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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.

FARM CREDIT SYSTEM INSURANCE CORPORATION

12 CFR Part 1411

RIN 3055-AA14

Rules of Practice and Procedure; Adjusting Civil Money Penalties for Inflation

AGENCY: Farm Credit System Insurance Corporation.

ACTION: Final rule.

SUMMARY: This rule implements inflation adjustments to civil money penalties (CMPs) that the Farm Credit System Insurance Corporation (FCSIC) may impose under the Farm Credit Act of 1971, as amended. These adjustments are required by 2015 amendments to the Federal Civil Penalties Inflation Adjustment Act of 1990.

DATES: This rule is effective January 26, 2018.

FOR FURTHER INFORMATION CONTACT: Howard Rubin, General Counsel, Farm Credit System Insurance Corporation, (703) 883-4380, TTY (703) 883-4390, rubinh@fcsic.gov.

SUPPLEMENTARY INFORMATION:

A. Background

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act)¹ to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. The Inflation Adjustment Act provides for the regular evaluation of CMPs and requires FCSIC, and every other Federal agency with authority to impose CMPs,

to ensure that CMPs continue to maintain their deterrent values.²

FCSIC must enact regulations that annually adjust its CMPs pursuant to the inflation adjustment formula of the amended Inflation Adjustment Act and rounded using a method prescribed by the Inflation Adjustment Act. The new amounts will apply to penalties assessed on or after the effective date of this rule. Agencies do not have discretion in choosing whether to adjust a CMP, by how much to adjust a CMP, or the methods used to determine the adjustment.

B. CMPs Imposed Pursuant to Section 5.65 of the Farm Credit Act

First, section 5.65(c) of the Farm Credit Act, as amended (Act), provides that any insured Farm Credit System bank that willfully fails or refuses to file any certified statement or pay any required premium shall be subject to a penalty of not more than \$100 for each day that such violations continue, which penalty FCSIC may recover for its use.³ Second, section 5.65(d) of the Act provides that, except with the prior written consent of the Farm Credit Administration, it shall be unlawful for any person convicted of any criminal offense involving dishonesty or a breach of trust to serve as a director, officer, or employee of any System institution.⁴ For each willful violation of section 5.65(d), the institution involved shall be subject to a penalty of not more than \$100 for each day during which the violation continues, which FCSIC may recover for its use.

FCSIC's current § 1411.1 provides that FCSIC can impose a maximum penalty of \$201 per day for a violation under section 5.65(c) and (d) of the Act.

C. Required Adjustments

The 2015 Act requires agencies to make annual adjustments for inflation. Annual inflation adjustments are based on the percent change between the October Consumer Price Index for all

Urban Consumers (CPI-U) preceding the date of the adjustment, and the prior year's October CPI-U. Based on the CPI-U for October 2017, not seasonally adjusted, the cost-of-living adjustment multiplier for 2018 is 1.02041.⁵ Multiplying 1.02041 times the current penalty amount of \$201, after rounding to the nearest dollar as required by the 2015 Act, results in a new penalty amount of \$205.

D. Notice and Comment Not Required by Administrative Procedure Act

In accordance with the 2015 Act, Federal agencies shall adjust civil monetary penalties "notwithstanding" Section 553 of the Administrative Procedures Act. This means that public procedure generally required for agency rulemaking—notice, an opportunity for comment, and a delay in effective date—is not required for agencies to issue regulations implementing the annual adjustment.

List of Subjects in 12 CFR Part 1411

Banks, banking, Civil money penalties, Penalties.

For the reasons stated in the preamble, part 1411 of chapter XIV, title 12 of the Code of Federal Regulations is amended as follows:

PART 1411—RULES OF PRACTICE AND PROCEDURE

■ 1. The authority citation for part 1411 continues to read as follows:

Authority: 12 U.S.C. 2277a–7(10), 2277a–14(c) and (d); 28 U.S.C. 2461 note.

■ 2. Revise § 1411.1 to read as follows:

§ 1411.1 Inflation adjustment of civil money penalties for failure to file a certified statement, pay any premium required or obtain approval before employment of persons convicted of criminal offenses.

In accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended, a civil money penalty imposed pursuant to section 5.65(c) or (d) of the Farm Credit Act of 1971, as amended, shall not exceed \$205 per day for each day the violation continues.

⁵ See Office of Management and Budget Memorandum M–18–03 (December 15, 2017).

¹ Public Law 101–410, Oct. 5, 1990, 104 Stat. 890, as amended by Public Law 104–134, title III, sec. 31001(s)(1), Apr. 26, 1996, 110 Stat. 1321–373; Public Law 105–362, title XIII, sec. 1301(a), Nov. 10, 1998, 112 Stat. 3293; Public Law 114–74, title VII, sec. 701(b), Nov. 2, 2015, 129 Stat. 599.

² Under the amended Inflation Adjustment Act, a CMP is defined as any penalty, fine, or other sanction that: (1) Either is for a specific monetary amount as provided by Federal law or has a maximum amount provided for by Federal law; (2) is assessed or enforced by an agency pursuant to Federal law; and (3) is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts. All three requirements must be met for a fine to be considered a CMP.

³ 12 U.S.C. 2277a–14(c).

⁴ 12 U.S.C. 2277a–14(d).

Dated: January 23, 2018.

Dale L. Aultman,

Secretary to the Board, Farm Credit System Insurance Corporation.

[FR Doc. 2018-01421 Filed 1-25-18; 8:45 am]

BILLING CODE 6710-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2017-0716; Product Identifier 2016-NM-165-AD; Amendment 39-19165; AD 2018-02-12]

RIN 2120-AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2016-02-01, which applied to certain Airbus Model A320-211, -212, and -231 airplanes. AD 2016-02-01 required repetitive inspections to detect cracks of the pressurized floor fittings at a certain frame, and renewal of the zone protective finish or replacement of fittings with new fittings if necessary. AD 2016-02-01 also provided an optional modification that was terminating action for the repetitive inspections. This new AD retains the requirements of AD 2016-02-01, and requires accomplishment of the modification that was optional in AD 2016-02-01. This AD was prompted by the results of an additional fatigue analysis of cracking of the pressurized floor fittings and a determination that the optional modification should become a required action. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective March 2, 2018.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of March 3, 2016 (81 FR 4878, January 28, 2016).

ADDRESSES: For service information identified in this final rule, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 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, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0716.

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-2017-0716; 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 AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone: 800-647-5527) is Docket Management Facility, 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: Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW, Renton, WA 98057-3356; telephone: 425-227-1405; fax: 425-227-1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2016-02-01, Amendment 39-18380 (81 FR 4878, January 28, 2016) (“AD 2016-02-01”). AD 2016-02-01 applied to certain Airbus Model A320-211, -212, and -231 airplanes. The NPRM published in the *Federal Register* on August 15, 2017 (82 FR 38618).

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2016-0181, dated September 13, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Airbus Model A320-211, -212, and -231 airplanes. The MCAI states:

During centre fuselage certification full scale fatigue testing, damage was found on the pressurized floor fittings at Frame (FR) 36, below the lower surface panel.

This condition, if not detected and corrected, could affect the structural integrity of the aeroplane.

To prevent such damage, Airbus developed modification 21282, which was introduced in production from MSN [manufacturer serial

number] 0105, to reinforce the pressurized floor fitting lower surface by changing material. For affected in-service aeroplanes, Airbus issued Service Bulletin (SB) A320-57-1028, introducing repetitive inspections, and SB A320-57-1029, which provides modification instructions.

DGAC [Direction Générale de l'Aviation Civile] France issued AD 95-099-067 to require these repetitive inspections and, depending on findings, corrective action(s), while the modification was specified in that [French] AD as optional terminating action for these inspections.

Following new analysis in the frame of Extended Service Goal exercise, the inspection thresholds and intervals were revised to meet the original Design Service Goal. Consequently, EASA issued AD 2013-0226 [which corresponds to FAA AD 2016-02-01 (81 FR 4878, January 28, 2016)] to retain the requirements of DGAC France AD 95-099-067, which was superseded, but required those actions within reduced compliance times.

Since that [EASA] AD was issued, in the frame of Widespread Fatigue Damages analysis, the situation has been reassessed and it has been decided to reclassify the modification, still stated as ‘optional’ terminating action in EASA AD 2013-0226, to the status ‘mandatory’.

For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2013-0226, which is superseded, but requires embodiment of the modification as specified in Airbus SB A320-57-1029.

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-2017-0716.

Comments

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

Request To Revise the Applicability

Allegiant Air noted that the applicability specified in paragraph (c) of the proposed AD included Airbus Model A320-214 airplanes. The commenter asked if Model A320-214 airplanes were included in the applicability in error. The commenter observed that neither the applicability of AD 2016-02-01 or EASA AD 2016-0181, nor the effectivity of Airbus Service Bulletin A320-57-1028, Revision 02, dated June 3, 2013, included Model A320-214 airplanes.

We infer that the commenter is requesting that Model A320-214 airplanes be removed from the applicability of the proposed AD. We agree, for the reasons provided by the commenter. This final rule is not applicable to Model A320-214 airplanes; therefore, we have revised the

applicability specified in paragraph (c) of this AD by removing Model A320–214 airplanes.

Conclusion

We reviewed the available data, including the comment 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 changes:

- Are consistent with the intent that was proposed in the NPRM for correcting 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

Airbus has issued Service Bulletin A320–57–1028, Revision 02, dated June 3, 2013. The service information describes procedures for an inspection to detect cracks of the pressurized floor fittings at FR 36, renewal of the zone protective finish, and replacement of fittings with new fittings.

Airbus has also issued Service Bulletin A320–57–1029, Revision 02,

dated June 16, 1999. The service information describes procedures for modification of the pressurized floor fittings at FR 36.

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 13 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	11 work-hours × \$85 per hour = \$935 per inspection cycle.	\$0	\$935 per inspection cycle.	\$12,155 per inspection cycle.
Modification	85 work-hours × \$85 per hour = \$7,225	5,320	\$12,545	\$163,085.

We have received no definitive data that will 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 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) 2016–02–01, Amendment 39–18380 (81 FR 4878, January 28, 2016), and adding the following new AD:

2018–02–12 Airbus: Amendment 39–19165; Docket No. FAA–2017–0716; Product Identifier 2016–NM–165–AD.

(a) Effective Date

This AD is effective March 2, 2018.

(b) Affected ADs

This AD replaces AD 2016–02–01, Amendment 39–18380 (81 FR 4878, January 28, 2016) ("AD 2016–02–01").

(c) Applicability

This AD applies to Airbus Model A320–211, –212, and –231 airplanes, certificated in any category, manufacturer serial numbers up through 0104 inclusive.

(d) Subject

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

(e) Reason

This AD is intended to complete certain mandated programs intended to support the airplane reaching its limit of validity (LOV) of the engineering data that support the established structural maintenance program. We are issuing this AD to prevent fatigue cracking in the pressurized floor fittings at frame (FR) 36, which could result in the reduced structural integrity of the floor

fittings and subsequent depressurization of the fuselage.

(f) Compliance

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

(g) Inspection

(1) At the latest of the times specified in paragraphs (g)(1)(i), (g)(1)(ii), and (g)(1)(iii) of this AD: Do a detailed inspection of the pressurized floor fittings at FR 36, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-57-1028, Revision 02, dated June 3, 2013. Repeat the inspection thereafter at intervals not to exceed 9,300 flight cycles or 18,600 flight hours, whichever occurs first.

(i) Before exceeding 20,900 flight cycles or 41,800 flight hours, whichever occurs first since first flight of the airplane.

(ii) Within 9,300 flight cycles or 18,600 flight hours since the most recent inspection accomplished in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-57-1028, Revision 02, dated June 3, 2013.

(iii) Within 1,250 flight cycles or 2,500 flight hours after March 3, 2016 (the effective date of AD 2016-02-01), without exceeding 12,000 flight cycles since the most recent inspection accomplished in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-57-1028, Revision 02, dated June 3, 2013.

(2) If any crack is found during any inspection required by paragraph (g)(1) of this AD: Before further flight, repair using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(h) Modification

Before exceeding 48,000 total flight cycles or 96,000 total flight hours, whichever occurs first since first flight of the airplane: Modify (replace aluminum fittings with titanium fittings) the pressurized floor fittings at FR 36, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-57-1029, Revision 02, dated June 16, 1999. Accomplishment of this modification is terminating action for the repetitive inspections required by paragraph (g) of this AD for the modified airplane only.

(i) Credit for Previous Actions

(1) This paragraph provides credit for the inspection required by paragraph (g) of this AD, if that inspection was performed before the effective date of this AD using Airbus Service Bulletin A320-57-1028, dated August 12, 1991; or Revision 01, dated April 19, 1996.

(2) This paragraph provides credit for the modification required by paragraph (h) of this AD, if that modification was performed before the effective date of this AD using Airbus Service Bulletin A320-57-1029, dated August 12, 1991; or Revision 01, dated November 10, 1992.

(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*: 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 EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2016-0181, dated September 13, 2016, 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-2017-0716.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW, Renton, WA 98057-3356; telephone: 425-227-1405; fax: 425-227-1149.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (l)(4) and (l)(5) of this AD.

(l) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on March 3, 2016 (81 FR 4878, January 28, 2016).

(i) Airbus Service Bulletin A320-57-1028, Revision 02, dated June 3, 2013.

(ii) Airbus Service Bulletin A320-57-1029, Revision 02, dated June 16, 1999.

(4) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 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>.

(5) You may view this service information at the FAA, Transport Standards Branch,

1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(6) 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 Renton, Washington, on January 10, 2018.

John P. Piccola, Jr.,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018-01197 Filed 1-25-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2017-1201; Product Identifier 2017-SW-068-AD; Amendment 39-19155; AD 2018-02-02]

RIN 2120-AA64

Airworthiness Directives; Airbus Helicopters

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

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for Airbus Helicopters Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350D, AS355E, AS355F, AS355F1, AS355F2, AS355N, AS355NP, EC130B4, and EC130T2 helicopters. This AD requires inspecting the main rotor (M/R) mast jet oil lubrication hose (oil hose). This AD is prompted by a report of a blocked oil hose. The actions of this AD are intended to prevent an unsafe condition on these helicopters.

DATES: This AD becomes effective February 12, 2018.

We must receive comments on this AD by March 27, 2018.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to <http://www.regulations.gov>. Follow the online instructions for sending your comments electronically.

- *Fax:* 202-493-2251.

- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590-0001.

- **Hand Delivery:** Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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-2017-1201; 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 AD, the European Aviation Safety Agency (EASA) AD, the economic 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 service information identified in this final rule, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641-0000 or (800) 232-0323; fax (972) 641-3775; or at http://www.helicopters.airbus.com/website/en/ref/Technical-Support_73.html. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N-321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Rao Edupuganti, Aviation Safety Engineer, Regulations and Policy Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5110; email rao.edupuganti@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments prior to it becoming effective. However, we invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that resulted from adopting this AD. The most helpful comments reference a specific portion of the AD, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit them only one time. We will file in the docket all comments that we receive, as well as a report summarizing

each substantive public contact with FAA personnel concerning this rulemaking during the comment period. We will consider all the comments we receive and may conduct additional rulemaking based on those comments.

Discussion

EASA, which is the Technical Agent for the Member States of the European Union, has issued AD No. 2017-0089, dated May 17, 2017 (AD 2017-0089), to correct an unsafe condition for Airbus Helicopters Model AS350B, AS350BA, AS350BB, AS350B1, AS350B2, AS350B3, AS350D, AS355E, AS355F, AS355F1, AS355F2, AS355N, AS355NP, EC130B4, and EC130T2 helicopters. EASA advises that an oil hose part number (P/N) 704A34-412-015 (manufacturing P/N 4T13) was found blocked during unscheduled maintenance. EASA states an investigation showed the hose had become completely blocked with solder during the manufacturing process, resulting in a complete absence of lubrication from the direct oil jet to the M/R mast upper bearing. According to EASA this condition could lead to degradation of the M/R mast bearings, loss of transmission function, and subsequent loss of control of the helicopter. To correct this condition, EASA AD 2017-0089 requires a one-time inspection of the oil hose to determine if there is any blockage, replacing the oil hose and the M/R mast if the oil hose is blocked, and marking unobstructed hoses with an "x" after the P/N.

FAA's Determination

These helicopters have been approved by the aviation authority of France and are approved for operation in the United States. Pursuant to our bilateral agreement with France, EASA, its technical representative, has notified us of the unsafe condition described in the EASA AD. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs.

Related Service Information

Airbus Helicopters has co-published as one document Emergency Alert Service Bulletin (EASB) No. 62.00.20 for non-FAA type-certificated AS550-series helicopters, EASB No. 62.00.23 for non-FAA type-certificated AS555-series helicopters, EASB No. 62.00.36 for AS355-series helicopters, EASB No. 62.00.39 for AS350-series helicopters, and EASB No. 62A015 for EC130 series helicopters, all Revision 1 and dated

May 19, 2017. This service information specifies procedures for inspecting the oil hose for the presence of oil, inspecting the oil hose for blockage, and marking the hose if there is no blockage.

AD Requirements

This AD requires, within 30 hours time-in-service (TIS):

- Removing the upper end of the oil hose and inspecting the inside of the hose to determine if there is any oil present. If there is no oil present, before further flight, replacing the M/R mast and the oil hose;
- If there is oil present, within 30 hours TIS of inspecting for the presence of oil, removing the hose and determining if there is blockage in the hose, first using an air gun and then using cable ties or a piece of wire. If there is blockage in the hose, before further flight, replacing the M/R mast and the oil hose; and
- If there is oil present and there is no blockage, before further flight, permanently marking the hose with an "X" following the P/N.

This AD also prohibits installing an oil hose, P/N 704A34-412-015, on any helicopter unless it has been inspected as required by this AD.

Differences Between This AD and the EASA AD

The EASA AD applies to Airbus Helicopters Model AS350BB helicopters, this AD does not as that model is not type certificated in the U.S.

Costs of Compliance

We estimate that this AD affects 1,246 helicopters of U.S. Registry.

We estimate that operators may incur the following costs in order to comply with this AD. At an average labor rate of \$85 per work-hour, inspecting the oil hose for oil and obstruction and marking the hose will require about one hour, for a cost per helicopter of \$85 and a cost of \$105,910 for the U.S. fleet.

If required, replacing the M/R mast and oil hose will require 16 hours and required parts will cost \$29,940 for a cost per helicopter of \$31,300.

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to the adoption of this rule because some of the required corrective actions must be accomplished within 30 hours TIS, a potentially short

period of time for helicopters primarily used for air ambulance operations.

Therefore, we find good cause that notice and opportunity for prior public comment are impracticable. In addition, for the reason stated above, we find that good cause exists for making this amendment effective in less than 30 days.

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.

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, 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 to the extent that it justifies making a regulatory distinction; 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.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

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):

2018-02-02 Airbus Helicopters:

Amendment 39-19155; Docket No. FAA-2017-1201; Product Identifier 2017-SW-068-AD.

(a) Applicability

This AD applies to Airbus Helicopters Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350D, AS355E, AS355F, AS355F1, AS355F2, AS355N, AS355NP, EC130B4, and EC130T2 helicopters, certificated in any category, with a main rotor (M/R) mast jet oil lubrication hose (oil hose) part number (P/N) 704A34-412-015 (manufacturing P/N 4T13), except those marked with an X following the P/N, installed.

(b) Unsafe Condition

This AD defines the unsafe condition as a blocked oil hose. This condition could result in failure of the direct oil jet to lubricate the M/R mast upper bearing, degradation of the M/R mast bearings, loss of M/R transmission function, and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective February 12, 2018.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) Within 30 hours time-in-service (TIS), disconnect the upper end of the oil hose and inspect the inside of the hose for oil.

(i) If there is no oil inside the hose, before further flight, replace the M/R mast and oil hose.

(ii) If there is oil inside the hose, within 30 hours TIS, remove the oil hose and blow air through the oil hose using an air gun.

(A) If no air flows through the oil hose, before further flight, replace the M/R mast and oil hose.

(B) If air does flow through the oil hose, inspect the oil hose for any blockage by inserting two cable ties or a semi-rigid piece of wire with a diameter of 2 to 2.3 millimeters (mm) a minimum of 100 mm into each end of the oil hose.

(1) If there is any blockage, before further flight, replace the M/R mast and oil hose.

(2) If there is no blockage, re-identify the oil hose by vibro-etching the letter "X" after the P/N.

(2) Do not install an oil hose P/N 704A34-412-015 on any helicopter unless it has been inspected as required by this AD.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Rao Edupuganti, Aviation Safety Engineer, Regulations and Policy Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5110; email 9-ASW-FTW-AMOC-Requests@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

(1) Airbus Helicopters Emergency Alert Service Bulletin No. 62.00.20, No. 62.00.23, No. 62.00.36, No. 62.00.39, and No. 62A015, all Revision 1 and dated May 19, 2017, which are co-published as one document and not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone (972) 641-0000 or (800) 232-0323; fax (972) 641-3775; or at http://www.helicopters.airbus.com/website/en/ref/Technical-Support_73.html. You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N-321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2017-0089, dated May 17, 2017. You may view the EASA AD on the internet at <http://www.regulations.gov> by searching for and locating it in Docket No. FAA-2017-1201.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6230 Main Gearbox Mast.

Issued in Fort Worth, Texas, on January 8, 2018.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2018-01196 Filed 1-25-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 97****[Docket No. 31176; Amdt. No. 3784]****Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments****AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective January 26, 2018. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 26, 2018.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590-0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. 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/code_of_federal_regulations/ibr_locations.html.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Thomas J. Nichols, Flight Procedure Standards Branch (AFS-420) Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954-4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDG)/Permanent Notice to Airmen (P-NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary.

This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each

separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under 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. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on January 12, 2018.

John S. Duncan,

Director, Flight Standards Service.

Adoption of The Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, part 97, (14 CFR part 97), is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and

ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * *Effective Upon Publication*

AIRAC Date	State	City	Airport	FDC No.	FDC Date	Subject
1-Mar-18	CO	Greeley	Greeley-Weld County	7/0041	12/27/17	ILS OR LOC/DME RWY 35, Amdt 3.
1-Mar-18	MS	Gulfport	Gulfport-Biloxi Intl	7/0124	1/3/18	RNAV (GPS) RWY 36, Amdt 2.
1-Mar-18	MS	Gulfport	Gulfport-Biloxi Intl	7/0125	1/3/18	RNAV (GPS) RWY 18, Amdt 2.
1-Mar-18	OR	Ontario	Ontario Muni	7/0542	1/9/18	NDB RWY 33, Amdt 6.
1-Mar-18	ME	Eastport	Eastport Muni	7/0546	12/27/17	RNAV (GPS) RWY 15, Amdt 1.
1-Mar-18	CO	Greeley	Greeley-Weld County	7/0992	12/27/17	RNAV (GPS) RWY 35, Amdt 1.
1-Mar-18	SC	Allendale	Allendale County	7/1027	12/27/17	RNAV (GPS) RWY 35, Orig-A.
1-Mar-18	OH	Lima	Lima Allen County	7/1170	1/9/18	RNAV (GPS) RWY 28, Amdt 2A.
1-Mar-18	CA	Van Nuys	Van Nuys	7/1257	1/9/18	VOR-B, Amdt 4.
1-Mar-18	MN	Hinckley	Field Of Dreams	7/1674	1/9/18	RNAV (GPS) RWY 6, Orig.
1-Mar-18	MN	Hinckley	Field Of Dreams	7/1678	1/9/18	RNAV (GPS) RWY 24, Orig.
1-Mar-18	OH	Upper Sandusky	Wyandot County	7/1878	12/27/17	VOR-A, Amdt 3C.
1-Mar-18	OK	Muskogee	Davis Field	7/2894	12/27/17	Takeoff Minimums and Obstacle DP, Orig.
1-Mar-18	TX	La Grange	Fayette Rgnl Air Center	7/3087	12/27/17	RNAV (GPS) RWY 16, Amdt 2A.
1-Mar-18	TX	La Grange	Fayette Rgnl Air Center	7/3088	12/27/17	RNAV (GPS) RWY 34, Amdt 2A.
1-Mar-18	CO	Greeley	Greeley-Weld County	7/4146	12/27/17	VOR-A, Amdt 10.
1-Mar-18	CO	Greeley	Greeley-Weld County	7/4186	12/27/17	RNAV (GPS) RWY 28, Amdt 1.
1-Mar-18	CO	Greeley	Greeley-Weld County	7/4191	12/27/17	RNAV (GPS) RWY 17, Amdt 1.
1-Mar-18	CO	Greeley	Greeley-Weld County	7/4201	12/27/17	RNAV (GPS) RWY 10, Amdt 1A.
1-Mar-18	MN	Thief River Falls	Thief River Falls Rgnl	7/5050	12/29/17	VOR RWY 31, Amdt 8C.
1-Mar-18	MS	Oxford	University-Oxford	7/6703	1/9/18	RNAV (GPS) RWY 27, Amdt 1.
1-Mar-18	OH	Cambridge	Cambridge Muni	7/6941	12/27/17	RNAV (GPS) RWY 22, Orig-C.
1-Mar-18	OH	Cambridge	Cambridge Muni	7/6942	12/27/17	RNAV (GPS) RWY 4, Orig-C.
1-Mar-18	MN	Mc Gregor	Isedor Iverson	7/8234	12/27/17	RNAV (GPS) RWY 32, Orig.
1-Mar-18	NY	New York	Laguardia	7/9835	12/27/17	RVAV (GPS) Y RWY 22, Amdt 2C.
1-Mar-18	NY	New York	Laguardia	7/9836	12/27/17	ILS OR LOC RWY 22, ILS RWY 22 (SA CAT I AND II), Amdt 21.

[FR Doc. 2018-01171 Filed 1-25-18; 8:45 a.m.]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31173; Amdt. No. 3782]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and

associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective January 26, 2018. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the

regulations is approved by the Director of the Federal Register as of January 26, 2018.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590-0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. 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/code-of-federal-regulations/ibr_locations.html.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Thomas J. Nichols, Flight Procedure Standards Branch (AFS-420) Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954-4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P-NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary.

This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are

necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under 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. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on December 29, 2017.

John S. Duncan,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, part 97, (14 CFR part 97), is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * *Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
1-Feb-18	OK	Muskogee	Davis Field	7/2896	12/5/17	This NOTAM, published in TL 18-03, is hereby rescinded in its entirety.
1-Feb-18	MO	Monroe City	Cpt Ben Smith Airfield—Monroe City.	7/1136	12/12/17	Takeoff Minimums and Obstacle DP, Orig.
1-Feb-18	AZ	Flagstaff	Flagstaff Pulliam	7/2172	12/18/17	VOR RWY 21, Amdt 1.
1-Feb-18	WI	Eau Claire	Chippewa Valley Rgnl	7/3746	12/18/17	Takeoff Minimums and Obstacle DP, Amdt 2.
1-Feb-18	OR	Salem	Mcnary Fld	7/4017	12/6/17	RNAV (GPS) RWY 31, Amdt 3A.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
1-Feb-18	OR	Salem	Mcnary Fld	7/4040	12/6/17	ILS OR LOC Z RWY 31, Amdt 31.
1-Feb-18	OR	Portland	Portland-Hillsboro	7/4123	12/4/17	ILS OR LOC RWY 13R, Amdt 10.
1-Feb-18	IN	Columbus	Columbus Muni	7/4145	12/4/17	RNAV (GPS) RWY 32, Orig.
1-Feb-18	OR	Portland	Portland-Hillsboro	7/4157	12/4/17	RNAV (GPS) RWY 13R, Amdt 2A.
1-Feb-18	IN	Columbus	Columbus Muni	7/4158	12/4/17	RNAV (GPS) RWY 23, Orig-A.
1-Feb-18	IN	Columbus	Columbus Muni	7/4162	12/4/17	RNAV (GPS) RWY 5, Orig.
1-Feb-18	IN	Columbus	Columbus Muni	7/4163	12/4/17	RNAV (GPS) RWY 14, Amdt 1A.
1-Feb-18	IN	Columbus	Columbus Muni	7/4167	12/4/17	ILS RWY 23, Amdt 7A.
1-Feb-18	CA	Watsonville	Watsonville Muni	7/4244	12/6/17	RNAV (GPS) RWY 2, Amdt 1B.
1-Feb-18	CA	Watsonville	Watsonville Muni	7/4245	12/6/17	LOC RWY 2, Amdt 4A.
1-Feb-18	CA	Watsonville	Watsonville Muni	7/4246	12/6/17	VOR/DME-A, Amdt 1.
1-Feb-18	NH	Manchester	Manchester	7/4318	12/5/17	RNAV (GPS) Y RWY 17, Amdt 1B.
1-Feb-18	OH	Wilmington	Wilmington Air Park	7/4346	12/6/17	RNAV (GPS) RWY 22R, Orig-A.
1-Feb-18	NV	Winnemucca	Winnemucca Muni	7/4640	12/5/17	VOR RWY 14, Orig-B.
1-Feb-18	NH	Manchester	Manchester	7/4754	12/5/17	RNAV (GPS) Y RWY 35, Amdt 1B.
1-Feb-18	OH	New Philadelphia	Harry Clever Field	7/5388	12/6/17	Takeoff Minimums and Obstacle DP, Amdt 3.
1-Feb-18	IA	Greenfield	Greenfield Muni	7/5443	12/5/17	RNAV (GPS) RWY 25, Orig-A.
1-Feb-18	IA	Greenfield	Greenfield Muni	7/5444	12/5/17	RNAV (GPS) RWY 7, Orig-A.
1-Feb-18	IA	Belle Plaine	Belle Plaine Muni	7/6720	12/4/17	VOR/DME-A, Amdt 1.
1-Feb-18	IA	Belle Plaine	Belle Plaine Muni	7/6730	12/4/17	RNAV (GPS) RWY 36, Orig-A.
1-Feb-18	IA	Belle Plaine	Belle Plaine Muni	7/6731	12/4/17	RNAV (GPS) RWY 18, Orig-A.
1-Feb-18	CA	Brawley	Brawley Muni	7/6988	12/4/17	RNAV (GPS) RWY 26, Orig.
1-Feb-18	CA	Brawley	Brawley Muni	7/7004	12/4/17	VOR/DME-B, Amdt 2B.
1-Feb-18	AR	Clarksville	Clarksville Muni	7/7891	12/4/17	RNAV (GPS) RWY 9, Orig-A.
1-Feb-18	AR	Clarksville	Clarksville Muni	7/7892	12/4/17	RNAV (GPS) RWY 27, Orig.
1-Feb-18	IA	Cedar Rapids	The Eastern Iowa	7/8225	12/6/17	RNAV (GPS) RWY 9, Amdt 2B.
1-Feb-18	MI	Ann Arbor	Ann Arbor Muni	7/8372	12/5/17	VOR RWY 24, Amdt 13E.
1-Feb-18	MI	Ann Arbor	Ann Arbor Muni	7/8375	12/5/17	VOR RWY 6, Amdt 13D.
1-Feb-18	MI	Ann Arbor	Ann Arbor Muni	7/8393	12/5/17	RNAV (GPS) RWY 6, Amdt 2B.
1-Feb-18	MI	Ann Arbor	Ann Arbor Muni	7/8402	12/5/17	RNAV (GPS) RWY 24, Amdt 2C.
1-Feb-18	NY	Elmira/Corning	Elmira/Corning Rgnl ...	7/8405	12/18/17	ILS OR LOC RWY 24, Amdt 19A.
1-Feb-18	TX	Caldwell	Caldwell Muni	7/8699	12/18/17	RNAV (GPS) RWY 33, Orig-A.
1-Feb-18	TX	Harlingen	Valley Intl	7/8832	12/6/17	RNAV (GPS) Y RWY 17R, Amdt 2A.
1-Feb-18	OH	Wilmington	Wilmington Air Park	7/8843	12/6/17	RNAV (GPS) RWY 4L, Orig-A.
1-Feb-18	NE	Hebron	Hebron Muni	7/8923	12/28/17	GPS RWY 12, Orig-D.
1-Feb-18	NE	Hebron	Hebron Muni	7/8928	12/4/17	GPS RWY 30, Orig-C.
1-Feb-18	OH	Columbus	Rickenbacker Intl	7/9089	12/6/17	RNAV (GPS) RWY 23L, Orig.
1-Feb-18	OH	Akron	Akron-Canton Rgnl	7/9156	12/5/17	ILS OR LOC RWY 19, Amdt 8.
1-Feb-18	WA	Moses Lake	Grant Co Intl	7/9177	12/6/17	RNAV (GPS) Y RWY 32R, Amdt 3A.
1-Feb-18	IA	Sioux City	Sioux Gateway/Col Bud Day Field.	7/9203	12/6/17	RNAV (GPS) RWY 31, Orig-E.
1-Feb-18	IN	Gary	Gary/Chicago Intl	7/9337	12/6/17	ILS OR LOC RWY 30, Amdt 6.
1-Feb-18	WA	Everett	Snohomish County (Paine Fld).	7/9637	12/6/17	ILS Z OR LOC Z RWY 16R, Amdt 1.

[FR Doc. 2018-01169 Filed 1-25-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 97****[Docket No. 31175; Amdt. No. 3783]****Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments****AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable

airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective January 26, 2018. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 26, 2018.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. 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/code_of_federal_regulations/ibr_locations.html.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Thomas J. Nichols, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, part 97 (14 CFR part 97), by establishing, amending, suspending, or removes SIAPs, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated

by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and/or ODPS as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as Amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the

TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under 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. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on January 12, 2018.

