisa Strutz (APHC); Donald Dempsey (CVS Health); and Peter Carbrey (VA) in the supporting materials of the docket for this final rulemaking (EPA–HQ–RCRA–2007–0932).

[334] See the email correspondence from Lisa Strutz (APHC) to Kristin Fitzgerald (EPA), dated February 9, 2017, in the supporting materials of the docket for this final rulemaking (EPA–HQ–RCRA–2007–0932).

[335] December 1994, RCRA Online #13718.

[336] Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788.

[337] Note that since this Q&A was issued, EPA issued guidance indicating that epinephrine salts are not included in the scope of the P042 listing and therefore, most, if not all, medical applications of epinephrine are not P042 (October 15, 2007; RCRA Online #14778).

minimize the potential for exposures of healthcare workers to the sharps, which may be contaminated with bloodborne pathogens, as well as to the contents of the syringes.

The preamble to the proposed rulemaking also noted that sharps containers containing syringes are typically autoclaved prior to disposal. EPA expressed concern that the residues remaining in the syringes could be aerosolized during autoclaving and inadvertently expose workers to the aerosolized hazardous waste residues, posing risks via pulmonary exposure to those present during venting of the autoclave. Research suggests that autoclaving may even increase the toxicity of certain drugs.[338] As a result, EPA requested comment on whether it is necessary to place a limit on the volume of residue or the volume of the syringe to which this new provision would apply or whether any other conditions would be appropriate.

2. Summary of Comments

As noted above, commenters generally supported EPA's goal of codifying new standards for defining when containers are considered empty, including syringes. EPA received many comments requesting that the Agency clarify what it means when it uses the term ''dispensed.'' Further, they noted that although the proposed regulations used the term ''dispensed,'' in several cases in the preamble, we used the term ''fully dispensed'' and they requested clarification about which was correct. Commenters also noted that EPA used the term ''dispensed'' inappropriately and stated that the term ''administered'' was more appropriate. The Agency received mixed comments on whether any residues or contents should be left in the syringes when disposing of the syringe. In the case of autoclaving residues in syringes, almost all commenters agreed that the hazardous waste pharmaceutical residues should not be autoclaved. Some commenters believed that the contents should be disposed of in a gauze pad or equivalent while others argued that this was in contradiction to NIOSH recommendations for minimizing exposure to hazardous drugs. Some commenters were comfortable with leaving contents in the syringes, suggesting that would be in compliance with OSHA [339] and DOT.[340]

3. Final Rule Provisions

We have made two substantive changes to this section of the regulations that define when syringes are considered empty for the sake of RCRA regulation. First, EPA agrees with commenters that we used the term ''dispensed'' inappropriately in the proposed rulemaking. FDA defines ''dispense to patients to mean the act of delivering a prescription drug product to a patient or an agent of the patient.'' [341] Dispensed pharmaceuticals are then administered directly to the patient. EPA has revised the regulations to address commenters' concerns. In the final rule, to avoid confusion, when discussing syringes we do not use the term dispensed, fully dispensed, or administered. Instead, under the final rule, a syringe is considered empty and the residues are not regulated as hazardous waste provided the contents have been removed by fully depressing the plunger of the syringe. Thus, the final regulations convey an intent that is more similar to the proposed preamble use of the term ''fully dispensed.'' This reflects commenters' and EPA's desire to avoid the possibility of autoclaving syringes that may have a large portion of their hazardous waste pharmaceutical contents remaining.

Commenters affirmed EPA's concerns about aerosolizing the autoclaved hazardous waste in sharps containers and we have concluded that hazardous waste incineration of hazardous waste pharmaceuticals remaining in non-empty syringes is more appropriate. A recent literature search also supports this position. The NIOSH and the American Society of Hospital Pharmacists (ASHP) have both published articles regarding autoclaving of sharps. The 2004 NIOSH alert states, ''Do not place hazardous drug-contaminated sharps in red sharps containers that are used for infectious wastes, since these are often autoclaved or microwaved.'' [342] The ASHP article states, ''Sharps used in the preparation of hazardous drugs should not be placed in red sharps containers or needle boxes, since these are most frequently disinfected by autoclaving or microwaving, not by incineration, and pose a risk of aerosolization to waste-handling employees.'' [343]

A syringe with a fully depressed plunger will have a minute amount of residue and the syringe can be considered empty under the final rule. Thus the residue in the empty syringe (as well as the syringe) will not be regulated as hazardous waste. A syringe that does not have a fully depressed plunger could have anything from a small amount to 99% of hazardous waste pharmaceutical contents still left in it. Therefore, we have concluded that it is impracticable to impose an alternate bright line for determining whether a partially administered syringe is empty. Further, we concur with ASHP and NIOSH regarding concerns about the safety of autoclave operators and believe the standard in this final rule will help prevent exposing workers to volatilized hazardous waste pharmaceutical residues during the autoclaving process.

The second substantive change we made in the final rule is to clarify that if a syringe contains a pharmaceutical that is a hazardous waste and it is not empty because the plunger is not fully depressed, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart as well as any applicable federal, state, and local requirements for sharps containers and medical or regulated waste. We note that the new empty syringe provisions being finalized today supersedes the previous EPA interpretations expressed in guidance memos in December 1994 and April 2008.[344] [345]

We note that a syringe can become empty in three ways: (1) Fully depressing the plunger of the syringe by administering the contents of the syringes to a patient, or (2) fully depressing the plunger by injecting the contents of the syringe into another delivery device such as an IV bag, or (3) fully depressing the plunger of the syringe by emptying the remaining contents into a hazardous waste collection container.

[338] Daughton CG, Drugs and the Environment: Stewardship & Sustainability, National Exposure Research Laboratory, Environmental Sciences Division, US EPA, Las Vegas, NV; NERL–LV–ES 10/081, EPA/600/R–10/106; September 2010 (*https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryID=228503*).

[339] OSHA Title 29 CFR 1910.1030 Bloodborne Pathogens.

[340] DOT Title 49 CFR 172.343 subpart D—Marking; 172 subpart E—Labeling Standards; 172.432 Subpart E.

[341] See 21 CFR 208.3.

[342] NIOSH. ''Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings.'' Publication Number 2004–165, Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), Cincinnati, OH, 2004. 58 pp; *http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf.*

[343] ASHP. ''ASHP guidelines on handling hazardous drugs.'' American Journal of Health-System Pharmacy 2006, 63:1172–1193; *http://dx.doi.org/10.2146/ajhp050529.*

[344] December 1994, RCRA Online #13718.

[345] Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788.

4. Consultation With OSHA

As part of the final rule process, EPA consulted with OSHA to gain a better understanding of its Bloodborne Pathogens standard and how it interacts with other regulations for the disposal of sharps and the contents within the syringes. The Bloodborne Pathogens standard states that ''[u]niversal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.'' [346] It also states that disposal of a sharp shall be done ''immediately or as soon as feasible.'' [347] Further, OSHA requires that containers for contaminated sharps shall be ''easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can reasonably anticipated to be found.'' [348] When workers travel to a remote location to discard a sharp, it increases the possibility of an accidental needlestick, increases the chances that needles and other sharps will be improperly discarded, and creates potential hazards for other staff members. The determination of whether or not a sharps disposal container is as close as feasible should be made on a case-by-case basis by OSHA.[349]

Therefore, the practice of emptying the contents of the syringe would not violate the OSHA standard if the containers are as close as feasible. Any related work practices must also be such that they do not create additional hazards to workers (*e.g.,* containers are located in close proximity to the work area to avoid employees travelling with used sharps to disposal receptacles located outside the point of use). Furthermore, nothing in this new subpart requires workers to recap needles or other sharps, or otherwise manually manipulate the sharp or needle during emptying, such as unscrewing the needle from the syringe.

As part of this consultation, OSHA addressed the issue of waste disposal. OSHA's Bloodborne Pathogens compliance directive states: ''[W]hile OSHA specifies certain features of the regulated waste containers, including appropriate tagging, the ultimate disposal method (landfilling, incinerating, and so forth) for medical waste falls under the purview of the EPA and possibly State and local regulations'' (''Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories'' (1910.1030(d)(4)(iii)(C))).[350]

The Agency also received comment that we should recommend the extra protective step that all syringes/sharps be incinerated. Any sharps container that contains hazardous waste must be treated to meet the LDR requirements in part 268. In most cases, the LDR treatment standard for hazardous waste pharmaceuticals is incineration. On the other hand, if a sharps container does not contain hazardous waste pharmaceuticals because all the syringes have been emptied by fully depressing the plunger, then the RCRA hazardous waste regulations would not apply to these sharps containers (although these sharps containers are still solid wastes).

Regardless of whether sharps containers have regulated hazardous waste pharmaceutical residues, they could contain bloodborne pathogens or other infectious materials. Thus, OSHA's Bloodborne Pathogens standard requires that ''disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.'' [351] Many states have medical waste regulations that require the treatment of regulated medical waste, including sharps containers, to render it non-infectious, which is often achieved by autoclaving, prior to disposal as solid waste.

D. Other Containers, Including Delivery Devices (§ 266.507(c) & (d))

1. Summary of Proposal

EPA proposed that the residues remaining in other types of unused or used containers, including delivery devices, such as IV bags and tubing, inhalers, aerosols, nebulizers, tubes of ointments, gels, or creams, would be regulated as hazardous waste if the residues are acute or non-acute hazardous waste. In some cases, such as with IV bags, the volume of hazardous waste being disposed is much larger than with residues contained in syringes or unit-dose containers. It is extremely difficult to determine how much residue remains in tubes of ointments, gel, or cream. In the case of aerosols, it would be inadvisable to remove the contents of the container. Since EPA proposed that hazardous waste pharmaceuticals managed under subpart P would not be counted towards a facility's generator category, we argued that managing these residues and containers as hazardous waste under the proposed provisions should not pose the same burden that generators had been facing in with keeping track of the monthly amount of residues in containers that are not ''RCRA empty.''

2. Summary of Comments

Comments were mixed in this section. Some commenters agreed with EPA that it is difficult to determine if containers such as inhalers, aerosol cans, tubes of ointments, gels, or creams meet the RCRA empty standards within § 261.7 and, therefore, managing them under the streamlined requirements of subpart P would be protective. Other commenters wanted EPA to allow these other containers to continue to meet the definition of empty within § 261.7 or develop specific empty container standards for them within subpart P. One commenter recommended that EPA revise the regulations to state that IV bags and their tubing, inhalers, aerosols, nebulizers, tubes of ointments, and gels or creams are RCRA empty and not subject to hazardous waste regulations if they contain non-acute hazardous waste and their contents are fully administered.

3. Final Rule Provision

In response to comments, the final rule contains an empty container standard for IV bags separate from other containers, including delivery devices. The Agency stated in the proposal that it is very hard to determine if aerosols, tubes of ointments, gels and creams, inhalers, and nebulizers are empty due to their containers and contents. As commenters pointed out, this is not the case for IV bags and tubing since they are transparent and the liquids inside can be easily observed.

Taking approaches suggested from commenters, EPA is finalizing in § 266.507(c) that an IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. In cases where the IV bag has not been fully administered and the IV bag held non-acute hazardous waste pharmaceuticals, then IV bag can be shown to be empty and the remaining residues not regulated as hazardous waste per § 261.7(b)(1). If an IV bag is not empty through either of these means because it either has not been fully

[346] See 29 CFR 1910.1030(d)(1).

[347] See 29 CFR 1910.1030(d)(4)(iii)(A)(*1*).

[348] See 29 CFR 1910.1030(d)(4)(iii)(A)(*2*)(*i*).

[349] OSHA Compliance Directive CPL 02–02–069 Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens *https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-069.pdf.*

[350] Ibid.

[351] See 29 CFR 1910.1030(d)(4)(iii)(C).

administered or cannot meet the requirements of § 261.7(b)(1) or because it contained an acute hazardous waste pharmaceutical, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart.

In the final rule, EPA has also altered the requirements for other types of containers including delivery devices. Commenters pointed out that a healthcare facility should not be precluded from proving that these containers meet the RCRA-empty standards in § 261.7 simply due to the type of container or contents. EPA agrees with the commenters that these types of containers which held non-acute hazardous waste pharmaceuticals should be able to use the RCRA empty container standards under § 261.7 and has changed the final rule to allow this. If the containers meet the RCRA empty standard under § 261.7 then the non-acute hazardous waste pharmaceutical residues (and the container) are not regulated as hazardous waste and can be managed as solid waste.

If these other containers, a category that includes but is not limited to inhalers, aerosols, nebulizers, tubes of ointments, gels or creams, once held an acute hazardous waste pharmaceutical or if they held a non-acute hazardous waste pharmaceutical but cannot meet the RCRA empty container standard of § 261.7, then the residues of these hazardous waste pharmaceuticals (and their containers) must be managed as non-creditable hazardous waste pharmaceuticals under this subpart.

4. Comments and Responses

One commenter was concerned that managing all other containers that held hazardous waste pharmaceuticals as non-empty could cause a VSQG healthcare facility to bump up in generator category to an LQG. This will no longer be a concern since a healthcare facility now has the option to prove that their other containers that held non-acute hazardous waste pharmaceuticals meet the RCRA empty container standards in § 261.7 and they can manage the residues (and containers) as non-hazardous waste. Otherwise, if these other containers are not considered empty, then the residues (and containers) must be managed as non-creditable hazardous waste pharmaceuticals under subpart P and hazardous waste pharmaceuticals managed under subpart P do not count towards determining the generator category. Further, we note that a healthcare facility can use the new empty container provisions in § 266.507 when determining whether they generate enough hazardous waste to become subject to part 266 subpart P.

XVI. Shipping Standards for Hazardous Waste Pharmaceuticals (§§ 266.508 and 266.509)

A. Shipping Non-Creditable Hazardous Waste Pharmaceuticals From Healthcare Facilities to Treatment, Storage, and Disposal Facilities (§ 266.508(a))

1. Summary of Proposal

Under part 266 subpart P, hazardous waste pharmaceuticals generated in a healthcare facility fall into two categories: (1) Non-creditable hazardous waste pharmaceuticals (*e.g.,* partially administered for patient care), and (2) potentially creditable hazardous waste pharmaceuticals (*e.g.,* unused, unadministered). This section discusses the proposed requirements for shipping non-creditable hazardous waste pharmaceuticals. For information regarding the shipment of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and reverse distributors, see section XVI.D. of this preamble.

Generally, non-creditable hazardous waste pharmaceuticals differ from potentially creditable hazardous waste pharmaceuticals in that they have been partially administered and often are not in their original packaging. In addition, since there is not a reasonable expectation that prescription non-creditable hazardous waste pharmaceuticals are eligible to receive manufacturer credit, they are shipped off site to a TSDF rather than a reverse distributor. Due to concerns that a healthcare facility might send all of its hazardous waste pharmaceuticals to a reverse distributor even if there is not a reasonable expectation of receiving manufacturer credit—essentially using the reverse distributor as a TSDF—EPA proposed that non-creditable hazardous waste pharmaceuticals generated at healthcare facilities, when shipped off site, must be shipped to a designated facility (*e.g.,* an interim status or permitted hazardous waste TSDF), as was required under part 262 (unless the healthcare facility has interim status or a RCRA permit to store or treat hazardous waste and chooses to store or treat the non-creditable hazardous waste pharmaceuticals on site instead of shipping them to a designated facility).

Specifically, EPA proposed that healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a designated facility for treatment or disposal must continue to comply with the existing Department of Transportation (DOT) pre-transport requirements for packaging, labeling and marking, and that the non-creditable hazardous waste pharmaceuticals must continue to be shipped using a hazardous waste transporter and be tracked with a hazardous waste manifest. However, to avoid unnecessarily burdening the healthcare facility staff, who the Agency assumes are typically unfamiliar with RCRA, EPA proposed that the hazardous waste numbers (often called hazardous waste codes) are not required to be entered into the hazardous waste manifest for non-creditable hazardous waste pharmaceuticals. In lieu of hazardous waste codes, EPA proposed that the words, ''hazardous waste pharmaceuticals'' must be entered in the ''special handling and additional information'' box on the manifest (this box was called Item 14 at the time of the proposal).

We also proposed that all existing RCRA recordkeeping requirements regarding hazardous waste manifesting as well as all applicable DOT shipping requirements continue to apply to healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF for treatment or disposal (see section X.K).

2. Summary of Comments

Comments on this section of the proposed rulemaking were mixed. Commenters generally agreed with the proposed standards for packaging, labeling, marking, placarding, and shipping papers. Adverse comments were mostly in regard to the decision to not require individual waste codes on the manifest for a healthcare facility sending non-creditable hazardous waste pharmaceuticals to a TSDF for disposal. In fact, commenters were generally concerned about the proposal to not require individual waste codes anywhere in the management standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals. Whether the comments were regarding waste code determinations, labeling containers with waste codes, or including waste codes on the manifest, the overarching concern was that TSDFs would not know the specific contents of shipments received, resulting in an increase to their burden, and possibly would be detrimental to human health and the environment. Therefore, the adverse comments regarding the lack of a proposed requirement to input individual waste codes on the manifest are applicable more broadly to the subject of whether or not the

information that individual waste codes convey should somehow be provided to a TSDF by the healthcare facility shipping non-creditable hazardous waste pharmaceuticals.

Some states agreed with the proposal to not require individual waste codes on the manifest, while others commented that it is important to have waste codes at all steps where they would otherwise be required under previous RCRA regulations. Comments from waste management companies were also mixed, with some supporting the proposal to not require individual hazardous waste codes on the manifest, while others agreed with the proposal but suggested including a profile of likely constituents to alert TSDFs of potential waste contents to aid in LDR compliance.

Those waste management companies that disagreed with the proposed standards cited the added burden imposed by not knowing the specific waste constituents included in a shipment, which would make compliance with LDR standards more difficult. They were primarily concerned about the added burden of having to either begin testing their ash for wastes that have a numeric treatment standard, or modify existing testing protocols. One commenter from the healthcare industry disagreed with the elimination of individual hazardous waste codes on manifests from healthcare facilities shipping non-creditable hazardous waste pharmaceuticals, arguing that healthcare workers are capable of making accurate hazardous waste determinations. They also stated that hazardous waste codes are integral to properly managing hazardous waste. One waste management commenter stated that continuing to require waste codes on LDR notices altogether negates any actual relief because healthcare facilities will have to determine appropriate waste codes before sending hazardous waste pharmaceuticals off site to a TSDF whether or not they are required on the container label or manifest.

One reverse distributor also agreed with the proposed standards under the condition that the Agency agree that pharmaceuticals being sent to a reverse distributor are not waste.

3. Final Rule Provisions

The agency is finalizing the majority of the proposed requirements in this section. Before being shipped off site, all shipments of non-creditable hazardous waste pharmaceuticals must comply with applicable DOT pre-transport requirements for packaging (49 CFR parts 173, 178, and 180), labeling (49 CFR part 172 subpart E), and marking (49 CFR part 172 subpart D). There are, however, three notable changes being finalized.

First, § 266.508(a)(1)(v) has been removed and a healthcare facility shipping hazardous waste pharmaceuticals to a TSDF for disposal must instead comply with § 266.508(a)(2)'s manifest requirement to meet DOT's shipping papers requirement.

Second, the agency has decided to modify the proposal to not require any hazardous waste codes in Item 13 (Waste Codes) of the hazardous waste manifest for shipments of non-creditable hazardous waste pharmaceuticals being sent to a TSDF, and write the words ''Hazardous Waste Pharmaceuticals'' in Item 14 (Special Handling Instructions and Additional Information). The Agency is instead finalizing a requirement to write only one waste code— ''PHARMS''—in Item 13, and not impose any requirements for what must be written in Item 14. After further consideration of the impacts this proposed requirement would impose on implementation and data collection, the Agency decided it had to be modified. During the development of this rule, the Agency has also been developing the electronic manifest system (e-Manifest) which requires that some code be written in Item 13. We chose the PHARMS code because it both meets the required number of characters and communicates the nature of the waste. Since the waste will now be sufficiently characterized in Item 13, the Agency feels there is no longer the need to require the words ''hazardous waste pharmaceuticals'' in Item 14.

This new PHARMS code is for manifesting and reporting purposes only and is not an official EPA hazardous waste code. Because it will be written in the same place as other official EPA hazardous waste codes, it may also be referred to colloquially as a ''hazardous waste code.'' However, it does not modify any existing LDR treatment standards, nor does it enact any new or alternate LDR treatment standards for hazardous waste pharmaceuticals. Many commenters throughout the proposed rulemaking suggested that EPA promulgate an alternative treatment standard of the ''CMBST'' code specifically for hazardous waste pharmaceuticals with numeric treatment standards. The agency considered incorporating these suggestions into the proposed rulemaking, but did not receive the necessary data to support such an action. The Agency does, however, generally agree that implementing a new alternative treatment standard for hazardous waste pharmaceuticals might help mitigate burden on the regulated community while remaining protective of human health and the environment. The Agency remains open to considering the addition of an alternative treatment standard for hazardous waste pharmaceuticals in future rulemakings.

Although the Agency is now requiring the PHARMS code in Item 13 for shipments of non-creditable hazardous waste pharmaceuticals from a healthcare facility to a TSDF, hazardous waste codes are not required on the manifest, which was preferred by some commenters. As a result, TSDFs treating hazardous waste pharmaceuticals will have to assume that shipments of hazardous waste pharmaceuticals contain the few that have numeric treatment standards in order to demonstrate compliance with LDRs.

The third change made to the regulations was to modify the regulatory language in § 266.508(a) slightly to clarify that shipments of non-creditable hazardous waste pharmaceuticals being sent from a healthcare facility for disposal must be sent to a designated facility and accompanied by a hazardous waste manifest. As part of the manifest requirements in 40 CFR part 262 subpart B, shipments of non-creditable and evaluated hazardous waste pharmaceuticals must be sent to a designated facility via a hazardous waste transporter. One commenter noted that the proposed language could have been interpreted to mean that such shipments are also allowed to go elsewhere, which was not the Agency's intent.

Another substantive change to the regulatory language that resulted from incorporating commenters' concerns was to remove the requirements for shipping papers in § 266.508(a)(1)(v). A commenter pointed out that the requirement is unnecessary given the requirements in § 266.508(a)(2) and the Agency agreed. Section 266.508(a)(1)(v) would have required a healthcare facility shipping non-creditable hazardous waste pharmaceuticals to a TSDF to prepare shipping papers in accordance with 49 CFR 172 subpart C; however, the subsequent paragraph (§ 266.508(a)(2)) outlines the requirements for manifesting a shipment of non-creditable hazardous waste pharmaceuticals. Requiring both shipping papers and a manifest is redundant and could have possibly resulted in confusion and contradictory requirements. The hazardous waste manifest requirements, if complied

with, duly satisfy DOT's shipping paper requirements.

The wording in § 266.508(a) was modified slightly to clarify that healthcare facilities and reverse distributors that ship non-creditable and evaluated hazardous waste pharmaceuticals off site, respectively, are required to send them to a designated facility.

Finally, to be consistent with the Hazardous Waste Generator Improvements final rule, we have added paragraph 266.508(a)(1)(iii)(C) to mirror § 262.32(d), which addresses marking for lab packs. Specifically, lab packs of hazardous waste pharmaceuticals that will be treated using the alternative treatment standard of incineration, as allowed by § 268.42(c), do not have to marked or labeled with EPA hazardous waste numbers. However, lab packs that contain D004 (arsenic), D005 (barium), D006 (cadmium), D007 (chromium), D008 (lead), D010 (selenium) or D011 (silver), the EPA hazardous waste number must be marked or labeled with the EPA hazardous waste numbers (or electronic means may be used). These specific metals must be identified because § 268.42(c)(4) requires any incinerator residues from lab packs that contain any of these specific metals to undergo further treatment prior to land disposal.