John S. Duncan,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 1 March 2018

Salmon, ID, Lemhi County, RNAV (GPS)-D, Amdt 2

Yakima, WA, Yakima Air Terminal/McAllister Field, RNAV (GPS) W RWY 27, Amdt 1B

- Yakima, WA, Yakima Air Terminal/
McAllister Field, RNAV (GPS) X RWY 27,
Amdt 1D
- Yakima, WA, Yakima Air Terminal/
McAllister Field, RNAV (RNP) Y RWY 27,
Orig-C
- Yakima, WA, Yakima Air Terminal/
McAllister Field, RNAV (RNP) Z RWY 27,
Orig-C
- Watertown, WI, Watertown Muni, NDB RWY
5, Amdt 1E
- Effective 29 March 2018*
- Cordova, AK, Merle K (Mudhole) Smith, ILS
OR LOC RWY 27, Amdt 11C
- Cordova, AK, Merle K (Mudhole) Smith,
Takeoff Minimums and Obstacle DP, Amdt
8
- Little Rock, AR, Bill and Hillary Clinton
National/Adams Field, ILS OR LOC RWY
4L, Amdt 26A
- Little Rock, AR, Bill and Hillary Clinton
National/Adams Field, ILS OR LOC RWY
4R, Amdt 2D
- Little Rock, AR, Bill and Hillary Clinton
National/Adams Field, ILS OR LOC RWY
22L, Orig-D
- Little Rock, AR, Bill and Hillary Clinton
National/Adams Field, RNAV (GPS) RWY
36, Orig-C
- Little Rock, AR, Bill and Hillary Clinton
National/Adams Field, Takeoff Minimums
and Obstacle DP, Amdt 9
- Bishop, CA, Bishop, Takeoff Minimums and
Obstacle DP, Amdt 4A
- Oxnard, CA, Oxnard, ILS OR LOC RWY 25,
Amdt 13C
- Santa Barbara, CA, Santa Barbara Muni,
Takeoff Minimums and Obstacle DP, Amdt
8A
- Cortez, CO, Cortez Muni, RNAV (GPS) RWY
3, Orig-A
- Washington, DC, Ronald Reagan Washington
National, ILS OR LOC RWY 1, ILS RWY 1
(SA CAT I), ILS RWY 1 (CAT II), Amdt 41C
- Washington, DC, Ronald Reagan Washington
National, LDA Y RWY 19, Amdt 1A
- Washington, DC, Ronald Reagan Washington
National, RNAV (GPS) RWY 33, Amdt 1A
- Washington, DC, Ronald Reagan Washington
National, RNAV (RNP) RWY 19, Amdt 2B
- Washington, DC, Ronald Reagan Washington
National, Takeoff Minimums and Obstacle
DP, Amdt 8A
- Middletown, DE, Summit, Takeoff
Minimums and Obstacle DP, Amdt 2A
- Apalachicola, FL, Apalachicola Rgnl-Cleve
Randolph Field, NDB RWY 14, Amdt 2C
- Perry, FL, Perry-Foley, Takeoff Minimums
and Obstacle DP, Amdt 1A
- St Petersburg-Clearwater, FL, St Pete-
Clearwater Intl, Takeoff Minimums and
Obstacle DP, Amdt 3B
- Tampa, FL, Tampa Intl, ILS OR LOC RWY
19L, ILS RWY 19L (SA CAT I), ILS RWY
19L (CAT II), Amdt 40D
- St Marys, GA, St Marys, RNAV (GPS) RWY
4, Orig, CANCELED
- St Marys, GA, St Marys, RNAV (GPS) RWY
13, Amdt 1, CANCELED
- St Marys, GA, St Marys, RNAV (GPS) RWY
31, Amdt 1A, CANCELED
- St Marys, GA, St Marys, Takeoff Minimums
and Obstacle DP, Amdt 4, CANCELED
- Valdosta, GA, Valdosta Rgnl, RNAV (GPS)
RWY 4, Amdt 1C
- Valdosta, GA, Valdosta Rgnl, RNAV (GPS)
RWY 17, Amdt 2B
- Decorah, IA, Decorah Muni, RNAV (GPS)
RWY 29, Orig-B
- Decorah, IA, Decorah Muni, VOR RWY 29,
Amdt 3E
- Ottumwa, IA, Ottumwa Rgnl, RNAV (GPS)
RWY 13, Orig-B
- Chicago, IL, Chicago Midway Intl, RNAV
(GPS) RWY 4L, Orig-D
- Chicago, IL, Chicago Midway Intl, RNAV
(GPS) RWY 13L, Orig-E
- Chicago, IL, Chicago Midway Intl, RNAV
(GPS) RWY 31R, Orig-E
- Chicago, IL, Chicago Midway Intl, RNAV
(GPS) Z RWY 4R, Amdt 3D
- Chicago, IL, Chicago O'Hare Intl, ILS OR LOC
RWY 15, Amdt 30D, CANCELED
- Chicago, IL, Chicago O'Hare Intl, ILS OR LOC
RWY 28L, ILS RWY 28L (SA CAT I), ILS
RWY 28L (CAT II), ILS RWY 28L (CAT III),
Orig-A
- Chicago, IL, Chicago O'Hare Intl, ILS Y OR
LOC Y RWY 10R, Orig-B
- Chicago, IL, Chicago O'Hare Intl, ILS PRM Y
RWY 10R, (CLOSE PARALLEL), Orig-B
- Chicago, IL, Chicago O'Hare Intl, ILS Z OR
LOC Z RWY 10R, ILS Z RWY 10R (SA CAT
I), ILS Z RWY 10R (CAT II), ILS Z RWY
10R (CAT III), Orig-A
- Chicago, IL, Chicago O'Hare Intl, RNAV
(GPS) RWY 15, Amdt 2E, CANCELED
- Chicago, IL, Chicago O'Hare Intl, Takeoff
Minimums and Obstacle DP, Amdt 20C
- Chicago/Lake in The Hills, IL, Lake in The
Hills, RNAV (GPS) RWY 26, Orig-A
- Chicago/Romeoville, IL, Lewis University,
LOC RWY 2, Amdt 1A
- Chicago/Romeoville, IL, Lewis University,
LOC/DME RWY 9, Amdt 1A
- Chicago/Romeoville, IL, Lewis University,
RNAV (GPS) RWY 2, Amdt 2A
- Chicago/West Chicago, IL, Dupage, ILS OR
LOC RWY 2L, Amdt 2E
- Chicago/West Chicago, IL, Dupage, ILS OR
LOC RWY 10, Amdt 8D
- Chicago/West Chicago, IL, Dupage, RNAV
(GPS) RWY 2L, Orig-E
- Chicago/West Chicago, IL, Dupage, RNAV
(GPS) RWY 20L, Orig-D
- Galesburg, IL, Galesburg Muni, RNAV (GPS)
RWY 21, Orig-B
- Galesburg, IL, Galesburg Muni, VOR RWY 21,
Amdt 7B
- Moline, IL, Quad City Intl, ILS OR LOC RWY
9, Amdt 31C
- Moline, IL, Quad City Intl, ILS OR LOC RWY
27, Amdt 2B
- Moline, IL, Quad City Intl, RNAV (GPS) RWY
9, Amdt 1D
- Moline, IL, Quad City Intl, RNAV (GPS) RWY
13, Amdt 1C
- Moline, IL, Quad City Intl, RNAV (GPS) RWY
27, Amdt 1D
- Moline, IL, Quad City Intl, RNAV (GPS) RWY
31, Amdt 1C
- Indianapolis, IN, Indianapolis Intl, ILS OR
LOC RWY 23R, ILS RWY 23R (SA CAT I),
ILS RWY 23R (SA CAT II), Amdt 6
- Boston, MA, General Edward Lawrence
Logan Intl, RNAV (GPS) RWY 4L, Orig-A,
SUSPENDED
- Cambridge, MD, Cambridge-Dorchester Rgnl,
NDB RWY 34, Amdt 8, CANCELED
- Cambridge, MD, Cambridge-Dorchester Rgnl,
RNAV (GPS) RWY 34, Amdt 1
- Alma, MI, Gratiot Community, VOR RWY 18,
Amdt 1B
- Battle Creek, MI, W K Kellogg, RNAV (GPS)
RWY 23R, Amdt 1C
- Charlotte, MI, Fitch H Beach, RNAV (GPS)
RWY 21, Amdt 1A
- Detroit, MI, Coleman A Young Muni, VOR
RWY 33, Amdt 28B, CANCELED
- East Tawas, MI, Iosco County, VOR-A, Amdt
8, CANCELED
- Gladwin, MI, Gladwin Zettel Memorial,
RNAV (GPS) RWY 27, Orig-B
- Grand Rapids, MI, Gerald R Ford Intl, RNAV
(GPS) RWY 26L, Amdt 1C
- Ionia, MI, Ionia County, VOR-A, Amdt 1,
CANCELED
- Mason, MI, Mason Jewett Field, VOR-A,
Amdt 5, CANCELED
- Duluth, MN, Duluth Intl, COPTER ILS OR
LOC RWY 27, Amdt 2B
- Duluth, MN, Duluth Intl, ILS OR LOC RWY
9, ILS RWY 9 (SA CAT I), ILS RWY 9 (CAT
II), Amdt 22B
- Duluth, MN, Duluth Intl, ILS OR LOC RWY
27, Amdt 10C
- Moorhead, MN, Moorhead Muni, RNAV
(GPS) RWY 30, Amdt 1C
- St Louis, MO, St Louis Lambert Intl, ILS OR
LOC RWY 12L, ILS RWY 12L (CAT II), ILS
RWY 12L (CAT III), Amdt 6C
- St Louis, MO, St Louis Lambert Intl, ILS OR
LOC RWY 12R, Amdt 22C
- St Louis, MO, St Louis Lambert Intl, ILS OR
LOC RWY 30L, Amdt 12C
- St Louis, MO, St Louis Lambert Intl, ILS OR
LOC RWY 30R, ILS RWY 30R (CAT II), ILS
RWY 30R (CAT III), Amdt 11A
- St Louis, MO, St Louis Lambert Intl, RNAV
(GPS) Y RWY 12L, Amdt 2D
- St Louis, MO, St Louis Lambert Intl, RNAV
(GPS) Y RWY 12R, Amdt 1D
- St Louis, MO, St Louis Lambert Intl, RNAV
(GPS) Y RWY 30L, Amdt 1D
- St Louis, MO, St Louis Lambert Intl, RNAV
(GPS) Y RWY 30R, Amdt 2A
- St Louis, MO, St Louis Lambert Intl, RNAV
(RNP) Z RWY 12L, Orig-C
- St Louis, MO, St Louis Lambert Intl, RNAV
(RNP) Z RWY 12R, Orig-C
- St Louis, MO, St Louis Lambert Intl, RNAV
(RNP) Z RWY 30L, Orig-C
- St Louis, MO, St Louis Lambert Intl, RNAV
(RNP) Z RWY 30R, Orig-C
- Shelby, MT, Shelby, NDB RWY 23, Amdt 7A,
CANCELED
- Gwinner, ND, Gwinner-Roger Melroe Field,
RNAV (GPS) RWY 34, Amdt 4A
- Belen, NM, Alexander Muni, Takeoff
Minimums and Obstacle DP, Amdt 1A
- Hudson, NY, Columbia County, RNAV (GPS)
RWY 21, Amdt 1
- Watertown, NY, Watertown Intl, ILS OR LOC
RWY 7, Amdt 8
- Dayton, OH, James M Cox Dayton Intl, ILS
OR LOC RWY 18, Amdt 10A
- Dayton, OH, James M Cox Dayton Intl, ILS
OR LOC RWY 24L, Amdt 10A
- Dayton, OH, James M Cox Dayton Intl, ILS
OR LOC RWY 24R, Amdt 10A
- Chandler, OK, Chandler Muni, NDB RWY 35,
Amdt 1A, CANCELED
- Perkasie, PA, Pennridge, RNAV (GPS) RWY
8, Amdt 1C
- Aiken, SC, Aiken Rgnl, Takeoff Minimums
and Obstacle DP, Amdt 1A
- Aberdeen, SD, Aberdeen Rgnl, RNAV (GPS)
RWY 13, Amdt 1

Fort Hood/Killeen, TX, Robert Gray AAF, NDB RWY 15, Amdt 6A, CANCELED

Fort Hood/Killeen, TX, Robert Gray AAF, RADAR-2, Orig-A

Fort Worth, TX, Fort Worth Alliance, ILS OR LOC RWY 16L, ILS RWY 16L (CAT II), ILS RWY 16L (CAT III), Amdt 7

Fort Worth, TX, Fort Worth Alliance, ILS OR LOC RWY 34R, Amdt 7

Fort Worth, TX, Fort Worth Alliance, RNAV (GPS) RWY 16L, Amdt 2

Fort Worth, TX, Fort Worth Alliance, RNAV (GPS) RWY 34R, Amdt 3

Fort Worth, TX, Fort Worth Alliance, Takeoff Minimums and Obstacle DP, Amdt 2

Abingdon, VA, Virginia Highlands, VOR/DME-B, Amdt 6, CANCELED

Richlands, VA, Tazewell County, LOC/DME RWY 25, Amdt 1B

Boscobel, WI, Boscobel, RNAV (GPS) RWY 7, Orig-A

Mineral Point, WI, Iowa County, NDB RWY 22, Amdt 6A, CANCELED

Bluefield, WV, Mercer County, ILS OR LOC RWY 23, Amdt 15C

Bluefield, WV, Mercer County, VOR RWY 23, Amdt 5C

Pineville, WV, Kee Field, RNAV (GPS) RWY 8, Orig-C

Pineville, WV, Kee Field, RNAV (GPS) RWY 26, Orig-C

[FR Doc. 2018-01170 Filed 1-25-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31172; Amdt. No. 3781]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective January 26, 2018. The compliance date for each

SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 26, 2018.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC, 20590-0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. 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/code_of_federal_regulations/ibr_locations.html.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Thomas J. Nichols, Flight Procedure Standards Branch (AFS-420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) Telephone: (405) 954-4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, part 97 (14 CFR part 97), by establishing, amending, suspending, or removes SIAPs, Takeoff Minimums and/or ODPs. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA forms are FAA Forms 8260-3, 8260-4, 8260-5, 8260-15A, and 8260-15B when required by an entry on 8260-15A.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as Amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find

that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under 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. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC on December 29, 2017.

John S. Duncan,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 1 February 2018

Anchorage, AK, Ted Stevens Anchorage Intl, ILS OR LOC RWY 7L, ILS RWY 7L (SA CAT I), ILS RWY 7L (SA CAT II), Amdt 3C
Anchorage, AK, Ted Stevens Anchorage Intl, ILS OR LOC RWY 7R, ILS RWY 7R (SA CAT I), ILS RWY 7R (CAT II), ILS RWY 7R (CAT III), Amdt 3C
Kipnuk, AK, Kipnuk, RNAV (GPS) RWY 17, Orig
Kipnuk, AK, Kipnuk, RNAV (GPS) RWY 35, Orig

Kipnuk, AK, Kipnuk, Takeoff Minimums and Obstacle DP, Amdt 2
Sacramento, CA, Sacramento Intl, ILS OR LOC RWY 16L, ILS RWY 16L (SA CAT II), Amdt 4A
Santa Ana, CA, John Wayne Airport-Orange County, RNAV (GPS) Y RWY 20R, Amdt 3A
Santa Monica, CA, Santa Monica Muni, RNAV (GPS) RWY 21, Amdt 1
Santa Monica, CA, Santa Monica Muni, RNAV (GPS) Y RWY 3, Amdt 1
Santa Monica, CA, Santa Monica Muni, RNAV (GPS) Z RWY 3, Amdt 1
Weno Island, FM, Chuuk Intl, GPS RWY 22, Orig, CANCELED
Weno Island, FM, Chuuk Intl, NDB RWY 4, Amdt 1
Weno Island, FM, Chuuk Intl, NDB RWY 22, Orig
Weno Island, FM, Chuuk Intl, NDB OR GPS-A, Orig-A, CANCELED
Weno Island, FM, Chuuk Intl, NDB OR GPS-B, Amdt 4A, CANCELED
Weno Island, FM, Chuuk Intl, RNAV (GPS) RWY 4, Amdt 1
Weno Island, FM, Chuuk Intl, RNAV (GPS) RWY 22, Orig
Milledgeville, GA, Baldwin County, NDB RWY 28, Amdt 4
Milledgeville, GA, Baldwin County, RNAV (GPS) RWY 10, Amdt 2
Milledgeville, GA, Baldwin County, RNAV (GPS) RWY 28, Amdt 2
Paducah, KY, Barkley Rgnl, RNAV (GPS) RWY 4, Amdt 1
Bedford, MA, Laurence G Hanscom Fld, ILS OR LOC RWY 11, Amdt 26B
Bedford, MA, Laurence G Hanscom Fld, ILS OR LOC RWY 29, Amdt 8
Bedford, MA, Laurence G Hanscom Fld, VOR RWY 23, Amdt 10
Saginaw, MI, MBS Intl, Takeoff Minimums and Obstacle DP, Amdt 1
St Louis, MO, Creve Coeur, RNAV (GPS) RWY 16, Amdt 1A
St Louis, MO, St Louis Lambert Intl, RNAV (GPS) Y RWY 30R, Amdt 2
St Louis, MO, St Louis Lambert Intl, ILS OR LOC RWY 30R, ILS RWY 30R (CAT II), ILS RWY 30R (CAT III), Amdt 11
West Yellowstone, MT, Yellowstone, RNAV (GPS) RWY 1, Orig-A
Raeford, NC, P K Airpark, RNAV (GPS)-A, Orig
Raeford, NC, P K Airpark, VOR-A, Amdt 4
Ellendale, ND, Ellendale Muni, RNAV (GPS) RWY 31, Orig
Ellendale, ND, Ellendale Muni, Takeoff Minimums and Obstacle DP, Orig
Reno, NV, Reno/Stead, ILS OR LOC RWY 32, Orig-A
Reno, NV, Reno/Stead, RNAV (GPS) RWY 32, Amdt 1B
Galion, OH, Galion Muni, RNAV (GPS) RWY 5, Orig-B
Galion, OH, Galion Muni, RNAV (GPS) RWY 23, Orig-B
Lawton, OK, Lawton-Fort Sill Rgnl, ILS OR LOC RWY 35, Amdt 8
Lawton, OK, Lawton-Fort Sill Rgnl, RNAV (GPS) RWY 35, Amdt 1A
Lawton, OK, Lawton-Fort Sill Rgnl, VOR RWY 35, Amdt 21
Oklahoma City, OK, Will Rogers World, ILS OR LOC RWY 35R, ILS RWY 35R (SA CAT I), ILS RWY 35R (CAT II), Amdt 10D

Grants Pass, OR, Grants Pass, RNAV (GPS) RWY 13, Orig
Pittsburg, PA, Pittsburg Intl, ILS OR LOC RWY 10L, ILS RWY 10L (CAT II), ILS RWY 10L (CAT III), Amdt 26
Pittsburg, PA, Pittsburg Intl, ILS OR LOC RWY 10R, ILS RWY 10R (SA CAT I), ILS RWY 10R (CAT II), ILS RWY 10R (CAT III), Amdt 10G
Pittsburg, PA, Pittsburg Intl, ILS OR LOC RWY 28L, Amdt 11
Pittsburg, PA, Pittsburg Intl, ILS OR LOC RWY 28R, ILS RWY 28R (SA CAT I), ILS RWY 28R (CAT II), Amdt 10
Pittsburg, PA, Pittsburg Intl, ILS OR LOC RWY 32, Amdt 14
Pittsburg, PA, Pittsburg Intl, RNAV (GPS) RWY 10L, Amdt 4
Pittsburg, PA, Pittsburg Intl, RNAV (GPS) RWY 14, Amdt 3C
Pittsburg, PA, Pittsburg Intl, RNAV (GPS) Y RWY 10C, Amdt 4B
Pittsburg, PA, Pittsburg Intl, RNAV (GPS) Y RWY 10R, Amdt 3C
Pittsburg, PA, Pittsburg Intl, RNAV (GPS) Y RWY 28C, Amdt 4B
Pittsburg, PA, Pittsburg Intl, RNAV (GPS) Y RWY 28L, Amdt 5
Pittsburg, PA, Pittsburg Intl, RNAV (GPS) Y RWY 28R, Amdt 5
Pittsburg, PA, Pittsburg Intl, RNAV (GPS) Y RWY 32, Amdt 6
Pittsburg, PA, Pittsburg Intl, RNAV (RNP) Z RWY 10C, Orig-D
Pittsburg, PA, Pittsburg Intl, RNAV (RNP) Z RWY 10R, Orig-D
Pittsburg, PA, Pittsburg Intl, RNAV (RNP) Z RWY 28C, Orig-D
Pittsburg, PA, Pittsburg Intl, RNAV (RNP) Z RWY 28L, Amdt 1
Pittsburg, PA, Pittsburg Intl, RNAV (RNP) Z RWY 28R, Amdt 1
Pittsburg, PA, Pittsburg Intl, RNAV (RNP) Z RWY 32, Amdt 2
North Kingstown, RI, Quonset State, ILS OR LOC RWY 16, Amdt 11
North Kingstown, RI, Quonset State, RNAV (GPS) RWY 16, Amdt 1
North Kingstown, RI, Quonset State, RNAV (GPS) RWY 34, Amdt 1
North Kingstown, RI, Quonset State, VOR RWY 34, Amdt 3
North Kingstown, RI, Quonset State, VOR-A, Amdt 6
Onida, SD, Onida Muni, RNAV (GPS) RWY 13, Orig
Onida, SD, Onida Muni, RNAV (GPS) RWY 31, Orig
Onida, SD, Onida Muni, Takeoff Minimums and Obstacle DP, Orig
Mc Minnville, TN, Warren County Memorial, Takeoff Minimums and Obstacle DP, Amdt 2
Dallas-Fort Worth, TX, Dallas-Fort Worth Intl, CONVERGING ILS RWY 36L, Amdt 3
Dallas-Fort Worth, TX, Dallas-Fort Worth Intl, ILS OR LOC RWY 36L, ILS RWY 36L (SA CAT II), Amdt 4
Kenedy, TX, Karnes County, Takeoff Minimums and Obstacle DP, Amdt 2
Salt Lake City, UT, South Valley Rgnl, Takeoff Minimums and Obstacle DP, Amdt 6
Pullman/Moscow, WA, Pullman/Moscow Rgnl, Takeoff Minimums and Obstacle DP, Amdt 4A

Milwaukee, WI, General Mitchell Intl, ILS OR LOC RWY 19R, Amdt 12B
 Milwaukee, WI, General Mitchell Intl, LOC RWY 25L, Amdt 5B
 Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 1L, Amdt 1D
 Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 1R, Orig-A
 Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 7L, Orig-B
 Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 13, Orig-B
 Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 19L, Orig-B
 Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 19R, Amdt 2B
 Milwaukee, WI, General Mitchell Intl, RNAV (GPS) Z RWY 7R, Amdt 1D
 Milwaukee, WI, General Mitchell Intl, RNAV (GPS) Z RWY 25L, Amdt 1D

RESCINDED: On December 26, 2017 (82 FR 60862), the FAA published an Amendment in Docket No. 31170, Amdt No. 3779, to Part 97 of the Federal Aviation Regulations under section 97.29 and 97.37. The following entries for Buckland, AK, and Philadelphia, PA, effective February 1, 2018, are hereby rescinded in their entirety:

Buckland, AK, Buckland, Takeoff Minimums and Obstacle DP, Amdt 2
 Philadelphia, PA, Philadelphia Intl, ILS Z OR LOC Z RWY 9R, ILS Z RWY 9R (SA CAT I), ILS Z RWY 9R (CAT II), ILS Z RWY 9R (CAT III), Amdt 10A

[FR Doc. 2018-01167 Filed 1-25-18; 8:45 am]

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 170804727-7727-01]

RIN 0694-AH43

Addition of Certain Entities; Removal of Certain Entities; and Revisions of Entries on the Entity List

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule amends the Export Administration Regulations (EAR) by adding twenty-one persons under twenty-three entries to the Entity List. The twenty-one persons who are added to the Entity List have been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States. These twenty-one persons will be listed on the Entity List under the destinations of Bulgaria, China, Kazakhstan, Russia, Syria, and the United Arab Emirates (U.A.E.). In addition, this rule amends the EAR by removing three entities from the Entity List. This rule removes one entity listed

under the destination of Taiwan and two entities listed under the destination of the U.A.E. from the Entity List. All three of the removals are the results of requests for removal received by BIS pursuant to the section of the EAR used for requesting removal or modification of an Entity List entry and a review of information provided in the removal requests. Finally, this final rule modifies two existing entries on the Entity List. This rule modifies one entry under China and one entry under Pakistan to provide additional or modified addresses and/or names for these persons.

DATES: This rule is effective January 26, 2018.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482-5991, Email: ERC@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

The Entity List (supplement No. 4 to part 744) identifies entities and other persons reasonably believed to be involved, or to pose a significant risk of being or becoming involved, in activities contrary to the national security or foreign policy interests of the United States. The EAR imposes additional license requirements on, and limits the availability of most license exceptions for, exports, reexports, and transfers (in-country) to those listed. The “license review policy” for each listed entity or other person is identified in the License Review Policy column on the Entity List and the impact on the availability of license exceptions is described in the **Federal Register** document adding entities or other persons to the Entity List. BIS places entities and other persons on the Entity List pursuant to sections of part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and all decisions to remove or modify an entry by unanimous vote.

ERC Entity List Decisions

Additions to the Entity List

This rule implements the decision of the ERC to add twenty-one persons under twenty-three entries to the Entity List. These twenty-one persons are being added on the basis of § 744.11 (License requirements that apply to entities acting contrary to the national security or foreign policy interests of the United States) of the EAR. The twenty-three entries added to the Entity List consist of four entities located in Bulgaria, one entity located in China, two entities located in Kazakhstan, two entities located in Russia, two entities located in Syria, and twelve entities located in the U.A.E. There are twenty-three entries for the twenty-one persons because two of the persons are listed in multiple locations, resulting in two additional entries.

The ERC reviewed § 744.11(b) (Criteria for revising the Entity List) in making the determination to add these twenty-one persons under twenty-three entries to the Entity List. Under that paragraph, persons for whom there is reasonable cause to believe, based on specific and articulable facts, that they have been involved, are involved, or pose a significant risk of being or becoming involved in, activities that are contrary to the national security or foreign policy interests of the United States and those acting on behalf of such persons may be added to the Entity List. Paragraphs (b)(1) through (5) of § 744.11 provide an illustrative list of activities that could be contrary to the national security or foreign policy interests of the United States.

The ERC determined that eleven entities, Advanced Aerospace Industries, Deira General Marketing, DGL Clearing and Forwarding LLC, Emitech Middle East FZC, Eurotech DMCC, Foremost International FZE, Jazirah Aviation Club, Modest Marketing LLC, Pearltrainer FZE, Sky Gulf Consultancy and Researches LLC, and Stealth Telecom FZC, all located in the U.A.E., be added to the Entity List for actions contrary to the national security or foreign policy interests of the United States. The ERC determined that there is reasonable cause to believe, based on specific and articulable facts, that these entities have been involved in the procurement of items for an entity on the Entity List, in circumvention of the licensing requirements set forth in § 744.11 of the EAR.

The ERC determined that one entity, Chengdu Spaceon Technology Co. Ltd., located in China, be added to the Entity List for actions contrary to the national security or foreign policy interests of the

United States. The ERC determined that there is reasonable cause to believe, based on specific and articulable facts, that this entity has been involved in transshipping items to a person on the Entity List in China for an unauthorized military end-use.

The ERC determined that seven entities, Adib Zeno, Ammar Almounajed, Iskren Georgiev, Lyubka Hristova, Mihaela Nenova, Rizk Ali, and Zhelyaz Andreev, located in the destinations of Bulgaria, Syria and the U.A.E., be added to the Entity List for actions contrary to the national security or foreign policy interests of the United States. The ERC determined that there is reasonable cause to believe, based on specific and articulable facts, that these entities unlawfully conspired to procure and divert controlled aircraft parts to Syrian Arab Airlines, an entity on the Department of the Treasury's Office of Foreign Assets Control's (OFAC) Specially-Designated Nationals list (SDN).

The ERC determined that two entities, Abtronics and Timofey Telegin, located in the destinations of Russia and Kazakhstan, be added to the Entity List on the basis of their procurement of U.S.-origin items for activities contrary to the national security or foreign policy interests of the United States. Specifically, these entities procured U.S.-origin items and transferred them to entities of the Russian military and parties on the Entity List without the necessary licenses.

Pursuant to § 744.11(b) of the EAR, the ERC determined that the conduct of these twenty-one persons raises sufficient concern that prior review of exports, reexports or transfers (in-country) of all items subject to the EAR involving these persons, and the possible imposition of license conditions or license denials on shipments to the persons, will enhance BIS's ability to prevent violations of the EAR.

For the twenty-one persons added to the Entity List, BIS imposes a license requirement for all items subject to the EAR, and a license review policy of presumption of denial. The license requirements apply to any transaction in which items are to be exported, reexported, or transferred (in-country) to any of the persons or in which such persons act as purchaser, intermediate consignee, ultimate consignee, or end-user. In addition, no license exceptions are available for exports, reexports, or transfers (in-country) to the persons being added to the Entity List in this rule. The acronym "a.k.a." (also known as) is used in entries on the Entity List to identify aliases and help exporters,

reexporters and transferors to better identify persons on the Entity List.

This final rule adds the following twenty-one persons under twenty-three entries to the Entity List:

Bulgaria

- (1) *Iskren Georgiev*, 51 Aleksandar Malinov Blvd., Sofia 1712, Bulgaria;
- (2) *Lyubka Hristova*, 51 Aleksandar Malinov Blvd., Sofia 1712, Bulgaria;
- (3) *Mihaela Nenova*, a.k.a., the following one alias:
—*Mihaela Nenova-Muhy*, 51 Aleksandar Malinov Blvd., Sofia 1712, Bulgaria; and
- (4) *Zhelyaz Andreev*, 51 Aleksandar Malinov Blvd., Sofia 1712, Bulgaria.

China

- (1) *Chengdu Spaceon Technology Co., Ltd.*, a.k.a., the following one alias:
—*Tianao Electronics Co., Ltd.*, No. 88 Xinye Road, West High Tech Zone, Chengdu, China; and *Spaceon Building*, No. 1 Wulidun Road, Chadianzi, Chengdu, China; and *Tianao Building*, No. 1 Wulidun Road, Chadianzi, Chengdu, China.

Kazakhstan

- (1) *Abtronics*, 21 Solodovnikova Street, Almaty 50046, Kazakhstan (See alternate address under Russia); and
- (2) *Timofey Telegin*, 21 Solodovnikova Street, Almaty 50046, Kazakhstan (See alternate address under Russia).

Russia

- (1) *Abtronics*, 18, bld. 2, Frontovyyh Brigad Street, Yekaterinburg 620017, Russia; and 15 A Kulakova Prospect, Office 307, Stavropol 355044, Russia; and 12/11 Bld 12, 1-st Bukhvostova Street, Moscow 107076, Russia (See alternate address under Kazakhstan); and
- (2) *Timofey Telegin*, 18, bld. 2, Frontovyyh Brigad Street, Yekaterinburg 620017, Russia; and 15 A Kulakova Prospect, Office 307, Stavropol 355044, Russia; and 12/11 Bld 12, 1-st Bukhvostova Street, Moscow 107076, Russia (See alternate address under Kazakhstan).

Syria

- (1) *Adib Zeno*, Damascus International Airport, Damascus Airport Motorway, Damascus, Syria; and
- (2) *Rizk Ali*, Damascus International Airport, Damascus Airport Motorway, Damascus, Syria.

United Arab Emirates

- (1) *Advanced Aerospace Industries*, Industrial City of Abu Dhabi, Abu Dhabi, U.A.E.;

(2) *Ammar Almounajed*, a.k.a., the following one alias:

- Ammar al-Mounjad*, Warehouse No. 1017, Old Agent Bldg., Dubai Air Cargo Village, Dubai, U.A.E.;
- (3) *Deira General Marketing*, P.O. Box 26412, Abu Dhabi, U.A.E.;
- (4) *DGL Clearing and Forwarding LLC*, P.O. Box 94353, Abu Dhabi, U.A.E.;
- (5) *Emitech Middle East FZC*, P.O. Box 513364, SAIF Zone, Sharjah, U.A.E.;
- (6) *Eurotech DMCC*, Office No. 3404, HDS Tower, Sheikh Zayed Road, Dubai, U.A.E.; and P.O. Box 643650, Jumeirah Lakes Towers, Dubai U.A.E.;
- (7) *Foremost International FZE*, P.O. Box 123833, Q4-163, SAIF Zone, Sharjah, U.A.E.;
- (8) *Jazirah Aviation Club*, Al Jazirah, Al Hamra, Ras al Khaimah, U.A.E.;
- (9) *Modest Marketing LLC*, P.O. Box 51436, Dubai, U.A.E.;
- (10) *Pearltrainer FZE*, P.O. Box 32707, Sharjah, U.A.E.;
- (11) *Sky Gulf Consultancy and Researches LLC*, P.O. Box 25298, Abu Dhabi, U.A.E.; and
- (12) *Stealth Telecom FZC*, P.O. Box 7755, Sharjah, U.A.E.

Removals From the Entity List

This rule implements a decision of the ERC to remove the following three entities from the Entity List on the basis of removal requests received by BIS, as follows: Hosoda Taiwan Limited, located in Taiwan; and Euro Vision Technology LLC and Noun Nasreddine, both located in the U.A.E. The entry for Hosoda Taiwan Limited was added to the Entity List on April 23, 2015 (see 80 FR 22640). The entries for Euro Vision Technology LLC and Noun Nasreddine were added to the Entity List on February 23, 2016 (see 81 FR 8829).

The ERC decided to remove these three entities based on information received by BIS pursuant to § 744.16 of the EAR and further review conducted by the ERC.

This final rule implements the decision to remove the following one entity located in Taiwan, and two entities located in the U.A.E. from the Entity List:

Taiwan

- (1) *Hosoda Taiwan Limited*, 3F-1 No. 52, SEC 2, Chung Shan N. Road, Taipei 104 Taiwan.

United Arab Emirates

- (1) *Euro Vision Techonology LLC*, #701 Damas Tower, 702 Al Maktoum St, Dubai, U.A.E.; and 701 Attar Tower, Maktoum St, Dubai, U.A.E.; and *City Tower*, Al Maktoum St. Office No. 701, Dubai U.A.E.; and P.O. Box 40595,

Dubai, U.A.E.; and Warehouse No. 8, Plot No. 238, Rashidiya, Dubai, U.A.E.; and

(2) *Noun Nasreddine*, a.k.a., the following one alias:

—N.A. Nasreddine. #701 Damas Tower, 702 Al Maktoum St, Dubai, U.A.E.; and 701 Attar Tower, Maktoum St, Dubai, U.A.E.; and City Tower, Al Maktoum St. Office No. 701, Dubai U.A.E.; and P.O. Box 40595, Dubai, U.A.E.; and Warehouse No. 8, Plot No. 238, Rashidiya, Dubai, U.A.E.

The removal of the entities referenced above, which was approved by the ERC, eliminates the existing license requirements in supplement No. 4 to part 744 for exports, reexports and transfers (in-country) to these entities. However, the removal of these entities from the Entity List does not relieve persons of other obligations under part 744 of the EAR or under other parts of the EAR. Neither the removal of an entity from the Entity List nor the removal of Entity List-based license requirements relieves persons of their obligations under General Prohibition 5 in § 736.2(b)(5) of the EAR which provides that, “you may not, without a license, knowingly export or reexport any item subject to the EAR to an end-user or end-use that is prohibited by part 744 of the EAR.” Additionally, this removal does not relieve persons of their obligation to apply for export, reexport or in-country transfer licenses required by other provisions of the EAR. BIS strongly urges the use of supplement No. 3 to part 732 of the EAR, “BIS’s ‘Know Your Customer’ Guidance and Red Flags,” when persons are involved in transactions that are subject to the EAR.

Modifications to the Entity List

This final rule implements decisions of the ERC to modify two existing entries on the Entity List. Under the destination of China, the ERC made a determination to revise one entry by removing one address and adding one additional address to the entry for Beijing Aeronautical Manufacturing Technology Research Institute. Under the destination of Pakistan, the ERC made a determination to revise one entry by adding an alias and two additional addresses to the entry for Advanced Engineering Research Organization (AERO).

This final rule makes the following modifications to two entries on the Entity List:

China

(1) *Beijing Aeronautical Manufacturing Technology Research*

Institute, a.k.a., the following two aliases:

—BAMTRI; and

—Aviation Industry Corporation of China’s (AVIC) Institute 625.

No. 1 East Military Village, North Baligiao Station, Chaoyang District, Beijing, China; and

No. 1 Dongjunzhuang, BaligiaoBei, Chaoyang District, Beijing, China.

Pakistan

(1) *Advanced Engineering Research Organization (AERO)*, a.k.a., the following one alias:

—Integrated Solutions. Lub Thatoo Hazara Road, The Taxila District, Rawalpindi, Pakistan; and 53/2 26th Street, near Badara Commercial Area Phase 5 Extension, DHA Karachi, Pakistan; and House No. 334, Street No. 102, Sector I-8/4, near Pakeeza Market, Islamabad, Pakistan.

Export Administration Act of 1979

Although the Export Administration Act of 1979 expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 15, 2017, 82 FR 39005 (August 16, 2017), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act of 1979, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222, as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty

for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications, and carries a burden estimate of 43.8 minutes for a manual or electronic submission.

Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to Jasmeet.K.Seehra@omb.eop.gov, or by fax to (202) 395–7285.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. For the twenty-one persons under twenty-three entries added to the Entity List in this final rule, the provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation and a 30-day delay in effective date are inapplicable, because this regulation involves a military or foreign affairs function of the United States (5 U.S.C. 553(a)(1)). BIS implementation of this rule is necessary to protect U.S. national security or foreign policy interests by preventing items from being exported, reexported, or transferred (in-country) to the persons being added to the Entity List. If this rule were delayed to allow for notice and comment and a delay in effective date, the entities being added to the Entity List by this action would continue to be able to receive items without a license and to conduct activities contrary to the national security or foreign policy interests of the United States. In addition, publishing a proposed rule would give these parties notice of the U.S. Government’s intention to place them on the Entity List, which could create an incentive for these persons to accelerate receiving items subject to the EAR to conduct activities that are contrary to the national security or foreign policy interests of the United States, including taking steps to set up additional aliases, change addresses, and other measures to

try to limit the impact of the listing on the Entity List once a final rule is published. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

5. For the three entities removed from the Entity List in this final rule, pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(B), BIS finds good cause to waive requirements that this rule be subject to notice and the opportunity for public comment because it would be contrary to the public interest.

In determining whether to grant a request for removal from the Entity List, a committee of U.S. Government agencies (the End-User Review Committee (ERC)) evaluates information about and commitments made by listed entities or persons requesting removal from the Entity List, the nature and terms of which are set forth in 15 CFR part 744, supplement No. 5, as noted in 15 CFR 744.16(b). The information, commitments, and criteria for this extensive review were all established through the notice of proposed rulemaking and public comment process (72 FR 31005 (June 5, 2007) (proposed rule), and 73 FR 49311 (August 21, 2008) (final rule)). These three removals have been made within the established regulatory framework of the Entity List. If the rule were to be delayed to allow for public comment, U.S. exporters may face unnecessary economic losses as they turn away potential sales to the entities removed by this rule because the customer remained a listed person on the Entity List even after the ERC approved the removal pursuant to the rule published at 73 FR 49311 on August 21, 2008. By publishing without prior notice and comment, BIS allows the applicants to receive U.S. exports immediately because the applicants already have received approval by the ERC pursuant to 15 CFR part 744, supplement No. 5, as noted in 15 CFR 744.16(b).

Removals from the Entity List granted by the ERC involve interagency deliberation and result from review of public and non-public sources, including sensitive law enforcement information and classified information, and the measurement of such information against the Entity List removal criteria. This information is extensively reviewed according to the criteria for evaluating removal requests from the Entity List, as set out in 15 CFR part 744, supplement No. 5, and 15 CFR 744.16(b). For reasons of national security, BIS is not at liberty to provide to the public detailed information on which the ERC relied to make the

decisions to remove these entities. In addition, the information included in the removal request is information exchanged between the applicant and the ERC, which by law (section 12(c) of the Export Administration Act of 1979), BIS is restricted from sharing with the public. Moreover, removal requests from the Entity List contain confidential business information, which is necessary for the extensive review conducted by the U.S. Government in assessing such removal requests.

Section 553(d) of the APA generally provides that rules may not take effect earlier than thirty (30) days after they are published in the **Federal Register**. BIS finds good cause to waive the 30-day delay in effectiveness under 5 U.S.C. 553(d)(1) because this rule is a substantive rule which relieves a restriction. This rule's removal of three entities under three entries from the Entity List removes requirements (the Entity-List-based license requirement and limitation on use of license exceptions) on these three entities being removed from the Entity List. The rule does not impose a requirement on any other person for these removals from the Entity List. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule.

6. The Department finds that there is good cause under 5 U.S.C. 553(b)(3)(B) to waive the provisions of the Administrative Procedure Act (APA) requiring prior notice and the opportunity for public comment for the two modifications included in this rule because, as described above, they are impracticable and are contrary to the public interest. In addition, these two changes are limited to providing additional or modified addresses and/or an alias for these entities on the Entity List, which will assist the public in more easily identifying these listed entities on the Entity List.

7. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—[AMENDED]

■ 1. The authority citation for 15 CFR part 744 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of January 13, 2017, 82 FR 6165 (January 18, 2017); Notice of August 15, 2017, 82 FR 39005 (August 16, 2017); Notice of September 18, 2017, 82 FR 43825 (September 19, 2017); Notice of November 6, 2017, 82 FR 51971 (November 8, 2017).

■ 2. Supplement No. 4 to part 744 is amended:

■ a. By adding in alphabetical order, a heading for Bulgaria and four Bulgarian entities;

■ b. Under China:

■ i. By revising one Chinese entity; and

■ ii. By adding, in alphabetical order, one Chinese entity;

■ c. By adding, in alphabetical order, under Kazakhstan, two Kazakhstani entities;

■ d. By revising, under Pakistan, one Pakistani entity;

■ e. By adding, in alphabetical order, under Russia, two Russian entities;

■ f. By adding, in alphabetical order, under Syria, two Syrian entities;

■ g. By removing under Taiwan, one Taiwanese entity, “Hosoda Taiwan Limited, 3F–1 No. 52, SEC 2, Chung Shan N. Road, Taipei 104 Taiwan”;

■ h. Under United Arab Emirates:

■ i. By removing two Emirati entities, “Euro Vision Technology LLC, #701 Damas Tower, 702 Al Maktoum St, Dubai, U.A.E.; and 701 Attar Tower, Maktoum St, Dubai, U.A.E.; and City Tower, Al Maktoum St. Office No. 701, Dubai U.A.E.; and P.O. Box 40595, Dubai, U.A.E.; and Warehouse No. 8, Plot No. 238, Rashidiya, Dubai, U.A.E.”; and “Noun Nasreddine, a.k.a., the following one alias: -N.A. Nasreddine. #701 Damas Tower, 702 Al Maktoum St, Dubai, U.A.E.; and 701 Attar Tower, Maktoum St, Dubai, U.A.E.; and City Tower, Al Maktoum St. Office No. 701, Dubai U.A.E.; and P.O. Box 40595, Dubai, U.A.E.; and Warehouse No. 8, Plot No. 238, Rashidiya, Dubai, U.A.E.”; and

■ ii. By adding, in alphabetical order, twelve Emirati entities.

The additions and revisions read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	Federal Register citation
*	*	*	*	*
BULGARIA	Iskren Georgiev, 51 Aleksandar Malinov Blvd., Sofia 1712, Bulgaria.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	Lyubka Hristova, 51 Aleksandar Malinov Blvd., Sofia 1712, Bulgaria.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	Mihaela Nenova, a.k.a., the following one alias: Mihaela Nenova-Muhy, 51 Aleksandar Malinov Blvd., Sofia 1712, Bulgaria.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	Zhelyaz Andreev, 51 Aleksandar Malinov Blvd., Sofia 1712, Bulgaria.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
*	*	*	*	*
CHINA, PEOPLE'S REPUBLIC OF.	Beijing Aeronautical Manufacturing Technology Research Institute, a.k.a., the following two aliases: —BAMTRI; and —Aviation Industry Corporation of China's (AVIC) Institute 625. No. 1 East Military Village, North Baligiao Station, Chaoyang District, Beijing, China; and No. 1 Dongjunzhuang, Baligiaobei, Chaoyang District, Beijing, China.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of approval for EAR99; case-by-case review for all items on the CCL.	79 FR 24566, 5/1/14. 83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	Chengdu Spaceon Technology Co., Ltd., a.k.a., the following one alias: —Tianao Electronics Co., Ltd. No. 88 Xinye Road, West High Tech Zone, Chengdu, China; and Spaceon Building, No. 1 Wulidun Road, Chadianzi, Chengdu, China; and Tianao Building, No. 1 Wulidun Road, Chadianzi, Chengdu, China.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
*	*	*	*	*
KAZAKHSTAN	Abtronics, 21 Solodovnikova Street, Almaty 50046, Kazakhstan (See alternate address under Russia).	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	Timofey Telegin, 21 Solodovnikova Street, Almaty 50046, Kazakhstan (See alternate address under Russia)	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
*	*	*	*	*
PAKISTAN	Advanced Engineering Research Organization (AERO), a.k.a., the following one alias: —Integrated Solutions.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	79 FR 56003, 9/18/14. 83 FR [INSERT FR PAGE NUMBER], 1/26/18.

Country	Entity	License requirement	License review policy	Federal Register citation
	Lub Thatoo Hazara Road, The Taxila District, Rawalpindi, Pakistan; <i>and</i> 53/2 26th Street, near Badara Commercial Area Phase 5 Extension, DHA Karachi, Pakistan; <i>and</i> House No. 334, Street No. 102, Sector I-8/4, near Pakeeza Market, Islamabad, Pakistan.			
	*	*	*	*
	*	*	*	*
RUSSIA	*	*	*	*
	Abtronics, 18, bld. 2, Frontovyyh Brigad Street, Yekaterinburg 620017, Russia; <i>and</i> 15 A Kulakova Prospect, Office 307, Stavropol 355044, Russia; <i>and</i> 12/11 Bld 12, 1-st Bukhvostova Street, Moscow 107076, Russia (See alternate address under Kazakhstan)	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	*	*	*	*
	Timofey Telegin, 18, bld. 2, Frontovyyh Brigad Street, Yekaterinburg 620017, Russia; <i>and</i> 15 A Kulakova Prospect, Office 307, Stavropol 355044, Russia; <i>and</i> 12/11 Bld 12, 1-st Bukhvostova Street, Moscow 107076, Russia (See alternate address under Kazakhstan)	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	*	*	*	*
	*	*	*	*
SYRIA	*	*	*	*
	Adib Zeno, Damascus International Airport, Damascus Airport Motorway, Damascus, Syria	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	*	*	*	*
	Rizk Ali, Damascus International Airport, Damascus Airport Motorway, Damascus, Syria.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	*	*	*	*
	*	*	*	*
UNITED ARAB EMIRATES.	*	*	*	*
	Advanced Aerospace Industries, Industrial City of Abu Dhabi, Abu Dhabi, U.A.E.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	*	*	*	*
	Ammar Almounajed, a.k.a., the following one alias: —Ammar al-Mounjad. Warehouse No. 1017, Old Agent Bldg., Dubai Air Cargo Village, Dubai, U.A.E.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	*	*	*	*
	Deira General Marketing, P.O. Box 26412, Abu Dhabi, U.A.E.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	DGL Clearing and Forwarding LLC, P.O. Box 94353, Abu Dhabi, U.A.E.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	*	*	*	*
	Emitech Middle East FZC, P.O. Box 513364, SAIF Zone, Sharjah, U.A.E.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	*	*	*	*

Country	Entity	License requirement	License review policy	Federal Register citation
	Eurotech DMCC, Office No. 3404, HDS Tower, Sheikh Zayed Road, Dubai, U.A.E.; and P.O. Box 643650, Jumeirah Lakes Towers, Dubai U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial.	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	* * *	* * *	* * *	* * *
	Foremost International FZE, P.O. Box 123833, Q4-163, SAIF Zone, Sharjah, U.A.E.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial.	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	* * *	* * *	* * *	* * *
	Jazirah Aviation Club, Al Jazirah, Al Hamra, Ras al Khaimah, U.A.E.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial.	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	* * *	* * *	* * *	* * *
	Modest Marketing LLC, P.O. Box 51436, Dubai, U.A.E.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial.	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	* * *	* * *	* * *	* * *
	Pearltrainer FZE, P.O. Box 32707, Sharjah, U.A.E.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial.	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	* * *	* * *	* * *	* * *
	Sky Gulf Consultancy and Researches LLC, P.O. Box 25298, Abu Dhabi, U.A.E.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial.	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	* * *	* * *	* * *	* * *
	Stealth Telecom FZC, P.O. Box 7755, Sharjah, U.A.E.	For all items subject to the EAR (See § 744.11 of the EAR).	Presumption of denial.	83 FR [INSERT FR PAGE NUMBER], 1/26/18.
	* * *	* * *	* * *	* * *
	* * *	* * *	* * *	* * *

Dated: January 12, 2018.

Richard E. Ashooh,
Assistant Secretary for Export
Administration.

[FR Doc. 2018-01332 Filed 1-25-18; 8:45 am]

BILLING CODE 3510-33-P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2016-0017]

16 CFR Part 1308

Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Revision of Determinations Regarding Certain Plastics

AGENCY: Consumer Product Safety
Commission.

ACTION: Direct final rule.

SUMMARY: On August 30, 2017, the Commission issued a final rule determining that certain plastics and additives would not contain the phthalates that the Consumer Product Safety Improvement Act of 2008 (CPSIA) prohibits from use in children's toys and child care articles. Subsequently, the Commission issued a final rule that removes some phthalates

from the statutory prohibition and adds others. This direct final rule revises the determinations rule to cover the phthalates that the phthalates final rule prohibits from use in children's toys and child care articles.

DATES: The rule is effective on April 25, 2018, unless we receive significant adverse comment by February 26, 2018. If we receive timely significant adverse comment, we will publish notification in the **Federal Register**, withdrawing this direct final rule before its effective date.

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2016-0017, by any of the following methods:

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (email), except through www.regulations.gov.

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety

Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this document. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

FOR FURTHER INFORMATION CONTACT: For information, contact: John W. Boja, Lead Compliance Officer, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814-4408; telephone: 301-504-7300; email: jboja@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

Statutory Prohibitions

Section 108 of the CPSIA established permanent and interim prohibitions that prohibited the use of certain phthalates in children's toys and child care articles. 15 U.S.C. 2057c(a) and (b). The

CPSIA also directed the Commission to issue a rule deciding whether to make the interim prohibitions permanent and whether to prohibit other children's products containing any phthalates. *Id.* 2057c(b)(3). In the following discussion, we refer to rulemaking under section 108 of the CPSIA as the phthalates rule or rulemaking.

Third Party Testing and Burden Reduction

Section 14(a) of the CPSA requires that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, be certified as complying with all applicable CPSC requirements. 15 U.S.C. 2063(a). For children's products, certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* Public Law 112–28 (August 12, 2011) amended the CPSA and directed the CPSC to seek comment on “opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation.” Public Law 112–28 also authorized the Commission to issue new or revised third party testing regulations if the Commission determines “that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.” 15 U.S.C. 2063(d)(3)(B).

The Commission may issue determinations that specific materials do not contain prohibited substances such as lead or phthalates. Based on such a determination, the specified material would not require third party testing for compliance with the applicable mandatory prohibition.

The determinations only relieve the manufacturer's obligation to have the specific materials tested by a CPSC-accepted third party conformity assessment body. Children's products must still comply with the applicable substantive requirements, regardless of any relief from third party testing requirements. Additionally, the manufacturer must issue a certificate stating that the product complies with CPSC requirements.

Determinations Rule

On August 30, 2017, the Commission published a final rule determining that specified plastics and additives would not contain materials subject to the prohibition of children's toys and child care articles containing specified

phthalates. 82 FR 41163. The rule created a new part 1308 for “Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics.” The rule determined that the specified plastics and accompanying additives do not contain the statutorily prohibited phthalates (DEHP, DBP, BBP, DINP, DIDP, DnOP) in concentrations above 0.1 percent, and thus, are not required to be third party tested to assure compliance with section 108 of the CPSIA. At the time the Commission issued the determinations rule, the Commission had issued a proposed rule in the phthalates rulemaking, but had not yet promulgated a final rule in that proceeding. The preambles of both the NPR and final rule for the determinations noted that the research providing the basis for the determinations covering the six phthalates subject to the statutory prohibition, applied as well to the additional four phthalates the Commission had proposed prohibiting in children's toys and child care articles in the phthalates NPR. In the preamble to the final determinations rule, the Commission indicated that when the Commission published the final phthalates rule, the Commission would amend the determinations rule to reflect the phthalates regulated in the phthalates final rule. 82 FR 41163, at 41164.

Phthalates Final Rule

On October 27, 2017, the Commission published the final phthalates rule in the **Federal Register**. 82 FR 49938. The phthalates rule, which is codified at 16 CFR part 1307, makes permanent the interim statutory prohibition on diisononyl phthalate (DINP) and expands that restriction to prohibit all children's toys and child care articles that contain concentrations of more than 0.1 percent of DINP. The phthalates rule also lifts the interim prohibitions on children's toys that can be placed in a child's mouth and child care articles that contain concentrations of more than 0.1 percent of di-n-octyl phthalate (DNOP) or diisodecyl phthalate (DIDP). Additionally, the phthalates rule also prohibits children's toys and child care articles that contain concentrations of more than 0.1 percent of diisobutyl phthalate (DIBP), di-n-pentyl phthalate (DPENP), di-n-hexyl phthalate (DHEXP), and dicyclohexyl phthalate (DCHP). The permanent prohibitions on children's toys and child care articles that contain concentrations of more than 0.1 percent on the use of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and

benzyl butyl phthalate (BBP) in children's toys and child care articles in section 108 of the CPSIA are unchanged by the phthalate rule. The phthalates rule takes effect on April 25, 2018.

B. Revisions to 16 CFR Part 1308

This direct final rule amends 16 CFR 1308.1 to cover the phthalates listed in the phthalates final rule discussed in section A of the preamble. This action will bring the determinations into alignment with the phthalates final rule so that firms will be able to use the determinations to reduce testing burdens related to the final phthalates rule as they have with the statutory prohibitions. The amendment does not make any other changes to the determinations rule.

C. Direct Final Rule Process

The Commission is issuing this rule as a direct final rule. The Administrative Procedure Act (APA) generally requires notice and comment rulemaking. 5 U.S.C. 553. The direct final rule process is an appropriate way to satisfy this requirement in certain circumstances. In Recommendation 95–4, the Administrative Conference of the United States (ACUS) endorsed direct final rulemaking as an appropriate procedure to expedite promulgation of rules that are noncontroversial and that are not expected to generate significant adverse comment. *See* 60 FR 43108 (August 18, 1995). The Commission concludes that a direct final rule is appropriate here. The Commission is taking the limited action of amending the determinations rule at 16 CFR part 1308 to reflect the phthalates that are restricted under the Commission's phthalates rule. The previous determinations rule explained that the reports supporting the determinations regarding the phthalates that are covered by the statutory prohibitions in section 108 of the CPSIA also apply to the phthalates covered by the Commission's phthalates rule. We also note that this determination rule is separate from the Commission's phthalates rulemaking which was concluded with the Commission's issuance of a final rule on October 27, 2017. Because this document merely updates the regulated phthalates in the determinations rule, the Commission believes this rulemaking is a non-controversial matter which is not likely to generate comments. Therefore, the Commission concludes that the direct final rule process is appropriate.

Unless we receive a significant adverse comment within 30 days, the rule will take effect on April 25, 2018. In accordance with ACUS's

recommendation, the Commission considers a significant adverse comment to be one where the commenter explains why revising the list of regulated phthalates would be inappropriate. We note that comments on either the underlying determinations or phthalates final rules are not considered significant adverse comments because the only change this rule makes is to revise the list of covered phthalates.

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

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that agencies review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603 and 604. CPSC conducted a final regulatory flexibility analysis (FRFA) for the determinations rule that the Commission issued in August 2017. The FRFA found that “the impact of the determinations on small businesses would be to reduce the burden of third party testing for phthalate content and would be expected to be entirely beneficial.” 82 FR 41171. As explained above, this direct final rule takes the limited action of revising the list of covered phthalates to bring the determinations rule into line with the phthalates rule so that companies will be able to use the determinations to reduce third party testing under the phthalates rule as they have under the statutory prohibitions.

E. Effective Date

As discussed in section C of this preamble, this is a direct final rule. Unless we receive a significant adverse comment within 30 days, the rule will take effect on April 25, 2018.

List of Subjects in 16 CFR Part 1308

Business and industry, Consumer protection, Imports, Infants and children, Product testing and certification, Toys.

Accordingly, the Commission amends 16 CFR part 1308 as follows:

PART 1308—PROHIBITION OF CHILDREN’S TOYS AND CHILD CARE ARTICLES CONTAINING SPECIFIED PHTHALATES: DETERMINATIONS REGARDING CERTAIN PLASTICS

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: Sec. 3, Pub. L. 110–314, 122 Stat. 3016; 15 U.S.C. 2063(d)(3)(B).

■ 2. Revise § 1308.1 to read as follows:

§ 1308.1 Prohibited children’s toys and child care articles containing specified phthalates and testing requirements.

Section 108(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) permanently prohibits any children’s toy or child care article that contains concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). In accordance with section 108(b)(3) of the CPSIA, 16 CFR part 1307 prohibits any children’s toy or child care article that contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisobutyl phthalate (DIBP), di-n-pentyl phthalate (DPENP), di-n-hexyl phthalate (DHEXP), or dicyclohexyl phthalate (DCHP) is prohibited. Materials used in children’s toys and child care articles subject to section 108(a) of the CPSIA and 16 CFR part 1307 must comply with the third party testing requirements of section 14(a)(2) of the Consumer Product Safety Act (CPSA), unless listed in § 1308.2.

Alberta E. Mills,

Acting Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2018–01451 Filed 1–25–18; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF LABOR

Veterans’ Employment and Training Service

20 CFR Part 1011

RIN 1293–AA21

Honoring Investments in Recruiting and Employing American Military Veterans (HIRE Vets) Medallion Program; Agency Information Collection Activities; OMB Approvals

AGENCY: Veterans’ Employment and Training Service, Labor.

ACTION: OMB approval of information collections under Paperwork Reduction Act.

SUMMARY: This document announces that the Office of Management and

Budget (OMB) has approved the information collections associated with the Honoring Investments in Recruiting and Employing American Military Veterans (HIRE Vets) Medallion Program rule under the Paperwork Reduction Act of 1995 (PRA).

DATES: On January 9, 2018, OMB approved the information collection request (ICR) the Veterans’ Employment and Training Service (VETS) submitted to implement the HIRE Vets Medallion Program Rule published on November 13, 2017 (82 FR 52186) and an associated program demonstration for 2018. Employers seeking recognition under the HIRE Vets Medallion Program Demonstration may submit applications once the Program Demonstration begins on or about January 31, 2018.

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 of charge by contacting Randall Smith, Veterans’ Employment and Training Service, U.S. Department of Labor, Room S–1325, 200 Constitution Avenue NW, Washington, DC 20210, *email:* HIREVETS@dol.gov, *telephone:* (202) 693–4700 or TTY (877) 889–5627 (these are not toll-free numbers).

FOR FURTHER INFORMATION CONTACT: Randall Smith, Veterans’ Employment and Training Service, U.S. Department of Labor, Room S–1325, 200 Constitution Avenue NW, Washington, DC 20210, *email:* HIREVETS@dol.gov, *telephone:* (202) 693–4700 or TTY (877) 889–5627 (these are not toll-free numbers).

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501 *et seq.*, and its attendant regulations, 5 CFR part 1320, require a Federal agency to consider the impact of paperwork and other information collection burdens imposed on the public and to solicit public comments on the information collections. The PRA also provides that an agency may not collect or sponsor the collection of information unless it displays a currently valid OMB control number. See 5 CFR 1320.8(b)(3)(vi). OMB has approved the HIRE Vets Medallion Program information collections under control number 1293–0015.

In accordance with the PRA, VETS solicited comments on the HIRE Vets Medallion Program information collections as they were proposed in a Notice of Proposed Rulemaking published August 18, 2017 (82 FR 39371). See 44 U.S.C. 3506(c)(2). The Department also submitted a

contemporaneous request for OMB review of the proposed HIRE Vets Medallion Program information collections, in accordance with 44 U.S.C. 3507(d). On October 25, 2017, OMB issued a notice of action instructing the Department of Labor (DOL) to resubmit the information collections after taking public comments on the NPRM into consideration. See OMB ICR Reference Number 201707–1293–001. VETS published the HIRE Vets Medallion Program Final Rule in the **Federal Register** on November 13, 2017 (82 FR 52186). On the same day, DOL submitted the ICR that OMB requested, and OMB approved the ICR on January 9, 2018. See OMB ICR Reference Number 201710–1293–002. For additional substantive information about this ICR, see the related documents published in the **Federal Register** on August 18, 2017 (82 FR 39371), and November 13, 2017 (82 FR 52186).

The information collection and its annual burden on the public may be summarized as follows:

Agency: DOL–VETS.

Title of Collection: Honoring Investments in Recruiting and Employing (HIRE) American Military Veterans (HIRE Vets) Medallion Program.

OMB Control Number: 1293–0015.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Annual Responses: 34,184.

Total Estimated Annual Time Burden: 58,556 hours.

Total Estimated Annual Other Costs Burden: \$1,045,486.

Authority: 44 U.S.C. 3507(a)(1)(D).

OMB Control Number: 1293–0015.

Authority: 44 U.S.C. 3506(c).

Dated: January 18, 2018.

J.S. Shellenberger,

Deputy Assistant Secretary for the Veterans' Employment and Training Service.

[FR Doc. 2018–01262 Filed 1–25–18; 8:45 am]

BILLING CODE 4510–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. FDA–2017–N–7007]

RIN 0910–AH49

Removal of Certain Time of Inspection and Duties of Inspector Regulations for Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is amending the general biologics regulations relating to time of inspection requirements and also removing duties of inspector requirements. FDA is taking this action to remove outdated requirements and accommodate new approaches, such as a risk-based inspection frequency for drug establishments, thereby providing flexibility without diminishing public health protections. This action is part of FDA's implementation of Executive Orders (E.O.s) 13771 and 13777. Under these E.O.s, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction while allowing the Agency to achieve our public health mission and fulfill statutory obligations. The Agency is issuing these amendments directly as a final rule because we believe they are noncontroversial and FDA anticipates no significant adverse comments.

DATES: This rule is effective June 11, 2018. Submit either electronic or written comments on the direct final rule or its companion proposed rule by April 11, 2018. If FDA receives no significant adverse comments within the specified comment period, the Agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the Agency will publish a document in the **Federal Register** withdrawing this direct final rule within 30 days after the comment period on this direct final rule ends.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 11, 2018. The <https://www.regulations.gov>

electronic filing system will accept comments until midnight Eastern Time at the end of April 11, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions.”)

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2017–N–7007 for “Removal of Certain Time of Inspection and Duties of Inspector Regulations for Biological Products.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff

between 9 a.m. and 4 p.m., Monday through Friday.

• **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.

FOR FURTHER INFORMATION CONTACT: Melissa Segal, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Direct Final Rule

FDA is issuing this direct final rule to amend the general biologics regulations relating to time of inspection requirements and to remove duties of inspector requirements. FDA is taking this action to remove outdated requirements and accommodate new approaches, such as a risk-based

inspection frequency for drug establishments, thereby providing flexibility without diminishing public health protections.

B. Summary of the Major Provisions of the Direct Final Rule

This direct final rule revises the time of inspection requirements contained in § 600.21 (21 CFR 600.21) and also removes the duties of inspector requirements contained in § 600.22 (21 CFR 600.22). These changes to the biological product regulations eliminate outdated requirements and accommodate new approaches, such as a risk-based inspection frequency for drug establishments, thereby providing flexibility without diminishing public health protections. Revision and removal of these regulations does not change the biological product establishment inspection requirements and duties of an investigator requirements that apply under sections 704 and 510(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 374 and 360(h)) and section 351(c) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(c)).

C. Legal Authority

FDA is taking this action under the biological product provisions of the PHS Act, and the drugs and general administrative provisions of the FD&C Act, including sections 704 and 510(h) of the FD&C Act and section 351(c) of the PHS Act.

D. Costs and Benefits

Because this direct final rule does not impose any additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

II. Direct Final Rulemaking

In the document entitled “Guidance for FDA and Industry: Direct Final Rule Procedures,” announced and provided in the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described its procedures on when and how the Agency will employ direct final rulemaking. The guidance may be accessed at: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm>. We have determined that this rule is appropriate for direct final rulemaking because we believe that it includes only noncontroversial amendments and we anticipate no significant adverse comments. Consistent with our procedures on direct final rulemaking, FDA is also publishing elsewhere in this issue of the **Federal Register** a companion proposed

rule proposing to amend the general biological products regulations by removing certain time of inspection requirements and the duties of inspector requirements. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event that the direct final rule is withdrawn because of any significant adverse comments. The comment period for the direct final rule runs concurrently with the companion proposed rule. Any comments received in response to the companion proposed rule will be considered as comments regarding the direct final rule.

We are providing a comment period on the direct final rule of 75 days after the date of publication in the **Federal Register**. If we receive any significant adverse comments, we intend to withdraw this direct final rule before its effective date by publication of a notice in the **Federal Register**. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule’s underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process.

Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in the direct final rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to a part of this rule and that part can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of the significant adverse comment.

If any significant adverse comments are received during the comment period, FDA will publish, before the effective date of this direct final rule, a notice of significant adverse comment and withdraw the direct final rule. If we withdraw the direct final rule, any comments received will be applied to the proposed rule and will be considered in developing a final rule using the usual notice-and-comment procedure.

If FDA receives no significant adverse comments during the specified

comment period, FDA intends to publish a document confirming the effective date within 30 days after the comment period ends.

III. Background

On February 24, 2017, President Donald Trump issued Executive Order 13777, “Enforcing the Regulatory Reform Agenda” (82 FR 12285, March 1, 2017). One of the provisions in the Executive Order requires Agencies to evaluate existing regulations and make recommendations to the Agency head regarding their repeal, replacement, or modification, consistent with applicable law. As one step in implementing the Executive Order, FDA published a notice in the **Federal Register** of September 8, 2017 (82 FR 42492) entitled “Review of Existing Center for Biologics Evaluation and Research Regulatory and Information Collection Requirements.” In that notice, FDA announced that it was conducting a review of existing regulations to determine, in part, whether they can be made more effective in light of current public health needs and to take advantage of, and support, advances in innovation that have occurred since those regulations took effect. As part of this initiative, FDA is updating outdated regulations as specified in this rule.

FDA’s general biological products regulations in part 600 (21 CFR part 600) are intended to help ensure the safety, purity, and potency of biological products administered to humans. The revision and removal of certain general biological products regulations are designed to eliminate outdated requirements and accommodate new approaches, such as a risk-based inspection frequency for drug establishments and provide flexibility without diminishing public health protections.

A. Section 600.21

The authority for FDA to conduct establishment inspections is included in both the FD&C Act and the PHS Act. Specifically, section 704 of the FD&C Act and section 351(c) of the PHS Act authorize the Agency to inspect establishments that manufacture biological products. Before July 9, 2012—the date the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) was signed into law—section 510(h) of the FD&C Act further provided, among other things, that drug and device establishments registered with FDA must be inspected at least once in the 2-year period beginning with the date of registration and at least once in every successive 2-year period thereafter.

Section 510(h) of the FD&C Act applies to biological product establishments because all biological products are subject to regulation under the drug or device provisions of the FD&C Act (in addition to the biological product provisions of the PHS Act). Since 1983, FDA’s biological product regulation at § 600.21 has also included a biennial inspection requirement (“[A]n inspection of each licensed establishment and its additional location(s) shall be made at least once every 2 years”); this was consistent with the pre-FDASIA biennial inspection requirement in section 510(h) of the FD&C Act.

With the enactment of FDASIA, however, the biennial inspection requirement for drug establishments in section 510(h) of the FD&C Act was replaced with a requirement that FDA inspect drug establishments in accordance with a risk-based schedule established by FDA. Accordingly, for biological product establishments that are registered as drug establishments under section 510(h), the requirement in § 600.21 regarding the frequency of inspections is no longer consistent with the FD&C Act and is outdated (e.g., the risk-based inspection schedule for drug establishments may result in scheduling inspections at intervals of greater than 2 years for certain biological product establishments). For this reason, and to provide for greater flexibility in general with respect to determining the frequency of biological product establishment inspections under the authority provided in the FD&C Act and the PHS Act, FDA is revising § 600.21 to remove the biennial inspection requirement for biological product establishments that are registered as drug establishments and for those that are registered as device establishments.

In addition, § 600.21 includes provisions concerning inspectional notice and the timing of pre-licensure reinspections of biological product establishments. These provisions are outdated and unnecessary. Inspectional notice is addressed in the Agency’s practices for inspections in its Standard Operating Procedures and Policies and in the Investigations Operations Manual (IOM). With respect to the timing of a reinspection of a biological product establishment following the denial of a biologics license application, the general biologics licensing provision at 21 CFR 601.4, which was issued subsequent to § 600.21, sets forth the administrative procedures following the denial of a license; accordingly, the specific provision in § 600.21 regarding timing of a reinspection following denial of a license is unnecessary.

Therefore, FDA is removing these provisions.

B. Section 600.22

Current § 600.22 requires specific duties of an FDA inspector. These existing codified requirements are unnecessary because they are duplicative of statutory requirements that apply to biological product inspections under section 704 of the FD&C Act. Specifically, the inspection requirements in section 704 of the FD&C Act encompass all of the requirements outlined in § 600.22. Thus, we are removing § 600.22(a) through (h).

The removal of these regulations, however, does not change the establishment inspection requirements and duties of an investigator requirements specified in sections 704 and 510(h) of the FD&C Act, section 351(c) of the PHS Act, or the procedures described in the IOM. Additionally, it does not change the established process for risk-based inspection planning and work planning.

IV. Highlights of the Direct Final Rule

FDA is revising the general biologics regulations by revising time of inspection requirements contained in § 600.21 and also by removing the duties of inspector requirements contained in § 600.22. These changes are designed to remove the existing codified requirements that are outdated and to accommodate new approaches, such as a risk-based inspection frequency for biological product establishments, thereby providing flexibility without diminishing public health protections. FDA is issuing these revisions directly as a final rule because the Agency believes they include only noncontroversial amendments and FDA anticipates no significant adverse comments.

V. Legal Authority

FDA is issuing this rule under the biological products provisions of the PHS Act (42 U.S.C. 216, 262, 263, 263a, 264, and 300aa–25) and the drugs and general administrative provisions of the FD&C Act (21 U.S.C. 321, 351, 352, 353, 355, 356c, 356e, 360, 360i, 371, 374, and 379k–l). Under these provisions of the PHS Act and the FD&C Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, and potent, and prevent the introduction, transmission, and spread of communicable disease.