B. Shipping Evaluated Hazardous Waste Pharmaceuticals From Reverse Distributors to Treatment, Storage, and Disposal Facilities (§ 266.508(a))

1. Summary of Proposal

For reverse distributors, once a potentially creditable hazardous waste pharmaceutical has been evaluated and it has been determined that it is not destined for another reverse distributor for further evaluation or verification of credit, EPA proposed that the hazardous waste pharmaceuticals be referred to as ''evaluated hazardous waste pharmaceuticals.'' As with shipping non-creditable hazardous waste pharmaceuticals, when evaluated hazardous waste pharmaceuticals are shipped off-site, EPA proposed that they must be shipped in accordance with the existing DOT pre-transport requirements under 49 CFR parts 172–80 for packaging, labeling, marking, placarding, and shipping papers. We also proposed that they must be shipped in accordance with the existing RCRA manifest requirements of 40 CFR part 262 subpart B, which requires all relevant waste codes be listed in Item 13 and that they be shipped via a hazardous waste transporter to a designated facility. This continues current practices under existing regulations for this type of hazardous waste pharmaceutical and does not represent an increase in burden. EPA argued that the use of a hazardous waste manifest and a hazardous waste transporter are appropriate at this point for two reasons. First, once credit for the hazardous waste pharmaceuticals has been verified, the potential for mismanagement is greater because evaluated pharmaceuticals no longer retain any value and will cost the reverse distributor money to dispose. Second, TSDFs are accustomed to receiving hazardous waste via a hazardous waste transporter with a hazardous waste manifest and it would place administrative and compliance burdens on the receiving TSDF to accept shipments of hazardous waste with alternative tracking.

EPA proposed that a reverse distributor must list all appropriate hazardous waste codes on the manifest when shipping evaluated hazardous waste pharmaceuticals to a TSDF. This differs from the requirements for a healthcare facility shipping non-creditable hazardous waste pharmaceuticals to a TSDF. Unlike non-creditable hazardous waste pharmaceuticals generated at a healthcare facility, hazardous waste pharmaceuticals received by reverse distributors are typically in the manufacturer's original, intact, and labeled packaging (if not, they are likely non-creditable hazardous waste pharmaceuticals and should be sent to a TSDF), so the information needed to determine the appropriate hazardous waste codes once evaluated should be readily available to the reverse distributor. Also, reverse distributors are currently required to include hazardous waste codes on the manifest and it is expected that they have the necessary expertise in the management of these hazardous wastes that healthcare personnel lack. Under the reverse distributor standards in § 266.510(c)(10)(ii), EPA also proposed that reverse distributors must keep copies of hazardous waste manifests for three years from the date evaluated hazardous waste pharmaceuticals are shipped to a TSDF.

2. Summary of Comments

Comments in this section were mixed. Many commenters addressed the standards for healthcare facilities sending shipments of non-creditable hazardous waste pharmaceuticals to a TSDF but did not specifically mention the standards for shipping evaluated hazardous waste pharmaceuticals to a TSDF. Nevertheless, many of the concerns expressed by commenters with the standards for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF are relevant because the standards in § 266.508 are the same for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals as they are for reverse distributors shipping evaluated hazardous waste pharmaceuticals, with the exception of § 266.508(a)(2)(i) and (ii). The few that commented directly on the proposed shipping standards for evaluated hazardous waste pharmaceuticals being shipped from a reverse distributor to a TSDF agreed with the standards as proposed.

Reverse distributor and waste management industry commenters were in agreement with the proposed standards for shipping evaluated hazardous waste pharmaceuticals to a TSDF, but to reiterate, did not agree with the standards for shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility to a TSDF (no waste codes on the manifest). Many commenters on this section simply stated that waste codes should be included on a manifest, referring to the requirements in § 266.508(a)(2)(i) and (ii) which do not require waste codes on the manifest for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF. Since those standards only apply to healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF and not reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF, the agency assumes that those same commenters are generally in agreement with the requirement for reverse distributors shipping evaluated hazardous waste pharmaceuticals to a TSDF to comply with all of the manifest standards in 40 CFR part 262 subpart B, which includes a requirement to list all applicable EPA hazardous waste codes on the manifest.

3. Final Rule Provisions

The Agency is finalizing the standards for shipping evaluated hazardous waste pharmaceuticals from a reverse distributor to a TSDF with minor changes. First, § 266.508(a)(1)(v) has been removed. The standards for shipping papers for reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF are contained instead in subparagraph § 266.508(a)(2) (*i.e.,* the manifest).

Second, the clarification to the regulatory language mentioned previously, which specifies that non-creditable hazardous waste

pharmaceuticals must go only to a TSDF, also applies to evaluated hazardous waste pharmaceuticals. As mentioned above, commenters were concerned that the proposed regulatory language appeared to make it optional for a reverse distributor to ship evaluated hazardous waste pharmaceuticals to a TSDF for disposal, although it was not intended to read that way. The finalized regulatory language was modified to clarify that a reverse distributor shipping evaluated hazardous waste pharmaceuticals must send them to a TSDF for treatment and disposal. This change pertains to both evaluated pharmaceuticals being shipped from a reverse distributor as well as non-creditable hazardous waste pharmaceuticals being shipped from a healthcare facility.

To summarize, reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF for disposal are required to comply with all standards in § 266.508(a), which includes a requirement to list all applicable waste codes in Item 13 of the manifest, even though healthcare facilities sending non-creditable hazardous waste pharmaceuticals to a TSDF do not. They are not, however, required to write the word PHARMS in Item 13 or on the container label in addition to all other applicable waste codes.

C. Shipping Non-Creditable or Evaluated Hazardous Waste Pharmaceuticals for Import or Export (§§ 266.508(b) and 266.508(c))

1. Summary of Proposal

Under part 262, a healthcare facility or reverse distributor may not import hazardous waste pharmaceuticals unless it has a RCRA permit or interim status that allows it to accept hazardous waste from off site and complies with the requirements for importing hazardous waste in 40 CFR part 262 subpart H. Under part 266, EPA did not propose to change the regulations as they apply to the import of non-creditable or evaluated hazardous waste pharmaceuticals. Likewise, under part 262, a healthcare facility or reverse distributor may not export (non-creditable nor evaluated) hazardous waste pharmaceuticals unless it complies with requirements for exporting hazardous waste in 40 CFR part 262 subpart H. Under part 266, EPA did not propose to change the regulations as they apply to the export of (non-creditable or evaluated) hazardous waste pharmaceuticals.[352]

EPA requested comment on the likelihood that non-creditable hazardous waste pharmaceuticals that are shipped from a healthcare facility to a domestic TSDF, would then be exported to a TSDF in a foreign country. In addition, EPA did not anticipate that hazardous waste pharmaceuticals would be destined for transboundary shipments for purposes of recovery operations and therefore potentially subject to 40 CFR part 262 subpart H; however, we also requested comment on whether this is the case.

2. Summary of Comments

We received no comments on the proposed standards for importing and exporting non-creditable or evaluated hazardous waste pharmaceuticals.

3. Final Rule Provisions

Since part 266 subpart P was proposed, the hazardous waste import and export regulations under part 262 have been revised.[353] The export regulations which had been in part 262 subpart E are now in part 262 subpart H. Likewise, the import regulations which had been in part 262 subpart F are also now in part 262 subpart H. The requirements for both importing and exporting non-creditable hazardous waste pharmaceuticals are being substantially finalized as proposed. The only change being made from the proposed requirements is to update the reference to the revised part 262 regulations, in order to conform to the changes implemented in the Hazardous Waste Imports and Exports Improvement Rule. Whereas the proposed § 266.508(b) and (c) refer to the standards in 40 CFR part 262 subpart E and F, they now refer to 40 CFR part 262 subpart H.

D. Shipping Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.509).

1. Summary of Proposal

This section discusses the proposed requirements for shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility to a reverse distributor and between reverse distributors. The return of potentially creditable waste pharmaceuticals (hazardous and non-hazardous) to a reverse distributor can involve multiple shipping steps before the pharmaceuticals are transported for ultimate treatment and disposal. In comments on the 2008 Pharmaceutical Universal Waste proposal and in response to EPA's request for information,[354] reverse distributors described various scenarios. For example, a healthcare facility typically sends waste pharmaceuticals to the reverse distributor with which it has a contract. However, some manufacturers will only provide manufacturer credit after the pharmaceuticals have been returned to the reverse distributor with which the manufacturer has a contract. Thus, if the reverse distributor with which the healthcare facility has a contract differs from the reverse distributor with which the manufacturer has a contract, then the healthcare facility's reverse distributor must send the pharmaceuticals on to the manufacturer's reverse distributor for the manufacturer credit to be given to the healthcare facility. In some cases, a pharmaceutical manufacturer may require the reverse distributor to ship the pharmaceuticals back to them so they can perform the verification and issue credit themselves. The estimated amount of pharmaceuticals transported from reverse distributors to manufacturers for verification varies. Based on our request for information, reverse distributors indicated that the percent of potentially creditable hazardous waste pharmaceuticals transported to manufacturers ranged from an estimated 25 percent to 93 percent of total volume, depending on the contractual agreement between the reverse distributor and the manufacturer. The scenarios described previously occur routinely and are an integral part of the process by which manufacturers issue credit.

As explained in section IV.A, EPA proposed that all pharmaceuticals transported to reverse distributors for manufacturer credit are solid wastes, some of which would also be considered hazardous wastes. The finalized regulations have been modified, however, such that only prescription pharmaceuticals going through reverse distribution for manufacturer credit are solid wastes, while OTC pharmaceuticals going through reverse logistics are outside of this rule. Under the part 262 regulations, hazardous waste, including hazardous waste pharmaceuticals, must be manifested to a permitted or interim

[352] In the proposed rule we referenced part 262 subparts E and F when discussing this provision. Part 262 subparts E and F have since been replaced by part 262 subpart H; see the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

[353] See the final Hazardous Waste Export-Import Revisions rule, 81 FR 85696; December 31, 2016.

[354] See the survey of reverse distributors in docket number: EPA–HQ–RCRA–2007–0932–0158 through 0160.

status TSDF and shipped using a hazardous waste transporter to ensure the cradle-to-grave system of RCRA is maintained. However, compared to other hazardous wastes, EPA believes that the risk of environmental release posed by most potentially creditable hazardous waste pharmaceuticals during accumulation and transport is relatively low. The risk is low because of the form and packaging of most potentially creditable hazardous waste pharmaceuticals, which is typically in small, individually packaged doses (such as with many tablets and capsules) or small vials. These small volumes of individually wrapped or packaged pharmaceuticals, when aggregated in a larger container, are unlikely to spill or be released into the environment since they are essentially double-packed when transported to a reverse distributor. Potentially creditable hazardous waste pharmaceuticals that are in liquid and aerosol forms may pose more of a risk during accumulation and transport due to possible spillage or leakage, but the small quantities in which they are generated, along with the DOT packaging requirements of 49 CFR parts 173, 178, and 180, would likely mitigate this risk (see EPA's recommendation regarding liquids and aerosols in section XI.C.1). Further, the 2008 Pharmaceutical Universal Waste proposal specifically sought comment regarding the risks of transportation of hazardous waste pharmaceuticals and no commenters identified environmental risks.

Due to the low risk to human health and release to the environment, EPA proposed to allow potentially creditable hazardous waste pharmaceuticals to be shipped without a hazardous waste manifest and without the use of hazardous waste transporters when the healthcare facility is sending potentially creditable hazardous waste pharmaceuticals to a reverse distributor or when a reverse distributor is sending potentially creditable hazardous waste pharmaceuticals to another reverse distributor. The same DOT shipping requirements would continue to apply to shipments of potentially creditable hazardous waste pharmaceuticals (provided they are classified as DOT hazardous materials) that applied prior to this final rule. Nothing in this final rule changes how DOT shipping requirements apply to shipments of prescription pharmaceuticals to reverse distributors.

EPA proposed an alternate tracking method for potentially creditable hazardous waste pharmaceuticals—with two requirements in lieu of requiring a hazardous waste manifest and the use of hazardous waste transporters. First, EPA proposed that for each shipment, healthcare facilities and reverse distributors must provide in writing (via letter or electronic communication), advance notice of the intent to send a shipment to the receiving reverse distributor. We also proposed that the receiving reverse distributor must provide acknowledgement to the shipper that they received the advance notice. This requirement was intended to function like a manifest, tracking the potentially creditable hazardous waste pharmaceuticals en route to the reverse distributor. Second, EPA proposed that for each shipment, the receiving reverse distributor must provide confirmation to the healthcare facility or reverse distributor that initiated the shipment, that the shipment of potentially creditable hazardous waste pharmaceuticals has been received. The Agency proposed this requirement in direct response to concerns expressed by commenters over the lack of tracking of pharmaceutical waste in the 2008 Pharmaceutical Universal Waste proposal.

The Agency proposed that, if a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within seven calendar days, that the healthcare facility or reverse distributor that initiated the shipment must contact the shipper and the intended recipient promptly to (1) report that the confirmation was not received, and (2) to determine the status and whereabouts of the potentially creditable hazardous waste pharmaceuticals that were shipped.

The Agency proposed that if a healthcare facility or reverse distributor exports potentially creditable hazardous waste pharmaceuticals, it must generally comply with 40 CFR part 262 subpart E, except that it is not required to manifest the potentially creditable hazardous waste pharmaceuticals. The Agency also proposed that any person that imports potentially creditable hazardous waste pharmaceuticals, must comply with the proposed requirements for the shipment of potentially creditable hazardous waste pharmaceuticals, in lieu of the requirements for hazardous waste imports found at 40 CFR part 262 subpart F.[355]

[355] Part 262 subparts E and F have since been replaced by part 262 subpart H; see the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

EPA proposed to require healthcare facilities (§ 266.503(d)) and reverse distributors (§ 266.510(b)(4)) to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Specifically, we proposed that healthcare facilities and reverse distributors that initiate a shipment to a reverse distributor must keep (1) records of advance notification regarding shipments of potentially creditable hazardous waste pharmaceuticals, (2) delivery confirmation for three years after the shipment was initiated, and (3) shipping papers or bills of lading. The Agency argued that these records are necessary to ensure that potentially creditable hazardous waste pharmaceuticals reach their intended destination and are not diverted.

In most cases, retaining records for three years should be sufficient for inspection purposes; however, we proposed that the periods of retention would be automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator. The Agency sought comment on whether additional recordkeeping is necessary to document the cases when the reverse distributor does not receive a shipment of potentially creditable pharmaceuticals within seven calendar days and the steps must be taken to locate the shipment.

2. Summary of Comments

The majority of comments focused on the provision to allow shipments of potentially creditable hazardous waste pharmaceuticals to be sent via carrier (*i.e.,* not by hazardous waste transporter), the requirements for advance notice of shipment and delivery confirmation, and the time frame within which delivery confirmation is received before the shipper must take action to locate a missing shipment.

Comments on whether the Agency should allow shipments of potentially creditable hazardous waste pharmaceuticals to be sent via carriers such as USPS, UPS, and FedEx without a manifest were mixed. Only a few states commented on this provision specifically. The majority of states agreed that shipping via carriers provides sufficiently low risk of release or illicit diversion. However, one state was concerned that we did not propose a requirement to reconcile the contents of what was shipped with what was received. That same commenter, as well as a handful of others, also voiced concern about whether DOT regulations would permit hazardous waste

pharmaceuticals to be lawfully shipped via carrier in the first place. Manufacturers, waste management companies, healthcare industry groups, and pharmacy trade associations were all generally in agreement with the proposed shipping standards for potentially creditable hazardous waste pharmaceuticals.

One of the primary points of contention in this subsection was the proposed standard that would require a shipper to provide advance notice of its intent to ship potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Reverse distributors objected, arguing it would impart undue financial and administrative burden, which would require them to hire additional staff to adequately process advance notices, track, and confirm the delivery of thousands of shipments per year. A national trade association of retailers expressed similar concerns. They did not support the proposed advance notice and delivery confirmation requirements and argued the requirements would add undue burden due to the high volume of shipments large retailers send per year. The commenters suggested that the proposed notification and delivery standards either be removed or modified to match current inventory and accounting practices.[356] One pharmaceutical manufacturer also disagreed with the proposed standard, but gave no reasoning as to why, other than they thought it was unnecessary. States generally agreed with the proposed standard and a few suggested the Agency finalize additional requirements like reconciling what was in the notice with the contents of the package after delivery which would also require an inventory of each container. One state was concerned about its ability to confirm that a shipment has reached its final destination (TSDF) in scenarios where a shipment is sent to an out-of-state reverse distributor or a second reverse distributor. Healthcare facilities and pharmacist trade groups either agreed with the proposed standards or did not mention these standards specifically. One pharmacist trade group said they want some clarification about what constitutes advance notice.[357]

There were numerous comments both in agreement with and opposition to the proposed requirement to take action to locate a shipment of potentially creditable hazardous waste pharmaceuticals if no delivery confirmation is received within seven days from the day the shipment leaves the shipper's facility. Most comments were related to the time frame within which the shipper must receive delivery confirmation, but a few commenters from the retail and reverse distribution industries opposed the requirement altogether because of the added financial, procedural, and administrative burden they argue it would impose. Many commenters were concerned that the proposed time frame was too short and would result in frequent situations in which the shipper would be required to undertake efforts to locate a shipment that eventually arrives without intervention sometime after the seven days. Some commenters noted that seven days is the minimum transit time for a standard cross-country shipment under ideal conditions, which provides no buffer for unforeseen circumstances that may cause delays such as inclement weather or some other service disruption. One state suggested a 35-day time frame as an alternative because it would be the same as the time frame specified for delivery confirmation of universal waste shipped via carrier per the universal waste rule.[358]

There were limited comments regarding the proposed standards for healthcare facilities and reverse distributors importing and/or exporting potentially creditable hazardous waste pharmaceuticals. The only concern raised was whether shipments sent to or received from U.S. territories (*e.g.,* Puerto Rico, Guam) are considered exports/imports, and if so, they recommended that the Agency confer with other appropriate federal agencies and their reverse distributor contractors.

3. Final Rule Provisions

In response to comments, the Agency has made several changes to the proposed standards for shipping potentially creditable hazardous waste pharmaceuticals. First, we have made a minor change to make our regulatory language more consistent with DOT's terminology and clarify to whom the regulations refer. Specifically, in § 266.509(c), we changed the word shipper to carrier. As originally proposed, the word shipper could have been interpreted to refer to the party that prepares and offers a shipment of potentially creditable hazardous waste pharmaceuticals, whereas the regulations apply to the company providing transportation of a shipment of potentially creditable hazardous waste pharmaceuticals. To clarify, a shipper is the party that prepares and offers a shipment to be transported by a carrier.

Second, we have eliminated the requirement in § 266.509(a)(1) for a healthcare facility or reverse distributor that ships potentially creditable hazardous waste pharmaceuticals to provide advance notice of the shipment. The Agency believes that the proposed advance notice requirement goes beyond the manifest requirements and would have resulted in undue burden on both the shippers and the receiving reverse distributors while only nominally more protective of human health and the environment. We would, however, recommend that, as a best practice, shippers of potentially creditable hazardous waste pharmaceuticals provide advance notice to the recipients to the extent practicable. Conforming changes have been made throughout the regulations that reflect the elimination of the requirement to provide advance notice of shipments of potentially creditable hazardous waste pharmaceuticals.

Third, the proposed requirement that a reverse distributor that receives a shipment of potentially creditable hazardous waste pharmaceuticals must provide delivery confirmation to the facility that initiated the shipment is being finalized as proposed, with the added clarification that the shipment is not considered delivered until it is under the custody and control of the receiving reverse distributor. Requiring delivery confirmation provides assurance that the shipment was actively received by the reverse distributor and the chain of custody maintained. Without this confirmation from the receiving reverse distributor personnel, it is possible for a shipment to be delivered to the destination location but not necessarily taken into their custody and control (*e.g.,* left unattended outside the building).

Under this final rule, healthcare facilities and reverse distributors may use carriers, such as USPS, UPS, and FedEx for shipments of potentially creditable hazardous waste pharmaceuticals to and between reverse distributors, as long as personnel are present to receive and take control of the shipments upon arrival. EPA believes that carriers are able to provide safe shipment since these potentially creditable hazardous waste pharmaceuticals present low risk of release during transport.

In addition, all of the carriers EPA is aware of offer services that meet the delivery confirmation requirement.

[356] See comment number EPA–HQ–RCRA–2007–0932–0295.

[357] See comment number EPA–HQ–RCRA–2007–0932–0284.

[358] See comment number EPA–HQ–RCRA–2007–0932–0238.

Delivery confirmation can be paper-based or electronic and must indicate that personnel from the receiving reverse distributor have taken the shipment into their custody and control. One way for healthcare facilities and reverse distributors sending shipments of potentially creditable hazardous waste pharmaceuticals to a reverse distributor via carrier may comply with the delivery confirmation requirement would be to utilize the delivery confirmation service provided by most carriers (*e.g.,* Return Receipt from USPS, Delivery Confirmation from UPS, or Signature Proof of Delivery from FedEx). Typically, personnel at the receiving reverse distributor will sign for a shipment confirming that it is now in their custody and control. That signature will then be made available to the shipper, which satisfies the delivery confirmation requirement.

EPA has learned that some stakeholders use alternative electronic tracking methods outside of those offered by carriers. One alternative electronic tracking method is to apply barcoding on pharmaceutical packaging or on containers containing multiple pharmaceutical packages. A barcode is a unique identifier that links the container to a database with detailed information about its contents and includes the exact quantities of each item included in the shipment (inventories). Typically, when a reverse distributor receives a barcoded shipment, it will scan the barcodes upon receipt, and the sender will receive electronic notification that the shipment has arrived at its destination and is in the custody and control of the reverse distributor. This type of barcode tracking would meet the delivery confirmation requirement of this final rule. Another type of alternative electronic tracking that would satisfy the delivery confirmation requirement is radio frequency identification (RFID). Similar to barcodes, RFID tags are placed inside a container, or integrated into the container itself, and linked to inventories and other detailed information. The RFID tags are read when they arrive at the receiving facility and that information is made available to the shipper, confirming that the shipment has been taken into the custody and control of the receiving reverse distributor.[359]

Fourth, we have eliminated the regulatory language that was proposed in § 266.509(a)(2). We had referenced the DOT pre-transport regulations that apply to shipments of non-creditable hazardous waste pharmaceuticals. However, in 2016, DOT revised the Hazardous Materials Regulations (HMR) as they apply to shipments of items in reverse logistics.[360] As a result, many of the DOT pre-transport requirements we had referenced no longer apply to shipments of hazardous materials in reverse logistics. In response, we have eliminated the reference to the DOT pre-transport requirements and instead modified our final regulations in § 266.509(a) to refer to the entire HMR, rather than specific provisions within the HMR. Healthcare facilities and reverse distributors that send shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors need only comply with the applicable sections of DOT's HMR for shipments in reverse logistics.

We note that healthcare facilities and reverse distributors must meet the applicable DOT hazardous material shipping requirements only when shipping potentially creditable hazardous waste pharmaceuticals that meet the definition of DOT hazardous material. Under the DOT regulations, a RCRA hazardous waste that requires a manifest is considered a Class 9 hazardous material. Potentially creditable hazardous waste pharmaceuticals do not require a manifest; therefore, the DOT shipping requirements will apply when potentially creditable hazardous waste pharmaceuticals are shipped to reverse distributors only when the hazardous wastes are otherwise classified as DOT hazardous materials (*i.e.,* DOT hazard class 1–8). We added regulatory language (that was adapted from the Universal Waste regulations) to reflect this.