VI. Economic Analysis of Impacts

We have examined the impacts of the direct final rule under Executive Order

12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” We believe that this direct final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the direct final rule does not impose any additional regulatory burdens, we certify that this direct final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This direct final rule would not result in an expenditure in any year that meets or exceeds this amount.

This rule is being issued to amend the general biologics regulations by removing time of inspection requirements and the duties of inspector requirements. This action is being taken to remove outdated requirements, accommodate new approaches, and provide flexibility without diminishing public health protections. Because this rulemaking would remove regulations to be consistent with updated practice and does not impose any additional regulatory burdens, this rulemaking is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

We have analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

IX. Paperwork Reduction Act of 1995

This direct final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 600 is amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

- 1. The authority citation for part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 356c, 356e, 360, 360i, 371, 374, 379k–l; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25.

§ 600.21 [Amended]

- 2. Amend § 600.21 by removing the last three sentences.

§ 600.22 [Removed and Reserved]

- 3. Remove and reserve § 600.22.

Dated: January 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01468 Filed 1–25–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 60

[Docket No. FR–6077–I–01]

Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects

AGENCY: Office of the Assistant Secretary for Policy, Development and Research, HUD.

ACTION: Interim final rule; delay of effective and compliance dates; request for comments.

SUMMARY: On January 19, 2017, HUD and other federal departments and agencies published a final rule which revised the Federal Policy for the Protection of Human Subjects (2018 Requirements). Most of the 2018 Requirements were scheduled to become effective on January 19, 2018, with a general compliance date of January 19, 2018. On January 22, 2018, the Federal departments and agencies that adopted the 2018 Requirements published an interim final rule (“the interagency interim final rule”) that delays the effective date and general compliance date of the 2018 Requirements for six months, to July 19, 2018. The purpose of the delay is to provide additional time to regulated entities for the preparations necessary to implement the 2018 requirements. Due to statutory prepublication requirements applicable to HUD rules, HUD was unable to be a signatory to the interagency interim final rule. Through this interim final rule, HUD adopts the interagency interim final rule.

DATES: *Effective date:* February 26, 2018.
Comment due date: March 27, 2018.

ADDRESSES: You may submit comments, identified by docket ID number HHS–OPHS–2017–0001 by one of the following methods:

- *Federal eRulemaking Portal* (<http://www.regulations.gov>):

- Enter the following link into your web browser’s address bar: <https://www.regulations.gov/document?D=HHS-OPHS-2017-0001>.

- Click the blue “Comment Now!” button in the upper right-hand corner and follow the instructions on how to submit a comment.

- Alternatively, you can enter the docket ID number into the “search” box on the main page of the Federal eRulemaking Portal (<http://www.regulations.gov>) to find the electronic docket.

- *Mail/Hand delivery/Courier* [For paper, disk, or CD–ROM submissions]

to: Jerry Menikoff, M.D., J.D., OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

• Comments received, including any personal information, will be posted without change to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Barry L. Steffen, Policy Development Division, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street SW, Room 8114, Washington, DC 20410-8000, telephone 202-402-5926. (This is not a toll-free number.) Persons with hearing- or speech-impairments may access this number through TTY number by calling the Federal Relay Service number at 800-877-8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

On January 19, 2017, HUD and other Federal departments and agencies that are subject to the Federal Policy for the Protection of Human Subjects published a final rule amending that policy (82 FR 7149) (2018 Requirements). The Department of Health and Human Services (HHS) is the lead agency on this rulemaking. The 2018 Requirements were scheduled to become effective on January 19, 2018, with a general compliance date of January 19, 2018 (with the exception of the revisions to the cooperative research provision at 24 CFR 60.114(b), for which the compliance date is January 20, 2020). After publication of the 2018 Requirements, representatives of the regulated community expressed concern regarding their ability to implement all of the 2018 Requirements by the scheduled general compliance date and some asked for a delay. The HHS Secretary's Advisory Committee on Human Research Protections recommended in August 2017 that the required implementation of the 2018 Requirements be delayed.

On January 22, 2018, at 83 FR 2885, the Federal departments and agencies published an interagency interim final rule, which delays the effective date and general compliance date of the 2018 Requirements for six months, to July 19, 2018. The interagency interim final rule also solicits public comment on whether changes to the rule are justified. Due to statutory prepublication requirements applicable to HUD rules, HUD was unable to be a signatory to the interagency interim final rule. Specifically, section 7(o) the Department of Housing and Urban Development Act (42 U.S.C. 3535(o)) provides for 15-day Congressional

prepublication review of certain HUD rules. Rather than potentially delay publication of the interagency rule to comply with this HUD-specific requirement, HUD has opted to issue this interim final rule. HUD's rule adopts the interagency interim final rule and also solicits public comment on whether changes to the effective and compliance dates are justified. Please see the interagency interim final rule for further background and explanation.

II. Justification for Interim-Final Rulemaking

HUD generally publishes a rule for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking in 24 CFR part 10. However, part 10 provides for exceptions to the general rule if the agency finds good cause to omit advanced notice and public participation. The good cause requirement is satisfied when prior public procedure is "impractical, unnecessary, or contrary to the public interest" (see 24 CFR 10.1). For the following reasons, HUD has determined that it would be contrary to the public interest to delay the effectiveness of this rule in order to solicit prior public comments.

The rule does not substantively alter the requirements of the 2018 Requirements, which were issued following advance notice and an opportunity for comment. Rather, the sole purpose of this rulemaking is to delay the effective date and general compliance date of those requirements. As noted, the delay is being issued in response to concerns from the public. HUD is issuing this rule separately from the other agencies due to statutory prepublication review requirements. A delay for prior public procedure would result in HUD program participants being subject to a unique set of regulatory requirements different than those applicable for other, substantially identical, Federal activities. Participants in programs administered by HUD as well as those of other agencies would be required with two different set of regulations for undertaking similar activities.

Given the burdensome outcomes resulting from a delay, the non-substantive nature of the rule, and the fact that the rule responds to concerns raised by the public, HUD believes that good cause exists to publish this rule for effect without prior public comment. HUD, however, recognizes the value of public comment in the development of its regulations. HUD has, therefore, issued these regulations on an interim basis and has provided the public with

a 60-day comment period. HUD welcomes comments on the regulatory amendments made by this interim rule. The public comments will be addressed in the final rule.

III. Findings and Certifications

Regulatory Review—Executive Orders 12866 and 13563

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are "outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned." For further discussion of the significance of this interim final rule and its anticipated benefits and costs, see the interagency interim final rule.

Paperwork Reduction Act (PRA)

This interim final rule does not impose any additional information collection burden under the PRA. If finalized, this interim final rule will not contain any information collection activities beyond the information collection already approved by OMB under control number 0990-0260.

Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This interim final rule does not impose a regulatory burden for regulated small entities because it delays the effective date and the general compliance date of the 2018 Requirements, allowing the status quo to be retained for the period of delay. Therefore, the undersigned certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Environmental Impact

This interim final rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or

construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this rule is categorically excluded from environmental review under the National Environmental Policy Act (42 U.S.C. 4321).

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. This interim final rule does not impose any federal mandates on any state, local, or tribal governments or the private sector within the meaning of UMRA.

Executive Order 13132: Federalism

Executive Order 13132 (entitled “Federalism”) prohibits an agency from publishing any rule that has federalism implications if the rule either (1) imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or (2) preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This interim final rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs was issued on January 30, 2017. For further discussion of E.O. 13771, please see the interagency interim final rule.

List of Subjects for 24 CFR Part 60

Human research subjects, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HUD amends part 60 of title 24 of the Code of Federal Regulations as follows:

PART 60—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b) and 3535(d).

■ 2. Amend § 60.101 by revising paragraphs (l)(3) and (4) to read as follows:

§ 60.101 To what does this policy apply?

* * * * *

(l) * * *

(3) Research initially approved by an IRB, for which such review was waived pursuant to § 60.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to § 60.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

* * * * *

Dated: January 11, 2018.

Todd M. Richardson,

Acting General Deputy Assistant Secretary for Policy Development and Research.

[FR Doc. 2018–01497 Filed 1–25–18; 8:45 am]

BILLING CODE 4210–67–P

NATIONAL INDIAN GAMING COMMISSION

25 CFR Part 517

RIN 3141–AA21

Freedom of Information Act Procedures

AGENCY: National Indian Gaming Commission.

ACTION: Final rule.

SUMMARY: This rule amends the procedures followed by the National Indian Gaming Commission when processing a request under the Freedom of Information Act, as amended. These amendments update certain Commission information, conform to changes made in the Freedom of Information Act Improvements Act of 2016, and streamline how the Commission processes its Freedom of Information Act requests.

DATES: This rule is effective on February 26, 2018.

FOR FURTHER INFORMATION CONTACT: Tana Fitzpatrick at (202) 632–7003 or by fax (202) 632–7066 (these numbers are not toll free).

SUPPLEMENTARY INFORMATION:

I. Background

II. Contents of Final Rule

III. Responses to Comments

IV. Regulatory Matters

A. Regulatory Flexibility Act

B. Unfunded Mandates Reform Act

C. Takings

D. Civil Justice Reform

E. Small Business Regulatory Enforcement Fairness Act

F. Paperwork Reduction Act

G. National Environmental Policy Act

H. Tribal Consultation

I. Background

In 1966, Congress enacted the Freedom of Information Act (FOIA). Later, on October 17, 1988, Congress enacted the Indian Gaming Regulatory Act (IGRA), which established the National Indian Gaming Commission (Commission). On August 23, 1993, the Commission adopted FOIA procedures and, on April 19, 2006, subsequently amended its FOIA procedures. Since that time, the United States Congress has amended the FOIA twice, and the Commission has changed the location of its headquarters office and streamlined the way it processes its FOIA requests.

On October 17, 2017, the Commission published a proposed rule (82 FR 48205) that proposed changes to the Commission's regulations and requested public comments for 30 days. This final rule implements the proposed changes and responds to public comments received on the proposed rule. This rule updates the location of the Commission's headquarters, conforms to changes made in the FOIA Improvements Act of 2016, and streamlines how the Commission processes its FOIA requests.

II. Contents of Final Rule

This rule finalizes updates in each section of the Commission's FOIA regulations. Under 25 CFR 517.1, *General provisions*, the Commission incorporates revisions providing that requests for information under this part may also be simultaneously processed under the Privacy Act regulation under 25 CFR part 515. Additionally, under 25 CFR 517.2, *Public reading room*, the Commission updates its headquarters to its new address.

This rule also updates certain definitions under 25 CFR 517.3 to conform to case law and statutory requirements. The Commission made the following changes:

(1) Changed definition of ‘record.’ The Commission revised the definition because the present definition of ‘record’ is too narrow based on the Supreme Court's interpretation of what constitutes a ‘record’ under FOIA;

(2) Expanded ‘representatives of the news media’ to comport with the FOIA's definition;

(3) Updated 'confidential commercial information' to be consistent with case law;

(4) Updated 'direct costs' to incorporate statutory and OMB guidelines;

In addition, this rule updates the definition of 'duplication' to incorporate newer technologies and references to electronic records.

Section 517.4, *Requirements for making requests*, includes additional updates, as well. Section 517.4 updates include providing an electronic means of submitting FOIA requests and clarifying language for NIGC's search criteria. Finally, this section notifies requesters of their right to obtain the records they seek in their preferred form or format.

This rule updates section 517.5, *Responsibility for responding to requests*, by amending the standard the Commission uses when referring or consulting with another federal agency by providing the Commission's FOIA Office with broader discretion. In addition, the present § 517.6(d) is now § 517.5(c), which has been updated to remove a provision that suggests that requesters are required to make advance payments for FOIA requests. This rule also includes a modified provision under the new § 517.5(d), presently located under 25 CFR 517.6(e), which now defines 'adverse determination' and requires the Commission to inform the requester of dispute resolution services. Finally, § 517.5 now includes a new provision for 'coordination', which is designed to protect the personal privacy interests of certain individuals.

This rule incorporates several updates to § 517.6, *Timing of responses to requests*. First, the Commission must now notify the requester of his or her right to seek dispute resolution services from the Office of Government Information Services, which is now consistent with the FOIA Improvements Act of 2016. Second, this section expands methods of communication to include electronic methods. Finally, this rule removes duplicative timeline information in this section and inserts requirements for expedited review that codify provisions under FOIA.

Section 517.7, *Confidential commercial information*, is updated to include the requirements of Executive Order 12600, *Pre-disclosure Notification Procedures for Confidential Commercial Information*. Exec. Order No. 12600, 52 FR 23781 (June 23, 1987). Section 517.7(a) is revised to state that when a submitter provides confidential commercial information to the Commission, rather than solely the FOIA Officer, then the FOIA Officer

shall provide notice of a FOIA request or administrative appeal encompassing the confidential commercial information if required to be disclosed under FOIA. Section 517.7(b) is amended to remove 'substantial harm' as there is more than one standard for allowing information to be withheld under FOIA. Additionally, § 517.7(c) is amended to allow the FOIA Officer additional flexibility in determining whether to notify a submitter, particularly on whether or not other FOIA exemptions may apply to their request.

Section 517.8, *Appeals*, is updated to lengthen the amount of time a requester has to appeal an adverse agency determination from 30 working days after notification to 90 days after the date of the adverse determination. In addition, this section is amended to include a notice of the availability of dispute resolution services. Section 517.8 also updates the methods by which the Commission accepts appeals by including an option for electronic submission of appeals. Finally, this section now includes the addition of an exhaustion requirement, stating that requesters must generally seek an administrative appeal prior to filing a complaint in federal court.

Last, § 517.9, *Fees*, is updated to conform to requirements of the FOIA Improvements Act of 2016 that restrict when agencies are permitted to charge fees when statutory timelines are not met. This section is also updated to include references to additional methods of duplication and a statement that the requester may select the form or format in which a record is provided. Section 517.9(b)(2) is amended to include a reference to 16% as the appropriate percentage for benefits, on top of the employee's basic pay, being charged for search fees. Additionally, § 517.9(b)(2)(ii) is amended by removing language stating that the Commission is not required to alter or develop programming to conduct computer searches. Finally, this section now includes a reference to the Commission's debt collection regulations.

III. Responses to Comments

A. Removal of the Definition 'Record'

Commenters on the proposed rule expressed concern for the removal of the definition 'record.' Commenters noted that the term 'record' is used throughout the regulation and 'describes what is being sought in a FOIA request.' Commenters also stated that federal agencies have the discretion to adopt their own definitions of 'record,' including the Department of Interior.

Finally, commenters suggest the Commission re-insert its present definition of 'record,' as it adequately describes the scope of materials that can be requested under FOIA.

Response: The Commission agrees with commenters that a definition of "record" is needed, but disagrees that the current definition should be maintained because the present definition does not adequately encompass the Supreme Court's interpretation of 'record' for the purposes of FOIA requests. The current regulation uses the definition of record from the Federal Records Act (FRA), 44 U.S.C.A. section 3301. However, under *Dep't of Justice v. Tax Analysts*, 492 U.S. 136, 144–145 (1989), the Supreme Court construed agency records requested under FOIA to be (1) either created or obtained by an agency and (2) under agency control at the time the request is made. Although the Supreme Court's definition overlaps with the FRA definition, Congress created the FRA for record management purposes and not for purposes of providing the public information on public policy, as is the purpose of FOIA. Thus, if information is under the control of the agency, it will be subject to the FOIA regardless of whether it would otherwise be 'appropriate for preservation.' See Department of Justice, *FOIA Update Vol. II, No. 1: What is an "Agency Record?"* (January 1, 1980).

Rather than maintain the current definition, then, the Commission adopts a definition of 'record' that reflects these considerations.

IV. Regulatory Matters

A. Regulatory Flexibility Act

The Commission certifies that the proposed rule 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.*). The factual basis for this certification is as follows: This rule is procedural in nature and will not impose substantive requirements that would be considered impacts within the scope of the Act.

B. Unfunded Mandates Reform Act

The Commission is an independent regulatory agency, and, as such, is exempt from the Unfunded Mandates Reform Act, 2 U.S.C. 1501 *et seq.*

C. Takings

In accordance with Executive Order 12630, the Commission has determined that this proposed rule does not have significant takings implications. A takings implication assessment is not required.

D. Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Executive Order.

E. Small Business Regulatory Enforcement Fairness Act

The proposed rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The proposed rule will not result in an annual effect on the economy of more than \$100 million per year; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S. based enterprises.

F. Paperwork Reduction Act

The proposed rule does not contain any information collection requirements for which the Office of Management and Budget approval under the Paperwork Reduction Act (44 U.S.C. 3501–3520) would be required.

G. National Environmental Policy Act

The Commission has determined that the proposed rule does not constitute a major Federal Action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969.

H. Tribal Consultation

The National Indian Gaming Commission is committed to fulfilling its tribal consultation obligations—whether directed by statute or administrative action such as Executive Order (E.O.) 13175 (Consultation and Coordination with Indian Tribal Governments)—by adhering to the consultation framework described in its Consultation Policy published July 15, 2013. The NIGC's consultation policy specifies that it will consult with tribes on Commission Action with Tribal Implications, which is defined as: Any Commission regulation, rulemaking, policy, guidance, legislative proposal, or operational activity that may have a substantial direct effect on an Indian tribe on matters including, but not limited to the ability of an Indian tribe to regulate its Indian gaming; an Indian Tribe's formal relationship with the Commission; or the consideration of the Commission's trust responsibilities to Indian tribes. The changes proposed in

this final rule do not fall into any of those categories. Many of the changes are required by law and those that are not are being done to improve our FOIA process, which affects the public in general. Accordingly, the Commission did not consult with tribal governments on these changes. The Commission, though, requested and welcomed any and all tribal comments to the final rule.

List of Subjects in 25 CFR Part 517

Administrative practice and procedure, Freedom of information.

■ For the reasons set forth in the preamble, the Commission revises 25 CFR part 517 to read as follows:

PART 517—FREEDOM OF INFORMATION ACT PROCEDURES

Sec.

- 517.1 General provisions.
- 517.2 Public reading room.
- 517.3 Definitions.
- 517.4 Requirements for making requests.
- 517.5 Responsibility for responding to requests.
- 517.6 Timing of responses to requests.
- 517.7 Confidential commercial information.
- 517.8 Appeals.
- 517.9 Fees.

Authority: 5 U.S.C. 552

§ 517.1 General provisions.

This part contains the regulations the National Indian Gaming Commission (Commission) follows in implementing the Freedom of Information Act (FOIA), 5 U.S.C. 552. These regulations provide procedures by which you may obtain access to records compiled, created, and maintained by the Commission, along with procedures the Commission must follow in response to such requests for records. These regulations should be read together with the FOIA, which provides additional information about access to records maintained by the Commission. Requests made by individuals for records about themselves under the Privacy Act of 1974, 5 U.S.C. 552(a), are processed in accordance with the Commission's Privacy Act regulations, 25 CFR part 515, as well as under this part.

§ 517.2 Public reading room.

Records that are required to be maintained by the Commission shall be available for public inspection and copying at 90 K Street NE, Suite 200, Washington, DC 20002. Reading room records created on or after November 1, 1996, shall be made available electronically via the Commission's website.

§ 517.3 Definitions.

(a) *Commercial use requester* means a requester seeking information for a use or purpose that furthers the commercial, trade, or profit interests of himself or the person on whose behalf the request is made, which can include furthering those interests through litigation. In determining whether a request properly belongs in this category, the FOIA Officer shall determine the use to which the requester will put the documents requested. Where the FOIA Officer has reasonable cause to doubt the use to which the requester will put the records sought, or where that use is not clear from the request itself, the FOIA Officer shall contact the requester for additional clarification before assigning the request to a specific category.

(b) *Confidential commercial information* means records or information provided to the government by a submitter that arguably contains material exempt from disclosure under Exemption 4 of the FOIA.

(c) *Direct costs* mean those expenditures by the Commission actually incurred in searching for and duplicating (and, in the case of commercial use requests, reviewing) records in response to the FOIA request. Direct costs include the salary of the employee or employees performing the work (*i.e.*, the basic rate of pay for the employee plus 16 percent of that rate to cover benefits) and the cost of operating computers and other electronic equipment, such as photocopiers and scanners. Direct costs do not include overhead expenses, such as the cost of space, heating, or lighting of the facility in which the records are stored.

(d) *Duplication* refers to the process of making a copy of a record, or the information contained in it, necessary to respond to a FOIA request. Such copies can take the form of, among other things, paper copy, microfilm, audio-visual materials, or electronic records (*e.g.*, compact discs or USB flash drives). The copies provided shall be in a form that is reasonably usable by the requester.

(e) *Educational institution* refers to a preschool, a public or private elementary school, an institute of undergraduate higher education, an institute of graduate higher education, an institute of professional education, or an institute of vocational education which operates a program of scholarly research. To qualify for this category, the requester must show that the request is authorized by and is made under the auspices of a qualifying institution and that the records are not sought for a commercial use, but are sought to further scholarly research.

(f) *Freedom of Information Act Officer* means the person designated by the Chairman to administer the FOIA.

(g) *Non-commercial scientific institution* refers to an institution that is not operated on a "commercial" basis as that term is used in paragraph (a) of this section, and which is operated solely for the purpose of conducting scientific research the results of which are not intended to promote any particular product or industry. To qualify for this category, the requester must show that the request is authorized by and is made under the auspices of a qualifying institution and that the records are not sought for a commercial use, but are sought to further scholarly research.

(h) *Record* means an agency record that is either created or obtained by an agency and is under agency control at the time of the FOIA request.

(i) *Representative of the news media* means any person or entity that gathers information of potential interest to a segment of the public, uses editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. The term "news" means information that is about current events or that would be of current interest to the public. Examples of news media entities include television or radio stations that broadcast "news" to the public at large and publishers of periodicals that disseminate "news" and make their products available for purchase by or free distribution to the general public, including news organizations that disseminate solely on the internet. For a "freelance journalist" to be regarded as working for a news organization, the requester must demonstrate a solid basis for expecting publication through that organization, such as a publication contract. Absent such showing, the requester may provide documentation establishing the requester's past publication record. To qualify for this category, the requester must not be seeking the requested records for a commercial use. However, a request for records supporting a news-dissemination function shall not be considered to be for a commercial use.

(j) *Requester* means any person, including an individual, Indian tribe, partnership, corporation, association, or public or private organization other than a Federal agency, that requests access to records in the possession of the Commission.

(k) *Review* means the process of examining a record in response to a FOIA request to determine if any portion of that record may be withheld under one or more of the FOIA Exemptions. It also includes processing any record for disclosure, for example,

redacting information that is exempt from disclosure under the FOIA. Review time includes time spent considering any formal objection to disclosure made by a business submitter under § 517.7(c). Review time does not include time spent resolving general legal or policy issues regarding the use of FOIA Exemptions.

(l) *Search* refers to the time spent looking for material that is responsive to a request, including page-by-page or line-by-line identification of material within a document and also includes reasonable efforts to locate and retrieve information from records maintained in electronic form or format. The FOIA Officer shall ensure that searches are conducted in the most efficient and least expensive manner reasonably possible.

(m) *Submitter* means any person or entity who provides information directly or indirectly to the Commission. The term includes, but is not limited to, corporations, Indian tribal governments, state governments and foreign governments.

(n) *Working day* means a Federal workday that does not include Saturdays, Sundays, or Federal holidays.

§ 517.4 Requirements for making requests.

(a) *How to make a FOIA request.* Requests for records made pursuant to the FOIA must be in writing. Requests may be mailed, dropped off in person, or faxed to (202) 632-7066 (not a toll free number). Requests that are dropped off in person should be made at 90 K Street NE, Suite 200, Washington, DC 20002 during the hours of 9 a.m. to 12 noon and 2 p.m. to 5 p.m. Requests that are mailed should be sent to NIGC Attn: FOIA Officer, 1849 C Street NW, Mail Stop #1621, Washington, DC 20240. Requests may also be sent via electronic mail addressed to FOIARequests@nigc.gov or submitted through the Commission's website.

(b) *First person requests for records.* If the requester is making a request for records about himself/herself, the requester must provide verification of identity. Verification requirements are described in 25 CFR 515.3.

(c) *Requests for records about another individual.* If the requester is making a request for records about another individual, the requester may receive greater access by submitting either a notarized authorization signed by that individual, a declaration made in compliance with the requirements set forth in 28 U.S.C. 1746 by that individual authorizing disclosure of the records to the requester or by submitting proof that the individual is deceased

(for example, a copy of the death certificate or a copy of the obituary).

(d) *Description of records sought.* Requests for records shall describe the records requested with as much specificity as possible to enable Commission employees to locate the information requested with a reasonable amount of effort. Whenever possible, the request should describe the subject matter of the records sought, the time periods in which the records were generated, and any tribe or tribal gaming facility with which they were associated. Before submitting a request, requesters may contact the Commission's FOIA contact or FOIA Public Liaison to discuss the records being sought and receive assistance describing the records. If after receiving a request the FOIA Officer determines that it does not reasonably describe the records sought, the FOIA Officer must inform the requester of what additional information is needed or why the request is otherwise insufficient. Requesters who are attempting to reformulate or modify such a request may discuss their request with the Commission's FOIA contact or FOIA Public Liaison. If a request does not reasonably describe the records sought, the agency's response to the request may be delayed.

(e) *Agreement to pay fees.* Requests shall also include a statement indicating the maximum amount of fees the requester is willing to pay to obtain the requested information, or a request for a waiver or reduction of fees. If the requester is requesting a waiver or reduction of fees the requester must include justification for such waiver or reduction (see § 517.9(c) for more information). If the request for a fee waiver is denied, the requester will be notified of this decision and advised that fees associated with the processing of the request will be assessed. The requester must send an acknowledgment to the FOIA Officer indicating his/her willingness to pay the fees. Absent such acknowledgment within the specified time frame, the request will be considered incomplete, no further work shall be done, and the request will be administratively closed.

(f) *Form or format of records requested.* Requesters may specify their preferred form or format (including electronic formats) for the records sought. The Commission will accommodate such requests where the record is readily reproducible in that form or format.

(g) *Types of records not available.* The FOIA does not require the Commission to:

(1) Compile or create records solely for the purpose of satisfying a request for records;

(2) Provide records not yet in existence, even if such records may be expected to come into existence at some future time; or

(3) Restore records destroyed or otherwise disposed of, except that the FOIA Officer must notify the requester that the requested records have been destroyed or disposed.

§ 517.5 Responsibility for responding to requests.

(a) *In general.* In determining which records are responsive to a request, the Commission ordinarily will include only records in its possession as of the date it begins its search for records. If any other date is used, the FOIA Officer shall inform the requester of that date.

(b) *Authority to grant or deny requests.* The FOIA Officer shall make initial determinations either to grant or deny in whole or in part a request for records.

(c) *Granting of requests.* When the FOIA Officer determines that the requested records shall be made available, the FOIA Officer shall notify the requester in writing and provide copies of the requested records in whole or in part. Records disclosed in part shall be marked or annotated to show the exemption applied to the withheld information and the amount of information withheld unless to do so would harm the interest protected by an applicable exemption. If a requested record contains exempted material along with nonexempt material, all reasonably segregable material shall be disclosed.

(d) *Adverse Determinations.* If the FOIA Officer makes an adverse determination denying a request in any respect, it must notify the requester of that adverse determination in writing. Adverse determinations include decisions that: The requested record is exempt from release, in whole or in part; the request does not reasonably describe the records sought; the information requested is not a record subject to the FOIA; the requested record does not exist, cannot be located, or has been destroyed; or the requested record is not readily reproducible in the form or format sought by the requester; denials involving fees or fee waiver matters; and denials of requests for expedited processing.

(e) *Content of adverse determination.* Any adverse determination issued by the FOIA Officer must include:

(1) A brief statement of the reasons for the adverse determination, including any FOIA exemption applied by the

agency in denying access to a record unless to do so would harm the interest protected by an applicable exemption;

(2) An estimate of the volume of any records or information withheld, such as the number of pages or other reasonable form of estimation, although such an estimate is not required if the volume is otherwise indicated by deletions marked on records that are disclosed in part or if providing an estimate would harm an interest protected by an applicable exemption;

(3) A statement that the adverse determination may be appealed under § 517.8 of this part and a description of the appeal requirements; and

(4) A statement notifying the requester of the assistance available from the Commission's FOIA Public Liaison and the dispute resolution services offered by the Office of Government Information Services.

(f) *Consultation, referral, and coordination.* When reviewing records located in response to a request, the FOIA Officer will determine whether another agency of the Federal Government is better able to determine whether the record is exempt from disclosure under the FOIA. As to any record determined to be better suited for review by another Federal Government agency, the FOIA Officer must proceed in one of the following ways.

(1) *Consultation.* When records originating with the Commission contain information of interest to another Federal Government agency, the FOIA Officer should typically consult with that other entity prior to making a release determination.

(2) *Referral.* (i) When the FOIA Officer believes that a different Federal Government agency is best able to determine whether to disclose the record, the FOIA Officer should typically refer the responsibility for responding to the request regarding that record to that agency. Ordinarily, the agency that originated the record is presumed to be the best agency to make the disclosure determination. If the Commission and another Federal Government agency jointly agree that the agency processing the request is in the best position to respond regarding the record, then the record may be handled as a consultation.

(ii) Whenever the FOIA Officer refers any part of the responsibility for responding to a request to another agency, he or she must document the referral, maintain a copy of the record that it refers, and notify the requester of the referral.

(iii) After the FOIA Officer refers a record to another Federal Government agency, the agency receiving the referral

shall make a disclosure determination and respond directly to the requester. The referral of a record is not an adverse determination and no appeal rights accrue to the requester by this act.

(3) *Coordination.* The standard referral procedure is not appropriate where disclosure of the identity of the agency to which the referral would be made could harm an interest protected by an applicable exemption, such as the exemptions that protect personal privacy interests. For example, if the FOIA Officer in responding to a request for records on a living third party locates records originating with a criminal law enforcement agency, and if the existence of that law enforcement interest in the third party was not publicly known, then to disclose that law enforcement interest could cause an unwarranted invasion of the personal privacy of the third party. In such instances, in order to avoid harm to an interest protected by an applicable exemption, the FOIA Officer should coordinate with the originating agency to obtain its views on whether the record may be disclosed. The FOIA Officer should then convey the determination as to whether the record will be released to the requester.

§ 517.6 Timing of responses to requests.

(a) *In general.* The FOIA Officer ordinarily shall respond to requests according to their order of receipt. All statutory and regulatory timelines will commence on the date that the request is received by the Commission's Headquarters FOIA Office that is designated to receive requests in § 517.4(a). In instances of requests misdirected to Commission field offices, the response time will commence on the date that the request is received by the Commission's Headquarters FOIA Office, but in any event no later than 10 working days after the request is first received by any Commission office.

(b) *Multitrack processing.* (1) The FOIA Officer may use multi-track processing in responding to requests. Multi-track processing means placing simple requests requiring rather limited review in one processing track and placing more voluminous and complex requests in one or more other tracks. Requests in either track are processed on a first-in/first-out basis.

(2) The FOIA Officer may provide requesters in its slower track(s) with an opportunity to limit the scope of their requests in order to qualify for faster processing within the specified limits of faster track(s). The FOIA Officer will do so either by contacting the requester by letter, telephone, electronic mail, or facsimile whichever is more efficient in

each case. When providing a requester with the opportunity to limit the scope of their request, the FOIA Officer shall also advise the requester of the availability of the Commission's FOIA Public Liaison to aid in the resolution of any dispute arising between the requester and the Commission as well as the requester's right to seek dispute resolution services from the Office of Government Information Services.

(c) *Initial determinations.* (1) The FOIA Officer shall make an initial determination regarding access to the requested information and notify the requester within twenty (20) working days after receipt of the request. This 20 day period may be extended if unusual circumstances arise. If an extension is necessary, the FOIA Officer shall promptly notify the requester of the extension, briefly stating the reasons for the extension, and estimating when the FOIA Officer will respond. Unusual circumstances warranting extension are:

(i) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(ii) The need to search for, collect, and appropriately examine a voluminous amount of records which are demanded in a single request; or

(iii) The need for consultation with another agency having a substantial interest in the determination of the request, which consultation shall be conducted with all practicable speed.

(2) If the FOIA Officer decides that an initial determination cannot be reached within the time limits specified in paragraph (c)(1) of this section, the FOIA Officer shall notify the requester of the reasons for the delay and include an estimate of when a determination will be made. The requester will then have the opportunity to modify the request or arrange for an alternative time frame for completion of the request. To assist in this process, the FOIA Officer shall advise the requester of the availability of the Commission's FOIA Public Liaison to aid in the resolution of any disputes between the requester and the Commission, and notify the requester of his or her right to seek dispute resolution services from the Office of Government Information Services.

(3) If no initial determination has been made at the end of the 20 day period provided for in paragraph (c)(1) of this section, including any extension, the requester may appeal the action to the FOIA Appeals Officer.

(d) *Expedited processing of request.* (1) A requester may make a request for expedited processing at any time.

(2) When a request for expedited processing is received, the FOIA Officer must determine whether to grant the request for expedited processing within ten (10) calendar days of its receipt. Requests will receive expedited processing if one of the following compelling needs is met:

(i) The requester can establish that failure to receive the records quickly could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(ii) The requester is primarily engaged in disseminating information and can demonstrate that an urgency to inform the public concerning actual or alleged Federal Government activity exists.

(3) A requester who seeks expedited processing must submit a statement, certified to be true and correct, explaining in detail the basis for making the request for expedited processing. As a matter of administrative discretion, the FOIA Officer may waive the formal certification requirement.

(4) Administrative appeals of denials of expedited processing will be given expeditious consideration. If the denial of expedited processing is upheld by the FOIA Appeals Officer, that decision is immediately subject to judicial review in the appropriate Federal district court.

§ 517.7 Confidential commercial information.

(a) *Notice to submitters.* The FOIA Officer shall, to the extent permitted by law, provide a submitter who provides confidential commercial information to the Commission, with prompt notice of a FOIA request or administrative appeal encompassing the confidential commercial information if the Commission may be required to disclose the information under the FOIA. Such notice shall either describe the exact nature of the information requested or provide copies of the records or portions thereof containing the confidential commercial information. The FOIA Officer shall also notify the requester that notice and opportunity to object has been given to the submitter.

(b) *Where notice is required.* Notice shall be given to a submitter when:

(1) The information has been designated by the submitter as confidential commercial information protected from disclosure. Submitters of confidential commercial information shall use good faith efforts to designate, either at the time of submission or a reasonable time thereafter, those portions of their submissions they deem protected from disclosure under Exemption 4 of the FOIA. Such designation shall be deemed to have expired ten years after the date of

submission, unless the requester provides reasonable justification for a designation period of greater duration; or

(2) The FOIA Officer has reason to believe that the information may be protected from disclosure under Exemption 4 of the FOIA.

(c) *Where notice is discretionary.* If the FOIA Officer has reason to believe that information submitted to the Commission may be protected from disclosure under any other exemption of the FOIA, the FOIA Officer may, in his or her discretion, provide the submitter with notice and an opportunity to object to the release of that information.