Fifth, the Agency has finalized the requirement that the shipper of potentially creditable hazardous waste pharmaceuticals must receive a delivery confirmation from the reverse distributor, however, the Agency has extended the time frame within which the shipper must receive the delivery confirmation from the reverse distributor from the proposed seven days to 35 days, after which the shipper must begin taking actions to locate a shipment if the delivery confirmation is not received. Many commenters suggested 14 days as an alternative to the proposed seven-day time frame, while others suggested far longer or to eliminate the time frame altogether. Upon reconsideration of the issue and how it pertains more generally to other RCRA hazardous waste programs, the Agency decided that 35 days was more appropriate, while remaining duly protective of human health and the environment and reducing burden on the regulated community. The time frame to receive delivery confirmation for shipments of potentially creditable hazardous waste pharmaceuticals is also now in line with the standard for delivery confirmation under universal waste, which is also 35 days. In addition, one of the overarching goals of this rule was to enact universal waste-like standards for hazardous waste pharmaceuticals, to which this provision conforms. Some states wanted the Agency to go further and require that the EPA Regional Administrator be notified whenever a shipment has not been received within the allotted time frame. Although the Agency understands the utility of such a provision, it is not being adopted because of the added burden it would impose on both states and the regulated community. In addition, the Agency prefers, in this instance, to allow states the flexibility to implement more stringent reporting standards for missing shipments of potentially creditable hazardous waste pharmaceuticals according to their individual circumstances and preferences.

After considering these comments, the Agency determined that it is necessary to require a delivery confirmation in order to ensure shipments of potentially creditable hazardous waste pharmaceuticals have been received and taken into the custody and control of the destination facility as a way to approximate the manifest system without requiring the use of hazardous waste transporters or manifests. In response to comments, we have reconsidered the proposed seven-day time frame for the shipper to receive delivery confirmation; the Agency decided that 35 days is more appropriate. It strikes a balance between being duly protective of human health and the environment, reducing burden, and is now in line with universal waste standards.

Sixth, we have made several changes to the pre-transport requirements that we proposed in § 266.509(a)(1) and (2). Because of the removal of the requirement for advance notice of shipments of potentially creditable hazardous waste pharmaceuticals, we renumbered the section such that it all appears in § 266.509(a) now. What was proposed in § 266.509(a)(2) and is now in § 266.509(a), has been modified to reflect the removal of § 266.508(a)(1)(v) which previously contained a requirement that DOT shipping papers be generated. The Agency believes that the shipping papers requirement—

[359] See comment number EPA–HQ–RCRA–2007–0932–0268.

[360] March 31, 2016; 62 FR 18527.

although duplicative for shipments of non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor—is appropriate for shipments of potentially creditable hazardous waste pharmaceuticals given that they are not manifested. Therefore, the requirement for DOT shipping papers has been added to § 266.509(a). Language was also added to clarify that shipments of potentially creditable hazardous waste pharmaceuticals from a healthcare facility or reverse distributor to a reverse distributor do not require a manifest. This language was taken from the universal waste standards in § 273.52(a) which is consistent with the goal of developing universal waste-like shipping standards for potentially creditable hazardous waste pharmaceuticals.

As with the export of non-creditable hazardous waste pharmaceuticals, the proposed standards for healthcare facilities or reverse distributors that export potentially creditable hazardous waste pharmaceuticals to a foreign destination have also been modified to reflect the changes made to the import/export rules of part 262. Specifically, the Agency is finalizing requirements that exporters of potentially creditable hazardous waste pharmaceuticals must comply will all applicable sections of 40 CFR part 262 subpart H, except for the manifest requirements of § 262.83(c), in addition to the requirements for shipping potentially creditable hazardous waste pharmaceuticals in § 266.509(a) through (c).

Subsequent to when this rule was proposed in September 2015, the Hazardous Waste Import-Export Revisions rule was finalized in 2016.[361] As a result, the Agency has had to make conforming changes to this final rule to reflect the changes made by the Import-Export Revisions final rule. Because the regulations for importing and exporting hazardous waste were previously located in separate subparts—exports in subpart E and imports in subpart F—the proposed requirements in this rule were also separated into discreet subsections and referred to their respective subparts (exporting and importing) of 40 CFR part 262. A significant change enacted by the Import-Export Revisions Rule was to consolidate into subpart H the multiple related subparts in 40 CFR 262 regarding import, export, and transboundary movements of hazardous waste that had been in subparts E and F.

The essence of the proposed regulations has not changed in the finalized requirements. That is, a healthcare facility or reverse distributor exporting potentially creditable hazardous waste pharmaceuticals is still subject to the same or similar provisions as were proposed, only now they must comply with 40 CFR part 262 subpart H instead, except for the manifesting requirements, and paragraphs (a) through (c) of § 266.509.

For healthcare facilities and reverse distributors that import potentially creditable hazardous waste pharmaceuticals, the requirements are being finalized as proposed, except that due to the conforming changes necessitated by the Hazardous Waste Export-Import Revisions Final Rule, they must now comply with the shipping standards for potentially creditable hazardous waste pharmaceuticals in lieu of 40 CFR part 262 subpart H (instead of part 262 subpart F). One other clarification was added to the regulatory language specifying that potentially creditable hazardous waste pharmaceuticals are subject to all applicable provisions in this subpart immediately after entering the United States.

4. Comments and Responses

The commenter that requested an official definition of advance notice also requested an official definition for delivery confirmation.[362] The Agency is purposely leaving this standard sufficiently broad as to allow the implementing agencies discretion to determine the best implementation strategies on a case-by-case basis.

EPA notes that a reverse distributor is not required to segregate the potentially creditable hazardous waste pharmaceuticals from the potentially creditable non-hazardous waste pharmaceuticals when they are destined for another reverse distributor. However, if the potentially creditable pharmaceuticals are not segregated, the reverse distributor must follow the tracking procedures for the entire shipment. On the other hand, if a reverse distributor chooses to segregate the potentially creditable hazardous waste pharmaceuticals from the non-hazardous waste pharmaceuticals prior to shipping to another reverse distributor, only the potentially creditable hazardous waste pharmaceutical portion would have to be shipped according to these standards.

XVII. Standards for Reverse Distributors (§ 266.510)

A. Background on Reverse Distributor Operations

Reverse distributors act as intermediaries between healthcare facilities and pharmaceutical manufacturers. They receive shipments of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for these pharmaceuticals. From stakeholder input, EPA site visits, and comments on the proposed rulemaking, EPA's understanding is that when a reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its computer system. Based on manufacturers' ''business rules'' (*i.e.,* manufacturers' return policies), the reverse distributors determine which potentially creditable hazardous waste pharmaceuticals can receive manufacturer credit, as well as which must be sent on to another reverse distributor for completion of the crediting process. ''Business rules'' (*i.e.* manufacturers' return policies) refers to the rules that govern the disposition of retail items agreed to by the manufacturer, retailer, and reverse distributor or reverse logistics center.[363]

In many cases, there is more than one reverse distributor involved in establishing and verifying manufacturer credit for a particular potentially creditable hazardous waste pharmaceutical. For instance, reverse distributors may have contracts with specific pharmaceutical manufacturers such that only a specific reverse distributor may facilitate credit for a particular manufacturer's pharmaceuticals. If the receiving reverse distributor has a contract with the healthcare facility, but not with the pharmaceutical manufacturer, then the receiving reverse distributor sends the returned pharmaceutical on to the reverse distributor that has a contract with the pharmaceutical manufacturer in order to facilitate the manufacturer credit process.

Because manufacturers' business rules change over time, sometimes a reverse distributor receives a potentially creditable hazardous waste

[361] See the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

[362] See comment number EPA–HQ–RCRA–2007–0932–0284.

[363] This definition is derived from the definition of ''business rules'' in the ''Surplus Household Consumer Products and Wastes: Report to the Legislature.'' Available at: *http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

pharmaceutical that is not eligible for credit immediately, and the reverse distributor retains the potentially creditable hazardous waste pharmaceutical on site until it is credit eligible (often called ''aging'' a pharmaceutical). For example, manufacturers only issue credit for expired pharmaceuticals. As a result, sometimes a reverse distributor receives an unexpired hazardous waste pharmaceutical that is otherwise creditable but awaiting its expiration date. The reverse distributor then retains the potentially creditable hazardous waste pharmaceutical on site until after it has expired and thus becomes eligible for manufacturer credit. In some cases, even after the reverse distributor has awarded manufacturer credit, a pharmaceutical manufacturer may request that the hazardous waste pharmaceuticals be transported back to the manufacturer to verify the amount of pharmaceuticals and manufacturer credit.

On the other hand, if the potentially creditable hazardous waste pharmaceuticals are not sent on to another reverse distributor and the reverse distributor awards the manufacturer credit to the healthcare facility itself, it then manages the hazardous waste pharmaceuticals on site until they are sent off site for treatment and disposal. As discussed previously, after a potentially creditable hazardous waste pharmaceutical has been evaluated and no additional reverse distributors will be involved in the manufacturer's crediting process, EPA uses the term ''evaluated hazardous waste pharmaceutical.'' This is to distinguish between the potentially creditable hazardous waste pharmaceuticals awaiting determination within the reverse distribution system versus the evaluated hazardous waste pharmaceuticals that will not be sent to another reverse distributor for evaluation. Both are considered hazardous waste pharmaceuticals, but they are managed differently under this subpart.

EPA is not aware of any reverse distributor that facilitates manufacturer credit that also has interim status or a permit to treat or dispose of hazardous waste on-site.[364] Therefore, EPA anticipates that reverse distributors eventually send all evaluated hazardous waste pharmaceuticals off site for treatment and disposal.

[364] Several DEA reverse distributors have RCRA interim status or a permit to treat or dispose of hazardous waste, but these DEA reverse distributors do not facilitate manufacturer credit.

B. EPA's Rationale for Finalizing New RCRA Management Standards for Reverse Distributors

This final rule establishes standards for the management of both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that reverse distributors receive and manage. The management standards discussed in this section apply only to reverse distributors of prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. The management standards discussed in this section do not apply to the reverse logistics systems that may exist for other retail items. In response to comments, EPA is codifying our existing interpretation that nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed (see the definition of hazardous waste pharmaceutical under section VIII and section IX, the applicability section). Additionally, EPA is establishing a policy that other retail items that are sent through reverse logistics are not solid waste at the retail store if they have a reasonable expectation of being legitimately used/reused or reclaimed (see section VI). Therefore, reverse logistics centers that receive and manage nonprescription pharmaceuticals will not be regulated under this subpart and will not be subject to the standards for reverse distributors.

The current federal RCRA hazardous waste generation regulations at 40 CFR part 262 provide that only designated facilities, such as RCRA-permitted and interim status TSDFs, may receive hazardous waste from off site for treatment, storage, or disposal. However, the Agency does not believe it is necessary for reverse distributors to obtain permits or have interim status to store hazardous waste pharmaceuticals in order to protect human health and the environment. Thus, EPA is finalizing a new category of hazardous waste management facilities under RCRA called a ''reverse distributor,'' which is defined as any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. The definition specifies that any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription hazardous waste pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor. EPA is finalizing that reverse distributors are not required to have interim status or a RCRA permit to accumulate hazardous waste pharmaceuticals and they may only accept potentially creditable hazardous waste pharmaceuticals from off site provided they comply with the standards in this final rule. Reverse distributors may not treat or dispose of hazardous waste on-site unless authorized to do so as a RCRA-permitted or interim status TSDF.

As discussed earlier in this document, EPA's previous interpretation allows reverse distributors to be generators of hazardous waste pharmaceuticals after a decision is made about whether the pharmaceuticals will be repurposed. As a hazardous waste generator, a reverse distributor had to comply with the LQG, SQG, or VSQG generator regulations, depending on the total volume of hazardous waste generated in a calendar month. Some smaller reverse distributors might have stayed under the hazardous waste quantity limits for VSQGs, which would mean that under the federal RCRA regulations, these VSQG reverse distributors would not have had to notify EPA as a generator and their hazardous waste pharmaceuticals could be disposed of with municipal and non-municipal solid waste (see § 262.14). However, the Agency has concerns with VSQG reverse distributors not notifying EPA that they are managing hazardous waste. EPA is even more concerned about reverse distributors that currently qualify as VSQGs placing the hazardous waste pharmaceuticals into the municipal and non-municipal solid waste stream and sending them to non-hazardous waste landfills. Some studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems.[365] [366] Landfill leachate is generally transported to a wastewater treatment

[365] Barnes, K.K., Christenson, S.C., Kolpin, D.W., Focazio, M.J., Furlong, E.T., Zaugg, S.D., Meyer, M.T. and Barber, L.B. (2004), Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill. Groundwater Monitoring & Remediation, 24: 119–126.

[366] Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (2009), Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. Bulletin of Environmental Contamination and Toxicology, 82.6:635–659.

plant to be treated before discharge; however, some pharmaceutical compounds pass through treatment and are discharged, becoming a potential contributor of the pharmaceutical compounds detected in our nation's waters.

In this final rule, EPA is revising its position regarding prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals, such that they will be considered discarded at the healthcare facilities, not at the reverse distributors. This revision is based on new information demonstrating to EPA that prescription pharmaceuticals returned to a reverse distributor are rarely, if ever, recycled or reused, and therefore the decision to send a potentially creditable hazardous waste pharmaceutical to a reverse distributor is a decision to discard the pharmaceutical (as discussed previously in section VI). Comments on the December 2008 Pharmaceutical Universal Waste proposal indicated that notification to EPA by reverse distributors and tracking of shipments of potentially creditable hazardous waste pharmaceuticals are critical and must be included in any regulatory scheme to ensure the safe management of potentially creditable hazardous waste pharmaceuticals.

Although EPA maintains its position as stated in the proposed rulemaking preamble that hazardous waste pharmaceuticals going to reverse distributors are solid wastes at the healthcare facility, there are important differences between reverse distributors and traditional TSDFs. Only between 2–6 percent of the potentially creditable pharmaceuticals that are received by reverse distributors are listed or characteristic hazardous wastes.[367] Therefore, the vast majority of the potentially creditable pharmaceutical waste that a reverse distributor receives is not considered a characteristic or listed hazardous waste pharmaceutical under the existing definition of hazardous waste. This stands in contrast to a typical TSDF, whose primary function is to manage hazardous waste. As a result, a reverse distributor generally manages a smaller volume of hazardous waste than a typical permitted TSDF.

In addition, because the pharmaceuticals in the reverse distribution system are receiving manufacturer credit, they are moved through the system efficiently. In fact, one national pharmacy retail chain informed EPA that the value of the credit they receive from manufacturers for returned pharmaceuticals is approximately $1 billion a year.[368] Healthcare facilities and reverse distributors have a vested interest in having potentially creditable hazardous waste pharmaceuticals processed and credited quickly and managed appropriately so money is not lost in the process.

Furthermore, potentially creditable hazardous waste pharmaceuticals generally present a low risk of release to the environment as they typically are still in the manufacturer's packaging, which in some cases includes inner and outer packaging (*e.g.,* plastic bottle inside a box). Since there is a relatively low human health and environmental risk of release associated with the low volumes of potentially creditable hazardous waste pharmaceuticals shipped to reverse distributors for crediting purposes, and because EPA is not aware of any incidents of mismanagement resulting in environmental harm or releases of hazardous waste pharmaceuticals by reverse distributors, EPA believes that it is not necessary to require reverse distributors to obtain RCRA hazardous waste storage permits with respect to typical reverse distribution operations, such as receiving, sorting, consolidating, and reshipping potentially creditable hazardous waste pharmaceuticals.

Thus, EPA is taking a tailored approach to regulating reverse distributors by regarding them as a new type of RCRA hazardous waste entity—a reverse distributor. This approach balances EPA's revised interpretation that the point of generation for prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, not the reverse distributor, with the fact that potentially creditable hazardous waste pharmaceuticals have value which provides an incentive for proper management.

EPA is establishing new management standards for reverse distributors in 40 CFR part 266 subpart P. These entities will not be subject to 40 CFR parts 262, 264, 265, or 270. Generally, EPA is finalizing that reverse distributors comply with standards that are similar to the current federal LQG standards, in combination with certain requirements that permitted or interim status hazardous waste TSDFs must meet. We are establishing one set of requirements for all reverse distributors, regardless of the amount of potentially creditable hazardous waste pharmaceuticals they receive. EPA believes this uniform set of standards will make it easier for reverse distributors to comply with the new subpart, in part because the burden of having to count hazardous waste pharmaceuticals on a monthly basis, especially the 1 kg of acute hazardous waste pharmaceuticals, will be removed.

EPA is finalizing that a reverse distributor will not be required to have a hazardous waste permit or interim status for on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals provided it follows the final reverse distributor standards. As mentioned previously, the on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals generally presents low risk of release to the environment because they are typically in the manufacturer's packaging. However, for activities such as treatment or disposal of hazardous waste pharmaceuticals or other hazardous waste, a reverse distributor must either obtain a RCRA permit or have interim status, as these activities pose a higher risk of release. EPA has determined that requirements similar to LQG standards for on-site accumulation of hazardous waste that are found in § 262.17 are appropriate. As discussed previously, the value of the potentially creditable pharmaceuticals creates an incentive for proper management and the risk of release is low. Furthermore, many reverse distributors are already LQGs and, therefore, this final rule should not represent a large shift in current practices or increased burden.[369] However, once credit is provided, the value of the pharmaceuticals is eliminated and therefore the evaluated hazardous waste pharmaceuticals have a greater potential for mismanagement. As a result, EPA is finalizing additional standards for the management of evaluated hazardous waste pharmaceuticals at reverse distributors.

EPA received numerous comments that expressed concern that the standards for reverse distributors would be burdensome for reverse logistics

[367] See EPA's request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA–HQ–RCRA–2007–0932–0157, EPA–HQ–RCRA–2007–0932–0158, EPA–HQ–RCRA–2007–0932–0159, EPA–HQ–RCRA–2007–0932–0160, EPA–HQ–RCRA–2007–0932–0161, EPA–HQ–RCRA–2007–0932–0162, EPA–HQ–RCRA–2007–0932–0163, EPA–HQ–RCRA–2007–0932–0164.

[368] Meeting with representatives from CVS (August 11, 2012); see the docket for meeting notes (EPA–HQ–RCRA–2007–0932–0188).

[369] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

centers that handle nonprescription pharmaceuticals. For example, one commenter expressed concern that the reverse distributor inventory requirements for both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals would be burdensome for facilities that receive and manage nonprescription pharmaceuticals because these reverse logistics centers do not currently maintain an inventory for these retail items.[370] EPA is codifying our existing interpretation that nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed (see section VI for more discussion). Therefore, reverse logistics centers will not be regulated under part 266 subpart P and will not be subject to the standards for reverse distributors. As a result, comments received on the impact of the reverse distributor standards on reverse logistics centers that receive and manage nonprescription pharmaceuticals are outside the scope of the final rule and are not discussed in this section. EPA also received numerous general comments expressing concern that finalizing new RCRA management standards for reverse distributors would be burdensome. However, some specific provisions included in the proposed reverse distributor standards received few comments.

C. Detailed Discussion of Final Reverse Distributor Standards

The final standards for reverse distributors are organized into three sections. The first section applies to the reverse distributor for the management of all potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals (§ 266.510(a)). The second section includes additional standards that would apply to the management of the potentially creditable hazardous waste pharmaceuticals that will be sent to another reverse distributor for further evaluation or verification of credit and therefore continue to be regulated as potentially creditable hazardous waste pharmaceuticals (§ 266.510(b)). The third section includes additional standards that apply to the management of the evaluated hazardous waste pharmaceuticals that will not be sent to another reverse distributor, but instead will be sent to a permitted or interim status TSDF (§ 266.510(c)).

1. Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals (§ 266.510(a))

This portion of the preamble discusses the standards that apply to reverse distributors for the management of all hazardous waste pharmaceuticals on site, including potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Unlike the following two sections, the standards discussed in this section apply to all prescription hazardous waste pharmaceuticals at a reverse distributor, regardless of the subsequent destination of the hazardous waste pharmaceuticals. We note that a reverse distributor must follow these standards for the management of hazardous waste pharmaceuticals even if it generates other, non-pharmaceutical hazardous waste that is managed under 40 CFR part 262. Note that we have reorganized § 266.510(a) since the proposal to more accurately reflect the flow of hazardous waste pharmaceuticals at a reverse distributor. The subsequent preamble section follows the organization of the final regulations.

a. Notification

Summary of Proposal. EPA proposed that a reverse distributor must notify EPA of its hazardous waste pharmaceutical activities using the Site ID Form (EPA Form 8700–12). Under the RCRA Subtitle C program, SQGs, LQGs, and TSDFs must submit a Site ID Form to EPA. EPA proposed that a reverse distributor that does not have an EPA ID number will be required to submit the Site ID Form to obtain one and that a reverse distributor that already has an EPA ID number will need to notify EPA as a reverse distributor.

Summary of Comments. EPA received two comments in support of the proposed notification requirements. One state supported all of the proposed notification requirements.[371] Inmar, Inc. supported the requirement that reverse distributors must notify EPA using EPA Form 8700–12.[372]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(1) that a reverse distributor must notify EPA of its hazardous waste pharmaceutical activities using the Site ID Form (EPA Form 8700–12). The Agency will revise the Site ID Form to include a box to allow notifications by reverse distributors. EPA believes it is appropriate, and in line with comments received on the proposal, to require reverse distributors to notify EPA. Under the final rule, a reverse distributor that does not have an EPA ID number will be required to submit the Site ID Form to obtain one. A reverse distributor that already has an EPA ID number will need to notify EPA as a reverse distributor. The time frame in both cases is within 60 days of the effective date of this subpart or within 60 days of becoming subject to this subpart. Some reverse distributors may also be generators of other types of hazardous waste (*e.g.,* from cleaning and maintenance operations). Therefore, it is possible that a reverse distributor may notify on the same notification form as both a generator of hazardous waste and as a reverse distributor.

b. Inventory

Summary of Proposal. EPA proposed that reverse distributors must keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on site. EPA proposed that the inventory must include the identity (*e.g.,* name or National Drug Code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical. EPA also proposed that a reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the reverse distributor.

Summary of Comments. EPA received comments from states and industry in support of the proposed inventory requirement.[373] One state suggested that EPA also require reverse distributors to include the name of the healthcare facility that shipped the potentially creditable hazardous waste pharmaceuticals to the reverse distributor.[374]

Retail Industry Leaders Association argued that the inventory requirements for reverse distributors should be reduced.[375] Inmar, Inc. did not support the inventory requirements and argued

[370] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[371] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[372] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[373] See comment numbers EPA–HQ–RCRA–2007–0932–0235, EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0280, EPA–HQ–RCRA–2007–0932–0296, EPA–HQ–RCRA–2007–0932–0300, and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[374] See comment number EPA–HQ–RCRA–2007–0932–0235 in the docket for this rulemaking.

[375] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

that they are duplicative because reverse distributors must already inventory and track prescription pharmaceuticals.[376] Inmar, Inc. wrote that at least four states currently require the maintenance of drug inventories by law.[377] Both Inmar, Inc. and RILA expressed concern that the inventory requirements would be particularly burdensome for their facilities that handle nonprescription pharmaceuticals. Inmar, Inc. pointed out that their reverse logistics centers do not maintain an inventory for nonprescription pharmaceuticals.[378]

EPA received multiple comments from industry that expressed concern that the reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival.[379] One commenter expressed concern that the reverse distributor must complete an inventory upon arrival because packages of potentially creditable hazardous waste pharmaceuticals can remain unopened for up to 5 business days.[380] Healthcare Distribution Management Association [381] pointed out that reverse distributors sometimes receive tens of thousands of products in a day and do individual product accounting when the credit determination is made.[382]

Commenters on the proposed rulemaking also pointed out that reverse distributors are already required to inventory and track prescription pharmaceuticals under licensing and accreditation programs overseen by the National Association of Boards of Pharmacy.[383]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(2) that reverse distributors must keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on site. In response to comments, we have made several changes to what was proposed but have determined that an inventory is a key requirement to protect public health by helping to prevent the diversion of hazardous waste pharmaceuticals. An inventory will allow the reverse distributor to know which hazardous waste pharmaceuticals they have on-site at any time. Based on stakeholder input and site visits, the Agency believes that in many cases, reverse distributors already maintain inventories of pharmaceuticals and this requirement is not expected to be burdensome for the reverse distributors to implement. According to responses from reverse distributors to a 2011 request for information, four out of eight of them indicated that they already keep inventories as best management practices or because it is required by the Board of Pharmacy in their state.[384] The inventory must include the identity (*e.g.,* name or National Drug Code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceuticals. In response to commenter concern that the inventory requirement would be duplicative, EPA clarified in the regulatory language of the final rule that if the reverse distributor already meets the inventory requirements because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory.

EPA proposed that a reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the reverse distributor. The final rule has been revised to state that reverse distributors must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of arriving at the reverse distributor. EPA made this change in response to commenter concern that the Agency did not provide enough time for reverse distributors to inventory potentially creditable hazardous waste pharmaceuticals. As previously mentioned, comments pointed out that reverse distributors sometimes receive tens of thousands of products in one day and need additional time to inventory each potentially creditable hazardous waste pharmaceutical.[385] EPA is also aware that many reverse distributors inventory the potentially creditable hazardous waste pharmaceutical at the same time that they evaluate the potentially creditable hazardous waste pharmaceutical to determine if it will receive manufacturer credit. When a reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its system and make a credit determination. EPA believes that 30 days is an adequate amount of time for the reverse distributor to sort through shipments of hazardous waste pharmaceuticals and inventory the potentially creditable hazardous waste pharmaceuticals. The Agency has determined that because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, increasing the amount of time reverse distributors have to complete the inventory will not increase risk of release to the environment.

c. Evaluating Potentially Creditable Hazardous Waste Pharmaceuticals Within 30 Days

Summary of Proposal. The key role the reverse distributor plays in managing the issuing of credit from a manufacturer to a healthcare facility is sorting through shipments of potentially creditable hazardous waste pharmaceuticals and evaluating them to determine which must be transported to another reverse distributor for further evaluation of manufacturer credit and which will be sent off site for treatment and disposal. The reverse distributors often use barcodes to scan items into their systems.

EPA proposed that this evaluation process must be completed within 21 days of arriving at the reverse distributor. Likewise, EPA proposed that if the reverse distributor is a manufacturer, the manufacturer must finish verifying the appropriate credit within 21 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals. The Agency proposed that the 21 calendar days for evaluating the potentially creditable hazardous pharmaceuticals counts as part of the total 90 calendar days that each reverse distributor is allowed to accumulate hazardous waste pharmaceuticals on site.

Summary of Comments. The most frequent comment EPA received on the proposed requirement that reverse distributors complete the evaluation process within 21 days of arriving at the reverse distributor is that the proposed time frame was too short. Waste Management National Services, Inc.

[376] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[377] See the EPA correspondence with Inmar dated March 29, 2017 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

[378] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[379] See comment numbers EPA–HQ–RCRA–2007–0932–0295, EPA–HQ–RCRA–2007–0932–0276, EPA–HQ–RCRA–2007–0932–0352, and EPA–HQ–RCRA–2007–0932–0340 in the docket for this rulemaking.

[380] See comment number EPA–HQ–RCRA–2007–0932–0278 in the docket for this rulemaking.

[381] Now renamed Heathcare Distribution Alliance.

[382] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

[383] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[384] See EPA's request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA–HQ–RCRA–2007–0932–0157, EPA–HQ–RCRA–2007–0932–0158, EPA–HQ–RCRA–2007–0932–0159, EPA–HQ–RCRA–2007–0932–0160, EPA–HQ–RCRA–2007–0932–0161, EPA–HQ–RCRA–2007–0932–0162, EPA–HQ–RCRA–2007–0932–0163, EPA–HQ–RCRA–2007–0932–0164.

[385] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

requested that EPA allow additional time for reverse distributors to evaluate potentially creditable hazardous waste pharmaceuticals.[386] One state requested that EPA allow reverse distributors to have 30 days to complete the evaluation process.[387] RILA and PharmaLink, Inc. requested that EPA allow reverse distributors to have 60 days to complete the evaluation process.[388] GENCO, Qualanex, LLC, and Healthcare Waste Institute of the National Waste and Recycling Association requested that there be no time limit set for reverse distributors to complete the evaluation process.[389] One state suggested that it is not critical to require the evaluation to take place in a certain number of days if the days count toward the total number of days that hazardous waste pharmaceuticals are allowed to accumulate on site.[390]

EPA also received multiple comments in support of the requirement that reverse distributors complete the evaluation process in a short time frame. One state supported the requirement that reverse distributors complete the evaluation process in a short time frame.[391] Clean Harbors Environmental Services argued that 21 days is more than adequate for a reverse distributor to evaluate potentially creditable hazardous waste pharmaceuticals.[392]

Final Rule Provisions. Under the final rule, EPA is requiring in § 266.510(a)(3) that reverse distributors evaluate potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Likewise, EPA is finalizing in § 266.510(a)(4) that if the reverse distributor is a manufacturer, the manufacturer must finish verifying the appropriate credit within 30 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals.

EPA is now aware that reverse distributors sometimes receive tens of thousands of products in one day and that sometimes reverse distributors need more than 21 days to evaluate the potentially creditable hazardous waste pharmaceuticals.[393] As mentioned previously, commenters pointed out that many reverse distributors inventory the potentially creditable hazardous waste pharmaceuticals at the same time that they evaluate the potentially creditable hazardous waste pharmaceuticals to determine if they will be credited.[394] Therefore, the Agency is finalizing that both the inventory and the evaluation process must be completed in 30 days to ensure that reverse distributors have adequate time to sort through shipments of potentially creditable hazardous waste pharmaceuticals.[395] In the case where healthcare facilities do not segregate hazardous waste pharmaceuticals from non-hazardous waste pharmaceuticals as part of the evaluation process, reverse distributors will effectively make a hazardous waste determination in order to determine which pharmaceuticals are hazardous waste pharmaceuticals and thus subject to this subpart.

The Agency is finalizing that the 30 calendar days for evaluating the potentially creditable hazardous pharmaceuticals do not count as part of the total 180 calendar days that the hazardous waste pharmaceuticals are allowed to accumulate on site at the reverse distributor. The Agency has determined that because of the value of the potentially creditable hazardous waste pharmaceuticals and the low risk these materials present, increasing the amount of time reverse distributors have to evaluate shipments of potentially creditable hazardous waste pharmaceuticals will not increase risk of release to the environment. Additionally, because most potentially creditable hazardous waste pharmaceuticals are in their original packaging, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (*e.g.,* for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard, and therefore EPA has determined that having a longer accumulation time is not a hazard to human health and the environment.[396]

EPA is finalizing that once an evaluation is made on the incoming potentially creditable hazardous waste pharmaceuticals, if they are destined for another reverse distributor, they are still considered potentially creditable hazardous waste pharmaceuticals. There are additional regulations in this subpart at § 266.510(b) that pertain to these potentially creditable hazardous waste pharmaceuticals. If, however, they are destined for an interim status or permitted TSDF, they are considered ''evaluated hazardous waste pharmaceuticals.'' There are additional regulations in this rule at § 266.510(c) that pertain to these evaluated hazardous waste pharmaceuticals.

d. Accumulation Time Limit

Summary of Proposal. EPA proposed that, like LQGs, reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for up to 90 calendar days without having interim status or a permit. However, because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present because they are in original manufacturer's packaging that would meet our typical requirement for closed containers, the Agency decided not to propose specific container management standards.

The Agency proposed that the 90-day time limit begin when the potentially creditable hazardous waste pharmaceuticals initially arrive at the reverse distributor. The Agency also proposed that there is a 90-day accumulation limit for the hazardous waste pharmaceuticals at each reverse distributor. Some potentially creditable hazardous waste pharmaceuticals travel through more than one reverse distributor to receive manufacturer credit. The Agency proposed that in such cases, each reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a 90-day accumulation limit.

EPA did not propose a specific method that reverse distributors must use to document that accumulation does not exceed 90 calendar days. EPA

[386] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[387] See comment number EPA–HQ–RCRA–2007–0932–0313 in the docket for this rulemaking.

[388] See comment numbers EPA–HQ–RCRA–2007–0932–0295 and EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

[389] See comment numbers EPA–HQ–RCRA–2007–0932–0336, EPA–HQ–RCRA–2007–0932–0352, and EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

[390] See comment number EPA–HQ–RCRA–2007–0932–0235 in the docket for this rulemaking.

[391] See comment number EPA–HQ–RCRA–2007–0932–0315 in the docket for this rulemaking.

[392] See comment number EPA–HQ–RCRA–2007–0932–0333 in the docket for this rulemaking.

[393] See comment numbers EPA–HQ–RCRA–2007–0932–0276 and EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[394] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

[395] Although RILA requested that EPA allow reverse distributors to have 60 days to complete the evaluation process, RILA was primarily concerned that it would be difficult for reverse distributors to sort through over-the-counter pharmaceuticals and dietary supplements within the proposed time frame (see comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking). However, the Agency thinks that 30 days is a sufficient amount of time for reverse distributors to sort through shipments of potentially creditable hazardous waste pharmaceuticals, which does not include over-the-counter pharmaceuticals and dietary supplements under the final regulations (see the definition of ''potentially creditable hazardous waste pharmaceuticals'' in 266.500).

[396] For more discussion of the closed container standard see memo from Devlin to RCRA Division Directors, November 3, 2011 (RCRA Online #14826).

anticipated that most reverse distributors would use the inventory system to verify the 90-calendar day time frame rather than taking the extra step of labeling containers with dates for verification. EPA also proposed to allow a reverse distributor to request from EPA an extension of the 90-day accumulation time limit for situations when the hazardous waste pharmaceuticals are involved in litigation, a recall, or in unforeseen circumstances beyond the control of the reverse distributor. Under the part 262 generator regulations, the extension of time typically allowed is limited to an extra 30 days for LQGs. However, due to the complex nature of pharmaceutical litigation and recalls, EPA proposed to allow the EPA Regional Administrator to grant a time extension at their discretion on a case-by-case basis.

Summary of Comments. The most frequent comment EPA received on the proposed on-site accumulation time limit was that the 90-day accumulation limit was too short. Waste Management National Services, Inc. did not support the 90-day accumulation limit, arguing that there are many reasons why a reverse distributor would experience significant changes in the volumes of returns it receives, including recalls.[397] Inmar, Inc. did not support the 90-day accumulation limit, arguing that its facilities receive thousands of shipments every day and it would be impractical to ensure a 90-day accumulation limit.[398] Healthcare Distribution Management Association pointed out that the 90-day accumulation limit is too short because manufacturers frequently take longer than 90 days to make credit determinations.[399] Waste Management National Services, Inc., Qualanex, LLC, and PharmaLink, Inc. requested that EPA not require the 90-day accumulation to begin until the potentially creditable hazardous waste pharmaceuticals become evaluated hazardous waste pharmaceuticals.[400] Stericycle, Inc. requested that EPA extend the accumulation time limit from 90 days to 180 days and suggested that there should not be an accumulation time limit for hazardous waste pharmaceuticals being held due to recall.[401] GENCO and Healthcare Waste Institute of the National Waste and Recycling Association also requested that EPA extend the accumulation time limit from 90 days to 180 days.[402] RILA Association requested that EPA extend the accumulation time limit from 90 days to one year.[403] National Pharmaceutical Returns requested that EPA place no accumulation time limit on potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.[404]

EPA received multiple comments suggesting that the accumulation time limits did not accommodate situations where reverse distributors receive unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date or situations where reverse distributors ''age'' potentially creditable pharmaceuticals until they are eligible for manufacturer credit.[405]

One state supported the 90-day accumulation limit.[406] One state agreed that the 90-day accumulation limit is reasonable but did not support allowing each reverse distributor to have a 90-day accumulation period because it increases the potential for mismanagement.[407]

Final Rule Provisions. In response to comments, EPA is providing additional time for reverse distributors accumulating hazardous waste pharmaceuticals. Specifically, EPA is finalizing in § 266.510(a)(5) that reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for up to 180 calendar days without having interim status or a permit as long as they meet the conditions of this subpart. The Agency is finalizing that the 180-day time limit begins once the reverse distributor evaluates the potentially creditable hazardous waste pharmaceutical and determines if the potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor for further evaluation of manufacturer credit or if it will be sent off site for treatment and disposal. As mentioned in the previous section, reverse distributors are required to inventory and evaluate potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Therefore, the potentially creditable hazardous waste pharmaceuticals can be accumulated at each reverse distributor for no more than 210 days in total after arrival.

The Agency is finalizing that there is a 180-day accumulation limit for the hazardous waste pharmaceutical at each reverse distributor. Some potentially creditable hazardous waste pharmaceuticals travel through more than one reverse distributor to receive manufacturer credit. Under the final rule, each reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a new 180-day accumulation limit. Under the final rule, the 180-day time limit begins when the reverse distributor evaluates potentially creditable hazardous waste pharmaceuticals and to determine which potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor and which ones will be sent off site for treatment and disposal.

Under the final rule, EPA is not requiring a specific method that reverse distributors must use to document that accumulation does not exceed 180 calendar days. EPA anticipates that most reverse distributors will use the inventory system to verify the 180-calendar day time frame rather than taking an addition step of labeling containers with dates for verification. As discussed previously, EPA is finalizing that a reverse distributor must inventory potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Many reverse distributors utilize barcoding and scanners to log potentially creditable pharmaceuticals into a database upon arrival or soon after a shipment arrives.

Because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, the Agency is not requiring specific container management standards in the final rule. Furthermore, potentially creditable hazardous waste pharmaceuticals are typically still in the manufacturer's packaging, which would meet our typical requirement for closed containers.

Under the final rule, EPA has eliminated the proposed provision allowing reverse distributors to request an extension of the accumulation time limit. In order to accommodate situations where hazardous waste

[397] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[398] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[399] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

[400] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0352, and EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

[401] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[402] See comment numbers EPA–HQ–RCRA–2007–0932–0336 and EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

[403] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[404] See comment number EPA–HQ–RCRA–2007–0932–0310 in the docket for this rulemaking.

[405] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[406] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[407] See comment number EPA–HQ–RCRA–2007–0932–0300 in the docket for this rulemaking.

pharmaceuticals are involved in unforeseen circumstances beyond the control of the reverse distributor, the Agency increased the accumulation time limit from 90 days to 180 days. As discussed previously, the Agency also increased the amount of time reverse distributors can take to evaluate potentially creditable hazardous waste pharmaceuticals from 21 to 30 days. Additionally, in order to accommodate situations when hazardous waste pharmaceuticals are involved in litigation or a recall, under the final rule, the Agency decided that hazardous waste pharmaceuticals that are either involved in an investigation or judicial proceeding or are subject to a voluntary or federally-mandated recall are not required to be managed under subpart P (see section IX for a detailed discussion). As a result, we do not anticipate the need for reverse distributors to seek accumulation time extensions and therefore we have deleted proposed § 266.510(a)(5).

In order to accommodate situations when reverse distributors receive unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (*i.e.,* aging in a holding morgue), EPA has added a provision in § 266.510(a)(5)(ii) to allow reverse distributors to accumulate these unexpired pharmaceuticals for up to 180 days after the expiration date provided that the unexpired pharmaceuticals are managed in accordance with the container labeling and management standards for evaluated hazardous waste pharmaceuticals found at § 266.510(c)(4)(i)–(vi) while they are aging. This includes labeling containers with the words ''hazardous waste pharmaceuticals;'' ensuring the containers are in good condition, managed to prevent leaks and compatible with the contents; and keeping containers closed.

Once a reverse distributor evaluates a hazardous waste pharmaceutical and determines that it is not destined for another reverse distributor, the reverse distributor must manage that hazardous waste pharmaceutical according to the standards for evaluated hazardous waste pharmaceuticals (unless, as previously mentioned, the hazardous waste pharmaceuticals are unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date). The evaluated hazardous waste pharmaceuticals can be accumulated for up to 180 calendar days without having interim status or permits and they must be managed in accordance with the standards for evaluated hazardous waste pharmaceuticals in § 266.510(c). Although reverse distributors must manage the hazardous waste pharmaceuticals that are not destined for another reverse distributor in accordance with the standards for evaluated hazardous waste pharmaceuticals, the reverse distributor can decide at any point during the accumulation time that the evaluated hazardous waste pharmaceuticals have become eligible for manufacturer credit. If the evaluated hazardous waste pharmaceuticals become eligible for manufacturer credit, the reverse distributor does not get additional calendar days beyond the 180-day accumulation time limit to accumulate the hazardous waste pharmaceuticals. If the evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit, and the hazardous waste pharmaceutical will still not be sent to another reverse distributor for further evaluation, the reverse distributor must continue to manage the hazardous waste pharmaceutical in accordance with the standards for evaluated hazardous waste pharmaceuticals.

EPA does not anticipate a scenario where an evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit and the reverse distributor needs to send the hazardous waste pharmaceutical to another reverse distributor for further evaluation. A reverse distributor is unlikely to utilize resources to accumulate a pharmaceutical that another reverse distributor is required to evaluate due to contractual arrangements with pharmaceutical manufacturers. Although EPA does not anticipate this scenario, if an evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit and the reverse distributor determines that it should go to another reverse distributor to be further evaluated for manufacturer credit, the reverse distributor can then resume managing the hazardous waste pharmaceutical pursuant to the standards for potentially creditable hazardous waste pharmaceuticals that are going on to another reverse distributor (§ 266.510(b)). However, the reverse distributor does not get additional time to accumulate the hazardous waste pharmaceuticals. That is, the reverse distributor can only accumulate the hazardous waste pharmaceuticals for a total of 180 days after the initial evaluation process is complete. Overall, this approach balances the requests from commenters to accommodate situations where reverse anticipate that a manufacturer's policy might change and that evaluated hazardous waste pharmaceuticals might become eligible for manufacturer credit with EPA's belief that it is necessary to limit total accumulation time to 180 days.

e. Security

Summary of Proposal. EPA proposed that reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. Due to increased thefts of pharmaceuticals from pharmacies reported in recent years in major media outlets, EPA was concerned that reverse distributors could face such thefts since they accumulate unused pharmaceuticals.[408] Further, commenters on the 2008 Pharmaceutical Universal Waste proposal suggested that pharmaceutical universal waste handlers should meet the TSDF facility security requirement. EPA agreed with the commenters that the requirements in the interim status TSDF security regulations would be appropriate to adopt and apply to reverse distributors to prevent the illicit use of these pharmaceuticals, thereby safeguarding human health. EPA's proposal required that they must prevent unknowing entry, and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (*e.g.,* a receiving area and accumulation area).

Summary of Comments. Inmar, Inc. and RILA did not support the proposed security requirements and argued that they are duplicative because protective security measures are already required by other state and federal laws.[409] One state and two industry commenters expressed support that reverse distributors must meet a performance-based security standard.[410] One industry commenter pointed out that this requirement should not be an added burden since reverse distributors should already have significant security systems in place and one industry commenter pointed out that the requirements are consistent with the

[408] ''Pharmacies Besieged by Addicted Thieves'' by Abby Goodnough Published: February 6, 2011 *http://www.nytimes.com/2011/02/07/us/07pharmacies.html.*

[409] See comment numbers EPA–HQ–RCRA–2007–0932–0377 and EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[410] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0280, and EPA–HQ–RCRA–2007–0932–0315 in the docket for this rulemaking.

way that reverse distributors operate.[411] [412]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(6) that reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. EPA believes that the requirements that appear in the interim status TSDF security regulations are appropriate to adopt and apply to reverse distributors to prevent the illicit use of these pharmaceuticals thereby safeguarding human health. The security requirement of § 265.14(a) requires a facility to ''prevent the unknowing entry, and minimize the possibility for the unauthorized entry, of persons or livestock onto the active portion of his facility.'' EPA is finalizing a similar requirement for reverse distributors: they must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (*e.g.,* a receiving area and accumulation area).

Based on site visits and comments received on the proposed rulemaking, EPA recognizes that many reverse distributors may already meet the proposed security standard through the use of key cards that allow only authorized personnel into specific areas of the reverse distributor, camera surveillance systems, and cages for storing pharmaceuticals. Some reverse distributors may use fences and signs. EPA is including several examples of acceptable security measures in the regulatory text, but reverse distributors are not limited to the examples provided. Further, EPA does not believe this requirement is duplicative because we included a provision in the regulations that if a reverse distributor already meets the performance-based security standard by complying with other regulations, such as DEA's regulations, then the reverse distributor would not need to install additional security. Furthermore, in response to comments we added a reference to the State Board of Pharmacy regulations as a second example of other regulations that could be used to fulfill the performance based security requirement.

f. Contingency Plan and Emergency Procedures

Summary of Proposal. The Agency proposed to require that reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan and emergency procedures at 40 CFR part 265 subpart D. EPA noted in the proposal that a reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Since many reverse distributors are already LQGs, they should already have contingency plans to address the hazards on site. It may be possible that the reverse distributors would have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but the Agency pointed out in the proposal that such modifications should not impose much burden.

Summary of Comments. One state and two industry commenters supported the requirement that reverse distributors meet the same contingency planning standards as LQGs at 40 CFR part 265 subpart D.[413] Inmar, Inc. supported the proposed contingency plan and emergency procedures requirements and pointed out that most of their facilities are LQGs and already follow these requirements.[414] RILA argued that the contingency planning and emergency procedures requirements should not apply to reverse distributors that handle lower volumes of hazardous waste than an SQG generates because the nature of the waste does not warrant the more stringent requirements.[415]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(7) that reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan and emergency procedures. Since this rule was proposed, the 2016 Hazardous Waste Generator Improvements rule has been finalized and has placed the contingency plan and emergency procedures for LQGs in part 262 subpart M, entitled ''Preparedness, Prevention and Emergency Procedures for Large Quantity Generators.'' As a result, this final rule now references the LQG standards in part 262 subpart M rather than the interim status TSDF standards part 265 subpart D. EPA believes that a reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Reverse distributors that are LQGs should already have contingency plans to address the hazards on-site. Commenters pointed out that reverse distributors that currently operate as SQGs will face a burden under this requirement, but EPA's data shows that most reverse distributors are already LQGs.[416] It is possible that the reverse distributors will have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but EPA does not believe that such modifications will impose much burden.

Comments and Responses. One state recommended that EPA establish a similar requirement to 40 CFR 264.31 (failure of a facility owner or operator to maintain or operate facility to minimize possibility of fire, explosion or releases of hazardous waste or hazardous waste constituents) for reverse distributors.[417] EPA included similar language in the regulations at § 266.510(c)(4)(v).

g. Closure

Summary of Proposal. Due to the generally low risk of release to the environment of the hazardous waste pharmaceuticals that reverse distributors will accumulate on site, as well as the value of the hazardous waste pharmaceuticals, EPA proposed a performance-based closure standard for reverse distributors that incorporated the federal LQG closure standard found at § 265.111. Specifically, when a reverse distributor closes its operations related to hazardous waste pharmaceuticals, EPA proposed that it must control or minimize post-closure releases of hazardous waste into the environment. EPA expected that this would entail removing the containers of both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals from the facility before closure.