(d) *Opportunity to object to disclosure.* The FOIA Officer shall afford a submitter a reasonable period of time to provide the FOIA Officer with a detailed written statement of any objection to disclosure. The statement shall specify all grounds for withholding any of the information under any exemption of the FOIA, and if Exemption 4 applies, shall demonstrate the reasons the submitter believes the information to be confidential commercial information that is exempt from disclosure. Whenever possible, the submitter's claim of confidentiality shall be supported by a statement or certification by an officer or authorized representative of the submitter. In the event a submitter fails to respond to the notice in the time specified, the submitter will be considered to have no objection to the disclosure of the information. Information provided by the submitter that is received after the disclosure decision has been made will not be considered. Information provided by a submitter pursuant to this paragraph may itself be subject to disclosure under the FOIA.

(e) *Notice of intent to disclose.* The FOIA Officer shall carefully consider a submitter's objections and specific grounds for nondisclosure prior to determining whether to disclose the information requested. Whenever the FOIA Officer determines that disclosure is appropriate, the FOIA Officer shall, within a reasonable number of days prior to disclosure, provide the submitter with written notice of the intent to disclose which shall include a statement of the reasons for which the submitter's objections were overruled, a description of the information to be disclosed, and a specific disclosure date. The FOIA Officer shall also notify the requester that the requested records will be made available.

(f) *Notice of lawsuit.* If the requester files a lawsuit seeking to compel disclosure of confidential commercial

information, the FOIA Officer shall promptly notify the submitter of this action. If a submitter files a lawsuit seeking to prevent disclosure of confidential commercial information, the FOIA Officer shall notify the requester.

(g) *Exceptions to the notice requirements under this section.* The notice requirements under paragraphs (a) and (b) of this section shall not apply if:

(1) The FOIA Officer determines that the information should not be disclosed pursuant to Exemption 4 and/or any other exemption of the FOIA;

(2) The information lawfully has been published or officially made available to the public;

(3) Disclosure of the information is required by law (other than the FOIA);

(4) The information requested is not designated by the submitter as exempt from disclosure in accordance with this part, when the submitter had the opportunity to do so at the time of submission of the information or within a reasonable time thereafter, unless the agency has substantial reason to believe that disclosure of the information would result in competitive harm; or

(5) The designation made by the submitter in accordance with this part appears obviously frivolous. When the FOIA Officer determines that a submitter was frivolous in designating information as confidential, the FOIA Officer must provide the submitter with written notice of any final administrative disclosure determination within a reasonable number of days prior to the specified disclosure date, but no opportunity to object to disclosure will be offered.

§ 517.8 Appeals.

(a) *Right of appeal.* The requester has the right to appeal to the FOIA Appeals Officer any adverse determination.

(b) *Notice of Appeal*—(1) *Time for appeal.* To be considered timely, an appeal must be postmarked, or in the case of electronic submissions, transmitted, no later than ninety (90) calendar days after the date of the response or after the time limit for response by the FOIA Officer has expired. Prior to submitting an appeal any outstanding fees associated with FOIA requests must be paid in full.

(2) *Form of appeal.* An appeal shall be initiated by filing a written notice of appeal. The notice shall be accompanied by copies of the original request and adverse determination. To expedite the appellate process and give the requester an opportunity to present his/her arguments, the notice should contain a brief statement of the reasons

why the requester believes the adverse determination to have been in error. Requesters may submit appeals by mail, facsimile, or electronically. Appeals sent by mail shall be addressed to the National Indian Gaming Commission, Attn: FOIA Appeals Officer, 1849 C Street NW, Mailstop #1621, Washington, DC 20240. Appeals may also be submitted via electronic mail at FOIARequests@nigc.gov or through the NIGC's website. To facilitate handling, the requester should mark both the appeal letter and envelope, or subject line of the electronic transmission "Freedom of Information Act Appeal."

(c) *Final agency determinations.* The FOIA Appeals Officer shall issue a final written determination, stating the basis for its decision, within twenty (20) working days after receipt of a notice of appeal. If the determination is to provide access to the requested records, the FOIA Officer shall make those records immediately available to the requester. If the determination upholds the adverse determination, the FOIA Appeals Officer shall notify the requester of the determination, the ability to obtain mediation services offered by the Office of Government Information Services as a non-exclusive alternative to litigation, and the right to obtain judicial review in the appropriate Federal district court.

(d) *When appeal is required.* Before seeking review by a court of the FOIA Officer's adverse determination, a requester generally must first submit a timely administrative appeal.

§ 517.9 Fees.

(a) *In general.* Fees pursuant to the FOIA shall be assessed according to the schedule contained in paragraph (b) of this section for services rendered by the Commission in response to requests for records under this part. All fees shall be charged to the requester, except where the charging of fees is limited under paragraph (d) or (e) of this section or where a waiver or reduction of fees is granted under paragraph (c) of this section. Payment of fees should be by check or money order made payable to the Treasury of the United States.

(b) *Charges for responding to FOIA requests.* The following fees shall be assessed in responding to requests for records submitted under this part, unless a waiver or reduction of fees has been granted pursuant to paragraph (c) of this section:

(1) *Duplication.* The FOIA Officer will honor a requester's preference for receiving a record in a particular form or format where he or she can readily reproduce the record in the form or format requested. When photocopies are

supplied, the FOIA Officer shall charge \$0.15 per page for copies of documents up to 8½ x 14. For copies of records produced on tapes, compact discs, or other media, the FOIA Officer shall charge the direct costs of producing the copy, including operator time. Where paper documents must be scanned in order to comply with a requester's preference to receive the records in electronic format, the requester must also pay the direct costs associated with scanning those materials. For other methods of reproduction, the FOIA Officer shall charge the actual direct costs of producing the documents.

(2) *Searches*—(i) *Manual searches.* Whenever feasible, the FOIA Officer will charge at the salary rate (basic pay plus 16% percent for benefits) of the employee or employees performing the search. However, where a homogenous class of personnel is used exclusively in a search (e.g., all administrative/clerical or all professional/executive), the FOIA Officer shall charge \$4.45 per quarter hour for clerical time and \$7.75 per quarter hour for professional time. Charges for search time less than a full hour will be in increments of quarter hours.

(ii) *Computer searches.* The FOIA Officer will charge the actual direct costs of conducting computer searches. These direct costs shall include the cost of operating the central processing unit for that portion of operating time that is directly attributable to searching for requested records, as well as the costs of operator/programmer salary apportionable to the search. For requests that require the creation of a new computer program to locate requested records, the Commission will charge the direct costs associated with such program's creation. The FOIA Officer must notify the requester of the costs associated with creating such a program, and the requester must agree to pay the associated costs before the costs may be incurred.

(3) *Review fees.* Review fees shall be assessed only with respect to those requesters who seek records for a commercial use under paragraph (d)(1) of this section. Review fees shall be assessed at the same rates as those listed under paragraph (b)(2)(i) of this section. Review fees shall be assessed only for the initial record review, for example, review undertaken when the FOIA Officer analyzes the applicability of a particular exemption to a particular record or portion thereof at the initial request level. No charge shall be assessed at the administrative appeal level of an exemption already applied.

(c) *Statutory waiver.* Documents shall be furnished without charge or at a

charge below that listed in paragraph (b) of this section where it is determined, based upon information provided by a requester or otherwise made known to the FOIA Officer, that disclosure of the requested information is in the public interest. Disclosure is in the public interest if it is likely to contribute significantly to public understanding of government operations and is not primarily for commercial purposes. Requests for a waiver or reduction of fees shall be considered on a case by case basis. In order to determine whether the fee waiver requirement is met, the FOIA Officer shall consider the following six factors:

(1) *The subject of the request.*

Whether the subject of the requested records concerns the operations or activities of the government;

(2) *The informative value of the information to be disclosed.* Whether the disclosure is likely to contribute to an understanding of government operations or activities;

(3) *The contribution to an understanding of the subject by the general public likely to result from disclosure.* Whether disclosure of the requested information will contribute to public understanding;

(4) *The significance of the contribution to public understanding.* Whether the disclosure is likely to contribute significantly to public understanding of government operations or activities;

(5) *The existence and magnitude of commercial interest.* Whether the requester has a commercial interest that would be furthered by the requested disclosure; and, if so

(6) *The primary interest in disclosure.* Whether the magnitude of the identified commercial interest of the requester is sufficiently large, in comparison with the public interest in disclosure, that disclosure is primarily in the commercial interest of the requester.

(d) *Types of requesters.* There are four categories of FOIA requesters:

Commercial use requesters, educational and non-commercial scientific institutional requesters; representative of the news media; and all other requesters. These terms are defined in § 517.3. The following specific levels of fees are prescribed for each of these categories:

(1) *Commercial use requesters.* The FOIA Officer shall charge commercial use requesters the full direct costs of searching for, reviewing, and duplicating requested records.

(2) *Educational and non-commercial scientific institutions requesters.* The FOIA Officer shall charge educational and non-commercial scientific

institution requesters for document duplication only, except that the first 100 pages of copies shall be provided without charge.

(3) *News media requesters.* The FOIA Officer shall charge news media requesters for document duplication costs only, except that the first 100 pages of paper copies shall be provided without charge.

(4) *All other requesters.* The FOIA Officer shall charge requesters who do not fall into any of the categories in paragraphs (d)(1) through (3) of this section fees which cover the full reasonable direct costs incurred for searching for and reproducing records if that total costs exceeds \$15.00, except that the first 100 pages and the first two hours of manual search time shall not be charged. To apply this term to computer searches, the FOIA Officer shall determine the total hourly cost of operating the central processing unit and the operator's salary (plus 16 percent for benefits). When the cost of the search equals the equivalent dollar amount of two hours of the salary of the person performing the search, the FOIA Officer will begin assessing charges for the computer search.

(e) *Restrictions on charging fees.* (1) Ordinarily, no charges will be assessed when requested records are not found or when records located are withheld as exempt. However, if the requester has been notified of the estimated cost of the search time and has been advised specifically that the requested records may not exist or may be withheld as exempt, fees may be charged.

(2) If the Commission fails to comply with the FOIA's time limits for responding to a request, it may not charge search fees or, in cases where records are not sought for commercial use and the request is made by an educational institution, non-commercial scientific institution, or representative of the news media, duplication fees, except as described in paragraphs (e)(2)(i)–(iii) of this section.

(i) If the FOIA Officer determines that unusual circumstances, as defined by the FOIA, apply and provides timely written notice to the requester in accordance with the FOIA, then a failure to comply with the statutory time limit shall be excused for an additional 10 days.

(ii) If the FOIA Officer determines that unusual circumstances, as defined by the FOIA, apply and more than 5,000 pages are necessary to respond to the request, then the Commission may charge search fees and duplication fees, where applicable, if the following steps are taken. The FOIA Officer must:

(A) Provide timely written notice of unusual circumstances to the requester in accordance with the FOIA and

(B) Discuss with the requester via written mail, email, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request in accordance with 5 U.S.C. 552(a)(6)(B)(ii).

(iii) If a court determines that exceptional circumstances exist, as defined by the FOIA, then a failure to comply with the time limits shall be excused for the length of time provided by the court order.

(f) *Charges for interest.* The FOIA Officer may assess interest charges on an unpaid bill, accrued under previous FOIA request(s), starting the 31st day following the day on which the bill was sent to you. A fee received by the FOIA Officer, even if not processed will result in a stay of the accrual of interest. The Commission shall follow the provisions of the Debt Collection Act of 1982, as amended, its implementing procedures, and the Commission's debt collection regulations located in 25 CFR part 513 to recover any indebtedness owed to the Commission.

(g) *Aggregating requests.* The requester or a group of requesters may not submit multiple requests at the same time, each seeking portions of a document or documents solely in order to avoid payment of fees. When the FOIA Officer reasonably believes that a requester is attempting to divide a request into a series of requests to evade an assessment of fees, the FOIA Officer may aggregate such request and charge accordingly.

(h) *Advance payment of fees.* Fees may be paid upon provision of the requested records, except that payment may be required prior to that time if the requester has previously failed to pay fees or if the FOIA Officer determines that total fee will exceed \$250.00. When payment is required in advance of the processing of a request, the time limits prescribed in § 517.6 shall not be deemed to begin until the FOIA Officer has received payment of the assessed fee.

(i) *Payment of fees.* Where it is anticipated that the cost of providing the requested record will exceed \$25.00 after the free duplication and search time has been calculated, and the requester has not indicated in advance a willingness to pay a fee greater than \$25.00, the FOIA Officer shall promptly notify the requester of the amount of the anticipated fee or a portion thereof, which can readily be estimated. The notification shall offer the requester an opportunity to confer with agency

representatives for the purpose of reformulating the request so as to meet the requester's needs at a reduced cost.

Dated: January 12, 2018.

Jonodev O. Chaudhuri,
Chairman.

Kathryn Isom-Clause,
Vice Chair.

E. Sequoyah Simermeyer,
Associate Commissioner.

[FR Doc. 2018-01433 Filed 1-25-18; 8:45 am]

BILLING CODE 7565-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG-2017-1102]

RIN 1625-AA08

Special Local Regulation; Gasparilla Marine Parade; Hillsborough Bay; Tampa, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation for the 2018 Gasparilla Marine Parade on the waters of Hillsborough Bay in the vicinity of Tampa, Florida. This event is expected to attract over 600 spectator craft along the parade route, with approximately 18 vessels participating in the official flotilla. This regulation is necessary to ensure the safety of public, the official flotilla, and spectator vessels before, during, and after the conclusion of the parade.

DATES: This rule is effective from from 9 a.m. to 6 p.m. on January 27, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2017-1102 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Marine Science Technician First Class Michael D. Shackelford, Sector St. Petersburg Prevention Department, Coast Guard; telephone (813) 228-2191, email Michael.D.Shackelford@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations

DHS Department of Homeland Security

FR Federal Register
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because immediate action is needed to respond to the potential safety hazards associated with this event. It is impracticable to publish an NPRM because we must establish this safety zone by January 27, 2018.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** for the same reasons noted above.

III. Legal Authority and Need for Rule

The Coast Guard is establishing a special local regulation on the waters of the Hillsborough Bay, Tampa, Florida during the 2018 Gasparilla Marine Parade. This event is expected to attract over 600 spectator craft along the parade route, with approximately 18 vessels participating in the official flotilla. This rule is needed to ensure the safety of public, the official flotilla, and spectator vessels on these navigable waters of the United States during the 2018 Gasparilla Marine Parade. The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233.

IV. Discussion of the Rule

This rule establishes a temporary special local regulation for the Gasparilla Marine Parade on the waters of Hillsborough Bay in Tampa, Florida. This special regulation sets forth specific requirements for vessels operating within the regulated area during the period of enforcement.

Persons and vessels not meeting the requirements of this regulation may request authorization to enter, transit through, anchor in, or remain within the regulated area by contacting the Captain of the Port St. Petersburg by telephone

at (727) 824-7506, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port St. Petersburg or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port St. Petersburg or a designated representative. The Coast Guard will provide notice of the special local regulations by Local Notice to Mariners, Broadcast Notice to Mariners, and/or on-scene designated representatives.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on: (1) The special local regulation will be enforced for only nine hours; (2) although certain persons and vessels are prohibited to enter, transit through, anchor in, or remain within the regulated area without authorization from the Captain of the Port St. Petersburg or a designated representative, they may operate in the surrounding area during the enforcement period; (3) the Coast Guard will provide advance notification of the special local regulations to the local maritime community by Local Notice to Mariners and/or Broadcast Notice to Mariners; and (4) persons and vessels not meeting the requirements of this regulation may request authorization to enter, transit through, anchor in, or remain within the regulated area by contacting the Captain of the Port or a designated representative.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated area may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of

power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulation issued in conjunction with a regatta or marine parade. It is categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your

message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add temporary § 100.T07–1102 to read as follows:

§ 100.T07–1102 Special Local Regulation; Gasparilla Marine Parade; Hillsborough Bay; Tampa, FL.

(a) *Regulated area.* A regulated area is established consisting of the following waters of Hillsborough Bay and its tributaries north of 27°51′18″ N and south of the John F. Kennedy Bridge: Hillsborough Cut “D” Channel, Seddon Channel, Sparkman Channel and the Hillsborough River south of the John F. Kennedy Bridge. All coordinates referenced use datum: NAD 83.

(b) *Regulations.* (1) Entrance into the regulated area is prohibited to all commercial marine traffic from 9 a.m. to 6 p.m. EST on the day of the event.

(2) The regulated area will include a 100 yard Safety Zone around the vessel JOSE GASPARI while docked at the Tampa Yacht Club until 6 p.m. EST on the day of the event.

(3) The regulated area is a “no wake” zone.

(4) All vessels within the regulated area shall stay 50 feet away from and give way to all officially entered vessels in parade formation in the Gasparilla Marine Parade.

(5) When within the marked channels of the parade route, vessels participating in the Gasparilla Marine Parade may not exceed the minimum speed necessary to maintain steerage.

(6) Jet skis and vessels without mechanical propulsion are prohibited from the parade route.

(7) Vessels less than 10 feet in length are prohibited from the parade route unless capable of safely participating.

(8) Vessels found to be unsafe to participate at the discretion of a present Law Enforcement Officer are prohibited from the parade route.

(9) Northbound vessels in excess of 65 feet in length without mooring arrangement made prior to the date of the event are prohibited from entering

Seddon Channel unless the vessel is officially entered in the Gasparilla Marine Parade.

(10) Vessels not officially entered in the Gasparilla Marine Parade may not enter the parade staging area box within the following coordinates: 27°53'53" N, 082°27'47" W; 27°53'22" N, 082°27'10" W; 27°52'36" N, 082°27'55" W; 27°53'02" N, 082°28'31" W.

(c) *Enforcement period.* This rule will be enforced from 9 a.m. to 6 p.m. on January 27, 2018.

Holly L. Najarian,

Captain, U.S. Coast Guard, Captain of the Port Saint Petersburg.

[FR Doc. 2018-01564 Filed 1-25-18; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA-HQ-OPP-2017-0401; FRL-9972-62]

Bacillus thuringiensis Cry51Aa2.834_16; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the Cry51Aa2.834_16 protein derived from *Bacillus thuringiensis* in or on cotton, when used as a plant-incorporated protectant. Monsanto Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting this exemption from the requirement of a tolerance. This regulation eliminates the need under FFDCA to establish a maximum permissible level for such residues.

DATES: This regulation is effective January 26, 2018. Objections and requests for hearings must be received on or before March 27, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0401, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. 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 OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 174 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0401 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before March 27, 2018. Addresses for

mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0401, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background

In the **Federal Register** of October 23, 2017 (82 FR 49020 (FRL-9967-370)), EPA issued notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 7F8566) by Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167. The petition requested that 40 CFR part 174 be amended by establishing permanent exemption from the requirement of a tolerance for the plant-pesticide *Bacillus thuringiensis* Cry51Aa2.834_16 protein in or on cotton. A summary of the petition prepared by the petitioner Monsanto Company, is available in the docket via <http://www.regulations.gov>. There were no comments received in response to the notice.

One modification has been made to the original request for a tolerance exemption: EPA changed "plant-pesticide" to "plant-incorporated protectant", to align with the Agency's vocabulary, which is published in 40 CFR part 174.3.

III. Final Rule

A. EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue" Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

EPA evaluated the available toxicity and exposure data on Cry51Aa2.834_16 and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which EPA relied and its risk assessment based on that data can be found within the document entitled "Federal Food, Drug, and Cosmetic Act (FFDCA) Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry51Aa2.834_16." This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

Based upon available data, EPA concludes that the Cry51Aa2.834_16 protein, which is a modified version of the wild-type Cry51Aa2 protein derived from *Bacillus thuringiensis*, does not show evidence of toxicity. Moreover, the source is not allergenic, nor is there any significant similarity between the Cry51Aa2.834_16 protein and known toxins and allergens. In addition, the Cry51Aa2.834_16 protein readily digests

in simulated gastric fluids and therefore cumulative, chronic, and acute effects are unlikely.

Given the lack of toxicity or allergenicity of the Cry51Aa2.834_16 protein, the Agency has not identified any toxicological endpoints for assessing risk. Consequently, the Agency's assessment of exposure is qualitative. In addition, due to the lack of any threshold effects, EPA has determined that the provision to retain a 10X safety factor for the protection of infants and children does not apply. Similarly, the lack of any toxic mode of action or toxic metabolites means that the provision requiring an assessment of cumulative effects does not apply.

Oral exposure to Cry51Aa2.834_16 may occur from ingestion of cotton-derived foods, such as refined, bleached, and deodorized (RBD) cottonseed oil. Based on the lack of adverse effects and the rapid digestibility of the protein, however, the Agency does not anticipate any risk from reasonably foreseeable levels of exposure. Residues in drinking water may theoretically be present because cotton PIP plant stubble may release modified Cry51Aa2.834_16 protein into ground water upon decay. However, the protein would not be expected to survive in the soil due to microbial degradation, adherence to soil components, and removal upon drinking water treatment procedures. In addition, oral toxicity testing showed no adverse effects. Moreover, because the PIP is currently only proposed to be used only in plants grown for commercial use, the Agency does not anticipate residential exposures. In the event that future uses are sold for residential use, the Agency does not expect there to be residential, non-occupational dermal or inhalation exposures, due to containment of the Cry51Aa2.834_16 protein within the plant.

Based on the lack of any evidence of adverse effects in the toxicological database, dietary exposure to the Cry51Aa2.834_16 protein is not anticipated to pose any harm to the U.S. population. EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of the Cry51Aa2.834_16 protein derived from *Bacillus thuringiensis*. Therefore, an exemption from the requirement of a tolerance is established for residues of the plant-incorporated protectant *Bacillus thuringiensis* Cry51Aa2.834_16 protein in or on cotton.

B. Analytical Enforcement Methodology

An analytical method is not required because the lack of adverse effects makes enforcement and monitoring of residues unnecessary to ensure food safety.

IV. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*) nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled

“Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require EPA’s consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 174

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 28, 2017.

Hayley Hughes,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 174—[AMENDED]

- 1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 321(q), 346a and 371.

- 2. Add § 174.539 to subpart W to read as follows:

§ 174.539 Cry51Aa2.834_16 protein; exemption from the requirement of a tolerance.

Residues of the Cry51Aa2.834_16 protein, which is a modified protein derived from the Cry51Aa2 protein of *Bacillus thuringiensis*, in or on cotton are exempt from the requirement of a tolerance, when the Cry51Aa2.834_16 protein is used as a plant-incorporated protectant.

[FR Doc. 2018–01519 Filed 1–25–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0578; FRL–9970–96]

Calcium Salts of Phosphorous Acid; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for the calcium salts of phosphorous acid. Verdesian Life Sciences, LLC., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation eliminates the need to establish a maximum permissible level for residues of calcium salts of phosphorous acid under FFDCA when used in accordance with the terms of the exemption.

DATES: This regulation is effective January 26, 2018. Objections and requests for hearings must be received on or before March 27, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0578, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. 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 OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office’s e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2016–0578 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before March 27, 2018. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0578, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online

instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background

In the **Federal Register** of December 20, 2016 (81 FR 92758) (FRL–9956–04), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 6F8481) by Verdesian Life Sciences, LLC., 1001 Winstead Dr., Suite 480, Cary, NC 27513. The petition requested that 40 CFR 180.1210 be amended to include residues of the systemic fungicide/systemic acquired resistance (SAR) inducer calcium salts of phosphorous acid in or on all food commodities when used as an agricultural fungicide and in or on potatoes when applied as a post-harvest treatment at 35,600 ppm or less phosphorous acid. That document referenced a summary of the petition prepared by the petitioner Verdesian Life Sciences, LLC, which is available in the docket via <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

The exemption being established in this action varies slightly from what the petitioner requested, for the reasons described in Unit III.C. below.

III. Final Rule

A. EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in

residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue” Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] . . . residues and other substances that have a common mechanism of toxicity.” FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

EPA evaluated the available toxicity and exposure data on calcium salts of phosphorous acid and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk.

Because of the structural and functional similarity of calcium salts of phosphorous acid with potassium salts of phosphorous acid, Fosetyl-Al, and phosphonic acid, EPA was able to rely on toxicity data for those compounds to assess the toxicity potential of calcium salts of phosphorous acid. The resulting assessment indicates that calcium salts of phosphorous acid would not be considered acutely toxic nor present other concerns for subchronic or chronic toxicity, developmental toxicity, or mutagenicity. As such the Agency has not identified any endpoints of concern for calcium salts and has conducted a qualitative assessment of exposure. The Agency has determined that there is a potential for dietary exposure to residues of calcium salts of phosphorous acid in or on food from use as a pesticidal substance; exposures

in drinking water are not expected due to the dissolution of calcium salts of phosphorous acid in water, and non-occupational exposures are not expected since calcium salts of phosphorous acid are not intended for residential use. A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the November 8, 2017, document entitled “Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Calcium Salts of Phosphorous Acid.” This document, as well as other relevant information, is available in the docket for this action as described under

ADDRESSES.

Based upon its evaluation, EPA concludes that calcium salts of phosphorous acid are not toxic. Although there may be some exposure to residues in or on food when calcium salts of phosphorous acid are used as an agricultural fungicide or a systemic acquired resistance inducer, there is a lack of concern due to the lack of potential for adverse effects. EPA also determined that retention of the Food Quality Protection Act (FQPA) safety factor was not necessary due to the lack of threshold effects.

Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of calcium salts of phosphorous acid. Therefore, EPA is establishing an exemption from the requirement of a tolerance for residues of calcium salts of phosphorous acid.

B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes due to the lack of concern about safety for calcium salts of phosphorous acid at any exposure level.

C. Revisions to Petitioned-for Tolerances

EPA is establishing an exemption that varies slightly from what the petitioner requested. Because the petitioner requested the systemic acquired resistance inducer use specifically for calcium salts, which has not been assessed for the other salts of phosphorous acid, EPA is promulgating this exemption as a separate paragraph in the section for exemptions for residues of phosphorous acid and its salts. Moreover, the Agency is not including any specific reference for the post-harvest use on potatoes as requested for two reasons. First, unless otherwise specified, tolerances cover both pre-harvest and post-harvest applications. Second, because the original numerical limitation is written in terms of an amount of phosphorous

acid that may be used, this limitation has no effect for an exemption based only on the related calcium salts of phosphorous acid, which have been considered as a distinct fungicide, although it is related to all the other salts of phosphorous acid. In any case, residues of calcium salts of phosphorous acid are considered to be covered for all post-harvest uses without numerical limitation, including those on potatoes.

IV. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the

relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require EPA’s consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 5, 2018.

Richard P. Keigwin, Jr.,
Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Revise § 180.1210 to read as follows:

§ 180.1210 Phosphorous acid; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for residues of phosphorous acid and its ammonium, sodium and potassium salts in or on all food commodities when used as an agricultural fungicide and in or on potatoes when applied as a post-

harvest treatment at 35,600 ppm or less phosphorous acid.

(b) An exemption from the requirement of a tolerance is established for residues of calcium salts of phosphorous acid, including its metabolites and degradates, in or on all food commodities when used as a fungicide or as a systemic acquired resistance (SAR) inducer.

[FR Doc. 2018–01494 Filed 1–25–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0333; FRL–9970–88]

Chlorfenapyr; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of chlorfenapyr, 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile, in or on tea, dried. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 26, 2018. Objections and requests for hearings must be received on or before March 27, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0333, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. 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 OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, P.E., Director, Registration Division (750P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001;

main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0333 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before March 27, 2018. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified

by docket ID number EPA-HQ-OPP-2016-0333, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of July 20, 2016 (81 FR 47150) (FRL-9948-45), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E8473) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.513 be amended by establishing tolerances for residues of the insecticide chlorfenapyr, 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile, in or on tea, dried at 70 parts per million (ppm). That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. This tolerance was requested to cover residues of chlorfenapyr in or on tea resulting from uses of this pesticide on tea outside the United States. There is no current U.S. registration for use of chlorfenapyr on tea. In addition, there were no substantive comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes

exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for chlorfenapyr including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with chlorfenapyr follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Chlorfenapyr has moderate acute toxicity via the oral route of exposure and low acute toxicity via the dermal and inhalation routes of exposure. It is a mild eye irritant, but it is not a dermal irritant or sensitizer. Chlorfenapyr targets the central nervous system (CNS), inducing neurohistological changes (spongiform myelinopathy of the brain and spinal cord and vacuolization of the brain, spinal cord, and optic nerve) from subchronic and chronic dietary administration in mice and rats. In addition to neuropathology, rats also exhibited neurobehavioral changes on the day of dosing in the acute neurotoxicity study. Decreased motor activity was observed in the acute neurotoxicity study as well as in offspring in the developmental neurotoxicity (DNT) study. Several rat studies also noted effects in the liver (increased organ weights and tumors) at doses similar to or above those where CNS effects were seen. The liver was identified in metabolism studies as the single organ to have the highest recovery of administered dose.

There was evidence of increased quantitative susceptibility to offspring in the database as a result of chlorfenapyr exposure. In the two-

generation reproduction study, decreased pup weights were seen at a lower dose than parental toxicity (decreased body-weight). In the DNT study, offspring toxicity (decreased motor activity and increased pup deaths on postnatal days 1–4) was seen in the absence of maternal toxicity. Additional effects on the CNS (vacuolation of white matter in the brain and decreased hippocampus size) were also observed in offspring at a higher dose in this study. There was no evidence of increased susceptibility to offspring in the developmental toxicity studies. In both the rat and rabbit developmental toxicity studies, although no maternal or developmental effects were noted up to the highest doses tested (HDT), maternal observations are limited in these developmental studies. Consequently, the data from the DNT are considered more robust for assessing the effects of chlorfenapyr on the nervous system.

Given the lack of toxicity in the rat and rabbit developmental studies, the early pup deaths in the reproduction toxicity and DNT studies are suspected to be the result of postnatal exposure through lactation. Chlorfenapyr has a relatively high octanol-water partition coefficient ($\log K_{OW} = 4.83$) and has been shown to accumulate in milk due to its lipophilic nature in a dietary cow study. In addition, in a rat metabolism study, chlorfenapyr was found to accumulate in the fat, such that females exhibited greater accumulation than

males. This suggests chlorfenapyr is capable of accumulating in breast milk and likely causing the early pup deaths seen in the reproduction toxicity and DNT studies through lactation.

Chlorfenapyr did not show any evidence of mutagenicity in *in vitro* or *in vivo* studies. Chlorfenapyr is classified as “suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential.”

Specific information on the studies received and the nature of the adverse effects caused by chlorfenapyr as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document entitled “Chlorfenapyr: Revised Preliminary Human Health Risk Assessment for Registration Review,” dated September 7, 2016, which can be found in docket ID number EPA-HQ-OPP-2010-0467 as well in the document completed in support of this tolerance action entitled “Chlorfenapyr. Human Health Risk Assessment for the Establishment of a Tolerance without a U.S. Registration for Residues in/on Imported Tea,” dated March 1, 2017, which can be found in docket ID number EPA-HQ-OPP-2016-0333.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies

toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>. A summary of the toxicological endpoints for chlorfenapyr used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CHLORFENAPYR FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute Dietary (All populations)	NOAEL = 5 mg/kg/day. UF _A = 10X UF _H = 10X FQPA SF = 1X	Acute RfD = 0.05 mg/kg/day. aPAD = 0.05 mg/kg/day	Developmental Neurotoxicity Study (Rat). LOAEL = 10 mg/kg/day based on increased pup deaths (post-natal days 1–4) and decreased motor activity.
Chronic Dietary (All populations).	NOAEL = 5 mg/kg/day. UF _A = 10X UF _H = 10X FQPA SF = 1X	Chronic RfD = 0.05 mg/kg/day. cPAD = 0.05 mg/kg/day.	Developmental Neurotoxicity Study (Rat). LOAEL = 10 mg/kg/day based on increased pup deaths (post-natal days 1–4) and decreased motor activity. Chronic Neurotoxicity Study (Rat). NOAEL = 2.6 mg/kg/day. LOAEL = 13.6 mg/kg/day based on alterations of the myelin of the CNS and decreased water consumption in male rats, decreased food consumption in females, and decreased body-weight in both sexes.
Incidental Oral Short-Term (1–30 days) and Intermediate-Term (1–6 months).	NOAEL = 5 mg/kg/day. UF _A = 10X UF _H = 10X FQPA SF = 1X	Residential LOC for MOE = 100.	Developmental Neurotoxicity Study (Rat). LOAEL = 10 mg/kg/day based on increased pup deaths (post-natal days 1–4) and decreased motor activity.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CHLORFENAPYR FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Dermal Short-Term (1–30 days) and Intermediate-Term (1–6 months).	NOAEL = 5 mg/kg/day. UF _A = 10X UF _H = 10X FQPA SF = 1X	Residential LOC for MOE = 100.	Developmental Neurotoxicity Study (Rat). LOAEL = 10 mg/kg/day based on increased pup deaths (post-natal days 1–4) and decreased motor activity.
Inhalation Short-Term (1–30 days) and Intermediate-Term (1–6 months).	NOAEL = 5 mg/kg/day. UF _A = 10X UF _H = 10X FQPA SF = 1X	Residential LOC for MOE = 100.	Developmental Neurotoxicity Study (Rat). LOAEL = 10 mg/kg/day based on increased pup deaths (post-natal days 1–4) and decreased motor activity.
Cancer (oral, dermal, inhalation).	Classified as “suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential.” The Agency determined that quantification of risk using a non-linear approach (i.e., using a cRfD) adequately accounts for all chronic toxicity, including carcinogenicity that could result from exposure to chlorfenapyr.		

NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to chlorfenapyr, EPA considered exposure under the petitioned-for tolerances as well as all existing chlorfenapyr tolerances in 40 CFR 180.513. EPA assessed dietary exposures from chlorfenapyr in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for chlorfenapyr. In estimating acute dietary (food only) exposure, EPA used the Dietary Exposure Evaluation Model—Food Consumption Intake Database (DEEM-FCID), Version 3.16, which uses food consumption data from the U.S. Department of Agriculture’s National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) from 2003–2008. As to residue levels in food, EPA’s acute analysis was unrefined and used tolerance-level residues and 100% crop-treated (PCT). Tolerances for food/feed handling establishments are not included in the acute dietary assessment unless the food/feed handling establishment is the only use; however, this is not the case for chlorfenapyr. DEEM 7.81 default processing factors were used in the acute analysis for tomato commodities as there is a registered agricultural use on fruiting vegetables.

ii. *Chronic exposure.* In conducting the chronic dietary (food only) risk assessment, EPA used the DEEM-FCID, Version 3.16, which uses food consumption data from the U.S. Department of Agriculture’s NHANES/WWEIA from 2003–2008. As to residue levels in food, EPA’s chronic dietary exposure analysis for the all population subgroups was unrefined and used tolerance-level residues and 100% PCT. As most tolerances for chlorfenapyr are for food or feed handling establishment uses and residues are expected to be incurred after processing, DEEM 7.81 processing factors were set to 1 for all commodities except tomato commodities (as there is a registered agricultural use on fruiting vegetables). For tomato commodities, default processing factors were used in the analysis.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear approach using the chronic RfD for assessing

cancer risk is appropriate for chlorfenapyr; therefore, a separate quantitative cancer risk assessment is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for chlorfenapyr. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The acute and chronic dietary analysis did not include exposure from drinking water as contamination of drinking water with chlorfenapyr as a result of all registered uses, including greenhouses, is not expected to occur. Furthermore, as there are no U.S. registrations for tea, a dietary exposure assessment from drinking water is not needed.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Chlorfenapyr is currently registered for the following uses that could result in residential exposures: crack/crevice/spot treatment on indoor and outdoor residential sites (including as a bed bug treatment). Residential exposures are not expected to occur from use of chlorfenapyr on tea since chlorfenapyr will not be applied to tea in the United States. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be

found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found chlorfenapyr to share a common mechanism of toxicity with any other substances, and chlorfenapyr does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that chlorfenapyr does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Although there is evidence of increased quantitative susceptibility, concern is low since the offspring effects are well-characterized with clearly established NOAEL/LOAEL values and the endpoints selected for risk assessment are protective of observed offspring effects, including those observed in lactating pups.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for chlorfenapyr is complete.

ii. Although the central nervous system is the primary target for chlorfenapyr and neurotoxic effects were observed across studies, concern is low since the selected PODs are protective of observed neurotoxic effects.

iii. Although there is evidence of increased quantitative susceptibility, concern is low since the offspring effects are well-characterized with clearly established NOAEL/LOAEL values and the endpoints selected for risk assessment are protective of observed offspring effects.

iv. There are no residual uncertainties identified in the exposure databases. The acute and chronic analysis did not include exposure from drinking water as contamination of drinking water with chlorfenapyr as the result of all registered uses, including greenhouses, is not expected to occur. Furthermore, as there is no U.S. registration for tea, a dietary exposure assessment from drinking water is not needed. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by chlorfenapyr.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account the acute exposure assumptions discussed in this unit for acute exposure, the resulting acute (food only) risk estimates were less than EPA’s LOC (<100% of the aPAD) for the general U.S. population (15% of the aPAD) and all population subgroups. The most highly exposed population subgroup was children 1 to 2 years old with an estimated equivalent risk to 36% of the aPAD; therefore, the acute dietary exposure to chlorfenapyr is below the Agency’s LOC.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that the resulting chronic risk estimate utilizes 4.6% of the cPAD for the general U.S. population. The most

highly-exposed population subgroup was children 1 to 2 years old which utilized 9.9% of the cPAD; therefore, the chronic dietary exposure to chlorfenapyr for all population subgroups is below the Agency’s LOC. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of chlorfenapyr is not expected.

3. *Short- and Intermediate-term risk.* Short- and intermediate-term aggregate risk assessments were performed since there is potential for post-application exposure from the previously registered uses of chlorfenapyr in residential settings. Since the short- and intermediate-term endpoints and PODs are the same, the short-term aggregate assessment is protective of intermediate-term exposure. The short-term aggregate MOE of 840 for adults is greater than the LOC (100), and is, therefore, not a concern. For children (1 to <2 years old), the most highly exposed population subgroup, the short-term aggregate MOE of 140 is greater than the LOC (100), and is, therefore, not a concern.

4. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.C.1.iii., EPA concluded that regulation based on the cRfD will be protective for both chronic and carcinogenic risks. As noted in this unit, there are no chronic risks of concern; therefore, the Agency concludes that aggregate exposure to chlorfenapyr will not pose a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to chlorfenapyr residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The enforcement method is designated as M 2427, a gas chromatography/electron capture detection (GC/ECD) method with a limit of quantitation (LOQ) of 0.05 ppm. Method M 2427 has been subjected to a successful independent laboratory validation (ILV) as well as an acceptable radiovalidation using samples obtained from lettuce and tomato metabolism studies. This method is adequate for data collection and tolerance enforcement purposes.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural

practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for chlorfenapyr in or on tea, dried.

C. Revisions to Petitioned-for Tolerances

EPA is establishing a tolerance for “tea, dried”, as opposed to “tea” as requested by the petitioner, for consistency with the Agency’s food and feed commodity vocabulary. In addition, EPA is amending the introductory text of paragraph (a)(1) to be consistent with the Agency’s policy for drafting the tolerance expression. These revisions reflect the language in FFDCA section 408(a)(3), which includes metabolites and degradates of a pesticide chemical under the same tolerance unless otherwise excluded, as well as providing greater clarity for measuring residues to determine compliance. These revisions do not substantively change the existing tolerances in paragraph (a)(3).

V. Conclusion

Therefore, a tolerance is established without U.S. registrations for residues of chlorfenapyr, 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile, in or on tea, dried at 70 parts per million.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001); Executive Order 13045, entitled “Protection of

Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of

Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 18, 2017.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.513, revise paragraph (a)(1) to read as follows:

§ 180.513 Chlorfenapyr; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of chlorfenapyr, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only chlorfenapyr, 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile, in or on the commodity.

Commodity	Parts per million
Tea, dried ¹	70
Vegetable, fruiting, group 8–10 ..	1.0

¹ There are no U.S. registrations for Tea, dried as of January 26, 2018.

* * * * *

[FR Doc. 2018–01487 Filed 1–25–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0498; FRL–9971–94]

Flonicamid; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of

flonicamid in or on prickly pear, fruit and prickly pear, pads.

This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on prickly pear, fruit and prickly pear, pads. This regulation establishes a maximum permissible level for residues of flonicamid in or on these commodities. The time-limited tolerances expire on December 31, 2020.

DATES: This regulation is effective January 26, 2018. Objections and requests for hearings must be received on or before March 27, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0498, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. 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 OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNtices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to <https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp> and select "Test Methods and Guidelines."

C. How can I file an objection or hearing request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID EPA-HQ-OPP-2017-0498 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before March 27, 2018. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0498, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for residues of insecticide flonicamid, N-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide and its metabolites, TFNA (4-trifluoromethylnicotinic acid), TFNA-AM (4-trifluoromethylnicotinamide), and TFNG (N-(4-trifluoromethylnicotinoyl)glycine), calculated as the stoichiometric equivalent of flonicamid, in or on prickly pear, fruit at 1.5 parts per million (ppm) and prickly pear, pads at 1.5 ppm. These time-limited tolerances expire on December 31, 2020.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, *i.e.*, without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include

occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Flonicamid on Prickly Pear, Fruit and Prickly Pear, Pads and FFDCA Tolerances

The California Department of Pesticide Regulation (DPR) requested a specific emergency exemption for the use of flonicamid on prickly pear cactus fruit (*Opuntia spp.*) and nopalitos (pads) to control cochineal (*Dactylopius opuntiae*) in Monterey County, California. Cochineal insects are sap-sucking, aggressive scale insects that are considered to be a major pest for prickly pear cactus. These insects damage the cactus plant by inserting their mouth parts into the cactus and feeding on the plant’s sap. The feeding site of the cactus begins to swell and discolor. Eventually, the outer pads of the plant will fall off and the entire cactus plant dies. Cochineal colonies were first observed in the Salinas Valley cactus plantations in 2003. Birds heavily feed on cactus fruit, and while feeding on cochineal infected plants, the birds can pick up the nymphs on their feet and aid in spreading of the population. In 2013 and 2015 reduced amounts of precipitation in Salinas, California caused the cochineal population to flourish and build to uncontrollable levels. Even though 2016 and 2017 received normal levels of rain, cochineal infestations have not been inhibited due to the amount of cochineal present and the ineffective control from registered alternatives. As a result, growers are experiencing significant damage to their prickly pear cactus crops.

After having reviewed the submission, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for the use of flonicamid on prickly pear, fruit and prickly pear, pads for control of cochineal in California.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of flonicamid in or on prickly pear, fruit and prickly pear, pads. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent, non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2020, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on prickly pear, fruit and prickly pear, pads after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether flonicamid meets FIFRA’s registration requirements for use on prickly pear, fruit and prickly pear, pads or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of flonicamid by a State for special local needs under FIFRA section 24(c), nor does this tolerance by itself serve as the authority for persons in any State other than California to use this pesticide on the applicable crops under FIFRA section 18, absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for flonicamid, contact the Agency’s Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in

support of this action. EPA has sufficient data to assess the hazards of, and to make a determination on, aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerances for residues of flonicamid on prickly pear, fruit at 1.5 ppm and prickly pear, pads at 1.5 ppm. EPA’s assessment of exposures and risks associated with establishing time-limited tolerances follows.

A. Toxicological Points of Departure/ Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks>.

A summary of the toxicological endpoints for flonicamid used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of November 14, 2012 (77 FR 67771) (FRL–9368–7).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flonicamid, EPA considered exposure expected under the time-limited tolerances established by this action as well as all existing flonicamid tolerances in 40 CFR 180.613. EPA assessed dietary exposures from flonicamid in food as follows:

i. *Acute exposure.* No acute effects were observed at doses well above those

likely to be encountered; therefore, an endpoint was not selected, and a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA Survey. For the proposed section 18 use of flonicamid on prickly pear, fruit and pads, a dietary exposure assessment was not performed because there was no consumption reported for either commodity in NHANES/WWEIA. Due to the limited production and availability of prickly pear commodities, any increase in flonicamid dietary exposure from consumption of prickly pear commodities is expected to be insignificant compared to the flonicamid exposures pursuant to existing tolerances for flonicamid on various fruits and vegetables (40 CFR 180.613) which are produced in significantly greater quantities than prickly pear. These existing flonicamid tolerances are based on conservative (protective) exposure assumptions including use of tolerance level residues for all crops and 100% of the crops were treated. Therefore, any additional chronic risks from exposures of residues of flonicamid on prickly pear would likely be accounted for through the conservative assumptions underlying the existing tolerances.

iii. *Cancer.* As discussed in Unit III.B. of the final rule published in the **Federal Register** of November 14, 2012 (77 FR 67771), EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to flonicamid. For the same reasons discussed in Unit IV.B.ii., regarding chronic exposure, EPA believes that any additional cancer risks from exposures of residues of flonicamid on prickly pear would likely be accounted for through the conservative assumptions underlying the existing tolerances.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for flonicamid. Tolerance level residues and 100% CT were assumed for all food commodities included in the exposure assessment.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flonicamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flonicamid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at

<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of flonicamid for chronic exposures for non-cancer assessments are estimated to be 0.94 parts per billion (ppb) for surface water and 9.92 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration value of 9.92 ppb was used as the flonicamid contribution from drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Flonicamid is not registered for any specific use patterns that would result in residential exposure. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and” other substances that have a common mechanism of toxicity.”

EPA has not found flonicamid to share a common mechanism of toxicity with any other substances, and flonicamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that flonicamid does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

C. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of

safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for flonicamid includes prenatal developmental toxicity studies in rats and rabbits and, a multi-generation reproduction toxicity study in rats. There is no evidence that flonicamid results in increased susceptibility (qualitative or quantitative) *in utero* in rats or rabbits in the prenatal developmental studies or in young rats in the multi-generation reproduction study. No developmental effects were seen in rabbits. In the multi-generation reproduction study, developmental delays in the offspring (decreased body weights, delayed sexual maturation) were seen only in the presence of prenatal toxicity (kidney and blood effects). Also, there are clear NOAELs and LOAELs for all effects. The degree of concern for prenatal and/or postnatal susceptibility is, therefore low due to the lack of evidence of qualitative and quantitative susceptibility.

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X, except where assessing risk from inhalation exposure as discussed below. Those decisions are based on the following findings:

i. The toxicity database for flonicamid is essentially complete, except for an outstanding subchronic 28-day inhalation study. In the absence of a subchronic inhalation study, EPA has retained a 10X FQPA SF to assess risk from inhalation exposure, although at present, residential inhalation exposure is not expected from existing or pending uses of flonicamid.

ii. There is no indication that flonicamid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that flonicamid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment was based on 100 PCT, tolerance-level residues and where applicable, default processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to flonicamid in drinking water. These assessments will not underestimate the exposure and risks posed by flonicamid.

D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effects were observed to result from single oral exposures at doses well above those likely to be encountered, and therefore, flonicamid is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to flonicamid from food and water will utilize 59% of the cPAD for (children 1–2 years old), the population group receiving the greatest exposure. There are no residential uses for flonicamid.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Flonicamid is not registered for any use patterns that would result in short term residential exposures.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Flonicamid is not registered for any use patterns that would result in intermediate-term residential exposures.

5. *Aggregate cancer risk for U.S. population.* Based on the information referenced in Unit IV.A, EPA has

concluded that the cPAD is protective of possible cancer effects from flonicamid because, as noted in Unit IV.D.2, aggregate chronic exposure to flonicamid is below the cPAD.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to flonicamid residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology (FMC Method No. P–3561M, a liquid chromatography with tandem mass spectrometry (LC/MS/MS) method is available to enforce the tolerance expression for flonicamid and its metabolites in or on plant commodities. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for flonicamid.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of flonicamid, N-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide and its metabolites, TFNA (4-trifluoromethylnicotinic acid), TFNA-AM (4-trifluoromethylnicotinamide), and TFNG (N-(4-trifluoromethylnicotinoyl)glycine), calculated as the stoichiometric

equivalent of flonicamid, in or on prickly pear, fruit at 1.5 ppm and prickly pear, pads at 1.5 ppm. These tolerances expire on December 31, 2020.

VII. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply

to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 28, 2017.

Michael L. Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.613, revise paragraph (b) to read as follows:

§ 180.613 Flonicamid; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the flonicamid, N-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide and its metabolites, TFNA (4-trifluoromethylnicotinic acid), TFNA-AM (4-trifluoromethylnicotinamide), and TFNG (N-(4-trifluoromethylnicotinoyl)glycine), calculated as the stoichiometric equivalent of flonicamid, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration date
Prickly pear, fruit	1.5	12/31/2020
Prickly pear, pads	1.5	12/31/2020

* * * * *

[FR Doc. 2018-01480 Filed 1-25-18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0254; FRL-9971-95]

Difenoconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of difenoconazole in or on multiple commodities which are identified and discussed later in this document. In addition, this regulation removes several previously established tolerances that are superseded by this final rule. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). **DATES:** This regulation is effective January 26, 2018. Objections and requests for hearings must be received on or before March 27, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0254, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. 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 OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC

20460-0001; telephone number: (703) 305-7090; email address: RDfRNtices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0254 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before March 27, 2018. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified

by docket ID number EPA-HQ-OPP-2016-0254, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 26, 2017 (82 FR 34664) (FRL-9963-50), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E8484) by IR-4 Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.475 be amended by establishing tolerances for residues of the fungicide difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methoxy-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole, in or on *Brassica*, leafy greens, subgroup 4-16B at 35 parts per million (ppm); cranberry at 0.6 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 4.0 ppm; guava at 3.0 ppm; kohlrabi at 2.0 ppm; papaya at 0.6 ppm; and vegetable, *Brassica*, head and stem, group 5-16 at 2.0 ppm. Upon establishment of proposed tolerances above, the petition requested that 40 CFR part 180.475 be amended by removing existing tolerances for residues of difenoconazole in or on *Brassica*, head and stem, subgroup 5A at 1.9 ppm, *Brassica*, leafy greens, subgroup 5B at 35 ppm; grape at 4.0 ppm; and turnip, greens at 35 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Tolerances being established vary from what was requested, for the reasons explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for difenoconazole including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with difenoconazole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Difenoconazole exhibits low acute toxicity by the oral, dermal and inhalation routes of exposure. It is not an eye or skin irritant and is not a sensitizer. Subchronic and chronic toxicity studies with difenoconazole in mice and rats showed decreased body weights and effects on the liver (e.g. hepatocellular hypertrophy, liver necrosis, fatty changes in the liver). No systemic toxicity was observed at the limit dose in a rat dermal toxicity study.

The available toxicity studies indicated no increased susceptibility of rats or rabbits from *in utero* or postnatal exposure to difenoconazole. In prenatal

developmental toxicity studies in rats and rabbits and in the 2-generation reproduction study in rats, fetal and offspring toxicity, when observed, occurred at equivalent or higher doses than in the maternal and parental animals. In a rat developmental toxicity study, developmental effects were observed at doses higher than those which caused maternal toxicity. Developmental effects in the rat included increased incidence of ossification of the thoracic vertebrae and thyroid, decreased number of sternal centers of ossification, increased number of ribs and thoracic vertebrae, and decreased number of lumbar vertebrae. In the rabbit study, developmental effects (increases in post-implantation loss and resorptions and decreases in fetal body weight) were also seen at maternally toxic (decreased body weight gain and food consumption) doses. Since the developmental effects are more severe than the maternal effects, qualitative susceptibility is indicated in the rabbit developmental study; however, the selected POD is protective of this effect. In the 2-generation reproduction study in rats, toxicity to the fetuses and offspring, when observed, occurred at equivalent or higher doses than in the maternal and parental animals.

In an acute neurotoxicity study in rats, reduced fore-limb grip strength was observed on day one in males at the lowest-observed-adverse-effect-level of 200 mg/kg (LOAEL), and clinical signs of neurotoxicity were observed in females only at the highest dose tested (2,000 mg/kg). In a subchronic neurotoxicity study in rats, decreased hind limb strength was observed in males only at doses ≥ 17.5 mg/kg/day. The effects observed in acute and subchronic neurotoxicity studies are transient with no histologic findings.

Although there is some evidence that difenoconazole affects antibody levels at doses that cause systemic toxicity, there are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by difenoconazole. Difenoconazole is not mutagenic, and no evidence of carcinogenicity was seen in rats. Evidence for carcinogenicity was seen in mice as induction of liver tumors at doses which were considered to be excessively high for carcinogenicity testing. Difenoconazole has been classified as “Suggestive Evidence of Carcinogenic Potential” based on liver tumors observed in mice at 46.3 mg/kg/day and higher, the absence of tumors at two lower doses of 1.5 and 4.6 mg/kg/day, respectively, excessive toxicity

observed at the two highest doses of 423 and 819 mg/kg/day, respectively, the absence of genotoxicity, and no evidence of carcinogenicity in rats. EPA has concluded that the chronic point of departure (POD) for assessing chronic risk (0.96 mg/kg/day) will be protective of any cancer effects for the following reasons: (1) Tumors were seen in only one species; (2) carcinoma tumors were observed only at the two highest doses (2,500 and 4,500 ppm) in the mouse carcinogenicity study; (3) benign tumors and necrosis were observed at the mid-dose (300 ppm); (4) the absence of tumors at the study's lower doses (30 ppm); (5) the absence of genotoxic or mutagenic effects. The cRfD of 0.96 mg/kg/day is well below the no-observed-adverse-effect-level (NOAEL) of the mouse carcinogenicity study of 30 ppm (4.7 and 5.6 mg/kg/day in males and females, respectively), at which no effects on the biological endpoints relevant to tumor development (*i.e.*, hepatocellular hypertrophy, liver necrosis, fatty changes in the liver and bile stasis) were seen. As a result, EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to difenoconazole and a separate quantitative cancer exposure assessment is unnecessary.

Specific information on the studies received and the nature of the adverse effects caused by difenoconazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document "SUBJECT: Difenoconazole. Human Health Risk Assessment for Proposed New Foliar Uses on Cranberry, Guava, and Papaya. Expansion of Registered Foliar Use on Grape to Crop Subgroup 13-07F (Fruit, Small, Vine Climbing, Except Fuzzy Kiwifruit). Conversion of Registered Foliar Uses on Crop Subgroups 5A and 5B to Crop Group 5-16 (Vegetable, *Brassica*, Head and Stem), Crop Subgroup 4-16B (*Brassica*, Leafy Greens (includes Watercress)), and Kohlrabi, October 11, 2017" at pp. 42-50 in docket ID number EPA-HQ-OPP-2016-0254.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment.

PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for difenoconazole used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 2, 2015 (80 FR 17697) (FRL-9923-82).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to difenoconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing difenoconazole tolerances in 40 CFR 180.475. EPA assessed dietary exposures from difenoconazole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for difenoconazole. In estimating acute dietary exposure, EPA used Dietary Exposure Evaluation Model software with the Food Commodity Intake Database DEEM-FCID which incorporates consumption data from the United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/ WWEIA) conducted from 2003 to 2008. As to residue levels in food, EPA assumed tolerance-level residues, 100 percent crop treated (PCT), and available empirical or DEEM (ver. 7.81) default processing factors.

ii. *Chronic exposure.* In conducting a refined chronic dietary exposure

assessment EPA used the food consumption data from USDA's NHANES/WWEIA survey program. As to residue levels in food, EPA assumed tolerance-level residues for some commodities, average field trial residues and USDA Pesticide Data Program monitoring samples for the remaining commodities, available empirical or DEEM (ver.7.81) default processing factors, and average PCT assumptions for some commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to difenoconazole. Therefore, a separate quantitative cancer exposure assessment is unnecessary since the chronic dietary risk estimate will be protective of potential cancer risk.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the chronic dietary exposure analysis, the Agency used average PCT

estimates for existing uses as follows: Almond 10%, apple 20%, apricot 10%, broccoli 2.5%, Brussels sprout 2.5%, cabbage 5%, cantaloupe 2.5%, carrot 5%, cauliflower 2.5%, cherry 2.5%, cucumber 5%, garlic 5%, grape 10%, grapefruit 5%, hazelnut 1%, nectarine 2.5%, onion 5%, orange 2.5%, pecan 2.5%, peach 2.5%, pear 10%, pepper 5%, pistachio 5%, plum 10%, potato 20%, pumpkin 2.5%, soybean 2.5%, squash 5%, strawberry 2.5%, sugar beet 15%, tangerine 2.5%, tomato 25%, walnut 1%, watermelon 5%, and wheat 10%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT value for chronic dietary risk analysis. The average PCT value for each existing use is derived by combining available public and private market survey data for that use and averaged across all observations and is rounded up to the nearest multiple of 5%, for use in the analysis unless the average PCT value is estimated at less than 2.5% or 1%, in which case the Agency uses 2.5% or 1%, respectively, as the average PCT value in the analysis. EPA uses a maximum PCT value for acute dietary risk analysis. The maximum PCT value is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5% for use in the analysis, unless the maximum PCT value is estimated at less than 2.5%, in which case the Agency uses 2.5% as the maximum PCT value in the analysis.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the

Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which difenoconazole may be applied in a particular area.

2. *Dietary exposure from drinking water.* The drinking water assessment was performed using a total toxic residue method, which considers both parent difenoconazole and its major metabolite, CGA 205375, or total toxic residues (TTR) from difenoconazole uses, in surface and groundwater. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for difenoconazole and CGA 205375 in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of difenoconazole, plus CGA 205375. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Tier II Pesticide in Water Calculator (PWC v1.52) model and Tier 1 Rice Model, the estimated drinking water concentrations (EDWCs) of TTR of difenoconazole for acute exposures are estimated to be 33.4 parts per billion (ppb) for surface water and 2.0 ppb for ground water. For chronic exposures EDWCs of TTR of difenoconazole for non-cancer assessments are estimated to be 27.8 ppb for surface water and 0.60 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 33.4 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 27.8 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Difenoconazole is currently registered for the following uses that could result in residential exposures: Treatment of ornamental plants in commercial and residential landscapes and interior plantscapes. EPA assessed residential exposure using the following

assumptions: For residential handlers, adult short-term dermal and inhalation exposure is expected from mixing, loading, and applying difenoconazole on ornamentals (gardens and trees). For residential post-application exposures, short-term dermal exposure is expected for both adults and children from post-application activities in treated residential landscapes.

The scenarios used in the aggregate assessment were those that resulted in the highest exposures. The highest exposures consist of the short-term dermal exposure to adults from post-application activities in treated gardens and short-term dermal exposure to children 6 to 11 years old from post-application activities in treated gardens. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Difenoconazole is a member of the conazole class of fungicides containing the 1,2,4-triazole moiety. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events (EPA, 2002).

In conazoles, however, a variable pattern of toxicological responses is found; some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that difenoconazole shares a common mechanism of toxicity with any other conazole pesticide, and

EPA is not following a cumulative risk approach for this tolerance action. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

Difenoconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two conjugated triazole metabolites (triazolylalanine and triazolylacetic acid). To support existing tolerances and to establish new tolerances for triazole-containing pesticides, including difenoconazole, EPA previously conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine, and triazolylacetic acid resulting from existing and pending uses of any triazole-containing fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). The Agency retained a 3X for the LOAEL to NOAEL safety factor when the reproduction study was used. In addition, the Agency retained a 10X for the lack of studies including a developmental neurotoxicity (DNT) study. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at <http://www.regulations.gov>, docket ID number EPA-HQ-OPP-2005-0497.

The Agency's latest updated aggregate risk assessment for the triazole-containing metabolites was finalized on July 18, 2017 and includes the new uses in this rule. It is titled, "Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address the New Section 3 Registrations for Use of Difenoconazole and Tetraconazole." Aggregate risk estimates associated with 1,2,4-triazole (T) and the conjugated triazole metabolites (i.e., combined residues of triazolylalanine (TA) and triazolylacetic acid (TAA)), are below the Agency's level of concern. There are no human health risk issues for these metabolites that would preclude the new uses of difenoconazole. The assessment may be found at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2016-0254.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology database for difenoconazole includes rat and rabbit prenatal developmental toxicity studies and a 2-generation reproduction toxicity study in rats. The available Agency guideline studies indicated no increased qualitative or quantitative susceptibility of rats to *in utero* and/or postnatal exposure to difenoconazole. In the prenatal developmental toxicity studies in rats and rabbits and the 2-generation reproduction study in rats, toxicity to the fetuses/offspring, when observed, occurred at equivalent or higher doses than in the maternal/parental animals. In a rat developmental toxicity study developmental effects were observed at doses higher than those which caused maternal toxicity. In the rabbit study, developmental effects (increases in post-implantation loss and resorptions and decreases in fetal body weight) were also seen at maternally toxic doses (decreased body weight gain and food consumption). Since the developmental effects are more severe than the maternal effects, qualitative susceptibility is indicated in the rabbit developmental study; however, the selected POD is protective of this effect. In the 2-generation reproduction study in rats, toxicity to the fetuses/offspring, when observed, occurred at equivalent or higher doses than in the maternal/parental animals.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for difenoconazole is complete.
- ii. There are no clear signs of neurotoxicity following acute, subchronic or chronic dosing in

multiple species in the difenoconazole database. The effects observed in acute and subchronic neurotoxicity studies are transient and showed in one sex (males as reduced fore-limb grip strength with no histologic findings), and the selected endpoints of toxicity for risk assessment are protective of any potential neurotoxicity. Based on the toxicity profile, and lack of concern for neurotoxicity, there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no evidence that difenoconazole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. The qualitative susceptibility seen in the rabbit developmental study is adequately protected by the selected POD.

iv. There are no residual uncertainties identified in the exposure databases. The dietary risk assessment utilized tolerance-level residues and 100 PCT for the acute assessment; a refined chronic assessment incorporated USDA PDP monitoring data, average field-trial residues for some commodities, tolerance-level residues for remaining commodities, and average PCT for some commodities. These assumptions will not underestimate dietary exposure to difenoconazole. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to difenoconazole in drinking water. EPA used similarly conservative assumptions to assess post application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by difenoconazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to difenoconazole will occupy 52% of the aPAD for all infants <1 year old, the

population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to difenoconazole from food and water will utilize 51% of the cPAD for all infants <1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of difenoconazole is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Difenoconazole is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to difenoconazole.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of aggregate MOEs of 250 for children and 180 for adults. Because EPA's level of concern for difenoconazole is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, difenoconazole is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for difenoconazole.

5. *Aggregate cancer risk for U.S. population.* Based on the data summarized in Unit III.A., the chronic dietary risk assessment is protective of any potential cancer effects. Based on the results of that assessment, EPA concludes that difenoconazole is not

expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to difenoconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available to enforce the tolerance expression. An adequate enforcement method, gas chromatography with nitrogen-phosphorus detection (GC/NPD) method AG-575B, is available for the determination of residues of difenoconazole *per se* in/on plant commodities. An adequate enforcement method, GC/MSD method AG-676A, is also available for the determination of residues of difenoconazole *per se* in/on canola and barley commodities. A confirmatory method, GC/MSD method AG-676, is also available. The Limit of Quantitation (LOQs) are 0.01–0.05 ppm.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for difenoconazole in/on papaya at 0.2 ppm; grape at 3 ppm (a crop member of fruit, small, vine climbing, except fuzzy kiwifruit crop subgroup 13–07F); dried grapes at 6 ppm; and broccoli, Brussels sprouts, cabbage and cauliflower at 2 ppm (crop members of vegetables,

Brassica, head and stem crop group 5–16). The U.S. tolerances are harmonized with these Codex MRLs with the exception of the U.S. tolerance at 0.60 ppm in/on papaya due to differences in U.S. good agricultural practices (GAP) and concerns that the Codex MRL in/on papaya at 0.2 ppm is too low to cover residues in/on U.S. papaya commodities treated in accordance with approved label directions for difenoconazole.

C. Revisions to Petitioned-for Tolerances

EPA is establishing the tolerance for Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 3.0 ppm rather than the requested 4.0 ppm for harmonization with the currently established Codex MRL for residues of difenoconazole in/on grape which reflects U.S. GAP. In addition, EPA corrected the tolerance level to include an additional significant figure for cranberry and papaya from the requested 0.6 ppm to 0.60 ppm. This is to avoid the situation where rounding of an observed residue to the level of precision of the tolerance expression would be considered non-violative (such as 0.64 ppm being rounded to 0.6 ppm).

V. Conclusion

Therefore, tolerances are established for residues of the fungicide difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methoxy-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole, in or on *Brassica*, leafy greens, subgroup 4–16B at 35 ppm; Cranberry at 0.60 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 3.0 ppm; Guava at 3.0 ppm; Kohlrabi at 2.0 ppm; Papaya at 0.60 ppm; and Vegetable, *Brassica*, head and stem, group 5–16 at 2.0 ppm. In addition, established tolerances for “*Brassica*, head and stem, subgroup 5A”; “*Brassica*, leafy greens, subgroup 5B”; “Grape”; “Papaya”; and “Turnip, greens” are removed because they are superseded by the tolerances being established in this action.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning

Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001); Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national

government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection,
Administrative practice and procedure,
Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: December 27, 2017.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.475, paragraph (a)(1):

■ a. Remove the entries for “*Brassica*, head and stem, subgroup 5A” and “*Brassica*, leafy green, subgroup 5B”;

■ b. Add alphabetically the entry for “*Brassica*, leafy greens, subgroup 4–16B”;

■ c. Add alphabetically the entries for “Cranberry” and “Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F”;

■ d. Remove the entry for “Grape”;

■ e. Add alphabetically the entries for “Guava” and “Kohlrabi”;

■ f. Revise the entry for “Papaya”;

■ g. Remove the entry for “Turnip, greens”; and

■ h. Add alphabetically the entry for “Vegetable, *Brassica*, head and stem, group 5–16”.

The additions and revision read as follows:

§ 180.475 Difenoconazole; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
<i>Brassica</i> , leafy greens, subgroup 4–16B	35
Cranberry	0.60
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F	3.0
Guava	3.0
Kohlrabi	2.0
Papaya	0.60
Vegetable, <i>Brassica</i> , head and stem, group 5–16	2.0

* * * * *

[FR Doc. 2018-01479 Filed 1-25-18; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency****44 CFR Part 64****[Docket ID FEMA-2018-0002; Internal Agency Docket No. FEMA-8517]****Suspension of Community Eligibility****AGENCY:** Federal Emergency Management Agency, DHS.**ACTION:** Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at <https://www.fema.gov/national-flood-insurance-program-community-status-book>.

DATES: The effective date of each community's scheduled suspension is the third date ("Susp.") listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Adrienne L. Sheldon, PE, CFM, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 212-3966.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities

agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required

floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

- 1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

- 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region VI				
Texas:				
Bayview, Town of, Cameron County	480102	October 7, 1975, Emerg; September 1, 1981, Reg; February 16, 2018, Susp.	February 16, 2018.	February 16, 2018.
Brownsville, City of, Cameron County ..	480103	January 15, 1971, Emerg; December 1, 1978, Reg; February 16, 2018, Susp.do*	Do.
Combes, Town of, Cameron County	480104	September 6, 1978, Emerg; September 1, 1981, Reg; February 16, 2018, Susp.do	Do.
Harlingen, City of, Cameron County	485477	November 6, 1970, Emerg; June 23, 1972, Reg; February 16, 2018, Susp.do	Do.
Indian Lake, Town of, Cameron County	481695	N/A, Emerg; September 24, 2002, Reg; February 16, 2018, Susp.do	Do.
La Feria, City of, Cameron County	480106	October 31, 1973, Emerg; August 3, 1984, Reg; February 16, 2018, Susp.do	Do.
Laguna Vista, Town of, Cameron County.	485483	August 13, 1971, Emerg; July 21, 1972, Reg; February 16, 2018, Susp.do	Do.
Port Isabel, City of, Cameron County ...	480109	October 29, 1971, Emerg; October 6, 1976, Reg; February 16, 2018, Susp.do	Do.
Rancho Viejo, Town of, Cameron County.	481646	N/A, Emerg; July 10, 1992, Reg; February 16, 2018, Susp.do	Do.
Rio Hondo, City of, Cameron County ...	480112	April 3, 1975, Emerg; June 1, 1981, Reg; February 16, 2018, Susp.do	Do.
San Benito, City of, Cameron County ...	480113	May 13, 1974, Emerg; May 5, 1981, Reg; February 16, 2018, Susp.do	Do.
Santa Rosa, City of, Cameron County ..	480114	August 29, 1980, Emerg; May 5, 1981, Reg; February 16, 2018, Susp.do	Do.
South Padre Island, City of, Cameron County.	480115	November 26, 1973, Emerg; September 15, 1983, Reg; February 16, 2018, Susp.do	Do.
Region VII				
Iowa:				
Bussey, City of, Marion County	190710	N/A, Emerg; May 26, 2010, Reg; February 16, 2018, Susp.do	Do.
Centerville, City of, Appanoose County	190009	July 22, 1975, Emerg; July 2, 1987, Reg; February 16, 2018, Susp.do	Do.
Chariton, City of, Lucas County	190195	October 18, 1974, Emerg; February 1, 1987, Reg; February 16, 2018, Susp.do	Do.
Lamoni, City of, Decatur County	190110	June 4, 1975, Emerg; May 1, 1987, Reg; February 16, 2018, Susp.do	Do.
Lucas, City of, Lucas County	190196	December 29, 1975, Emerg; August 16, 1988, Reg; February 16, 2018, Susp.do	Do.
Marion County, Unincorporated Areas ..	190889	February 21, 1997, Emerg; November 7, 2001, Reg; February 16, 2018, Susp.do	Do.
Marysville, City of, Marion County	190456	N/A, Emerg; March 4, 2008, Reg; February 16, 2018, Susp.do	Do.
Melrose, City of, Monroe County	190465	September 16, 1981, Emerg; July 2, 1987, Reg; February 16, 2018, Susp.do	Do.
Pella, City of, Marion County	190837	N/A, Emerg; January 12, 2007, Reg; February 16, 2018, Susp.do	Do.
Pleasantville, City of, Marion County	190838	N/A, Emerg; June 20, 2011, Reg; February 16, 2018, Susp.do	Do.
Seymour, City of, Wayne County	190655	February 6, 1978, Emerg; July 1, 1987, Reg; February 16, 2018, Susp.do	Do.
Swan, City of, Marion County	190398	N/A, Emerg; April 20, 2017, Reg; February 16, 2018, Susp.do	Do.
Unionville, Town of, Appanoose County	190923	October 29, 1976, Emerg; July 1, 1988, Reg; February 16, 2018, Susp.do	Do.
Woodburn, City of, Clarke County	190070	November 23, 2007, Emerg; May 1, 2011, Reg; February 16, 2018, Susp.do	Do.