Summary of Comments. Waste Management National Services, Inc., the California Department of Toxic Substances Control, and the Connecticut Department of Energy and Environmental Protection support the requirement for a performance-based closure standard that is based on the

[411] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[412] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[413] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0341, and EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[414] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[415] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[416] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[417] See comment number EPA–HQ–RCRA–2007–0932–0235 in the docket for this rulemaking.

federal LQG closure standard.[418] Inmar, Inc. requested that EPA clarify that the reverse distributor closure requirement only apply to the closure of the facility and not to the closure of accumulation areas.[419]

Final Rule Provisions. Under the final rule at § 266.510(a)(8), EPA is requiring a performance-based closure standard that is based on the federal LQG closure standard. Since the rule was proposed, the 2016 Hazardous Waste Generator Improvements rule has been finalized and has incorporated the LQG closure standards into the new LQG regulations in § 262.17. As a result, this final rule now references the LQG closure standard in §§ 262.17(a)(8)(ii) and (iii) rather than incorporating the regulatory language of § 265.111. The LQG closure standards are substantially the same as before. Therefore, when a reverse distributor closes its operations related to hazardous waste pharmaceuticals, it must control or minimize post-closure releases of hazardous waste constituents into the environment. This will entail removing the containers of both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals from the facility before closure. The closure standards apply when the reverse distributor closes its operations related to hazardous waste pharmaceuticals rather than when the reverse distributor closes an accumulation area.

h. Reporting

Summary of Proposal. In some instances, a shipment arriving at a reverse distributor may inadvertently include items that are not potentially creditable pharmaceuticals. These shipments can include wastes that are clearly not eligible to receive credit, such as patient care waste (*e.g.,* IV bags and tubing), contaminated personal protective equipment (PPE), medical waste, or other inappropriate wastes. Reverse distributors are not the appropriate waste management facility for medical or infectious wastes and these wastes must be managed and transported from the healthcare facility to an appropriate waste disposal facility. In some cases, these non-creditable wastes may be hazardous waste. These non-creditable hazardous wastes are prohibited from being transported from a healthcare facility to a reverse distributor and should have been manifested from the healthcare facility to a designated facility, such as a permitted or interim status TSDF.

EPA proposed that if a shipment including these unauthorized wastes arrives at a reverse distributor from a healthcare facility, the reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 15 days. EPA adapted the existing requirement for situations when permitted and interim status TSDFs receive unmanifested hazardous waste (§ 264.76 and § 265.76, respectively) to make it appropriate for situations when unauthorized waste arrives at a reverse distributor. EPA also proposed additional requirements for when inappropriate hazardous waste arrives at a reverse distributor.

First, EPA proposed that the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility that sent the unauthorized waste. This requirement was intended to alert the healthcare facility of its mistake in order to prevent further shipments of non-creditable hazardous waste or non-pharmaceutical hazardous waste.

Second, EPA proposed that the reverse distributor must manage the unauthorized waste that it receives in accordance with all applicable regulations. Third, the Agency proposed that the EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

Summary of Comments. The most frequent comment that EPA received on the proposed reporting requirements is that 15 days is not enough time to submit an unauthorized waste report to the EPA Regional Administrator. Four commenters argued that 15 days is not enough time to submit an unauthorized waste report to the EPA Regional Administrator.[420] Two industry commenters pointed out that it may take up to 30 days for shipments to be processed.[421] Healthcare Waste Institute of the National Waste and Recycling Association suggested that reverse distributors be required to submit an unauthorized waste report within 15 days of processing a shipment of hazardous waste rather than within 15 days of receiving the hazardous waste.[422]

CT DEEP supported the reporting requirements and wrote that the requirement might incentivize healthcare facilities not to ship unauthorized wastes to reverse distributors.[423] RILA did not support the reporting requirements and wrote that reverse distributors should not be required to submit an unauthorized waste report when shipments of non-creditable hazardous waste pharmaceuticals arrive at the reverse distributors because the healthcare facilities are not capable of evaluating creditworthiness.[424] Waste Management National Services, Inc. requested that EPA only require reverse distributors to send a copy of the unauthorized waste report to a specific healthcare facility three times, arguing that it is not the reverse distributor's responsibility to continue this reporting.[425] National Pharmaceutical Returns pointed out that reverse distributors receive a large amount of unauthorized waste pharmaceuticals that healthcare facilities think are potentially creditable and therefore the reporting requirements will be time consuming.[426] One state requested the EPA clarify if a reverse distributor may refuse to take a shipment.[427]

Final Rule Provisions. In response to comments, EPA is finalizing at § 266.510(a)(9) that if a shipment from a healthcare facility arrives at a reverse distributor that includes hazardous waste that it is not authorized to receive, the reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 45 days of receiving the hazardous waste rather than the proposed 15 days. However, EPA is finalizing, as proposed, the additional requirements for when shipments of unauthorized waste arrive at reverse distributors. First, the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility that sent the unauthorized waste. Second, the reverse distributor cannot reject the shipment of non-creditable hazardous waste and must manage the unauthorized waste in accordance with all applicable

[418] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0315, and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[419] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[420] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0278, EPA–HQ–RCRA–2007–0932–0296, and EPA–HQ–RCRA–2007–0932–0352 in the docket for this rulemaking.

[421] See comment numbers EPA–HQ–RCRA–2007–0932–0257 and EPA–HQ–RCRA–2007–0932–0352 in the docket for this rulemaking.

[422] See comment number EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

[423] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[424] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[425] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[426] See comment number EPA–HQ–RCRA–2007–0932–0310 in the docket for this rulemaking.

[427] See comment number EPA–HQ–RCRA–2007–0932–0259 in the docket for this rulemaking.

regulations (*e.g.,* part 262 or medical waste regulations). Healthcare facilities are not equipped as well as reverse distributors to manage the hazardous waste and EPA is concerned that rejecting shipments of non-creditable hazardous waste will prolong mismanagement. Third, the Agency is finalizing as proposed that the EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. This provides the Agency with some flexibility in what reports may be required.

Comments and Responses. The Agency believes that commenters understood this provision to apply more broadly than we intended. We are aware that healthcare facilities often do not know whether a hazardous waste pharmaceutical will receive manufacturer credit at the reverse distributor. EPA did not intend for a reverse distributor to generate an unauthorized waste report each time a hazardous waste does not receive credit. Rather, a reverse distributor must generate an unauthorized waste report when it receives waste that it is not authorized to receive or manage. EPA reworded the regulations to include better examples of unauthorized waste, which includes, but is not limited to, non-pharmaceutical hazardous waste and medical or infectious waste.

In order to prevent exposing employees to unnecessary risk, EPA recommends as a best management practice that reverse distributors keep to a minimum the sorting of shipments that contain unauthorized waste since the shipment may include hazardous waste, including infectious or radioactive healthcare waste. As a result, it is possible that a reverse distributor that receives a shipment that includes non-creditable waste may be unsure whether the shipment includes hazardous waste. In such cases, EPA recommends that the reverse distributor assume the shipment includes hazardous waste and submit an unauthorized waste report. Further, we recommend that reverse distributors work with their clients to reduce the occurrence of further inappropriate shipments.

i. Recordkeeping

Summary of Proposal. EPA proposed three recordkeeping requirements to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, EPA proposed that a reverse distributor must keep a copy of its notification (EPA Form 8700–12) to EPA to indicate that it is a reverse distributor operating under 40 CFR part 266 subpart P. EPA proposed that a reverse distributor must keep the record of notification for as long as it is subject to these requirements. Second, EPA proposed that a reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This included a copy of the proposed advance notification from the healthcare facility or other reverse distributor, a copy of delivery confirmation, shipping papers or bills of loading, and any unauthorized waste reports. The Agency proposed that these shipping records must be kept for three years from the date the reverse distributor receives the shipment. Third, EPA proposed that a reverse distributor must keep a copy of its inventory at all times as long as the reverse distributor remains subject to this subpart. Finally, EPA proposed that periods of record retention indicated previously for a reverse distributor will be automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

Summary of Comments. EPA received multiple comments on the recordkeeping requirements. GENCO did not support the recordkeeping requirements, arguing the requirements would impose burden.[428] Inmar, Inc. argued that reverse distributors are already required to keep records under other regulatory requirements related to receipt, storage, duration, and shipping of controlled and uncontrolled substances.[429]

Stericycle, Inc., the Healthcare Waste Institute of the National Waste and Recycling Association, and Waste Management National Services, Inc. expressed concern about the requirement that a reverse distributor must keep a copy of its inventory for as long as the facility is subject to this subpart.[430] Stericycle, Inc. argued that it is not reasonable to require the inventory be maintained for the life of the facility.[431] The Illinois Council of Health-System Pharmacists requested that EPA clarify whether reverse distributors must maintain only a current inventory or that all inventories as they change must be maintained.[432]

Final Rule Provisions. EPA is finalizing the proposed recordkeeping requirements at § 266.510(a)(10) with some minor changes in order to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, EPA is finalizing that a reverse distributor must keep a copy of its notification (EPA Form 8700–12) to EPA to indicate that it is a reverse distributor operating under 40 CFR part 266 subpart P. A reverse distributor must keep the record of notification for as long as it is subject to these requirements.

Second, EPA is finalizing that a reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This includes a copy of delivery confirmation, shipping papers or bills of lading, and any unauthorized waste reports. We have revised the regulation language such that these shipping records must be kept for three years from the date the shipment arrives at the reverse distributor rather than when the reverse distributor ''receives'' the shipment since this standard is more precise.

Third, EPA is finalizing that a reverse distributor must keep a copy of its current inventory at all times as long as the reverse distributor remains subject to this subpart. The inventory is a living document that will constantly be updated and must be available for inspection. In order to clarify that a reverse distributor must maintain only a current inventory rather than all inventories even if they have changed, EPA revised the final regulatory language in § 266.510(a)(2) such that a reverse distributor must keep a copy of its current inventory. This recordkeeping change is being made to be consistent with that change in § 266.510(a)(2).

Finally, EPA is finalizing that periods of record retention referred to in this section are automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any

[428] See comment number EPA–HQ–RCRA–2007–0932–0336 in the docket for this rulemaking.

[429] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[430] See comment numbers EPA–HQ–RCRA–2007–0932–0280, EPA–HQ–RCRA–2007–0932–0296, and EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[431] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[432] See comment number EPA–HQ–RCRA–2007–0932–0228 in the docket for this rulemaking.

enforcement action. The Agency recommends reverse distributors keep electronic versions of these records rather than paper or hard copy versions of these records.

Note that additional recordkeeping requirements may also pertain to reverse distributors. For example, a reverse distributor that manifests its non-pharmaceutical hazardous waste is subject to the manifest recordkeeping requirements of § 262.40. Further, as discussed in subsequent sections, there are additional recordkeeping requirements that apply to reverse distributors for the management of potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor (§ 266.510(b)) and others that apply to reverse distributors for the management of evaluated hazardous waste pharmaceuticals (§ 266.510(c)).

2. Additional Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Reverse Distributor (§ 266.510(b))

This section discusses the additional standards that apply to a reverse distributor for the management of potentially creditable hazardous waste pharmaceuticals that require further evaluation or verification of manufacturer credit at another reverse distributor. Since these pharmaceuticals retain their value and there is greater incentive to manage them carefully in order to receive full manufacturer credit, EPA is requiring few regulatory standards for the management of the potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor.

a. *Where potentially creditable hazardous waste pharmaceuticals can be sent.*

Summary of Proposal. EPA proposed a limit of three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceuticals are ultimately transported to a permitted or interim status TSDF. The Agency proposed that the three possible types of transfers were: [433]

(1) A healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a reverse distributor, which may or may not be a manufacturer;

(2) the first reverse distributor may send the potentially creditable hazardous waste pharmaceuticals to another reverse distributor, which may or may not be a manufacturer;

(3) the second reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a reverse distributor that is a manufacturer.

Because EPA proposed that each reverse distributor could accumulate hazardous waste pharmaceuticals up to 90 days after arriving at the reverse distributor, this proposed chain of transfers ensured that the potentially creditable hazardous waste pharmaceuticals would be accumulated for no more than 270 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and disposal.[434] As described previously, this is consistent with current practice among reverse distributors because of the contractual arrangements that reverse distributors have with specific manufacturers.

Summary of Comments. One state did not support allowing three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceuticals are required to be transported to a TSDF and requested that EPA consider a maximum of two transfers prior to transportation to a TSDF.[435] Two industry commenters opposed EPA's proposed limit on the number of times a potentially creditable hazardous waste pharmaceutical may be transferred before it must be transported to a TSDF.[436] One of the industry commenters argued that reverse distributors have no knowledge about the pedigree of products prior to receipt and as such cannot be held accountable as to how many times a product is handled before transport to a TSDF.[437]

Final Rule Provisions. The final regulations for reverse distributors continue to be structured so that there is a limit to the number of transfers of potentially creditable hazardous waste pharmaceuticals that may occur before they are ultimately transported to a TSDF for treatment and disposal. Stakeholders expressed concern that the 2008 Pharmaceutical Universal Waste proposal would have allowed hazardous waste pharmaceuticals to be shipped repeatedly and indefinitely from one universal waste handler to another. From discussions with reverse distributors and reviewing comments received on the proposed rulemaking, the Agency believes a reasonable limit is three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceutical is ultimately transported to a TSDF. The three possible types of transfers are: [438]

(1) A healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a reverse distributor, which may or may not be a manufacturer;

(2) the first reverse distributor may send the potentially creditable hazardous waste pharmaceuticals to another reverse distributor, which may or may not be a manufacturer (§ 266.510(b)(1)); and

(3) the second reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a reverse distributor that is a manufacturer (§ 266.510(b)(2)).

Therefore, if a reverse distributor receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility, the reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor (which may or may not be a manufacturer) or must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c). However, a reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor is more limited in where it can send the potentially creditable hazardous waste pharmaceuticals. It can send potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is the manufacturer or else must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c).

The Agency disagrees with the commenter who argued that reverse distributors cannot be accountable for how many times a hazardous waste pharmaceutical is transferred because reverse distributors do not have a record of transfers of the potentially creditable hazardous waste pharmaceuticals prior to receipt.[439] It is not necessary for a reverse distributor to have a record of previous transfers. It is only necessary for a reverse distributor to know

[433] A healthcare facility or reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA-permitted or interim status TSDF.

[434] Although the proposal did allow for the possibility to request an accumulation time limit, the final rule does not.

[435] See comment number EPA–HQ–RCRA–2007–0932–0261 in the docket for this rulemaking.

[436] See comment numbers EPA–HQ–RCRA–2007–0932–0349 and EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[437] See comment number EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

[438] A healthcare facility or reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA-permitted or interim status TSDF.

[439] See comment number EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

whether a shipment of potentially creditable hazardous waste pharmaceuticals originated from a healthcare facility or another reverse distributor. EPA believes it is reasonable for a reverse distributor to know the origin of a shipment that arrives at their facility.

Regardless of the origin or the destination of the potentially creditable hazardous waste pharmaceuticals, each reverse distributor must make an evaluation of them within 30 calendar days and may only accumulate the hazardous waste pharmaceuticals on site for no more than 180 calendar days after the evaluation before it ships them off-site to another reverse distributor or a RCRA-permitted or interim status TSDF (resulting in a maximum of 210 days). The 180 calendar day accumulation time starts after the 30 calendar days to make an evaluation. In the proposal, reverse distributors only had 90 days to accumulate hazardous waste pharmaceuticals on-site, including the 21 calendar days to make an evaluation. EPA made this conforming change to align with the change in § 266.510(a)(5) that allows reverse distributors to accumulate hazardous waste pharmaceuticals on-site for up to 180 calendar days without having interim status or a permit. In addition, all shipments of evaluated hazardous waste pharmaceuticals are subject to § 266.508 and shipments of all potentially creditable hazardous waste pharmaceuticals are subject to § 266.509.

Although this chain of transfers will allow potentially creditable hazardous waste pharmaceuticals to be accumulated for up to 630 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and disposal, EPA does not expect that potentially creditable hazardous waste pharmaceuticals will be accumulated for this time period in practice. First, it is unlikely that a reverse distributor will expend resources to accumulate potentially creditable hazardous waste pharmaceuticals on site for the full 180 calendar days if the potentially creditable hazardous waste pharmaceuticals are destined for another reverse distributor. Second, the desire to receive manufacturer credit in a timely manner will also make it unlikely that reverse distributors will accumulate potentially creditable hazardous waste pharmaceuticals for the full 180 days.

EPA anticipated that some healthcare facilities that are VSQGs will send their potentially creditable hazardous waste pharmaceuticals directly to reverse distributors. We allow for this under § 266.504(a). On the other hand, healthcare facilities that are VSQGs may choose to consolidate all their hazardous waste pharmaceuticals (both creditable and non-creditable) at an off site healthcare facility, as allowed by § 266.504(b). In this later case, the consolidated potentially creditable hazardous waste pharmaceuticals at an off-site VSQG in § 266.504(b) are not counted as one of the 3 allowable transfers of potentially creditable hazardous waste pharmaceuticals under § 266.510(b).

Under the final rule, manufacturers cannot send hazardous waste pharmaceuticals to a reverse distributor because the hazardous waste pharmaceuticals are no longer considered potentially creditable hazardous waste pharmaceuticals. Since manufacturers are unable to issue credit to themselves, it is not possible for the hazardous waste pharmaceuticals to be considered potentially creditable hazardous waste pharmaceuticals.

b. *Recordkeeping for reverse distributors shipping potentially creditable hazardous waste pharmaceuticals to another reverse distributor.*

Summary of Proposal. EPA proposed that reverse distributors must keep records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor (whether it is a manufacturer or not). This included a copy of the advance notification provided to the other reverse distributor, a copy of delivery confirmation, as well as shipping papers or bill of lading. EPA proposed that the reverse distributor must keep these shipping records for three years from the date it initiates the shipment.

Summary of Comments. EPA received few comments on the recordkeeping requirements for reverse distributors that ship potentially creditable hazardous waste pharmaceuticals to another reverse distributor. One state asked EPA to clarify what it means by ''shipping papers.''[440]

Final Rule Provisions. EPA is finalizing in § 266.510(b)(4) that reverse distributors must keep records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor (whether it is a manufacturer or not). This includes a copy of delivery confirmation, as well as DOT shipping papers. EPA has clarified in the regulations that it is the DOT shipping papers prepared in accordance with 49 CFR part 172 subpart C we are referring to as ''shipping papers''; EPA is not adding a requirement for additional shipping papers. The regulations do not specifically mention that reverse distributors keep a copy of a bill of lading, as this is only one type of shipping paper that reverse distributors can use to comply with 49 CFR part 172 subpart C. EPA is finalizing that these shipping records must be kept for three years from the date of shipment.

3. Additional Standards for Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals (§ 266.510(c))

This section discusses the additional standards that apply to a reverse distributor for the management of evaluated hazardous waste pharmaceuticals. In general, the term evaluated hazardous waste pharmaceuticals refers to hazardous waste pharmaceuticals that were potentially creditable hazardous waste pharmaceuticals but have been evaluated by a reverse distributor to establish whether they are eligible for manufacturer credit and will not be sent to another reverse distributor for further evaluation or verification. While potentially creditable hazardous waste pharmaceuticals have value in the form of manufacturer credit, evaluated hazardous waste pharmaceuticals do not. Therefore, in order to minimize the potential for their mismanagement, EPA believes it is necessary to have additional standards for the evaluated hazardous waste pharmaceuticals. These standards generally resemble the standards for LQG CAAs.

a. *Accumulation area.*

Summary of Proposal. EPA proposed that once a reverse distributor completes its evaluation of a potentially creditable hazardous waste pharmaceutical and the reverse distributor knows that the hazardous waste pharmaceutical is destined for treatment and disposal at a RCRA-permitted or interim status TSDF, rather than another reverse distributor, the pharmaceutical is considered an evaluated hazardous waste pharmaceutical. EPA proposed that a reverse distributor must establish an on-site accumulation area where it will accumulate these evaluated hazardous waste pharmaceuticals. An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the

[440] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

potentially creditable hazardous waste pharmaceuticals.

Summary of Comments. One state supported the requirement for reverse distributors to establish on-site accumulation areas for evaluated hazardous waste pharmaceuticals.[441]

Final Rule Provisions. EPA is finalizing as proposed that a reverse distributor must establish an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals in § 266.510(c)(1). An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the potentially creditable hazardous waste pharmaceuticals that have fewer requirements and are destined for another reverse distributor.

b. *Weekly inspections.*

Summary of Proposal. EPA proposed that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at least weekly to ensure containers are not leaking and that diversion of the evaluated hazardous waste pharmaceuticals is not occurring. Under the recordkeeping requirements for reverse distributors, the Agency proposed that a reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

Summary of Comments. One state commented that weekly inspections are not sufficient to determine whether or not diversion of evaluated hazardous waste pharmaceuticals is occurring and requested EPA require additional security provisions.[442] Washington State Department of Ecology requested that EPA clarify the intent of ''at least weekly'' and argued that they interpret ''at least weekly'' to mean once within every seven days.[443]

Final Rule Provisions. In response to comments, EPA is finalizing that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at least once every seven days to ensure containers are not leaking and that diversion of the hazardous waste pharmaceuticals is not occurring. We agree with the commenter that phrasing the standard as ''at least once every seven days'' is more precise than ''at least weekly'' and will avoid the situation where a reverse distributor could inspect early in one week and late the following week and still claim it is inspecting weekly. Under the recordkeeping requirements for reverse distributors in § 266.510(c)(10), the Agency is finalizing that a reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

c. *Personnel training.*

Summary of Proposal. EPA proposed to require that reverse distributors meet the same federal classroom or on-the-job personnel training regulations that LQGs must meet (§ 265.16). However, the Agency specified in the proposal that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals in the on-site accumulation area. EPA argues that these personnel are the individuals handling and managing the evaluated hazardous waste pharmaceuticals and must have appropriate hazardous waste training.

Summary of Comments. Two industry commenters and one state supported the personnel training criteria for reverse distributors.[444] One state argued that the training requirements should be applied to the personnel who handle potentially creditable hazardous waste pharmaceuticals in addition to the personnel who handle evaluated hazardous waste pharmaceuticals on site.[445] Inmar, Inc. pointed out that personnel at reverse distributors are already required to receive training under other regulatory requirements.[446]

Final Rule Provisions. Under the final rule, reverse distributors must meet the same classroom or on-the-job personnel training requirements that LQGs must meet. EPA is finalizing that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals. Since these personnel are the individuals handling and managing the hazardous waste pharmaceuticals, they must have appropriate hazardous waste training. As mentioned previously, EPA received multiple comments in support of the training requirements for reverse distributors. Additionally, EPA does not believe the training requirements will add burden because EPA believes most reverse distributors currently operate as LQGs.[447] Since the proposed rulemaking, the 2016 Hazardous Waste Generator Improvement rule was finalized. As part of its reorganization, the personnel training regulations for LQGs are now incorporated into § 262.17(a)(7) and no longer refer to § 265.16. As a result, the § 266.510(c)(3) training requirements for personnel managing evaluated hazardous waste pharmaceuticals at reverse distributors now reference § 262.17(a)(7) instead of § 265.16.

d. *Labeling and management of containers in on-site accumulation area.*

Summary of Proposal. EPA proposed that while containers of evaluated hazardous waste pharmaceuticals are in the on-site accumulation area, they must be marked with the words, ''hazardous waste pharmaceuticals.'' EPA proposed this term in order to distinguish them from the non-hazardous waste pharmaceuticals and from the hazardous waste pharmaceuticals that are still considered potentially creditable. The Agency did not propose to require an accumulation start date on the label for the containers of evaluated hazardous waste pharmaceuticals.

In terms of container management standards, the Agency proposed requirements that are similar to the container management standards for LQGs, but the Agency proposed to include some requirements specific to evaluated hazardous waste pharmaceuticals. For example, LQGs must keep all containers of hazardous waste closed. However, EPA proposed to require that only containers with hazardous waste pharmaceuticals that are liquids or gels be kept closed during accumulation due to the low potential for release to the environment for those hazardous waste pharmaceuticals that are in a solid form. The Agency did not propose to require other containers of evaluated hazardous waste pharmaceuticals to be closed during accumulation, although we expect that reverse distributors would choose to do so as a best management practice. Further, because most evaluated hazardous waste pharmaceuticals are in their original packaging, we proposed that if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (*e.g.,* for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are

[441] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[442] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[443] See comment number EPA–HQ–RCRA–2007–0932–0272 in the docket for this rulemaking.

[444] See comment numbers EPA–HQ–RCRA–2007–0932–0280, EPA–HQ–RCRA–2007–0932–0296, and EPA–HQ–RCRA–2007–0932–0304 in the docket for this rulemaking.

[445] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[446] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[447] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

considered to meet the proposed closed container standard.

As with LQGs, EPA proposed that containers of evaluated hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the evaluated hazardous waste pharmaceuticals placed in the container. Another requirement that was tailored to reverse distributors was the proposal that reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals.

The LQG regulations in part 262 include management standards for several types of accumulation units that EPA did not propose to include for the management of evaluated hazardous waste pharmaceuticals. For instance, the proposal only set standards for the accumulation of evaluated hazardous waste pharmaceuticals in containers. EPA did not think it was necessary to include standards for accumulation units such as tanks, containment buildings, or drip pads because reverse distributors do not currently use these types of accumulation units. In addition, the Agency did not propose to require reverse distributors to meet the air emission standards found in 40 CFR part 265 subpart CC as required in § 262.34(a)(1)(i) for LQGs because the Agency anticipated that they will not be applicable. Additionally, 40 CFR part 265 subpart AA—air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are not applicable to the activities of a reverse distributor.

Summary of Comments. EPA received numerous comments on the proposed requirements for labeling and management of containers of evaluated hazardous waste pharmaceuticals in on-site accumulation areas at reverse distributors. One state supported that containers be marked with the words ''hazardous waste pharmaceuticals,'' but three states and one industry commenter requested that EPA require reverse distributors to label containers with the accumulation start date.[448] Stericycle, Inc. agreed that there is not a need to include standards for accumulation units such as tanks, containment buildings, or drip pads.[449] Clean Harbors argued that the only way to prevent diversion of hazardous waste pharmaceuticals is for all containers to be closed and sealed.[450] One state requested that EPA prohibit reverse distributors from mixing or commingling incompatible hazardous waste pharmaceuticals in the same container rather than only requiring reverse distributors to manage containers to prevent dangerous situations, such as fire explosion or release of toxic fumes.[451] One commenter agreed that the 40 CFR part 265 subpart AA—air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are not applicable to the activities of a reverse distributor and its management of hazardous waste pharmaceuticals.[452]

Final Rule Provisions. Final standards for labeling and management of containers at an on-site accumulation area are found at § 266.510(c)(4). EPA is finalizing that while containers of evaluated hazardous waste pharmaceuticals are in the accumulation area, they must be marked with the words, ''hazardous waste pharmaceuticals.'' Under the final rule, reverse distributors are not required to mark an accumulation start date on the label for the containers, because the reverse distributor's inventory will likely be used to verify the accumulation start date. However, a reverse distributor may choose an alternate method, such as marking the date on each container, to ensure that the containers of evaluated hazardous waste pharmaceuticals are not accumulated at the reverse distributor for more than 180 days. As explained previously, EPA prefers to allow a performance-based standard that allows flexibility to verify the 180-day accumulation time rather than require dating on the container labels. Most of the commenters that requested accumulation start dates on labels were states. Although the requirement is not being finalized at the federal level, any authorized state has the ability to impose more stringent regulations. If a state chooses to require the accumulation start date on the container label, that would be considered more stringent and permissible under RCRA.

In terms of container management standards, the Agency is finalizing the proposed requirements that are similar to the container management standards for LQGs as well as the additional management requirements specific to evaluated hazardous waste pharmaceuticals. Specifically, only containers with evaluated hazardous waste pharmaceuticals that are liquids or gels must be kept closed during accumulation, although EPA expects that all containers of evaluated hazardous waste pharmaceuticals will be closed given that evaluated hazardous waste pharmaceuticals are in their original packaging. As with the proposal, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (*e.g.,* for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard.

EPA is also finalizing that containers of evaluated hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the hazardous waste pharmaceuticals placed in the container. In addition, a reverse distributor that manages any container of ignitable or reactive evaluated hazardous waste pharmaceuticals or any container of commingled incompatible evaluated hazardous waste pharmaceuticals must manage the container to prevent dangerous situations, such as fire, explosion, or release of toxic fumes. These regulations are consistent with the LQG container management regulations in part 262 and already apply to LQG reverse distributors accumulating hazardous waste on site. The Agency is also finalizing that reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals. The dilution prohibition of § 268.3(c) already prohibits the incineration of some hazardous waste pharmaceuticals. This new provision highlights this prohibition to the reverse distributors accumulating the hazardous waste pharmaceuticals prior to sending off site for treatment and disposal.

Comments and Responses. EPA is finalizing management standards only for containers used to accumulate evaluated hazardous waste pharmaceuticals because commenters

[448] See comment numbers EPA–HQ–RCRA–2007–0932–0211, EPA–HQ–RCRA–2007–0932–0235, EPA–HQ–RCRA–2007–0932–0341, and EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[449] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[450] See comment number EPA–HQ–RCRA–2007–0932–0333 in the docket for this rulemaking.

[451] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[452] See comment number EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

confirmed that reverse distributors do not use other types of hazardous waste accumulation units, such as tanks, containment buildings, or drip pads.

In addition, the Agency is not requiring reverse distributors to meet the air emission standards found in 40 CFR part 265 subpart CC as required for LQGs in § 262.17(a)(1)(i) because the Agency anticipates that they will not be applicable. Specifically, § 265.1083(c) of subpart CC exempts tanks, surface impoundments, and containers from the organic air emission standards if the hazardous waste entering the accumulation unit has an average volatile organic concentration of less than 500 parts per million by weight, while § 265.1080(b)(2) of subpart CC exempts containers with a capacity of less than 0.1 m^3 (26 gallons) from the standards. EPA understands that the only evaluated hazardous waste pharmaceuticals that have the potential for air emissions are liquids and gels, but they generally do not contain volatile organics. Thus, they do not release organic air emissions, which is what the 40 CFR part 265 subpart CC air emission standards for tanks, surface impoundments, and containers were promulgated to control. Moreover, because evaluated hazardous waste pharmaceuticals are often in their original packaging, and EPA is requiring that liquid and gel evaluated hazardous waste pharmaceuticals must be in intact, sealed packaging or otherwise in closed containers, EPA believes that the container air emission standards are unnecessary. In addition, the Agency anticipates that the packaging and containers for hazardous waste pharmaceuticals will have a capacity of less than 0.1 m^3 (26 gallons) further limiting the applicability of the container air emission standards. Similarly, EPA does not anticipate that the 40 CFR part 265 subpart AA (air emissions standards for process vents) and subpart BB (air emission standards for equipment leaks) are applicable to the activities of a reverse distributor and its management of evaluated hazardous waste pharmaceuticals. Therefore, like 40 CFR part 265 subpart CC discussed previously, EPA is not requiring that 40 CFR part 265 subparts AA and BB apply to reverse distributors.

e. *Hazardous waste numbers (codes).*

Summary of Proposal. EPA proposed that RCRA hazardous waste numbers (commonly called ''hazardous waste codes'') must be marked on the container label in order to ensure that they are readily visible and cannot be separated from the hazardous waste. In the proposal, the Agency did not require that the reverse distributor be the party that adds the hazardous waste codes to the containers. The proposed regulations allowed a vendor to perform this duty on behalf of the reverse distributor.

Summary of Comments. Two states supported the requirement that hazardous waste codes be placed on containers of evaluated hazardous waste pharmaceuticals.[453] Waste Management National Services, Inc. argued that it is not practical to include all hazardous waste codes on each container label and instead suggested that codes be listed on the hazardous waste profile developed with the TSDF and on the manifest.[454]

Final Rule Provisions. Under the final rule, EPA is requiring that the containers of evaluated hazardous waste pharmaceuticals be marked with the applicable RCRA hazardous waste numbers (codes) at § 266.510(c)(5). The hazardous waste codes must be added prior to shipping evaluated hazardous waste pharmaceuticals off site, although they may be placed on the container label at any time during on-site accumulation. The hazardous waste numbers must be marked on the container label in order to ensure that it is readily visible and cannot be separated from the hazardous waste. It is necessary that the hazardous waste numbers are on the containers so that transporters, transfer facilities, and TSDFs know how to properly transport, consolidate, treat, store and dispose of the hazardous waste in compliance with the applicable RCRA regulations. In the final rule, the Agency is not requiring that the reverse distributor be the party that adds the hazardous waste numbers to the containers. The regulations allow a vendor to perform this duty on behalf of the reverse distributor. In practice, however, if a vendor is responsible for assigning hazardous waste numbers, personnel from the reverse distributor may need to assist in the process. To be consistent with the Hazardous Waste Generator Improvements final rule, we have added a sentence to § 266.510(c)(5) indicating that a nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste number(s).

f. *Shipping evaluated hazardous waste pharmaceuticals.*

Summary of Proposal. Although it is already stated in § 266.508(a) under the section of the regulations that pertains to shipping standards, for clarity, EPA proposed to repeat in the § 266.510 the reverse distributor regulations that reverse distributors that ship evaluated hazardous waste pharmaceuticals off site must do so in accordance with the proposed shipping requirements in § 266.508(a). This includes the applicable DOT packaging, marking and labeling requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a designated facility.

Summary of Comments. Two states generally supported the shipping requirements for evaluated hazardous waste pharmaceuticals.[455] One state supported that EPA repeat in § 266.510 the requirements pertaining to shipping standards although it is already stated in § 266.508(a).[456]

Final Rule Provisions. For clarity, the final reverse distributor regulations state that a reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in § 266.508(a) or (b). This includes the applicable DOT packaging, marking and labeling requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a permitted or interim status TSDF.

g. *Procedures for managing rejected shipments.*

Summary of Proposal. The Agency proposed to require that reverse distributors meet the same procedures that LQGs must meet for rejected shipments in § 262.42(c). Specifically, if a designated permitted or interim status TSDF identified on the hazardous waste manifest cannot accept a shipment of evaluated hazardous waste pharmaceuticals from a reverse distributor and the TSDF returns the shipment to the reverse distributor, EPA proposed that the reverse distributor must sign either item 18c of the original manifest or item 20 of a new manifest. In addition, the proposal allowed the reverse distributor to consolidate the rejected hazardous waste pharmaceuticals on site for up to 90 days provided they were managed in the on-site accumulation area and in accordance with the reverse distributor standards for evaluated hazardous waste pharmaceuticals. EPA also proposed that reverse distributors send a copy of

[453] See comment numbers EPA–HQ–RCRA–2007–0932–0300 and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[454] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[455] See comment numbers EPA–HQ–RCRA–2007–0932–0261 and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[456] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

the manifest to the designated facility that returned the shipment to the reverse distributor within 30 days of delivery.

Summary of Comments. One state requested the EPA clarify that a reverse distributor that receives a rejected shipment does not have to transport it off site upon receipt by the reverse distributor.[457] One state argued that a reverse distributor does not need 90 days to accumulate rejected hazardous waste pharmaceuticals in the on-site accumulation area and argued that 30 days is sufficient.[458]

Final Rule Provisions. The Agency is finalizing in § 266.510(c)(7) that reverse distributors must meet the same procedures that LQGs must meet for rejected shipments in § 262.42(c). Under part 262, these rejected shipment procedures already apply to LQG reverse distributors. Furthermore, EPA anticipates that a rejected shipment is a relatively infrequent occurrence and therefore should not be a burden to reverse distributors. In addition, the final rule allows the reverse distributor to consolidate the rejected hazardous waste pharmaceuticals on site for up to 90 days provided they are managed in the on-site accumulation area and in accordance with the reverse distributor standards for evaluated hazardous waste pharmaceuticals. Although one state requested EPA only allow accumulation for 30 days, any authorized state has the ability to impose more stringent regulations. If a state chooses to shorten the accumulation time, that would be considered more stringent and permissible under RCRA.

h. *Land disposal restrictions.*

Summary of Proposal. EPA proposed that reverse distributors are subject to the same LDRs that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition, EPA proposed to amend the testing, tracking, and recordkeeping requirements for generators, treaters and disposal facilities at § 268.7 to add the words, ''pharmaceutical reverse distributors'' to the title of that section to make the applicability of the treatment standards clear.

Summary of Comments. EPA received multiple comments in support of the requirement that reverse distributors meet the same LDRs that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals, including two states.[459] The Oregon Association of Clean Water Agencies wrote that applying the LDRs will reduce mobility of pharmaceutical constituents in landfill leachate, which is frequently routed to POTWs in Oregon.[460]

Final Rule Provisions. As required by HSWA, EPA is finalizing that reverse distributors are subject to the same land disposal restrictions that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition, EPA is amending the titles at §§ 268.7 and 268.7(a) to add the words, ''reverse distributors'' to make the applicability of the land disposal restrictions clear. SQG and LQG reverse distributors are already subject to LDRs for their hazardous waste pharmaceuticals. Therefore, this provision does not impose additional burden on reverse distributors.

i. *Reporting.*

Summary of Proposal. EPA proposed that reverse distributors submit a biennial report (BR) for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. The Agency proposed that the BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a reverse distributor sends to another reverse distributor. Specifically, EPA proposed that a reverse distributor comply with the LQG BR requirements in § 262.41, except for § 262.41(a)(7), which included the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. The Agency did not propose that a reverse distributor provide such information because it does not have control of the volume or toxicity of the hazardous waste pharmaceuticals it receives from healthcare facilities, and thus has no ability to reduce the volume or toxicity of the hazardous waste pharmaceuticals.

EPA proposed that reverse distributors provide an exception report when a TSDF does not return the hazardous waste manifest to the reverse distributor for shipments of evaluated hazardous waste pharmaceuticals. Likewise, EPA proposed that reverse distributors meet LQG exception reporting when a shipment from a reverse distributor is rejected by the designated facility and forwarded onto an alternate facility. These proposed standards were adapted from the exception reporting for LQGs in § 262.42(a).

Summary of Comments. One state supported both of the proposed reporting requirements for reverse distributors managing evaluated hazardous waste pharmaceuticals that are transported to a TSDF.[461] RILA argued that the requirement that reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF is effectively more stringent than current generator requirements that only require generators to submit a biennial report if they generate over 1000 kg of hazardous waste in a month.[462]

Final Rule Provisions. EPA is finalizing at § 266.510(c)(9)(i) that reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. The BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a reverse distributor sends to another reverse distributor. EPA does not expect that requiring reverse distributors to submit a BR for evaluated hazardous waste pharmaceuticals will be burdensome because most reverse distributors currently operate as LQGs and already submit a BR.[463] Specifically, under the final rule, reverse distributors must comply with the LQG BR requirements in § 262.41. EPA proposed that reverse distributors had to comply with the LQG BR requirements in § 262.41 except § 262.41(a)(7), which included the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. However, since the proposed rulemaking, the 2016 Hazardous Waste Generator Improvement rule was finalized. As part of that final rule, § 262.41(a)(7) was removed from the generator requirements. Thus, the final rule only states that reverse distributors must

[457] See comment number EPA–HQ–RCRA–2007–0932–0231 in the docket for this rulemaking.

[458] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[459] See comment numbers EPA–HQ–RCRA–2007–0932–0315 and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[460] See comment number EPA–HQ–RCRA–2007–0932–0288 in the docket for this rulemaking.

[461] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[462] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[463] See the Regulatory Impact Analysis in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

comply with the LQG BR requirements in § 262.41.

Consistent with the LQG regulations in part 262, EPA is finalizing at § 266.510(c)(9)(ii) that reverse distributors must provide an exception report when a TSDF does not return the signed hazardous waste manifest to the reverse distributor for shipments of hazardous waste pharmaceuticals to a designated facility within 45 days of shipment. Likewise, EPA is finalizing that reverse distributors must provide an exception report when a shipment from a reverse distributor is rejected by the designated facility and forwarded onto an alternate facility and the reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days. These standards were adapted from the exception reporting for LQGs in § 262.42(a), while the standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals were adapted from the exception reporting for SQGs § 262.42(b). EPA is finalizing that a reverse distributor that does not receive a copy of the manifest within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or TSDF to determinate the status of the evaluated hazardous waste pharmaceuticals. EPA is also finalizing that a reverse distributor must submit a copy of an exception report if it has not received a copy of the manifest within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The exception report must include a legible copy of the manifest for which the reverse distributor does not have confirmation of delivery and a cover letter explaining efforts taken to locate the evaluated hazardous waste pharmaceuticals.

j. *Recordkeeping.*

Summary of Proposal. In total, EPA proposed five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at reverse distributors. First, EPA proposed that a reverse distributor keep a log (written or electronic) of its weekly inspections of the on-site accumulation area. The other four recordkeeping requirements that EPA proposed for reverse distributors are the same as the LQG recordkeeping requirements that appear in §§ 262.17(a)(7)(iv) and (v), 262.40, and 262.42; these include training documentation, hazardous waste manifest records, records of biennial reports, and exception reporting.

Summary of Comments. Hennepin County supported the requirement for reverse distributors to document training.[464]

Final Rule Provisions. Many of the final recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals have been discussed in the sections previously, but for clarity, it is useful to restate them in this recordkeeping section, so that reverse distributors can refer to one section to determine their recordkeeping requirements related to evaluated hazardous waste pharmaceuticals. In total, EPA is finalizing five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at reverse distributors that can be found listed at § 266.510(c)(10). First, EPA is requiring that a reverse distributor keep a log (written or electronic) of its inspections of the on-site accumulation area. The other four recordkeeping requirements that EPA is requiring under the final rule for reverse distributors are the same as the LQG recordkeeping requirements in part 262. These include hazardous waste manifest records, records of biennial reports, exception reporting and training documentation.

4. When a Reverse Distributor Must Have a RCRA Hazardous Waste Permit (§ 266.510(d))

a. *Summary of proposal.* In the proposed rulemaking, EPA did not require that a reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the reverse distributor follows all the conditions of the permitting exemption in § 266.510. However, EPA proposed that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site.

b. *Summary of comments.* One state supported the proposed requirement that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site.[465] Clean Harbors argued that EPA's rationale for not requiring a hazardous waste storage permit is flawed and argued that the requirement for obtaining a full RCRA permit be based on the amount of time a potentially creditable hazardous waste pharmaceutical is stored.[466] The Environmental Technology Council argued that reverse distributors should be required to obtain permits or interim status for storage.[467]

c. *Final rule provisions.* Under the final rule, EPA is not requiring that a reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the reverse distributor follows all the conditions of the permitting exemption in § 266.510. In other words, a reverse distributor will be subject to regulation as a TSDF and require a RCRA permit (or interim status) if it does not meet the conditions of § 266.510. In addition, EPA is finalizing that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site. A reverse distributor is required to reject shipments of manifested hazardous waste that it may inadvertently receive from off site because a reverse distributor is not a designated facility and therefore is not eligible to receive hazardous waste shipped with a manifest. EPA believes that this approach to regulation of reverse distributors that accumulate potentially creditable and evaluated hazardous waste pharmaceuticals strikes an appropriate balance because it recognizes that reverse distributors are different from typical hazardous waste TSDFs for permitting purposes, while it still imposes certain conditions for exemption from permitting requirements that provide the necessary environmental protection.

XVIII. Amendments to the Part 268 Prohibitions on Storage

The Agency is finalizing conforming changes that we proposed to the prohibitions on storage of restricted waste in § 268.50. We are finalizing two new subparagraphs in § 268.50(a) to make it clear that the storage prohibitions apply to both healthcare facilities and reverse distributors operating under part 266 subpart P. Specifically, we are adding paragraph (4) for healthcare facilities and paragraph (5) for reverse distributors to extend the application of the existing storage prohibition to facilities operating under subpart P. Under the LDR storage prohibition the storage of restricted hazardous wastes is

[464] See comment number EPA–HQ–RCRA–2007–0932–0386 in the docket for this rulemaking.

[465] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[466] See comment number EPA–HQ–RCRA–2007–0932–0333 in the docket for this rulemaking.

[467] See comment number EPA–HQ–RCRA–2007–0932–0297 in the docket for this rulemaking.

prohibited unless certain conditions are met. Healthcare facilities must comply with the applicable requirements in §§ 266.502 and 266.503 and reverse distributors must comply with § 266.510 when accumulating hazardous waste pharmaceuticals on site.

XIX. Implementation and Enforcement

A. Healthcare Facilities

1. Determining Whether a Healthcare Facility Is Subject to Part 266 Subpart P

EPA is finalizing that healthcare facilities that are currently considered LQGs or SQGs are subject to the final 40 CFR part 266 subpart P requirements for the management of hazardous waste pharmaceuticals. Thus, a healthcare facility that generates more than 100 kg of hazardous waste per month, or more than 1 kg of acute hazardous waste per calendar month, or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute wastes listed in §§ 261.31, or 261.33(e), must manage its hazardous waste pharmaceuticals in compliance with the 40 CFR part 266 subpart P requirements. In addition, healthcare facilities that are VSQGs are subject to the prohibition on sewering hazardous waste pharmaceuticals in § 266.505, the empty container standards in § 266.507, and the optional standards of § 266.504.

To determine whether a healthcare facility is subject to 40 CFR part 266 subpart P or is a VSQG regulated under § 262.14, a healthcare facility must count all the hazardous waste—pharmaceutical and non-pharmaceutical—it generates in a calendar month. Note that in the final rule EPA has revised which pharmaceuticals are considered hazardous wastes. Specifically, EPA is finalizing that potentially creditable hazardous waste pharmaceuticals transported to a reverse distributor are considered a solid and hazardous waste from the point of generation at the healthcare facility and therefore must be counted when determining whether the healthcare facility is a VSQG regulated under § 262.14 or whether it is regulated under 40 CFR part 266 subpart P for its hazardous waste pharmaceuticals. This differs from previous healthcare facility practice of not counting the potentially creditable hazardous waste pharmaceuticals it sends to a reverse distributor towards its hazardous waste generator category. Therefore, although a healthcare facility may have been considered a VSQG under that previous practice, when it begins counting its potentially creditable hazardous waste pharmaceuticals, it may no longer be a VSQG. In that case, the healthcare facility would be subject to the 40 CFR part 266 subpart P requirements for its hazardous waste pharmaceuticals.

2. Healthcare Facilities Managing Hazardous Waste Pharmaceuticals Under Part 266 Subpart P

EPA is finalizing that all healthcare facilities operating Under part 266 subpart P will be subject to the same regulations for the management of their hazardous waste pharmaceuticals, regardless of the quantity of hazardous waste pharmaceuticals generated. A healthcare facility that generates both pharmaceutical and non-pharmaceutical hazardous waste must manage the non-pharmaceutical hazardous waste pursuant to part 262, but need not count its hazardous waste pharmaceuticals toward determining the facility's monthly hazardous waste generator category. Therefore, although a facility that previously may have been considered an LQG, once it no longer counts its hazardous waste pharmaceuticals towards its monthly hazardous waste generator category, it may no longer be an LQG. As a result, it is possible that the healthcare facility may not need to manage its non-pharmaceutical hazardous waste pursuant to the LQG regulations in § 262.17, but rather can operate under the reduced regulations for SQGs in § 262.16 or for VSQGs in § 262.14. In addition, if a healthcare facility that is a VSQG does not want to keep track of the amount of hazardous waste pharmaceuticals it generates to ensure it does not exceed the VSQG quantity limits, it can choose to operate under this final rule. If it chooses to operate under this final rule, however, a healthcare facility must comply with all the requirements of this subpart for the management of its hazardous waste pharmaceuticals.

Following publication of the final rule, EPA plans extensive outreach to educate healthcare facilities and reverse distributors on the provisions of this final rule.