*.....do and Do. = ditto.

Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: January 19, 2018.

Eric Letvin,

Deputy Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2018–01461 Filed 1–25–18; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2018–0002; Internal Agency Docket No. FEMA–8515]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at <https://www.fema.gov/national-flood-insurance-program-community-status-book>.

DATES: The effective date of each community's scheduled suspension is the third date ("Susp.") listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Adrienne L. Sheldon, PE, CFM, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 212–3966.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase

Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be

suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/ cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region VI				
Louisiana:				
Grand Isle, Town of, Jefferson Parish.	225197	August 28, 1970, Emerg; October 30, 1970, Reg; February 2, 2018, Susp.	Feb. 2, 2018	Feb. 2, 2018.
Gretna, City of, Jefferson Parish ..	225198	August 14, 1970, Emerg; June 18, 1971, Reg; February 2, 2018, Susp.do *	Do.
Harahan, City of, Jefferson Parish	225200	April 19, 1973, Emerg; June 15, 1973, Reg; February 2, 2018, Susp.do	Do.
Jean Lafitte, Town of, Jefferson Parish.	220371	N/A, Emerg; October 1, 1971, Reg; February 2, 2018, Suspdo	Do.
Westwego, City of, Jefferson Parish.	220094	April 27, 1973, Emerg; December 28, 1976, Reg; February 2, 2018, Susp.Do	Do.

*.....do and Do. = ditto.

Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: January 5, 2018.

Eric Letvin,

Deputy Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2018–01463 Filed 1–25–18; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 170803723–8016–01]

RIN 0648–BH09

Technical Amendment To Update Internet Web Addresses in Marine Mammal Protection Act and Dolphin Protection Consumer Information Act Regulations

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

ACTION: Final rule; technical amendments.

SUMMARY: NMFS is hereby making technical amendments without altering the substance of the regulations that govern importation into the United States of tuna product and dolphin-safe tuna labeling in the United States under the Marine Mammal Protection Act (MMPA), and the Dolphin Protection Consumer Information Act (DPCIA). The intent of this action is to update existing regulations containing Uniform Resource Locator (URL) addresses, more commonly referred to as internet web page addresses. The URL updates are necessary because NMFS is revising all

agency URLs under the NOAA Fisheries Web Modernization Project. These changes are solely administrative in nature.

DATES: This final rule is effective January 26, 2018.

ADDRESSES: 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802.

FOR FURTHER INFORMATION CONTACT: William Jacobson, NMFS West Coast Region, 562–980–4035.

SUPPLEMENTARY INFORMATION:

Background

Regulations at 50 CFR 216.24(f)(3) and 50 CFR part 216, subpart H contain URLs that provide importers, tuna processors, and fishermen that harvest tuna for the U.S. market, access to information critical to regulatory compliance. NMFS is undergoing an agency-wide modification of the naming convention used in all existing URLs. Failure to change the URLs in the regulatory text would render the URL references in the regulations unusable, confusing the regulated public.

Classification

The NMFS Assistant Administrator has determined that this final rule is consistent with the MMPA, the DPCIA, and other applicable laws.

Administrative Procedure Act

NOAA finds good cause under 5 U.S.C. 553(b)(B) and 553(d)(3) to issue this final rule without advance notice in a proposed rule or the opportunity for public comment, and to make the rule effective immediately without providing a 30-day delay, because the content of this rule makes a technical correction and does not affect the substance of regulations that affect the public. Public input is not necessary to determine the correct URL, and delaying codification

of the correct URL would not be in the public interest.

Executive Order 12866

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

List of Subjects in 50 CFR Part 216

Administrative practice and procedure, Fish, Imports, Labeling, Marine mammals.

Dated: January 19, 2018.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, 50 CFR part 216 is amended as follows:

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for 50 CFR part 216 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*, unless otherwise noted.

Subpart C—General Exceptions

■ 2. In § 216.24, revise introductory text of paragraph (f)(3) to read as follows:

§ 216.24 Taking and related acts incidental to commercial fishing operations by tuna purse seine vessels in the eastern tropical Pacific Ocean.

* * * * *

(f) * * *

(3) *Disposition of Fisheries Certificates of Origin.* The FCO described in paragraph (f)(4) of this section may be obtained from the Administrator, West Coast Region, or downloaded from the internet at <https://www.fisheries.noaa.gov/national/>

marine-mammal-protection/noaa-form-370-fisheries-certificate-origin.

* * * * *

Subpart H—Dolphin Safe Tuna Labeling

■ 3. The authority citation for 50 CFR part 216, subpart H, continues to read as follows:

Authority: 16 U.S.C. 1385.

■ 4. In § 216.91, revise paragraph (a)(3)(iii)(B), introductory text of paragraph (a)(3)(iv), and introductory text of paragraph (a)(3)(v) to read as follows:

§ 216.91 Dolphin-safe labeling standards.

- (a) * * *
- (3) * * *
- (iii) * * *

(B) The Captain of the vessel has completed the NMFS Tuna Tracking and Verification Program dolphin-safe captain's training course. The NMFS Tuna Tracking and Verification Program dolphin-safe captain's training course is available on the website of the NMFS Tuna Tracking and Verification Program at <https://www.fisheries.noaa.gov/dolphin-safe>.

(iv) For tuna caught in a fishery where the Assistant Administrator has determined that observers participating in a national or international observer program are qualified and authorized to issue observer statements for purposes of the dolphin-safe labeling program, and where such an observer is on board the vessel, a written statement executed by the observer, or by an authorized representative of a nation participating in the observer program based on information from the observer. Any determination by the Assistant Administrator shall be announced in a notice published in the **Federal Register**. Determinations under this paragraph (a)(3)(iv) will also be publicized on the website of the NMFS Tuna Tracking and Verification Program (<https://www.fisheries.noaa.gov/dolphin-safe>). The written statement shall certify:

* * * * *

(v) For tuna caught in a fishery in which the Assistant Administrator has determined that either a regular and significant association between dolphins and tuna (similar to the association between dolphins and tuna in the ETP) or a regular and significant mortality or serious injury of dolphins is occurring, a written statement, executed by the Captain of the vessel and an observer participating in a national or international program acceptable to the Assistant

Administrator, unless the Assistant Administrator determines an observer statement is unnecessary. Determinations under this paragraph (a)(3)(v) will also be publicized on the website of the NMFS Tuna Tracking and Verification Program (<https://www.fisheries.noaa.gov/dolphin-safe>). The written statement shall certify that:

* * * * *

■ 5. In § 216.95, revise paragraph (b) to read as follows:

§ 216.95 Official mark for "Dolphin-safe" tuna products.

* * * * *

(b) *Location and size of the official mark.* The official mark on labels must allow the consumer to identify the official mark and be similar in design and scale to figure 1. A full color version of the official mark is available at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/dolphin-safe-official-mark>.

[FR Doc. 2018–01375 Filed 1–25–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 161020985–7181–02]

RIN 0648–XF949

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Less Than 60 Feet (18.3 Meters) Length Overall Using Hook-and-Line or Pot Gear in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 meters (m)) length overall (LOA) using hook-and-line or pot gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2018 Pacific cod total allowable catch allocated to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), January 23, 2018, through 2400 hours, A.l.t., December 31, 2018.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2018 Pacific cod total allowable catch (TAC) allocated to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI is 5,027 metric tons (mt) as established by the final 2017 and 2018 harvest specifications for groundfish in the BSAI (82 FR 11826, February 27, 2017), inseason adjustment (82 FR 60329, December 20, 2017), and reallocation (83 FR 2932, January 22, 2018).

In accordance with § 679.20(d)(1)(iii), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2018 Pacific cod TAC allocated as a directed fishing allowance to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI will soon be reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of January 19, 2017.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of

prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: January 22, 2018.

Samuel D. Rauch, III

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

[FR Doc. 2018–01384 Filed 1–23–18; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 83, No. 18

Friday, January 26, 2018

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2017-0757; Product Identifier 2017-SW-022-AD]

RIN 2120-AA64

Airworthiness Directives; Bell Helicopter Textron Canada Limited Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain serial numbered Bell Helicopter Textron Canada Limited (BHTC) Model 429 helicopters. This proposed AD would require marking a serial number on life-limited forward spars and actuator fitting assemblies. The actions of this proposed AD are intended to prevent an unsafe condition on these products.

DATES: We must receive comments on this proposed AD by March 27, 2018.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to <http://www.regulations.gov>. Follow the online instructions for sending your comments electronically.

- *Fax:* 202-493-2251.

- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590-0001.

- *Hand Delivery:* Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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-2017-0757; 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 proposed AD, the Transport Canada AD, the economic 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 service information identified in this proposed rule, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437-2862 or (800) 363-8023; fax (450) 433-0272; or at <http://www.bellcustomer.com/files/>. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N-321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT:

Helene Gandy, Aviation Safety Engineer, Regulations & Policy Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy, Fort Worth, TX 76177; telephone (817) 222-5413; email helene.gandy@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this

proposal in light of the comments we receive.

Discussion

Transport Canada, which is the aviation authority for Canada, has issued Canadian AD No. CF-2017-02, dated January 16, 2017, to correct an unsafe condition for BHTC Model 429 helicopters, serial numbers (S/N) 57150, 57168, 57176, 57210, 57211 through 57216, 57265, 57266, 57267, and 57287. Transport Canada advises that forward spars part number (P/N) 429-031-213-103 and 429-031-213-104 and actuator fitting assembly P/N 429-031-222-101 and 429-031-222-102 have life limits of 30,000 and 19,000 Retirement Index Numbers, respectively. However, Transport Canada states these parts are not serialized and therefore their accumulated usage is difficult to track, which creates a risk that these parts could remain in service beyond their life limits. This condition could result in failure of the part.

FAA's Determination

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to our bilateral agreement with Canada, Transport Canada, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information Under 14 CFR Part 51

We reviewed Bell Helicopter Alert Service Bulletin 429-16-34, dated November 10, 2016, which specifies procedures for permanently marking each forward spar and actuator fitting assembly with the serial number of the helicopter.

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.

Other Related Service Information

We also reviewed Bell Helicopter Model 429 Maintenance Manual BHT-429-MM-1, Chapter 4, Airworthiness Limitations Schedule, Revision 26, dated September 9, 2016, which

specifies airworthiness life limits and inspection intervals for parts installed on Model 429 helicopters.

Proposed AD Requirements

This proposed AD would require cleaning and marking the helicopter's serial number on each forward spar P/N 429-031-213-103 and 429-031-213-104 and on each actuator fitting assembly P/N 429-031-222-101 and 429-031-222-102. This proposed AD would also prohibit installing any affected part on any helicopter unless it has been marked in accordance with this proposed AD.

Differences Between This Proposed AD and the Transport Canada AD

The Transport Canada AD requires compliance within 12 months from its effective date, unless already accomplished. This proposed AD would require compliance within 800 hours time in service.

Costs of Compliance

We estimate that this proposed AD would affect 6 helicopters of U.S. Registry and that labor costs average \$85 per work-hour. We estimate that marking the forward spars and actuator fitting assemblies would require 1 work-hour and no parts would be needed. Based on these estimates, we expect a total cost of \$85 per helicopter and \$510 for the U.S. fleet.

Authority for This Rulemaking

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

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.

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, 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 to the extent that it justifies making a regulatory distinction; 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.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

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):

Bell Helicopter Textron Canada Limited:
Docket No. FAA-2017-0757; Product Identifier 2017-SW-022-AD.

(a) Applicability

This AD applies to Bell Helicopter Textron Canada Limited Model 429 helicopters, serial number (S/N) 57150, 57168, 57176, 57210 through 57216, 57265, 57266, 57267, and 57287, with a forward spar part number (P/N) 429-031-213-103 or 429-031-213-104 or actuator fitting assembly P/N 429-031-222-101 or 429-031-222-102 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a forward spar or actuator fitting assembly remaining in service after reaching its life limit. This condition could result in failure of a forward spar or actuator fitting assembly and subsequent collapse of the landing gear.

(c) Comments Due Date

We must receive comments by March 27, 2018.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) Within 800 hours time-in-service, clean and identify each forward spar and actuator fitting assembly with the helicopter serial number in accordance with the Accomplishment Instructions, paragraphs 3 through 5 and with reference to Figure 1 of Bell Helicopter Alert Service Bulletin 429-16-34, dated November 10, 2016.

(2) After the effective date of this AD, do not install a forward spar P/N 429-031-213-103 or 429-031-213-104 or actuator fitting assembly P/N 429-031-222-101 or 429-031-222-102 on any helicopter unless it has been marked with a serial number in accordance with paragraph (e)(1) of this AD.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, FAA, may approve AMOCs for this AD. Send your proposal to: Helene Gandy, Aviation Safety Engineer, Regulations & Policy Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy, Fort Worth, TX 76177; telephone (817) 222-5413; email 9-ASW-FTW-AMOC-Requests@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

(1) Bell Helicopter Model 429 Maintenance Manual BHT-429-MM-1, Chapter 4, Airworthiness Limitations Schedule, Revision 26, dated September 9, 2016, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437-2862 or (800) 363-8023; fax (450) 433-0272; or at <http://www.bellcustomer.com/files/>. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N-321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in Transport Canada AD No. CF-2017-02, dated January 16, 2017. You may view the Transport Canada AD on the internet at <http://www.regulations.gov> in the AD Docket.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 1100, Placards and Markings.

Issued in Fort Worth, Texas, on January 12, 2018.

Lance T. Gant,

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

[FR Doc. 2018-01194 Filed 1-25-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

**[Docket No. FAA-2018-0036; Product
Identifier 2017-SW-015-AD]**

RIN 2120-AA64

Airworthiness Directives; Bell Helicopter Textron Inc.

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking
(NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Bell Helicopter Textron Inc. (Bell) Model 212, Model 412, and Model 412EP helicopters. This proposed AD would require replacing the emergency flotation system (EFS) tube assembly. This proposed AD is prompted by a report of an EFS tube assembly failure. The actions of this proposed AD are intended to address an unsafe condition on these helicopters.

DATES: We must receive comments on this proposed AD by March 27, 2018.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to <http://www.regulations.gov>. Follow the online instructions for sending your comments electronically.

- *Fax:* 202-493-2251.

- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590-0001.

- *Hand Delivery:* Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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-2018-0036; 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 proposed AD, the economic 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 service information identified in this proposed rule, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (817) 280-3391; fax (817) 280-6466; or at <http://www.bellcustomer.com/files/>. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Rory Rieger, Aviation Safety Engineer, DSCO Branch, AIR-7J0, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5193; email rory.rieger@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

We propose to adopt a new AD for Bell Model 212, Model 412, and Model 412EP helicopters with an EFS tube assembly part number (P/N) 412-073-820-101 with a date of manufacture before July 28, 2016. This proposed AD is prompted by a report from Bell that an EFS tube assembly separated from the valve during a 2-year inflation test.

A subsequent investigation found that excessive sleeve preset force during manufacturing caused cracks in the sleeve of the tube assembly, which may result in the EFS float failing to deploy. Bell determined that only those EFS tube assemblies with P/N 412-073-820-101 that were shipped prior to July 28, 2016, were subject to this manufacturing defect. Bell states that because this manufacturing defect is difficult to detect, affected EFS tube assemblies in service must be replaced. The affected parts were associated with a single Bell supplier that is no longer manufacturing the tube assembly.

Accordingly, this proposed AD would require replacing the EFS tube assemblies and would prohibit installing an affected EFS tube assembly on any helicopter. We are proposing this AD to prevent installing a cracked EFS tube assembly, which could result in failure of the EFS floats to deploy during an emergency water landing.

FAA's Determination

We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs.

Related Service Information

We reviewed Bell Alert Service Bulletin (ASB) 212-11-143 and ASB 412-11-147, both Revision C and dated December 22, 2016. Each ASB describes and illustrates procedures to replace the tube assembly within 600 flight hours or by March 31, 2017.

Proposed AD Requirements

This proposed AD would require, within 300 hours time-in-service (TIS), replacing any EFS tube assembly P/N 412-073-820-101 that was manufactured before July 28, 2016. This proposed AD would also prohibit installing an EFS tube assembly P/N 412-073-820-101 that was manufactured before July 28, 2016 on any helicopter.

Differences Between This Proposed AD and the Service Information

The ASBs require compliance within 600 flight hours or by March 31, 2017; this proposed AD would require compliance within 300 hours TIS.

Costs of Compliance

We estimate that this proposed AD would affect 250 helicopters of U.S. Registry.

We estimate that operators may incur the following costs in order to comply with this proposed AD. At an average

labor rate of \$85 per hour, replacing a tube assembly would require about 6 work-hours and required parts would cost \$4,902, for a total cost of \$5,412 per helicopter and \$1,353,000 for the U.S. fleet.

According to Bell's service information, some 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 by Bell. Accordingly, we have included all 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.

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, 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 to the extent that it justifies making a regulatory distinction; 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.

We prepared an economic evaluation of the estimated costs to comply with

this proposed AD and placed it in the AD docket.

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):

Bell Helicopter Textron Inc.: Docket No. FAA–2018–0036; Product Identifier 2017–SW–015–AD.

(a) Applicability

This AD applies to Bell Helicopter Textron Inc. (Bell) Model 212, Model 412, and Model 412EP helicopters, certificated in any category, with an emergency flotation system (EFS) tube assembly part number (P/N) 412–073–820–101 with a date of manufacture before July 28, 2016, or an unknown date of manufacture installed.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack on an EFS tube assembly. This condition could result in failure of the emergency floats to inflate during an emergency water landing.

(c) Comments Due Date

We must receive comments by March 27, 2018.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

- (1) Within 300 hours time-in-service:
 - (i) Remove the EFS tube assembly from service.
 - (ii) Lubricate the shoulder of the sleeves, threads, and seat of each mating fitting with anti-seize compound.
 - (iii) Install an EFS tube assembly not listed in paragraph (a) of this AD.
- (2) After the effective date of this AD, do not install an EFS tube assembly listed in paragraph (a) of this AD on any helicopter.

(f) Alternative Methods of Compliance (AMOC)

- (1) The Manager, DSCO Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Rory Rieger, Aviation Safety

Engineer, DSCO Branch, AIR–7J0, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5193; email rory.rieger@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

Bell Helicopter Alert Service Bulletins 212–11–143 and 412–11–147, both Revision C and dated December 22, 2016, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this proposed rule, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (817) 280–3391; fax (817) 280–6466; or at <http://www.bellcustomer.com/files/>. You may review a copy of information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 3212 Emergency Flotation Section.

Issued in Fort Worth, Texas, on January 12, 2018.

Scott A. Horn,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2018–01195 Filed 1–25–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. FDA–2017–N–7007]

RIN 0910–AH49

Removal of Certain Time of Inspection and Duties of Inspector Regulations for Biological Products; Companion to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing to amend the general biologics regulations relating to time of inspection requirements and also removing duties of inspector requirements. FDA is proposing this action to remove outdated requirements and accommodate new approaches,

such as a risk-based inspection frequency for drug establishments, thereby providing flexibility without diminishing public health protections. This action is part of FDA's implementation of Executive Orders (EOs) 13771 and 13777. Under these EOs, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction while allowing the Agency to achieve our public health mission and fulfill statutory obligations.

DATES: Submit either electronic or written comments on the proposed rule or its companion direct final rule by April 11, 2018. If FDA receives any timely significant adverse comments on the direct final rule with which this proposed rule is associated, the Agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA will apply any significant adverse comments received on the direct final rule to the proposed rule in developing the final rule. FDA will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 11, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 11, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions.")

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-7007 for "Removal of Certain Time of Inspection and Duties of Inspector Regulations for Biological Products." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **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.

FOR FURTHER INFORMATION CONTACT:

Melissa Segal, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing to amend the general biologics regulations relating to time of inspection requirements and to remove duties of inspector requirements. FDA is proposing this action to remove outdated requirements and accommodate new approaches, such as a risk-based inspection frequency for drug establishments, thereby providing flexibility without diminishing public health protections.

B. Summary of the Major Provisions of the Proposed Rule

This proposed rule would revise the time of inspection requirements contained in § 600.21 (21 CFR 600.21) and also remove the duties of inspector requirements contained in § 600.22 (21 CFR 600.22). These changes to the biological product regulations would eliminate outdated requirements and accommodate new approaches, such as a risk-based inspection frequency for drug establishments, thereby providing flexibility without diminishing public health protections. Revision and removal of these regulations would not change the biological product establishment inspection requirements and duties of an investigator requirements that apply under sections 704 and 510(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 374 and 360(h)) and section 351(c) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(c)).

C. Legal Authority

FDA is proposing this action under the biological product provisions of the PHS Act, and the drugs and general administrative provisions of the FD&C Act, including sections 704 and 510(h) of the FD&C Act and section 351(c) of the PHS Act.

D. Costs and Benefits

Because this proposed rule would not impose any additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

II. Companion Document to Direct Final Rulemaking

This proposed rule is a companion to the direct final rule published in the rules section of this issue of the **Federal Register**. This companion proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule receives any significant adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received in response to this companion proposed rule will also be considered as comments regarding the direct final rule. FDA is publishing the direct final rule because we believe the rule contains noncontroversial changes and there is little likelihood that there will be significant adverse comments opposing the rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in the direct final rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to a part of the direct final rule and that part can be severed from the remainder of the rule, we may

adopt as final those provisions of the rule that are not the subject of the significant adverse comment.

If any significant adverse comments to the direct final rule are received during the comment period, FDA will publish, within 30 days after the comment period ends, a notice of significant adverse comment and withdraw the direct final rule. If we withdraw the direct final rule, any comments received will be considered comments on the proposed rule and will be considered in developing a final rule using the usual notice-and-comment procedure.

If no significant adverse comment is received in response to the direct final rule during the comment period, no further action will be taken related to this proposed rule. Instead, we will publish a document confirming the effective date within 30 days after the comment period ends. Additional information about direct final rulemaking procedures is set forth in the document entitled "Guidance for FDA and Industry: Direct Final Rule Procedures," announced and provided in the **Federal Register** of November 21, 1997 (62 FR 62466). The guidance may be accessed at: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm>.

III. Background

On February 24, 2017, President Donald Trump issued Executive Order 13777, "Enforcing the Regulatory Reform Agenda" (82 FR 12285, March 1, 2017). One of the provisions in the Executive Order requires Agencies to evaluate existing regulations and make recommendations to the Agency head regarding their repeal, replacement, or modification, consistent with applicable law. As one step in implementing the Executive Order, FDA published a notice in the **Federal Register** of September 8, 2017 (82 FR 42492) entitled "Review of Existing Center for Biologics Evaluation and Research Regulatory and Information Collection Requirements." In that notice, FDA announced that it was conducting a review of existing regulations to determine, in part, whether they can be made more effective in light of current public health needs and to take advantage of, and support, advances in innovation that have occurred since those regulations took effect. As part of this initiative, FDA is updating outdated regulations as specified in this rule.

FDA's general biological products regulations in part 600 (21 CFR part 600) are intended to help ensure the safety, purity, and potency of biological products administered to humans. The proposed revision and removal of

certain general biological products regulations are designed to eliminate outdated requirements and accommodate new approaches, such as a risk-based inspection frequency for drug establishments and provide flexibility without diminishing public health protections.

A. Section 600.21

The authority for FDA to conduct establishment inspections is included in both the FD&C Act and the PHS Act. Specifically, section 704 of the FD&C Act and section 351(c) of the PHS Act authorize the Agency to inspect establishments that manufacture biological products. Before July 9, 2012—the date the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) was signed into law—section 510(h) of the FD&C Act further provided, among other things, that drug and device establishments registered with FDA must be inspected at least once in the 2-year period beginning with the date of registration and at least once in every successive 2-year period thereafter. Section 510(h) of the FD&C Act applies to biological product establishments because all biological products are subject to regulation under the drug or device provisions of the FD&C Act (in addition to the biological product provisions of the PHS Act). Since 1983, FDA's biological product regulation at § 600.21 has also included a biennial inspection requirement ("[A]n inspection of each licensed establishment and its additional location(s) shall be made at least once every 2 years"); this was consistent with the pre-FDASIA biennial inspection requirement in section 510(h) of the FD&C Act.

With the enactment of FDASIA, however, the biennial inspection requirement for drug establishments in section 510(h) of the FD&C Act was replaced with a requirement that FDA inspect drug establishments in accordance with a risk-based schedule established by FDA. Accordingly, for biological product establishments that are registered as drug establishments under section 510(h), the requirement in § 600.21 regarding the frequency of inspections is no longer consistent with the FD&C Act and is outdated (e.g., the risk-based inspection schedule for drug establishments may result in scheduling inspections at intervals of greater than 2 years for certain biological product establishments). For this reason, and to provide for greater flexibility in general with respect to determining the frequency of biological product establishment inspections under the

authority provided in the FD&C Act and the PHS Act, FDA proposes to revise § 600.21 to remove the biennial inspection requirement for biological product establishments that are registered as drug establishments and for those that are registered as device establishments.

In addition, § 600.21 includes provisions concerning inspectional notice and the timing of pre-licensure reinspections of biological product establishments. These provisions are outdated and unnecessary. Inspectional notice is addressed in the Agency's practices for inspections in its Standard Operating Procedures and Policies and in the Investigations Operations Manual (IOM). With respect to the timing of a reinspection of a biological product establishment following the denial of a biologics license application, the general biologics licensing provision at 21 CFR 601.4, which was issued subsequent to § 600.21, sets forth the administrative procedures following the denial of a license; accordingly, the specific provision in § 600.21 regarding timing of a reinspection following denial of a license is unnecessary. Therefore, FDA is proposing to remove these provisions.

B. Section 600.22

Current § 600.22 requires specific duties of an FDA inspector. These existing codified requirements are unnecessary because they are duplicative of statutory requirements that apply to biological product inspections under section 704 of the FD&C Act. Specifically, the inspection requirements in section 704 of the FD&C Act encompass all of the requirements outlined in § 600.22. Thus, we are proposing to remove § 600.22(a) through (h).

The removal of these regulations, however, would not change the establishment inspection requirements and duties of an investigator requirements specified in sections 704 and 510(h) of the FD&C Act, section 351(c) of the PHS Act, or the procedures described in the IOM. Additionally, it would not change the established process for risk-based inspection planning and work planning.

IV. Highlights of the Proposed Rule

FDA is proposing to amend the general biologics regulations by revising time of inspection requirements contained in § 600.21 and also by removing the duties of inspector requirements contained in § 600.22. These proposed changes are designed to remove the existing codified requirements that are outdated and to

accommodate new approaches, such as a risk-based inspection frequency for biological product establishments, thereby providing flexibility without diminishing public health protections.

V. Legal Authority

FDA is issuing this proposed rule under the biological products provisions of the PHS Act (42 U.S.C. 216, 262, 263, 263a, 264, and 300aa–25) and the drugs and general administrative provisions of the FD&C Act (21 U.S.C. 321, 351, 352, 353, 355, 356c, 356e, 360, 360i, 371, 374, and 379k–l). Under these provisions of the PHS Act and the FD&C Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, and potent, and prevent the introduction, transmission, and spread of communicable disease.

VI. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule does not impose any additional regulatory burdens, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more

(adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

This proposed rule proposes amendments to the general biologics regulations by removing time of inspection requirements and the duties of inspector requirements. FDA is proposing this action to remove outdated requirements, accommodate new approaches, and provide flexibility without diminishing public health protections. Because this rulemaking proposes removal of regulations to be consistent with updated practice and does not impose any additional regulatory burdens, this proposed rulemaking is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public

Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 600 be amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

■ 1. The authority citation for part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 356c, 356e, 360, 360i, 371, 374, 379k–l; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25.

§ 600.21 [Amended]

■ 2. Amend § 600.21 by removing the last three sentences.

§ 600.22 [Removed and Reserved]

■ 3. Remove and reserve § 600.22.

Dated: January 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01467 Filed 1–25–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 3280, 3282, and 3285

[Docket No. FR–6075–N–01]

Regulatory Review of Manufactured Housing Rules

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development, HUD.

ACTION: Request for comments on regulatory review.

SUMMARY: Consistent with Executive Order 13771 entitled “Reducing Regulation and Controlling Regulatory Costs,” and Executive Order 13777 entitled, “Enforcing the Regulatory Reform Agenda,” and as part of the efforts of HUD’s Regulatory Reform Task Force, this document informs the public that HUD is reviewing its existing and planned manufactured housing regulatory actions to assess their actual and potential compliance costs and reduce regulatory burden. HUD invites public comment to assist in identifying regulations that may be outmoded, ineffective or excessively burdensome and should be modified, streamlined, replaced or repealed.

DATES: *Comment Due Date:* February 26, 2018.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Regulations Division, Office of General Counsel, Department

of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title.

Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at www.regulations.gov. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the www.regulations.gov website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the notice.

No Facsimile Comments. Facsimile (fax) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an appointment to review the public comments must be scheduled in advance by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 1–800–877–8339 (this is a toll-free number). Copies of all comments submitted are available for inspection and downloading at www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Ariel Pereira, Associate General Counsel for Legislation and Regulations, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10282, Washington DC 20410; telephone number 202–402–5138 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Executive Orders 13771 and 13777

Under the leadership of Secretary Carson, HUD has undertaken an effort, consistent with Executive Order 13771 (82 FR 9339), entitled “Reducing Regulation and Controlling Regulatory Costs,” to identify and eliminate or streamline regulations that are wasteful, inefficient or unnecessary. Executive Order 13771 requires that agencies manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations. Toward this end, Executive Order 13771 directs that for each new regulation issued, at least two prior regulations be identified for elimination and requires that the cost of planned regulations be prudently managed and controlled. In furtherance of this objective, the Secretary has also led HUD’s implementation of Executive Order 13777 (82 FR 12285), entitled “Enforcing the Regulatory Reform Agenda.” Executive Order 13777 reaffirms the rulemaking principles of Executive Order 13771 by directing each agency to establish a Regulatory Reform Task Force to evaluate existing regulations to identify those that merit repeal, replacement, modification, are outdated, unnecessary, or are ineffective, eliminate or inhibit job creation, impose costs that exceed benefits, or derive from or implement Executive Orders that have been rescinded or significantly modified.

II. This Notice

Manufactured housing plays a vital role in meeting the nation’s affordable housing needs, providing 9.5 percent of the total single-family housing stock.¹ According to the Manufactured Housing Institute,² more than 22 million Americans reside in manufactured housing. Manufactured homes are particularly important in rural states, where manufactured homes are approximately 16.2 percent of occupied housing units. The manufactured housing industry is also an important economic engine, accounting for approximately 35,000 jobs nationwide.

HUD regulation of manufactured housing fulfills a critical role of both protecting consumers and ensuring a fair and efficient market. HUD may adopt, revise, and interpret HUD’s manufactured housing program regulations based on recommendations of the Manufactured Housing Consensus

¹ American Housing Survey, 2013. Available at: http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=AHS_2013_C01AH&prodType=table.

² <http://www.manufacturedhousing.org/research-and-data/>.

Committee, a statutory Federal Advisory Committee body.³ Given the significant role that manufactured housing plays in providing affordable housing, HUD has determined that it should undertake a substantive review of all current and planned federal regulation of manufactured housing. This review is intended to ensure that HUD can more effectively meet its responsibilities to facilitate the availability of affordable manufactured homes and encourage innovation and cost-effective construction techniques for manufactured housing while continuing to protect consumers by ensuring quality, durable, safe and affordable manufactured homes.

In conducting this review, HUD believes that it would benefit from information and perspectives among state, local and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector and the public as a whole. HUD is, therefore, requesting comment on all current and planned regulatory actions affecting manufactured housing. HUD specifically seeks comment on:

- Rules listed in its Unified Agenda of Regulatory and Deregulatory Actions regulations, including rules to update its Manufactured Home Construction and Safety Standards (FR-5739), and exempt Recreational Vehicles from its Manufactured Home Construction and Safety Standards and Procedural and Enforcement Regulations (FR-5787).

- How HUD should proceed with its Interpretative Bulletin that provides guidance for designing and installing manufactured home foundations in areas subject to freezing temperatures with seasonal ground freezing.

- The effectiveness of HUD's on-site completion of construction regulations, its Subpart I notification and corrections procedures, and its Alternative Construction approval process, both overall and specifically in review of manufactured homes with a carport-ready design or any other similar design that would permit the construction of an add-on at the final home site, that is not structurally independent from the home's structure, support and anchoring systems.

HUD does not anticipate moving forward with any manufactured housing program regulations pending completion of its review. HUD may make exceptions, however, on individual rules based on policy priorities or revised circumstances.

To assist in the formulation of comments, HUD encourages commenters to consider how HUD's manufactured housing regulatory agenda may be streamlined to reduce or eliminate costs and overall burden while ensuring that HUD can continue to meet its statutory responsibilities under the Manufactured Home Construction and Safety Standards Act of 1974 (42 U.S.C. 5401 *et seq.*), as amended.

Dated: January 8, 2018.

Dana T. Wade,

General Deputy Assistant Secretary for Housing.

[FR Doc. 2018-01276 Filed 1-25-18; 8:45 am]

BILLING CODE 4210-67-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51, 60, and 63

[EPA-HQ-OAR-2016-0510; FRL-9972-22-OAR]

RIN 2060-AS95

Revisions to Testing Regulations for Air Emission Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This action proposes corrections and updates to regulations for source testing of emissions. The proposed rule includes corrections to testing provisions that contain inaccuracies, updates to outdated procedures, and approved alternative procedures that provide testers enhanced flexibility. The revisions will improve the quality of data but will not impose new substantive requirements on source owners or operators.

DATES: *Comments.* Written comments must be received by March 27, 2018.

Public Hearing. The EPA will hold a public hearing on this rule if requested. Requests for a hearing must be made by February 5, 2018. Requests for a hearing should be made to Mrs. Lula H. Melton via email at melton.lula@epa.gov or by phone at (919) 541-2910. If a hearing is requested, it will be held on February 26, 2018 at EPA Headquarters, William Jefferson Clinton East Building, 1201 Constitution Avenue NW, Washington, DC 20004.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2016-0510 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 <http://www.epa.gov/dockets/commenting-epa-dockets>.