B. Reverse Distributors and Reverse Logistics Centers

1. Prescription Pharmaceuticals Sent to Reverse Distributors Are Solid Wastes

EPA proposed to change how RCRA would apply to pharmaceuticals returned to reverse distributors to obtain manufacturers credit. EPA proposed that the decision by a healthcare facility to send a pharmaceutical to a reverse distributor is the decision to discard the pharmaceutical. Due to many comments on this proposed change, the Agency is now making a clear distinction in the final rule between reverse distribution, in the case of prescription pharmaceuticals, and reverse logistics in the case of all other pharmaceuticals—including over-the counter pharmaceuticals and dietary supplements, as well as other unsold consumer items (see section VI for a discussion of the comments). EPA is finalizing that the decision by a healthcare facility to send a prescription pharmaceutical to a reverse distributor is the decision to discard the prescription pharmaceutical. Therefore, under this final rule, once the healthcare facility makes the decision to send a prescription pharmaceutical to a reverse distributor for credit, it is a solid waste at the healthcare facility. A portion of the potentially creditable solid waste prescription pharmaceuticals at healthcare facilities that are destined for a reverse distributor will also meet the definition of hazardous waste and as a result, these potentially creditable hazardous waste prescription pharmaceuticals would need to be managed in accordance with the final 40 CFR part 266 subpart P requirements.

In addition, the Agency notes that the change in EPA's position concerning reverse distribution and the management standards discussed in this final rule pertain only to the reverse distribution of prescription hazardous waste pharmaceuticals and does not apply to the reverse logistics of other pharmaceuticals or to the reverse logistics systems that may exist for other unsold consumer items.

2. Nonprescription Pharmaceuticals Sent to Reverse Logistics Centers Are Not Solid Wastes

EPA proposed that the decision by a healthcare facility to send any pharmaceutical to a reverse distributor is the decision to discard the pharmaceutical, but is now making a clear distinction in the final rule between reverse distribution of prescription pharmaceuticals and reverse logistics of nonprescription pharmaceuticals and other unsold retail items. In response to comments, EPA is codifying our previous policy that the decision by a healthcare facility to send nonprescription pharmaceuticals to a reverse logistics center is not a decision to discard if the nonprescription pharmaceuticals have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed. In other words, EPA is finalizing that nonprescription pharmaceuticals are not

solid wastes, and therefore not hazardous waste pharmaceuticals if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

3. Reverse Distributors Managing Hazardous Waste Pharmaceuticals Under Part 266 Subpart P

EPA is finalizing that all reverse distributors are subject to 40 CFR part 266 subpart P and will be subject to the same standards with respect to their hazardous waste pharmaceuticals, regardless of the amount of hazardous waste pharmaceuticals they manage. Even reverse distributors that are currently VSQGs will be regulated under 40 CFR part 266 subpart P for the management of their hazardous waste pharmaceuticals. Therefore, a reverse distributor subject to 40 CFR part 266 subpart P will no longer have to keep track of the amount of hazardous waste pharmaceuticals that it generates on a monthly basis.

C. Healthcare Facilities and Reverse Distributors Managing Non-Pharmaceutical Hazardous Waste in Accordance With 40 CFR Part 262 or Part 273 (i.e., Complying With ''More Than One RCRA'')

Most, if not all, healthcare facilities and reverse distributors generate at least some hazardous wastes other than pharmaceuticals. These non-pharmaceutical hazardous wastes will continue to be regulated under 40 CFR part 262 (and other applicable Subtitle C regulations). The standards established by this rulemaking apply only to the management of hazardous waste pharmaceuticals at healthcare facilities and reverse distributors. Healthcare facilities and reverse distributors likely generate or manage other types of hazardous wastes. For example, hospitals may generate non-pharmaceutical hazardous wastes, such as solvents in their diagnostic laboratories; those hazardous wastes must still be managed in accordance with the part 262 generator regulations (such as the RCRA SAA regulations (§ 262.15)), or if it is a teaching hospital, the Academic Laboratories Rule (if it has opted into part 262 subpart K). Retail stores, including pharmacies and grocery stores, may have non-pharmaceutical hazardous wastes on-site as well, which must be managed in accordance with the 40 CFR part 262 regulations and all other applicable RCRA Subtitle C regulations. For example, fluorescent bulbs may be managed under the universal waste program (40 CFR part 273). For reverse distributors, this rule only applies to the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Some reverse distributors may generate other non-pharmaceutical hazardous wastes from activities, such as cleaning and maintenance; other RCRA Subtitle C regulations will apply to those non-pharmaceutical hazardous wastes.

D. State Enforcement Activities and Interpretations

States have taken a variety of approaches regarding hazardous waste pharmaceuticals. One major goal of this final rule is to provide clarity on this topic, and thereby promote national consistency, which should promote better compliance among healthcare facilities, including pharmacies.

In 2012, Connecticut's Department of Energy and Environmental Protection (DEEP) took enforcement actions at seven CVS stores for violations of the RCRA hazardous waste regulations. Consent orders from CT DEEP direct CVS stores in the state to follow a set of best management practices.[468] A number of the practices developed in these consent orders mirror some of the practices EPA is finalizing in this rule, particularly with regard to pharmaceuticals destined for a reverse distributor. CT DEEP asserts RCRA jurisdiction over the pharmaceuticals destined for reverse distributors by applying specific management practices. For example, CVS must maintain records of each shipment of non-dispensable pharmaceuticals to a reverse distributor, including confirmation of receipt of the non-dispensable pharmaceuticals from the receiving reverse distributor. The best practices also include procedures for addressing situations when CVS does not receive delivery confirmation of shipment to a reverse distributor. Further, the consent order sets out separate, more comprehensive practices for the non-dispensable pharmaceuticals that are not suitable for reverse distribution.

Aside from best management practices developed by Connecticut as part of a consent order, at least two other states have developed guidance documents that apply conditions to the management of hazardous wastes pharmaceuticals in exchange for enforcement discretion. In particular, in 2008, the Washington State Department of Ecology issued guidance titled, Interim Enforcement Policy: Pharmaceutical Waste in Healthcare.[469] This interim enforcement discretion policy had some elements in common with this final rule for hazardous waste pharmaceuticals. For instance, a healthcare facility was required to notify the Department of Ecology that it was operating under the policy and had to train its staff involved in pharmaceutical waste management. Only a time limit, rather than a quantity limit, applied to the accumulation of the hazardous waste pharmaceuticals on site. Of particular note is that Washington State prohibited disposing of most hazardous waste pharmaceuticals down the toilet or drain. In anticipation of this final rule, Washington State updated the interim policy in June 2017 to provide regulated facilities with the opportunity to use some of the provisions outlined in the proposed rulemaking, such as allowing facilities to send creditable pharmaceuticals to a reverse distributor for evaluation without providing hazardous waste codes.[470]

In 2011, Minnesota's Pollution Control Agency (MPCA) issued a fact sheet titled Reverse Distribution of Pharmaceuticals: Guidance for Minnesota Healthcare Providers.[471] In this guidance, Minnesota states, ''Whether a pharmaceutical is eligible for return credit does not affect its product or waste status. In Minnesota, if a pharmaceutical is not used or reused for its intended purpose, it is a waste. The MPCA considers health care practitioners and pharmacies to be generators of these pharmaceutical wastes. Nevertheless, the MPCA believes that the established reverse distribution system provides an environmentally protective method for handling waste pharmaceuticals. Therefore, it will allow Minnesota health care practitioners and pharmacies to manage certain pharmaceuticals through reverse distribution, subject to additional requirements discussed in this fact sheet.'' This is similar to the approach that EPA is finalizing for potentially creditable hazardous waste pharmaceuticals. For example, like EPA's final rule, MPCA does not require hazardous waste pharmaceuticals destined for a reverse distributor to be

[468] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0173.

[469] See the 2008 interim enforcement policy in the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0181.

[470] See the 2017 interim enforcement policy at *https://fortress.wa.gov/ecy/publications/documents/0704024.pdf* or in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[471] See the guidance document in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932–0178).

counted toward determining a healthcare facility's generator category. In addition, MPCA does not require hazardous waste pharmaceuticals to be accompanied by a hazardous waste manifest when shipped to a reverse distributor. By finalizing a rule that is consistent with state approaches, EPA is bringing national consistency to the management of hazardous waste pharmaceuticals, while avoiding disruption to practices already in place.

E. Intersection of Part 266 Subpart P With the Hazardous Waste Generator Improvements Rule

The Hazardous Waste Generator Improvements rule was finalized on November 28, 2016.[472] This rule finalized a much-needed update to the hazardous waste generator regulations in part 262 to make the rules easier to understand, facilitate better compliance, provide greater flexibility in how hazardous waste is managed and close important gaps in the regulations. This section of preamble discusses three portions of the Hazardous Waste Generator Improvements final rule that might impact healthcare facilities and reverse distributors that are subject to part 266 subpart P.

1. Episodic Generation

One of the key provisions with which EPA added regulatory flexibility allows a hazardous waste generator to avoid increased burden of a higher generator category when generating episodic waste provided the episodic waste is properly managed in accordance with part 262 subpart L. Healthcare facilities and reverse distributors will be able to take advantage of this added regulatory flexibility (assuming their state has adopted this provision).

A healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste can use the episodic generation provision of part 262 subpart L for all of its hazardous waste, including its hazardous waste pharmaceuticals. If a healthcare facility is generally operating under § 262.14 as a VSQG, but has an episodic event, it would be far less burdensome to comply with part 262 subpart L than to come into compliance with all the provisions of part 266 subpart P for the short duration of the episodic event. For example, if a VSQG healthcare facility is directed to dispose of recalled pharmaceuticals, it could use the episodic generator provisions of part 262 subpart L to avoid an increase in hazardous waste generator category. However, if a healthcare facility that is a VSQG generates hazardous waste in excess of the allowable amounts as a VSQG,[473] and it chooses not to use the episodic generator provisions in part 262 subpart L, it would become subject to part 266 subpart P for its hazardous waste pharmaceuticals.

As discussed previously, healthcare facilities and reverse distributors that are subject to part 266 subpart P for their hazardous waste pharmaceuticals may still be subject to part 262 for the management of their non-pharmaceutical hazardous waste. A healthcare facility or reverse distributor operating under part 266 subpart P for its hazardous waste pharmaceuticals may not use the episodic generator standards of part 262 subpart L with respect to its hazardous waste pharmaceuticals. Under part 266 subpart P, all healthcare facilities are regulated the same regardless of amounts of hazardous waste pharmaceuticals generated and all reverse distributors are regulated the same, regardless of amounts of hazardous waste pharmaceuticals managed, making the need for episodic generation provisions unnecessary. On the other hand, if a healthcare facility or reverse distributor is generally operating as a VSQG or SQG for its non-pharmaceutical hazardous waste, but has an episodic event, the healthcare facility may use the provisions in part 262 subpart L for its non-pharmaceutical hazardous waste.

2. Small Quantity Generator Re-Notification

The 2016 Hazardous Waste Generator Improvements final rule added a new requirement for periodic re-notification by SQGs.[474] Under this new provision, SQGs must re-notify EPA starting in 2021 and every four years thereafter using EPA Form 8700–12. This re-notification must be submitted by September 1st of each year in which re-notifications are required.[475] Healthcare facilities and reverse distributors operating under part 266 subpart P may also be subject to part 262 for the management of its non-pharmaceutical hazardous waste. If a healthcare facility or reverse distributor is an SQG for its non-pharmaceutical hazardous waste, then it will be subject to this re-notification requirement under part 262. Therefore, in order to avoid duplicative notification requirements, under part 266 subpart P, EPA is not requiring re-notification by healthcare facilities and reverse distributors.

3. Very Small Quantity Generators That Accumulate More Than 1 Kg of Acute Hazardous Waste

The 2016 Hazardous Waste Generator Improvements final rule clarified in § 262.14(a)(3) that if a VSQG accumulates at any time greater than 1 kg of acute hazardous waste,[476] all quantities of that acute hazardous waste are subject to the additional conditions for exemption for LQGs. More specifically, the acute hazardous waste must be held on site for no more than 90 days beginning on the date when more than 1 kg is exceeded, and the acute hazardous waste is subject to the LQG conditions for exemption in § 262.17(a) through (g). In other words, while the acute hazardous waste becomes subject to the stricter standards for LQGs when the accumulation limits are exceeded, the generator continues to be considered a VSQG, provided the generator continues to generate within the VSQG thresholds identified in the definition of VSQG in § 260.10.

If a healthcare facility that is a VSQG accumulates more than 1 kg of acute hazardous waste,[477] then it will remain subject to § 262.14(a)(3); the healthcare facility will not become subject to part 262 subpart P.

XX. State Authorization

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize states to administer the RCRA Subtitle C hazardous waste program. Following authorization, the authorized state program operates in lieu of the federal regulations. EPA retains authority to enforce the authorized state Subtitle C program, although authorized states have primary enforcement authority. EPA also retains its authority under RCRA sections 3007, 3008, 3013, and 7003. The standards and requirements for state authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a state with final RCRA authorization administered its hazardous waste program entirely in

[472] See November 28, 2016; 81 FR 85732.

[473] See the definition of very small quantity generator in 40 CFR 2601.10.

[474] See 40 CFR 262.18(d)(1).

[475] See 81 FR 85777–8; November 28, 2016 for the preamble discussion explaining the need for re-notification.

[476] Or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or 261.33(e).

[477] Or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or 261.33(e).

lieu of EPA administering the federal program in that state. EPA did not issue permits for any facilities in that state, since the state was now authorized to issue RCRA permits. When new, more stringent federal requirements were promulgated, the state was obligated to enact equivalent authorities within specified time frames. However, the new requirements did not take effect in an authorized state until the state adopted the equivalent state requirements.

In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized states at the same time that they take effect in unauthorized states. While states must still adopt HSWA-related provisions as state law to retain authorization, EPA implements the HSWA provisions in authorized states, including the issuance of any permits pertaining to HSWA requirements, until the state is granted authorization to do so.

Authorized states are required to modify their programs only when EPA promulgates federal requirements that are more stringent or broader in scope than existing federal requirements.[478] RCRA section 3009 allows the states to impose standards more stringent than those in the federal program (see 40 CFR 271.1). Therefore, authorized states may, but are not required to, adopt federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous federal regulations.

B. Effect on State Authorization

This action adds a new subpart P to 40 CFR part 266, and it is being finalized in part under the authority of HSWA and in part under non-HSWA authority. The bulk of 40 CFR part 266 subpart P is being finalized under non-HSWA authority. Thus, the amendments promulgated under non-HSWA authority are applicable on the effective date only in those states that do not have final authorization of their base RCRA programs. Only the prohibition of sewering hazardous waste pharmaceuticals (§ 266.504) is being finalized under HSWA authority in section 3018 of RCRA. The amendments promulgated under the authority of HSWA (*i.e.,* the prohibition on sewering hazardous waste pharmaceuticals) are applicable on the effective date of the final rule in all states. Moreover, authorized states are required to modify their programs only when EPA promulgates federal regulations that are more stringent or broader in scope than the authorized state regulations. For those changes that are less stringent, states are not required to modify their programs.

While some provisions of part 266 subpart P are considered less stringent than the current federal standards, other provisions of the final rule are considered more stringent than the current federal standards. Taken as a whole, we consider the entire new subpart P under 40 CFR part 266 entitled ''Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities'' (sections VIII–XVII of this preamble) to be more stringent than the current federal standards. Therefore, authorized states will be required to modify their programs to adopt these revisions. When a state adopts this new subpart, if elements of the state program are more stringent than this new subpart, the state has the option of retaining those more stringent elements. Likewise, when a state adopts this new subpart, the state has the option of adding elements that are more stringent or broader in scope than this new subpart.

On the other hand, one final revision is less stringent than the current hazardous waste regulations. The amendment to exempt from the P075 listing the nicotine patches, gums and lozenges that are FDA-approved OTC nicotine replacement therapies is less stringent that the current hazardous waste regulations (section V of this preamble). Thus, authorized states may, but are not required to, adopt the change to the P075 listing.

C. Effect on State Authorization in States That Have Added Pharmaceuticals to the Universal Waste Program

The Universal Waste program allows states to add waste streams to their own state program, even when the waste stream has not been added to the federal Universal Waste program, provided the state has adopted and been authorized for the petition process in §§ 260.20 and 260.23. Two states have added hazardous waste pharmaceuticals to their Universal Waste programs: Florida and Michigan. Because the added subpart P under CFR part 266 is considered more stringent than either the ''traditional RCRA'' standards or the Universal Waste program, both Florida and Michigan will be required to modify their programs to adopt an approach at least as stringent as the amendments. Furthermore, because the Agency has determined that it is not appropriate to add hazardous waste pharmaceuticals to the Universal Waste program, both Florida and Michigan must remove hazardous waste pharmaceuticals from their Universal Waste program when they adopt this new subpart, although they may continue to regulate non-hazardous waste pharmaceuticals under the Universal Waste program, to the extent allowed under state law. In addition, states may choose to add non-hazardous waste pharmaceuticals to their Universal Waste program or may regulate them more stringently as part of their hazardous waste program but states may not add hazardous waste pharmaceuticals to their Universal Waste program in the future. Accordingly, we have amended the regulations in § 273.80(a) and added § 273.80(d) to reflect this decision that states may not add hazardous waste pharmaceuticals to their Universal Waste program.

XXI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Pursuant to the terms of Executive Order 12866, as affirmed in Executive Order 13563, the Agency has determined that this rule is a significant regulatory action because it contains novel policy issues, as defined under section 3(f)(4) of the Order. Any changes made in response to OMB recommendations have been documented in the docket.

As discussed in section I above, EPA prepared an economic analysis of the potential costs and benefits associated with this action. This analysis, *Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals,* indicates that the rule is projected to result in net annual cost savings of approximately $12.99 million to $14.96 million based on a discount rate of 7 percent or $12.98 to $14.95 million based on a discount rate of 3 percent. The full analysis is available in the docket for this rule.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory

[478] EPA notes that decisions regarding whether a state rule is more stringent or broader in scope than the federal program are made when the Agency authorizes a state program for a particular rule.

action. Details on the estimated cost savings of this final rule can be found in EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act

The information collection activities in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR number 2486.02, OMB control number 0250–0212. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

EPA is finalizing in this rule, under a new subpart P to 40 CFR part 266, new and revised reporting and recordkeeping requirements for healthcare facilities and reverse distributors. These requirements, which are also identified in the ICR supporting this action, will enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals. In addition, the requirements include provisions for tracking of hazardous waste pharmaceuticals that are sent to reverse distributors.

EPA will use the collected information to ensure that hazardous waste pharmaceuticals are being managed in a protective manner. The tracking requirements ensure that these wastes arrive at their intended destinations rather than diverted for illicit purposes or managed at facilities not equipped to manage these wastes. These tracking requirements will also help facilities identify shipments that do not arrive at their destination as planned, allowing generators to take corrective action that will ensure that future shipments are transported to the appropriate location. Information marked on containers of hazardous waste pharmaceuticals will assist handlers and transporters in ensuring proper management during storage and shipment.

Respondents/affected entities: Drug wholesalers, supermarkets and other grocery stores, pharmacies and drug stores, warehouse clubs and supercenters, veterinary clinics, physicians' offices, dentists' offices, other health practitioners, outpatient care centers, other ambulatory health care services, hospitals, nursing care facilities, continuing care retirement communities, and reverse distributors.

Respondent's obligation to respond: The recordkeeping and notification requirements are mandatory and are being promulgated under section 3001 of RCRA.

Estimated number of respondents: 13,373.

Frequency of response: The frequency of response varies.

Total estimated burden: EPA estimated the total annual burden to respondents to be approximately 43,577 hours. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: EPA estimated the total estimated annual cost of this paperwork burden to respondents to be approximately $2,543,409.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

D. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. As documented in the Regulatory Impact Analysis found in the docket for this proposal, EPA does not expect the rule to result in an adverse impact to a significant number of small entities. EPA estimates that there are at least 10,481 to 15,114 small entities that will be impacted by this rule. However, small entities are expected to experience a net cost savings under the final rule, and for the small entities that are expected to experience a net cost under the final rule, the RIA estimates the costs, at most, to represent 0.013 percent of annual revenues for small entities. We have therefore concluded that this action will either relieve regulatory burden or have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act

As documented in the Regulatory Impact Analysis found in the docket for this rule, this action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. As indicated previously, the annual net cost savings is estimated to be between approximately $13 million and $15 million (based on a discount rate of 7%). Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. While some hospitals are publicly owned, the requirements affecting those facilities are not unique in that they are the same as those affecting all facilities in the proposed rulemaking. Also, using data on revenues of hospitals owned by state and local governments, EPA estimated that the costs of the rule borne by state and local governments represent less than 0.001% of their revenues. Therefore, the costs incurred by small governments are not expected to be significant.

F. Executive Order 13132: Federalism

As documented in the Regulatory Impact Analysis found in the docket for this rule, this action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation With Tribal Governments

This action may have tribal implications as specified in Executive Order 13175. The final rule will neither impose substantial direct compliance costs on tribal government, not preempt tribal law. Under the RCRA statute, the federal government implements hazardous waste regulations directly in Indian Country. Thus, the final rule would not impose any direct costs on tribal governments.

To assess the potential tribal implications of the action, EPA compiled data on the number of tribally run healthcare facilities in the U.S. and estimated the costs of this action for these facilities. As documented in the Regulatory Impact Analysis in the docket for this rule, the rule is not expected to impose a substantial burden on tribal governments.

EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its

development. A summary of that consultation is provided in the docket for this rule (see EPA–HQ–RCRA–2008–0932).

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

H. Executive Order 13045: Children's Health

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866 and because the EPA does not believe the environmental health or safety risks addressed by this proposed action present a disproportionate risk to children. This action's health and risk assessments are contained in the *Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals,* found in the docket for this action.

I. Executive Order 13211: Energy Supply

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. The final rule does not directly regulate energy production or consumption. Changes in the management of hazardous waste pharmaceuticals stipulated in this action are not expected to impact energy production or distribution and will have minimal impact on energy consumptions.

J. National Technology Transfer and Advancement Act

This final rulemaking does not involve technical standards.

K. Executive Order 12898: Environmental Justice

EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in the Regulatory Impact Analysis, which can be found at regulations.gov under docket number EPA–HQ–RCRA–2007–0932.

To meet the requirements of Executive Order 12898, EPA analyzed potential environmental justice impacts associated with the diversion of hazardous waste pharmaceuticals from sewer disposal to hazardous waste combustion facilities. Populations living near and downstream from wastewater treatment plants may also benefit from the elimination of sewering of hazardous waste pharmaceuticals. To the extent that minority and/or low-income populations near or downstream from wastewater treatment plants make up a disproportionately high portion of the overall population, this final action may result in positive environmental justice impacts.

Overall, EPA expects that this action may positively affect U.S. environmental justice populations, although the size of the impact will vary by wastewater treatment plant. A reduction in sewering expected under the final rule may benefit relatively large minority and low-income populations in close proximity to or downstream from wastewater treatment plants. The diversion of hazardous waste pharmaceuticals from wastewater treatment plants to combustion facilities, however, may increase the environmental burden borne by environmental justice populations near these combustion facilities. Although these effects offset each other to a certain degree, the number of minority and low-income individuals near wastewater treatment facilities exceeds the number near hazardous waste combustion facilities. This suggests that, on the whole, the final action may benefit environmental justice populations.

L. Congressional Review Act

EPA will submit a report containing this rule and other information required by the Congressional Review Act (5 U.S.C. 801 *et seq.*) to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until sixty (60) days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This final authorization will be effective August 22, 2019.

List of Subjects

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

40 CFR Part 264

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds.

40 CFR Part 265

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

40 CFR Part 266

Environmental protection, Energy, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 268

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 270

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 273

Environmental protection, Hazardous materials transportation, Hazardous waste.

Dated: December 11, 2018.

Andrew R. Wheeler,

Acting Administrator.

For the reasons stated in the preamble, Title 40, chapter I, of the Code of Federal Regulations is amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

■ 2. Section 261.4 is amended by revising paragraph (a)(1)(ii) to read as follows:

§ 261.4 Exclusions.

(a) * * *

(1) * * *

(ii) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, except as prohibited by § 266.505 and Clean Water Act requirements at 40 CFR 403.5(b). ''Domestic sewage'' means

untreated sanitary wastes that pass through a sewer system.

* * * * *

■ 3. Section 261.7 is amended by adding paragraph (c) to read as follows:

§ 261.7 Residues of hazardous waste in empty containers.

* * * * *

(c) Containers of hazardous waste pharmaceuticals are subject to § 266.507 for determining when they are considered empty, in lieu of this section, except as provided by § 266.507(c) and (d).

■ 4. Section 261.33 is amended by:

■ a. Revising paragraph (c); and

■ b. Revising the four entries for ''P075'' in the table in paragraph (e).

The revisions read as follows:

§ 261.33 Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof.

* * * * *

(c) Any residue remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is empty as defined in § 261.7(b) or § 266.507 of this chapter.

[*Comment:* Unless the residue is being beneficially used or reused, or legitimately recycled or reclaimed; or being accumulated, stored, transported or treated prior to such use, re-use, recycling or reclamation, EPA considers the residue to be intended for discard, and thus, a hazardous waste. An example of a legitimate re-use of the residue would be where the residue remains in the container and the container is used to hold the same commercial chemical product or manufacturing chemical intermediate it previously held. An example of the discard of the residue would be where the drum is sent to a drum reconditioner who reconditions the drum but discards the residue.]

* * * * *

(e) * * *

Hazardous waste No.	Chemical abstracts No.	Substance
*	*	* * * * *
P075	[1] 54–11–5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * *
P075	[1] 54–11–5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * *
P075	[1] 54–11–5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * *
P075	[1] 54–11–5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * *

* * * * *

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 5. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, 6938, and 6939g.

■ 6. Section 262.10 is amended by adding paragraphs (m) and (n) to read as follows:

§ 262.10 Purpose, scope and applicability.

* * * * *

(m) All reverse distributors (as defined in § 266.500) are subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

(n) Each healthcare facility (as defined in § 266.500) must determine whether it is subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste). A healthcare facility that generates more than 100 kg (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, water, or other debris, resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in § 261.31 or § 261.33(e), is subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals in lieu of this part. A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is not subject to part 266 subpart P, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.

■ 7. Section 262.13 is amended by adding paragraph (c)(9) to read as follows:

[1] CAS Number given for parent compound only.

§ 262.13 Generator category determination.

* * * * *

(c) * * *

(9) Is a hazardous waste pharmaceutical, as defined in § 266.500, that is subject to or managed in accordance with 40 CFR part 266 subpart P or is a hazardous waste pharmaceutical that is also a Drug Enforcement Administration controlled substance and is conditionally exempt under § 266.506.

* * * * *

■ 8. Section 262.14 is amended by adding paragraphs (a)(5)(ix) and (x) to read as follows:

§ 262.14 Conditions for exemption for a very small quantity generator.

(a) * * *

(5) * * *

(ix) A reverse distributor (as defined in § 266.500), if the hazardous waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical generated by a healthcare facility (as defined in § 266.500).

(x) A healthcare facility (as defined in § 266.500) that meets the conditions in §§ 266.502(l) and 266.503(b), as applicable, to accept non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.

* * * * *

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 9. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, 6925, and 6939g.

■ 10. Section 264.1 is amended by adding paragraph (g)(13) to read as follows:

§ 264.1 Purpose, scope and applicability.

* * * * *

(g) * * *

(13) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P in lieu of this part for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

* * * * *

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 11. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, 6937, and 6939g.

■ 12. Section 265.1 is amended by adding paragraph (c)(16) to read as follows:

§ 265.1 Purpose, scope, and applicability.

* * * * *

(c) * * *

(16) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P in lieu of this part for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

* * * * *

PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

■ 13. The authority citation for part 266 continues to read as follows:

Authority: 42 U.S.C. 1006, 2002(a), 3001–3009, 3014, 3017, 6905, 6906, 6912, 6921, 6922, 6924–6927, 6934, and 6937.

Subpart O—[Reserved]

■ 14. Add reserved subpart O.

■ 15. Add subpart P, consisting of §§ 266.500 through 266.510, to read as follows:

Subpart P—Hazardous Waste Pharmaceuticals

Sec.

266.500 Definitions for this subpart.
266.501 Applicability.
266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.
266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.
266.504 Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.
266.505 Prohibition of sewering hazardous waste pharmaceuticals.
266.506 Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances and household hazardous waste pharmaceuticals collected in a take-back event or program.
266.507 Residues of hazardous waste pharmaceuticals in empty containers.
266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.
266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.
266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.

Subpart P—Hazardous Waste Pharmaceuticals

§ 266.500 Definitions for this subpart.

The following definitions apply to this subpart:

Evaluated hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.

Hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261 subpart D. A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (*e.g.,* lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed.

Healthcare facility means any person that is lawfully authorized to—

(1) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

(2) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Household waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1).

Long-term care facility means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

Non-creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

Non-hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C.

Non-pharmaceutical hazardous waste means a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical, as defined in this section.

Pharmaceutical means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (*e.g.,* electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (*e.g.,* pre-filled cartridges or vials). This definition includes, but is not limited to, dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 203.3(y); over-the-counter drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

Potentially creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is—

(1) In original manufacturer packaging (except pharmaceuticals that were subject to a recall);

(2) Undispensed; and

(3) Unexpired or less than one year past expiration date. The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.

Reverse distributor means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

§ 266.501 Applicability.

(a) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is *not* subject to this subpart, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.

(b) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with § 266.501(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with § 262.14 and the optional provisions of § 266.504.

(c) A healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in paragraph (a) of this section, a healthcare facility is subject to the following in lieu of parts 262 through 265:

(1) Sections 266.502 and 266.505 through 266.508 of this subpart with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals, and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.

(2) Sections 262.502(a), 266.503, 266.505 through 266.507, and 266.509 of this subpart with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.

(e) A reverse distributor is subject to §§ 266.505 through 266.510 of this subpart in lieu of parts 262 through 265 with respect to the management of hazardous waste pharmaceuticals.

(f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (*e.g.,* pharmaceutical manufacturers and reverse logistics centers) are not subject to this subpart. Other generators are subject to 40 CFR part 262 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

(g) The following are not subject to 40 CFR parts 260 through 273, except as specified:

(1) Pharmaceuticals that are not solid waste, as defined by § 261.2, because they are legitimately used/reused (*e.g.,* lawfully donated for their intended purpose) or reclaimed.

(2) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as

defined by § 261.2, because they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

(3) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 CFR part 7 subpart C. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

(4) Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR part 1115. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

(5) Pharmaceuticals stored according to a preservation order, or during an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded and/or a decision is made to discard the pharmaceuticals.

(6) Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR part 312. This subpart does apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

(7) Household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement Administration), provided the authorized collector complies with the conditional exemption in §§ 266.506(a)(2) and 266.506(b).

§ 266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

(a) *Notification and withdrawal from this subpart for healthcare facilities managing hazardous waste pharmaceuticals*—(1) *Notification.* A healthcare facility must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a healthcare facility operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each site or EPA identification number.

(i) A healthcare facility that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A healthcare facility that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(iii) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this subpart.

(2) *Withdrawal.* A healthcare facility that operated under this subpart but is no longer subject to this subpart, because it is a very small quantity generator under § 262.14, and elects to withdraw from this subpart, must notify the appropriate EPA Regional Administrator using the Site Identification Form (EPA Form 8700–12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA identification number.

(i) A healthcare facility must submit the Site Identification Form notifying that it is withdrawing from this subpart before it begins operating under the conditional exemption of § 262.14.

(ii) A healthcare facility must keep a copy of its withdrawal on file for three years from the date of signature on the notification of its withdrawal.

(b) *Training of personnel managing non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must ensure that all personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) *Hazardous waste determination for non-creditable pharmaceuticals.* A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical (*i.e.,* it exhibits a characteristic identified in 40 CFR part 261 subpart C or is listed in 40 CFR part 261 subpart D) in order to determine whether the waste is subject to this subpart. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under this subpart.

(d) *Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(i) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(iv) Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

(v) Through other like means threaten human health or the environment.

(3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and non-hazardous non-creditable waste pharmaceuticals in the same container, except that non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of § 268.3(c) must be accumulated in separate containers and

labeled with all applicable hazardous waste numbers (*i.e.,* hazardous waste codes).

(e) *Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase ''Hazardous Waste Pharmaceuticals.''

(f) *Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on site for one year or less without a permit or having interim status.

(2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that the non-creditable hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste;

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

(g) *Land disposal restrictions for non-creditable hazardous waste pharmaceuticals.* The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of 40 CFR part 268. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with § 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (*i.e.,* hazardous waste codes) on the land disposal restrictions notification.

(h) *Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals.* A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter may accumulate the returned non-creditable hazardous waste pharmaceuticals on site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with paragraphs (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must:

(1) Sign either:

(i) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(2) Provide the transporter a copy of the manifest;

(3) Within 30 days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of § 266.508(a).

(i) *Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals*—(1) *Biennial reporting by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to non-creditable hazardous waste pharmaceuticals managed under this subpart.

(2) *Exception reporting by healthcare facilities for a missing copy of the manifest*—(i) *For shipments from a healthcare facility to a designated facility.* (A) If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located; and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(ii) *For shipments rejected by the designated facility and shipped to an alternate facility.* (A) If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within 60 days of the date the non-creditable hazardous waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located; and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(3) *Additional reports.* The EPA Regional Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(j) *Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals.* (1) A healthcare facility must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(2) A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

(3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) consistent with § 262.11(f), for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal. A healthcare facility that manages all of its non-creditable non-hazardous waste pharmaceuticals as

non-creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

(4) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(5) All records must be readily available upon request by an inspector.

(k) *Response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with the requirements of this subpart.

(l) *Accepting non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.* A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person (as defined in § 260.10) as the very small quantity generator healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off-site (''control,'' for the purposes of this section, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person as defined in § 260.10 of this chapter shall not be deemed to ''control'' such healthcare facilities) or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its non-creditable hazardous waste pharmaceuticals;

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

§ 266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

(a) *Hazardous waste determination for potentially creditable pharmaceuticals.* A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical (*i.e.,* it is listed in 40 CFR part 261 subpart D or exhibits a characteristic identified in 40 CFR part 261 subpart C). A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this subpart.

(b) *Accepting potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.* A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the very small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

(c) *Prohibition.* Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(d) *Biennial Reporting by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

(e) *Recordkeeping by healthcare facilities.* (1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for three years from the date of shipment:

(i) The confirmation of delivery; and

(ii) The shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(3) All records must be readily available upon request by an inspector.

(f) *Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with this subpart.

§ 266.504 Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.

(a) *Potentially creditable hazardous waste pharmaceuticals.* A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(b) *Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a very small quantity generator.* A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided:

(1) The receiving healthcare facility meets the conditions in § 266.502(l) of this subpart and § 266.503(b), as applicable; or

(2) The very small quantity generator healthcare facility meets the conditions in § 262.14(a)(5)(viii) and the receiving large quantity generator meets the conditions in § 262.17(f).

(c) *Long-term care facilities that are very small quantity generators.* A long-

term care facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

(d) *Long-term care facilities with 20 beds or fewer.* A long-term care facility with 20 beds or fewer is presumed to be a very small quantity generator subject to § 262.14 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and *not* subject to this subpart, except for §§ 266.505 and 266.507 and the other optional provisions of this section. The EPA Regional Administrator has the responsibility to demonstrate that a long-term care facility with 20 beds or fewer generates quantities of hazardous waste that are in excess of the very small quantity generator limits as defined in § 260.10. A long-term care facility with more than 20 beds that operates as a very small quantity generator under § 262.14 must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by § 260.10.

§ 266.505 Prohibition of sewering hazardous waste pharmaceuticals.

All healthcare facilities—including very small quantity generators operating under § 262.14 in lieu of this subpart—and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1).

§ 266.506 Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take-back event or program.

(a) *Conditional exemptions.* Provided the conditions of paragraph (b) of this section are met, the following are exempt from 40 CFR parts 262 through 273:

(1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

(2) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).

(b) *Conditions for exemption.* The hazardous waste pharmaceuticals must be:

(1) Managed in compliance with the sewer prohibition of § 266.505; and

(2) Collected, stored, transported, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances; and

(3) Destroyed by a method that Drug Enforcement Administration has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the following:

(i) A permitted large municipal waste combustor, subject to 40 CFR part 62 subpart FFF or applicable state plan for existing large municipal waste combustors, or 40 CFR part 60 subparts Eb for new large municipal waste combustors; or

(ii) A permitted small municipal waste combustor, subject to 40 CFR part 62 subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 CFR part 60 subparts AAAA for new small municipal waste combustors; or

(iii) A permitted hospital, medical and infectious waste incinerator, subject to 40 CFR part 62 subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR part 60 subpart Ec for new hospital, medical and infectious waste incinerators.

(iv) A permitted commercial and industrial solid waste incinerator, subject to 40 CFR part 62 subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 CFR part 60 subpart CCCC for new commercial and industrial solid waste incinerators.

(v) A permitted hazardous waste combustor subject to 40 CFR part 63 subpart EEE.

§ 266.507 Residues of hazardous waste pharmaceuticals in empty containers.

(a) *Stock, dispensing and unit-dose containers.* A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (*e.g.,* a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

(b) *Syringes.* A syringe is considered empty and the residues are not regulated as hazardous waste under this subpart provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart and any applicable federal, state, and local requirements for sharps containers and medical waste.

(c) *Intravenous (IV) bags.* An IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. If an IV bag is not empty, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1).

(d) *Other containers, including delivery devices.* Hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under this subpart, unless the container held non-acute hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1) or (2). This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

§ 266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.

(a) *Shipping non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* A healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-

site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with:

(1) The following pre-transport requirements, before transporting or offering for transport off-site:

(i) *Packaging.* Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 178, and 180.

(ii) *Labeling.* Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172 subpart E.

(iii) *Marking.* (A) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable Department of Transportation (DOT) regulations on hazardous materials under 49 CFR part 172 subpart D;

(B) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Reverse distributor's Name and Address _____

Healthcare Facility's or Reverse distributor's EPA Identification Number _____

Manifest Tracking Number _____

(C) Lab packs that will be incinerated in compliance with § 268.42(c) are not required to be marked with EPA Hazardous Waste Number(s), except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(iv) *Placarding.* Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR part 172 subpart F.

(2) The manifest requirements of 40 CFR part 262 subpart B, except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste numbers (*i.e.,* hazardous waste codes) in Item 13 of EPA Form 8700–22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the word ''PHARMS'' in Item 13 of EPA Form 8700–22.

(b) *Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262 subpart H.

(c) *Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262 subpart H. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals unless they have a permit or interim status that allows them to accept hazardous waste from off site.

§ 266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.

(a) *Shipping potentially creditable hazardous waste pharmaceuticals.* A healthcare facility or a reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor must comply with all applicable U.S. Department of Transportation regulations in 49 CFR part 171 through 180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8. For purposes of the Department of Transportation regulations, a material is considered a hazardous waste if it is subject to the Hazardous Waste Manifest Requirements of the U.S. Environmental Protection Agency specified in 40 CFR part 262. Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under the Department of Transportation regulations.

(b) *Delivery confirmation.* Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor.

(c) *Procedures for when delivery confirmation is not received within 35 calendar days.* If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (*i.e.,* the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) *Exporting potentially creditable hazardous waste pharmaceuticals.* A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the applicable sections of 40 CFR part 262 subpart H, except the manifesting requirement of § 262.83(c), in addition to paragraphs (a) through (c) of this section.

(e) *Importing potentially creditable hazardous waste pharmaceuticals.* Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to paragraphs (a) through (c) of this section in lieu of 40 CFR part 262 subpart H. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this subpart.

§ 266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.

A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on site without a hazardous waste permit or without having interim status, provided that it complies with the following conditions:

(a) *Standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals*—(1) *Notification.* A reverse distributor must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a reverse distributor operating under this subpart.

(i) A reverse distributor that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a reverse

distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A reverse distributor that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(2) *Inventory by the reverse distributor.* A reverse distributor must maintain a current inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on site.

(i) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of each waste arriving at the reverse distributor.

(ii) The inventory must include the identity (*e.g.,* name or national drug code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(iii) If the reverse distributor already meets the inventory requirements of this paragraph because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory pursuant to this section.

(3) *Evaluation by a reverse distributor that is not a manufacturer.* A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 30 calendar days of the waste arriving at the reverse distributor to establish whether it is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

(i) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a ''potentially creditable hazardous waste pharmaceutical'' and must be managed in accordance with paragraph (b) of this section.

(ii) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage or disposal facility is considered an ''evaluated hazardous waste pharmaceutical'' and must be managed in accordance with paragraph (c) of this section.

(4) *Evaluation by a reverse distributor that is a manufacturer.* A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days of the waste arriving at the facility and following the evaluation must manage the evaluated hazardous waste pharmaceuticals in accordance with paragraph (c) of this section.

(5) *Maximum accumulation time for hazardous waste pharmaceuticals at a reverse distributor.* (i) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for 180 calendar days or less. The 180 days start after the potentially creditable hazardous waste pharmaceutical has been evaluated and applies to all hazardous waste pharmaceuticals accumulated on site, regardless of whether they are destined for another reverse distributor (*i.e.,* potentially creditable hazardous waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (*i.e.,* evaluated hazardous waste pharmaceuticals).

(ii) *Aging pharmaceuticals.* Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (*i.e.,* aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with paragraph (a) of this section and the container labeling and management standards in 266.510(c)(4)(i) through (vi).

(6) *Security at the reverse distributor facility.* A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize the possibility for unauthorized entry include, but are not limited to:

(A) A 24-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) A means to control entry, such as keycard access.

(ii) If the reverse distributor already meets the security requirements of this paragraph because of other regulatory requirements, such as Drug Enforcement Administration or State Board of Pharmacy regulations, the facility is not required to provide separate security measures pursuant to this section.

(7) *Contingency plan and emergency procedures at a reverse distributor.* A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off site must prepare a contingency plan and comply with the other requirements of 40 CFR part 262 subpart M.

(8) *Closure of a reverse distributor.* When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with § 262.17(a)(8)(ii) and (iii).

(9) *Reporting by a reverse distributor*—(i) *Unauthorized waste report.* A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off site that it is not authorized to receive (*e.g.,* non-pharmaceutical hazardous waste, regulated medical waste). The reverse distributor must prepare and submit an unauthorized waste report to the EPA Regional Administrator within 45 calendar days after the unauthorized waste arrives at the reverse distributor and must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor, or its authorized representative, and contain the following information:

(A) The EPA identification number, name and address of the reverse distributor;

(B) The date the reverse distributor received the unauthorized waste;

(C) The EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

(D) A description and the quantity of each unauthorized waste the reverse distributor received;

(E) The method of treatment, storage, or disposal for each unauthorized waste; and

(F) A brief explanation of why the waste was unauthorized, if known.

(ii) *Additional reports.* The EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(10) *Recordkeeping by reverse distributors.* A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(i) A copy of its notification on file for as long as the facility is subject to this subpart;

(ii) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date the shipment arrives at the reverse distributor;

(iii) A copy of its current inventory for as long as the facility is subject to this subpart.

(b) *Additional standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor.* A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in paragraph (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

(1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(3) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with § 266.509.

(4) *Recordkeeping by reverse distributors.* A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three years from the date of shipment. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(i) The confirmation of delivery; and

(ii) The DOT shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable

(c) *Additional standards for reverse distributors managing evaluated hazardous waste pharmaceuticals.* A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of paragraph (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

(1) *Accumulation area at the reverse distributor.* A reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) *Inspections of on-site accumulation area.* A reverse distributor must inspect its on-site accumulation area at least once every seven days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) *Personnel training at a reverse distributor.* Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of § 262.17(a)(7).

(4) *Labeling and management of containers at on-site accumulation areas.* A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(i) Label the containers with the words, ''hazardous waste pharmaceuticals'';

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(v) Manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that the container does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(E) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) (*e.g.,* arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

(5) *Hazardous waste numbers.* Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable hazardous waste numbers (*i.e.,* hazardous waste codes). A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(6) *Shipments.* A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in § 266.508(a) or (b).

(7) *Procedures for a reverse distributor for managing rejected shipments.* A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned evaluated hazardous waste pharmaceuticals on

site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with § 266.510(a) and (c). Upon receipt of the returned shipment, the reverse distributor must:

(i) Sign either:

(A) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(B) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 days of receipt of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

(iv) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of § 266.508(a) or (b).

(8) *Land disposal restrictions.* Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of 40 CFR part 268. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off site must comply with the land disposal restrictions in accordance with § 268.7(a) requirements.

(9) *Reporting by a reverse distributor for evaluated hazardous waste pharmaceuticals*—(i) *Biennial reporting by a reverse distributor.* A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of a biennial report to the EPA Regional Administrator by March 1 of each even numbered year in accordance with § 262.41.

(ii) *Exception reporting by a reverse distributor for a missing copy of the manifest.*

(A) *For shipments from a reverse distributor to a designated facility.* (*1*) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(*2*) A reverse distributor must submit an exception report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

(*i*) A legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(B*) For shipments rejected by the designated facility and shipped to an alternate facility.* (*1*) A reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35-day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(*2*) A reverse distributor must submit an Exception Report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The 45-day timeframe begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste pharmaceutical shipment from the designated facility to the alternate facility. The Exception Report must include:

(*i*) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(10) *Recordkeeping by a reverse distributor for evaluated hazardous waste pharmaceuticals.* (i) A reverse distributor must keep a log (written or electronic) of the inspections of the on-site accumulation area, required by paragraph (c)(2) of this section. This log must be retained as a record for at least three years from the date of the inspection.

(ii) A reverse distributor must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(iii) A reverse distributor must keep a copy of each biennial report for at least three years from the due date of the report.

(iv) A reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(v) A reverse distributor must keep records to document personnel training, in accordance with § 262.17(a)(7)(iv).

(vi) All records must be readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(d) *When a reverse distributor must have a permit.* A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the requirements of 40 CFR parts 264, 265, and 267 and the permit requirements of 40 CFR part 270, if the reverse distributor:

(1) Does not meet the conditions of this section;

(2) Accepts manifested hazardous waste from off site; or

(3) Treats or disposes of hazardous waste pharmaceuticals on site.

PART 268—LAND DISPOSAL RESTRICTIONS

■ 16. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

■ 17. Section 268.7 is amended by revising the section heading and the paragraph (a) subject heading to read as follows:

§ 268.7 Testing, tracking, and recordkeeping requirements for generators, reverse distributors, treaters, and disposal facilities.

(a) *Requirements for generators and reverse distributors.* * * *

* * * * *

■ 18. Section 268.50 is amended by adding paragraphs (a)(4) and (5) to read as follows:

§ 268.50 Prohibitions on storage of restricted wastes.

(a) * * *

(4) A healthcare facility accumulates such wastes in containers on site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the healthcare facility complies with the applicable requirements in §§ 266.502 and 266.503 of this chapter.

(5) A reverse distributor accumulates such wastes in containers on site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the reverse distributor complies with § 266.510 of this chapter.

* * * * *

PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

■ 19. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

■ 20. Section 270.1 is amended by adding paragraph (c)(2)(x) to read as follows:

§ 270.1 Purpose and scope of these regulations.

* * * * *

(c) * * *

(2) * * *

(x) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

* * * * *

PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT

■ 21. The authority citation for part 273 continues to read as follows:

Authority: 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

■ 22. Section 273.80 is amended by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 273.80 General.

(a) Except as provided in paragraph (d) of this section, any person seeking to add a hazardous waste or category of hazardous waste to this part may petition for a regulatory amendment under this subpart and 40 CFR 260.20 and 260.23.

* * * * *

(d) Hazardous waste pharmaceuticals are regulated by 40 CFR part 266 subpart P and may not be added as a category of hazardous waste for management under this part.

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