All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed on the website, 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. Publicly available docket materials are available either electronically at <http://www.regulations.gov> or in hard copy at the EPA Docket Center, Room 3334, EPA WJC West Building, 1301 Constitution Avenue NW, Washington, DC 20004. 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 EPA Docket Center is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Mrs. Lula H. Melton, Office of Air Quality Planning and Standards, Air Quality Assessment Division (E143-02), Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541-2910; fax number: (919) 541-0516; email address: melton.lula@epa.gov.

SUPPLEMENTARY INFORMATION:

The supplementary information in this preamble is organized as follows:

I. General Information

- Does this action apply to me?
- What action is the agency taking?

II. Background

III. Summary of Proposed Amendments

- Method 201A of Appendix M of Part 51
- Method 204 of Appendix M of Part 51
- Method 205 of Appendix M of Part 51

³ See HUD, Manufactured Housing Consensus Committee, https://www.hud.gov/program_offices/housing/rmra/mhs/cc1.

- D. General Provisions (Subpart A) of Part 60
- E. Fossil-Fuel-Fired Steam Generators (Subpart D) Part 60
- F. Electric Utility Steam Generating Units (Subpart Da) Part 60
- G. Industrial-Commercial-Institutional Steam Generating Units (Subpart Db) Part 60
- H. Small Industrial-Commercial-Institutional Steam Generating Units (Subpart Dc) Part 60
- I. Municipal Waste Combustors for Which Construction is Commenced After December 20, 1989 and on or Before September 20, 1994 (Subpart Ea) Part 60
- J. Glass Manufacturing Plants (Subpart CC) Part 60
- K. New Residential Wood Heaters, New Residential Hydronic Heaters and Forced-Air Furnaces (Subpart QQQQ) Part 60
- L. Method 2B of Appendix A–1 of Part 60
- M. Method 5 of Appendix A–3 of Part 60
- N. Method 5B of Appendix A–3 of Part 60
- O. Method 5I of Appendix A–3 of Part 60
- P. Method 7 of Appendix A–4 of Part 60
- Q. Method 8 of Appendix A–4 of Part 60
- R. Method 18 of Appendix A–6 of Part 60
- S. Method 22 of Appendix A–7 of Part 60
- T. Method 26 of Appendix A–8 of Part 60
- U. Method 26A of Appendix A–8 of Part 60
- V. Test Method 28WHH of Appendix A–8 of Part 60
- W. Performance Specification 1 of Appendix B of Part 60
- X. Performance Specification 2 of Appendix B of Part 60
- Y. Performance Specification 3 of Appendix B of Part 60
- Z. Performance Specification 11 of Appendix B of Part 60
- AA. Performance Specification 15 of Appendix B of Part 60
- BB. Performance Specification 18 of Appendix B of Part 60
- CC. Procedure 1 of Appendix F of Part 60
- DD. General Provisions (Subpart A) of Part 63
- EE. Wool Fiberglass Manufacturing (Subpart NNN) Part 63
- FF. Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters (Subpart DDDDD) Part 63
- GG. Coal- and Oil-Fired Electric Utility Steam Generating Units (Subpart UUUUU) Part 63
- HH. Method 303 of Appendix A of Part 63
- II. Method 308 of Appendix A of Part 63
- JJ. Method 320 of Appendix A of Part 63
- KK. Method 323 of Appendix A of Part 63
- LL. Method 325A of Appendix A of Part 63
- MM. Method 325B of Appendix A of Part 63
- IV. Statutory and Executive Order Reviews
 - A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
 - B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs
 - C. Paperwork Reduction Act (PRA)
 - D. Regulatory Flexibility Act (RFA)
 - E. Unfunded Mandates Reform Act (UMRA)

- F. Executive Order 13132: Federalism
- G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
- H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
- I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use
- J. National Technology Transfer and Advancement Act and 1 CFR Part 51
- K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. Does this action apply to me?

The proposed amendments apply to industries that are subject to the current provisions of parts 51, 60, and 63. We did not list all of the specific affected industries or their North American Industry Classification System (NAICS) codes herein since there are many affected sources in numerous NAICS categories. If you have any questions regarding the applicability of this action to a particular entity, consult either the air permitting authority for the entity or your EPA Regional representative as listed in 40 CFR 63.13.

B. What action is the agency taking?

This action makes corrections and revisions to source test methods, performance specifications (PS), quality assurance/quality control (QA/QC) procedures, and testing regulations. The corrections and revisions consist primarily of typographical errors, updates to testing procedures, and the addition of alternative equipment and methods the Agency has deemed acceptable to use.

II. Background

The EPA catalogs errors and corrections, as well as necessary revisions to test methods, PS, QA/QC procedures, and associated regulations in 40 CFR parts 51, 60, and 63 and periodically updates and revises these provisions. The most recent updates and revisions were promulgated on August 30, 2016 (81 FR 59800). This proposed rule addresses necessary corrections and revisions identified subsequent to that final action, many of which were brought to our attention by regulated sources and end-users, such as environmental consultants and compliance professionals. These revisions will improve the quality of data obtained and give source testers the flexibility to use newly-approved alternative procedures.

III. Summary of Proposed Amendments

The following amendments are being proposed.

A. Method 201A of Appendix M of Part 51

In Method 201A, in section 12.5, the denominator of equation 24 would be corrected.

B. Method 204 of Appendix M of Part 51

In Method 204, in section 8.2, the statement regarding equation 204–2 would be corrected to “The NEAR must be ≤ 0.05 .”

C. Method 205 of Appendix M of Part 51

In Method 205, section 2.1.1 would be revised to allow the use of National Institute of Standards and Technology (NIST)-traceable transfer standards to calibrate the gas dilution system because these standards are widely available and provide the accuracy necessary to perform the calibration. Section 2.1.1 would also be revised to require testers to report the results of the calibration of the dilution system to enable the regulatory authority to review this information.

D. General Provisions (Subpart A) of Part 60

In the General Provisions of part 60, section 60.17(h) would be revised to add American Society for Testing and Materials (ASTM) D6216–12 to the list of incorporations by reference and to re-number the remaining consensus standards that are incorporated by reference in alpha-numeric order.

E. Fossil-Fuel-Fired Steam Generators (Subpart D) Part 60

In subpart D, the allowed filter temperature in section 60.46(b)(2)(i) would be revised from 160 ± 14 °C to 160 ± 5 °C resulting in increased precision of the filterable PM measurements.

F. Electric Utility Steam Generating Units (Subpart Da) Part 60

In subpart Da, the allowed filter temperature in section 60.50Da (b)(1)(ii)(A) would be revised from 160 ± 14 °C to 160 ± 5 °C resulting in increased precision of the filterable PM measurements.

G. Industrial-Commercial-Institutional Steam Generating Units (Subpart Db) Part 60

In subpart Db, the allowed filter temperature in section 60.46b(d)(4) would be revised from 160 ± 14 °C to 160 ± 5 °C resulting in increased precision of the filterable PM measurements.

H. Small Industrial-Commercial-Institutional Steam Generating Units (Subpart Dc) Part 60

In subpart Dc, the allowed filter temperature in section 60.45c(a)(5) would be revised from 160 ± 14 °C to 160 ± 5 °C resulting in increased precision of the filterable PM measurements.

I. Municipal Waste Combustors for Which Construction Is Commenced After December 20, 1989 and on or Before September 20, 1994 (Subpart Ea) Part 60

In subpart Ea, the allowed filter temperature in section 60.58a(b)(3) would be revised from 160 ± 14 °C to 160 ± 5 °C resulting in increased precision of the filterable PM measurements.

J. Glass Manufacturing Plants (Subpart CC) Part 60

In subpart CC, the allowed filter temperature in section 60.293(f) would be revised from 120 ± 14 °C to 120 ± 5 °C resulting in increased precision of the filterable particulate matter (PM) measurements. The allowed filter temperature in section 60.296(d)(2) would be revised from 177 ± 14 °C to 177 ± 5 °C resulting in increased precision of the filterable PM measurements.

K. New Residential Wood Heaters, New Residential Hydronic Heaters and Forced-Air Furnaces Part 60

In subpart QQQQ, in Method 28WHH, in section 13.5.1, equation 8 would be corrected.

L. Method 2B of Appendix A–1 of Part 60

In Method 2B, in section 12.1, the definition of ambient carbon dioxide concentration would be revised because the global monthly mean (CO₂)_a concentration varies over time. Also, a website link would be added to the definition.

M. Method 5 of Appendix A–3 of Part 60

The allowed filter temperature in Method 5, sections 2.0, 6.1.1.2, 6.1.1.6, 6.1.1.7, and 8.5 would be revised from 120 ± 14 °C to 120 ± 5 °C resulting in increased precision of the filterable PM measurements. Section 6.1.1.9 would be revised to allow the use of a single temperature sensor in lieu of two temperature sensors on the dry gas meter as allowed by Technical Information Document 19 (TID–19) and the approved broadly applicable alternative, ALT–117 (see <https://www.epa.gov/emc>).

N. Method 5B of Appendix A–3 of Part 60

The allowed filter temperature in Method 5B, sections 2.0, 6.1, and 8.2 would be revised from 160 ± 14 °C to 160 ± 5 °C resulting in increased precision of the filterable PM measurements. Section 11.0 would be revised to replace the reference to Method 5, section 11.0 with specific analytical procedures and to report the results using Figure 5B–1 for complete data review. Section 17.0 would be revised to delete the word “Reserved” from the title, and Figure 5B–1 (Analytical Data Sheet) would be added.

O. Method 5I of Appendix A–3 of Part 60

In Method 5I, sections 2.1 and 8.5.2.2 would be revised to tighten the allowed filter temperature from 120 ± 14 °C to 120 ± 5 °C resulting in increased precision of the filterable PM measurements.

P. Method 7 of Appendix A–4 of Part 60

In Method 7, sections 10.1.2 and 11.3 reference erroneous sections; the correct sections would be inserted.

Q. Method 8 of Appendix A–4 of Part 60

In Method 8, sections 6.1.1.1 through 6.1.1.4 would be renumbered to 6.1.1.2 through 6.1.1.5; a new section 6.1.1.1 would be added to clarify the requirements that apply to the probe nozzle; and Figure 8–1 (Sulfuric Acid Sampling Train) would be corrected.

R. Method 18 of Appendix A–6 of Part 60

In Method 18, in section 13.1, the erroneous paragraph (c) designation would be re-designated as (b).

S. Method 22 of Appendix A–7 of Part 60

In Method 22, sections 11.2.1 and 11.2.2 would be revised to allow digital photography to be used for a subset of the recordkeeping requirements. Section 11.2.3 would be added to allow digital photographic records. Note that ALT–109 (see <https://www.epa.gov/emc>) is the associated broadly applicable alternative that allows the use of digital photographs for specific recordkeeping requirements.

T. Method 26 of Appendix A–8 of Part 60

In Method 26, section 6.2.2 would be revised to allow the use of glass sample storage containers as an option to allow flexibility and to be consistent with Method 26A.

U. Method 26A of Appendix A–8 of Part 60

In Method 26A, section 6.2.1 would be revised to remove the language regarding sample storage containers. We have determined that high-density polyethylene is an acceptable material for sample storage containers in addition to the currently allowed glass. Therefore, we would allow both high-density polyethylene and glass in a new section 6.2.4.

V. Test Method 28WHH of Appendix A–8 of Part 60

In Test Method 28WHH, equation 8 in section 13.5.1 would be corrected.

W. Performance Specification 1 of Appendix B of Part 60

In Performance Specification 1, references to ASTM D6216–98 (in sections 2.1, 3.1, 6.1, 8.1(1), 8.1(3)(ii), 8.2(1), 8.2(2), 8.2(3), 9.0, 12.1, 13.1, 13.2, and 16.0 reference 8. will be replaced with ASTM D6216–12. Note: If the initial certification of the continuous opacity monitoring system (COMS) has already occurred using D6216–98, D6216–03, or D6216–07, it will not be necessary to recertify using D6216–12.

X. Performance Specification 2 of Appendix B of Part 60

In Performance Specification 2, section 13.2 would be replaced with a table that indicates the relative accuracy performance specifications.

Y. Performance Specification 3 of Appendix B of Part 60

In Performance Specification 3, the two sentences in section 12.0 that read, “Calculate the arithmetic difference between the RM and the CEMS output for each run. The average difference of the nine (or more) data sets constitute the RA.” would be deleted; these two sentences are no longer necessary since equations 3–1 and 3–2 would be moved from section 13.2 to section 12.0.

Z. Performance Specification 11 of Appendix B of Part 60

In Performance Specification 11, section 13.1, the word “average” erroneously exists in the second sentence and would be deleted.

AA. Performance Specification 15 of Appendix B of Part 60

In Performance Specification 15, section 13.0 would be added as “Method Performance (Reserved).”

BB. Performance Specification 18 of Appendix B of Part 60

In Performance Specification 18, in section 11.8.7, the last sentence would

be revised to clarify the duration of the drift check. In Table 1, the erroneous acronym “NO₂” would be replaced with “NO.” In the appendix of Performance Specification 18, the inadvertently omitted reserved section 12.0 would be added.

CC. Procedure 1 of Appendix F of Part 60

In Procedure 1, in section 5.1.2 (1), the sentence immediately following the table that reads, “Challenge the CEMS three times at each audit point, and use the average of the three responses in determining accuracy.” would be replaced with, “Inject each of the audit gases, three times each for a total of six injections. Inject the gases in such a manner that the entire CEMS is challenged. Do not inject the same gas concentration twice in succession.” In section 5.1.2 (3), the reference to EPA’s traceability protocol for gaseous calibration standards would be updated, and the language regarding the use of EPA Method 205 for dilution of audit gases would be clarified.

DD. General Provisions (Subpart A) of Part 63

Sections 63.7(g)(2), 63.7(g)(2)(v), and 63.8(e)(5)(i) of the General Provisions (subpart A) of part 63 would be revised to require the reporting of specific test data for continuous monitoring system performance evaluation tests and ongoing QA tests. These data elements would be required regardless of the format of the report, *i.e.*, electronic or paper. These modifications will ensure that performance evaluation and quality assurance test reporting include all data necessary for the compliance authority to assess and assure the quality of the reported data and that the reported information describes and identifies the specific unit covered by the evaluation test report.

EE. Wool Fiberglass Manufacturing (Subpart NNN) Part 63

In subpart NNN, the allowed filter temperature in § 63.1385(a)(5) would be revised from 120 ±14 °C to 120 ±5 °C resulting in increased precision of the filterable PM measurements.

FF. Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters (Subpart DDDDD) Part 63

In Table 6 of subpart DDDDD, row 1.f. would be revised to allow the use of EPA SW-846-7471B (for liquid samples) in addition to EPA SW-846-7470A for measuring mercury to allow flexibility.

GG. Coal- and Oil-Fired Electric Utility Steam Generating Units (Subpart UUUUU) Part 63

In subpart UUUUU, the allowed filter temperature in § 63.10010(h)(7)(i)(1) would be revised from 160 ±14 °C to 160 ±5 °C resulting in increased precision of the filterable PM measurements. In Table 5, Method 5I would be allowed as a test method option because Method 5I is designed for low PM application.

HH. Method 303 of Appendix A of Part 63

In Method 303, section 12.4, equation 303-3 would be corrected by inserting “where y = ” in front of the equation.

II. Method 308 of Appendix A of Part 63

In Method 308, deionized distilled water would replace the aqueous n-propanol solution; the affected sections are 2.0, 7.2.2, 7.2.3.3, and 11.3.2. Section 7.2.2, which defines the aqueous n-propanol solution, would be removed. Section 8.1.2 would be revised to require a leak check prior to the sampling run (in addition to after the sampling run) for QA purposes; requiring a leak check prior to the sampling run would potentially save time and money. In section 9.1, methanol spike recovery check would be added as a QC measure in Table 9.1. In section 12.1, variables used in equations 308-4 and 308-5 would be added and section 12.5, which includes equations 308-4 and 308-5, would be added. In section 13.0, the title “Reserved” would be replaced with “Method Performance” and QA requirements would be added to be consistent with other methods.

JJ. Method 320 of Appendix A of Part 63

In section 8.2.2.4, the denominator in equation 2 would be corrected from P_{SS} to P_S. In section 9.2.3, the word “where” in the statement “Calculate the dilution ratio using the tracer gas as follows: where:” would be deleted. Also in section 9.2.3, “dir” on the definition of spike is inadvertently superscripted and would be subscripted.

KK. Method 323 of Appendix A of Part 63

In Method 323, section 12.9, the denominator in equation 323-8 would be corrected.

LL. Method 325A of Appendix A of Part 63

In Method 325A, section 8.2.1.3 would be revised to clarify that only one extra sampling site is required near known sources of volatile organic compounds (VOCs) when the source is within 50 meters of the boundary and

the source is located between two monitors. The label under Figure 8.1 would be corrected from Refinery (20° angle) to Refinery (20° angle). Section 8.2.3.2 would be revised to include facilities with a monitoring perimeter length equal to 7,315 meters (24,000 feet). Section 8.2.3.3 would be added to provide clarification and an equivalent procedure in Option 2 (linear distance between sites) for site locations that parallel section 8.2.2.4 in Option 1 (radial distance between sites).

MM. Method 325B of Appendix A of Part 63

In Method 325B, section 9.3.2 would be revised to correct an error in the number of field blank samples required for a sampling period and to provide consistency with the sample analysis required in Method 325B. In sections 9.13 and 11.3.2.5, the erroneous reference to section 10.6.3 would be corrected to 10.0. Also in section 11.3.2.5, the erroneous reference to section 10.9.5 would be corrected to 9.13. Section 12.2.2 would be revised to correct the calculation of target compound concentrations at standard conditions. Sections 12.2.3 and 12.2.4 would be deleted because the equations for target concentrations are incorrect. Table 17-1 would be revised to add inadvertently omitted QC criteria from section 9.3.3.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a “significant regulatory action” under the terms of Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993) and is, therefore, not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is expected to be an Executive Order 13771 deregulatory action. This proposed rule is expected to provide meaningful burden reduction by improving data quality and providing source testers the flexibility to use newly-approved alternative procedures.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. The amendments being proposed in this action to the test methods, performance specifications, and testing regulations do not substantively revise the existing information collection requirements but rather only make corrections and minor updates to existing testing methodology. In addition, the proposed amendments clarify performance testing requirements.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. 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. This proposed rule will not impose emission measurement requirements beyond those specified in the current regulations, nor does it change any emission standard. We have, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications, as specified in Executive Order 13175. This action would correct

and update existing testing regulations. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act and 1 CFR Part 51

This action involves technical standards. The EPA proposes to use ASTM D6216–12 for continuous opacity monitors in Performance Specification 1. The ASTM D6216–12 standard covers the procedure for certifying continuous opacity monitors and includes design and performance specifications, test procedures, and QA requirements to ensure that continuous opacity monitors meet minimum design and calibration requirements, necessary in part, for accurate opacity monitoring measurements in regulatory environmental opacity monitoring applications subject to 10 percent or higher opacity standards.

The ASTM D6216–12 standard was developed and adopted by the American Society for Testing and Materials. The standard may be obtained from <http://www.astm.org> or from the ASTM at 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This action

would correct and update existing testing regulations.

List of Subjects

40 CFR Part 51

Environmental protection, Air pollution control, Performance specifications, Test methods and procedures.

40 CFR Part 60

Environmental protection, Air pollution control, Incorporation by reference, Performance specifications, Test methods and procedures.

40 CFR Part 63

Environmental protection, Air pollution control, Performance specifications, Test methods and procedures.

Dated: December 11, 2017.

E. Scott Pruitt,
Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency proposes to amend title 40, chapter I of the Code of Federal Regulations as follows:

PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401–7671q.

■ 2. Amend appendix M to part 51 as follows:

■ a. Revise section 12.5, equation 24, in Method 201A.

■ b. Revise the last sentence in section 8.2 in Method 204.

■ c. Revise section 2.1.1 in Method 205.

The revisions read as follows:

Appendix M to Part 51—Recommended Test Methods for State Implementation Plans

* * * * *

Method 201A—Determination of PM₁₀ and PM_{2.5} Emissions From Stationary Sources (Constant Sampling Rate Procedure)

* * * * *

12.5 Equations. Use the following equations to complete the calculations required in this test method.

* * * * *

Sampling Dwell Time at Each Point. N_{tp} is the total number of traverse points. You must use the preliminary velocity traverse data.

$$t_n = \left[\frac{c_p \sqrt{\Delta P_n}}{\dot{c}_p (\Delta P)^{0.5}} \right]_{\text{avg}} \left[\frac{t_r}{N_{tp}} \right] \quad (\text{Eq. 24})$$

* * * * *

Method 204—Criteria for and Verification of a Permanent or Temporary Total Enclosure

* * * * *

8.2 * * *

The NEAR must be ≤ 0.05 .

* * * * *

Method 205—Verification of Gas Dilution Systems for Field Instrument Calibrations

* * * * *

2.1.1 The gas dilution system shall be recalibrated once per calendar year using NIST-traceable flow standards with an uncertainty ≤ 0.25 percent. You shall report the results of the calibration by the person or manufacturer who carried out the calibration whenever the dilution system is used, listing the date of the most recent calibration, the due date for the next calibration, calibration point, reference flow device (ID, S/N), and acceptance criteria. Follow the manufacturer's instructions for the operation and use of the gas dilution system. A copy of the manufacturer's instructions for the operation of the instrument, as well as the most recent calibration documentation shall be made available for inspection at the test site.

* * * * *

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 3. The authority citation for part 60 continues to read as follows:

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

■ 4. In § 60.17:

■ a. Redesignate paragraphs (h)(177) through (h)(209) as (h)(178) through (h)(210).

■ b. Add new paragraph (h)(177).

The addition reads as follows:

§ 60.17 Incorporations by reference.

* * * * *

(h) * * *

(177) ASTM D6216–12, Standard Practice for Opacity Monitor Manufacturers to Certify Conformance with Design and Performance Specifications, IBR approved for appendix B to part 60: Performance Specification 1.

* * * * *

Subpart D—Standards of Performance for Fossil-Fuel-Fired Steam Generators

■ 5. Revise § 60.46(b)(2)(i) to read as follows:

§ 60.46 Test methods and procedures.

* * * * *

(b) * * *

(2) * * *

(i) The sampling time and sample volume for each run shall be at least 60 minutes and 0.85 dscm (30 dscf). The probe and filter holder heating systems in the sampling train shall be set to provide an average gas temperature of 160 ± 5 °C (320 ± 9 °F).

* * * * *

Subpart Da—Standards of Performance for Electric Utility Steam Generating Units

■ 6. Revise § 60.50Da (b)(1)(ii)(A) to read as follows:

§ 60.50Da Compliance determination procedures and methods.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(A) The sampling time and sample volume for each run shall be at least 120 minutes and 1.70 dscm (60 dscf). The probe and filter holder heating system in the sampling train may be set to provide an average gas temperature of no greater than 160 ± 5 °C (320 ± 9 °F).

* * * * *

Subpart Db—Standards of Performance for Industrial-Commercial-Institutional Steam Generating Units

■ 7. Revise § 60.46b (d)(4) to read as follows:

§ 60.46b Compliance and performance test methods and procedures for particulate matter and nitrogen oxides.

* * * * *

(d) * * *

(4) For Method 5 of appendix A of this part, the temperature of the sample gas in the probe and filter holder is monitored and is maintained at 160 ± 5 °C (320 ± 9 °F).

* * * * *

Subpart Dc—Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units

■ 8. Revise § 60.45c(a)(5) to read as follows:

§ 60.45c Compliance and performance test methods and procedures for particulate matter.

(a) * * *

(5) For Method 5 or 5B of appendix A of this part, the temperature of the sample gas in the probe and filter holder shall be monitored and maintained at 160 ± 5 °C (320 ± 9 °F).

* * * * *

Subpart Ea—Standards of Performance for Municipal Waste Combustors for Which Construction Is Commenced After December 20, 1989 and On or Before September 20, 1994

■ 9. Revise § 60.58a(b)(3) to read as follows:

§ 60.58a Compliance and performance testing.

* * * * *

(b) * * *

(3) Method 5 shall be used for determining compliance with the particulate matter emission limit. The minimum sample volume shall be 1.7 cubic meters (60 cubic feet). The probe and filter holder heating systems in the sample train shall be set to provide a gas temperature of 160 ± 5 °C (320 ± 9 °F). An oxygen or carbon dioxide measurement shall be obtained simultaneously with each Method 5 run.

* * * * *

Subpart CC—Standards of Performance for Glass Manufacturing Plants

■ 10. Revise § 60.293(f) to read as follows:

§ 60.293 Standards for particulate matter from glass melting furnace with modified-processes.

* * * * *

(f) Test methods and procedures as specified in § 60.296 shall be used to determine compliance with this section except that to determine compliance for any glass melting furnace using modified processes and fired with either a gaseous fuel or a liquid fuel containing less than 0.50 weight percent sulfur, Method 5 shall be used with the probe and filter holder heating system in the sampling train set to provide a gas temperature of 120 ± 5 °C (248 ± 9 °F).

* * * * *

■ 11. Revise § 60.296(d)(2) to read as follows:

§ 60.296 Test methods and procedures.

* * * * *

(d) * * *

(2) Method 5 shall be used to determine the particulate matter concentration (c_s) and volumetric flow rate (Q_{sd}) of the effluent gas. The sampling time and sample volume for each run shall be at least 60 minutes and 0.90 dscm (31.8 dscf). The probe and filter holder heating system may be set to provide a gas temperature no greater than $177 \pm 5^\circ\text{C}$ ($350 \pm 9^\circ\text{F}$), except under the conditions specified in § 60.293(e).

* * * * *

■ 12. Revise “(CO₂)_a” in section 12.1 in Method 2B of appendix A–1 to part 60 to read as follows:

Appendix A–1 to Part 60—Test Methods 1 Through 2F

* * * * *

Method 2B—Determination of Exhaust Gas Volume Flow Rate From Gasoline Vapor Incinerators

* * * * *

12.1 Nomenclature.

* * * * *

(CO₂)_a = Ambient carbon dioxide concentration, ppm (if not measured during the test period, may be assumed to equal the global monthly mean CO₂ concentration posted at http://www.esrl.noaa.gov/gmd/ccgg/trends/global.html#global_data).

* * * * *

■ 13. In appendix A–3 to part 60:

■ a. Revise sections 2.0, 6.1.1.2, 6.1.1.6, 6.1.1.7, 6.1.1.9, and 8.5 in Method 5.

■ b. Revise sections 2.0, 6.1, 8.2, and 11.0 in Method 5B.

■ c. Add section 17.0 in Method 5B.

■ d. Revise sections 2.1 and 8.5.2.2 in Method 5I.

The revisions read as follows:

Appendix A–3 to Part 60—Test Methods 4 Through 5I

* * * * *

Method 5—Determination of Particulate Matter Emissions From Stationary Sources

* * * * *

2.0 Summary of Method. Particulate matter is withdrawn isokinetically from the source and collected on a glass fiber filter maintained at a temperature of $120 \pm 5^\circ\text{C}$ ($248 \pm 9^\circ\text{F}$) or such other temperature as specified by an applicable subpart of the standards or approved by the Administrator for a particular application. The PM mass, which includes any material that condenses at or above the filtration temperature, is determined gravimetrically after the removal of uncombined water.

* * * * *

6.1.1.2 Probe Liner. Borosilicate or quartz glass tubing with a heating system capable of maintaining a probe gas temperature during

sampling of $120 \pm 5^\circ\text{C}$ ($248 \pm 9^\circ\text{F}$), or such other temperature as specified by an applicable subpart of the standards or as approved by the Administrator for a particular application. Since the actual temperature at the outlet of the probe is not usually monitored during sampling, probes constructed according to APTD–0581 and utilizing the calibration curves of APTD–0576 (or calibrated according to the procedure outlined in APTD–0576) will be considered acceptable. Either borosilicate or quartz glass probe liners may be used for stack temperatures up to about 480°C (900°F); quartz glass liners shall be used for temperatures between 480 and 900°C (900 and $1,650^\circ\text{F}$). Both types of liners may be used at higher temperatures than specified for short periods of time, subject to the approval of the Administrator. The softening temperature for borosilicate glass is 820°C (1500°F), and for quartz glass it is 1500°C (2700°F). Whenever practical, every effort should be made to use borosilicate or quartz glass probe liners. Alternatively, metal liners (e.g., 316 stainless steel, Incoloy 825 or other corrosion resistant metals) made of seamless tubing may be used, subject to the approval of the Administrator.

* * * * *

6.1.1.6 Filter Heating System. Any heating system capable of monitoring and maintaining temperature around the filter shall be used to ensure the sample gas temperature exiting the filter of $120 \pm 5^\circ\text{C}$ ($248 \pm 9^\circ\text{F}$) during sampling or such other temperature as specified by an applicable subpart of the standards or approved by the Administrator for a particular application. The monitoring and regulation of the temperature around the filter may be done with the filter temperature sensor or another temperature sensor.

6.1.1.7 Filter Temperature Sensor. A temperature sensor capable of measuring temperature to within $\pm 3^\circ\text{C}$ (5.4°F) shall be installed so that the sensing tip of the temperature sensor is in direct contact with the sample gas exiting the filter. The sensing tip of the sensor may be encased in glass, Teflon, or metal and must protrude at least $\frac{1}{2}$ in. into the sample gas exiting the filter. The filter temperature sensor must be monitored and recorded during sampling to ensure a sample gas temperature exiting the filter of $120 \pm 5^\circ\text{C}$ ($248 \pm 9^\circ\text{F}$), or such other temperature as specified by an applicable subpart of the standards or approved by the Administrator for a particular application.

* * * * *

6.1.1.9 Metering System. Vacuum gauge, leak-free pump, calibrated temperature sensors, dry gas meter (DGM) capable of measuring volume to within 2 percent, and related equipment, as shown in Figure 5–1. Other metering systems capable of maintaining sampling rates within 10 percent of isokinetic and of determining sample volumes to within 2 percent may be used, subject to the approval of the Administrator. When the metering system is used in conjunction with a pitot tube, the system shall allow periodic checks of isokinetic rates. The average DGM temperature for use in the calculations of Section 12.0 may be obtained by averaging the two temperature

sensors located at the inlet and outlet of the DGM as shown in Figure 5–3 or alternatively from a single temperature sensor located at the immediate outlet of the DGM or the plenum of the DGM.

* * * * *

8.5 Sampling Train Operation. During the sampling run, maintain an isokinetic sampling rate (within 10 percent of true isokinetic unless otherwise specified by the Administrator) and a sample gas temperature through the filter of $120 \pm 5^\circ\text{C}$ ($248 \pm 9^\circ\text{F}$) or such other temperature as specified by an applicable subpart of the standards or approved by the Administrator. Note: After startup of the sampling system, it may take several minutes to equilibrate the system and temperature reading to within the required temperature threshold.

* * * * *

Method 5B—Determination of Nonsulfuric Acid Particulate Matter Emissions From Stationary Sources

* * * * *

2.0 Summary of Method

Particulate matter is withdrawn isokinetically from the source and collected on a glass fiber filter maintained at a temperature of $160 \pm 5^\circ\text{C}$ ($320 \pm 9^\circ\text{F}$). The collected sample is then heated in an oven at 160°C (320°F) for 6 hours to volatilize any condensed sulfuric acid that may have been collected, and the nonsulfuric acid particulate mass is determined gravimetrically.

* * * * *

6.1 Sample Collection.

The probe liner heating system and filter heating system must be capable of maintaining a sample gas temperature of $160 \pm 5^\circ\text{C}$ ($320 \pm 9^\circ\text{F}$).

* * * * *

8.2 Probe and Filter Temperatures.

Maintain the probe outlet and filter temperatures at $160 \pm 5^\circ\text{C}$ ($320 \pm 9^\circ\text{F}$). Note: After start-up of the sampling system, it may take several minutes to equilibrate the system and temperature reading to within the required temperature threshold.

* * * * *

11.0 Analytical Procedure

11.1 Record and report the data required on a sheet such as the one shown in Figure 5B–1.

11.2 Handle each sample container as follows:

11.2.1 Container No. 1. Leave the contents in the shipping container or transfer the filter and any loose PM from the sample container to a tared glass weighing dish. Oven dry the filter sample at a temperature of $160 \pm 5^\circ\text{C}$ ($320 \pm 9^\circ\text{F}$) for 6 hours. Cool in a desiccator for 2 hours, and weigh to constant weight. Report the results to the nearest 0.1 mg. For the purposes of this section, the term “constant weight” means a difference of no more than 0.5 mg or 1 percent of total weight less tare weight, whichever is greater, between two consecutive weighings, with no less than 6 hours of desiccation time between weighings.

11.2.2 Container No. 2. Note the level of liquid in the container, and confirm on the

analysis sheet whether leakage occurred during transport. If a noticeable amount of leakage has occurred, either void the sample or use methods, subject to the approval of the Administrator, to correct the final results. Measure the liquid in this container either volumetrically to ± 1 ml or gravimetrically to ± 0.5 g. Transfer the contents to a tared 250 ml beaker, and evaporate to dryness at ambient temperature and pressure. Then oven dry the probe sample at a temperature of 160 ± 5 °C (320 ± 9 °F) for 6 hours. Cool in a desiccator for 2 hours, and weigh to constant weight. Report the results to the nearest 0.1 mg.

11.2.3 Container No. 3. Weigh the spent silica gel (or silica gel plus impinger) to the nearest 0.5 g using a balance. This step may be conducted in the field.

11.2.4 Acetone Blank Container. Measure the acetone in this container either volumetrically or gravimetrically. Transfer the acetone to a tared 250 ml beaker, and evaporate to dryness at ambient temperature and pressure. Desiccate for 24 hours, and weigh to a constant weight. Report the results to the nearest 0.1 mg.

Note: The contents of Container No. 2 as well as the acetone blank container may be

evaporated at temperatures higher than ambient. If evaporation is done at an elevated temperature, the temperature must be below the boiling point of the solvent; also, to prevent "bumping," the evaporation process must be closely supervised, and the contents of the beaker must be swirled occasionally to maintain an even temperature. Use extreme care, as acetone is highly flammable and has a low flash point.

* * * * *

17.0 Tables, Diagrams, Flowcharts, and Validation Data

Container number	Weight of particulate collected, mg		
	Final weight	Tare weight	Weight gain
1.			
2.			
Total:			
Less acetone blank			
Weight of particulate matter			
	Volume of liquid water collected		g* ml
	Impinger volume, ml	Silica gel weight, g	
Final			
Initial			
Liquid collected			
Total volume collected			

*Convert weight of water to volume by dividing total weight increase by density of water (1 g/ml).

Figure 5B–1. Analytical Data Sheet

* * * * *

Method 51—Determination of Low Level Particulate Emissions From Stationary Sources

* * * * *

2.1. Description. The system setup and operation is essentially identical to Method 5. Particulate is withdrawn isokinetically from the source and collected on a 47 mm glass fiber filter maintained at a temperature of 120 ± 5 °C (248 ± 9 °F). The PM mass is determined by gravimetric analysis after the removal of uncombined water. Specific measures in this procedure designed to improve system performance at low particulate levels include:

1. Improved sample handling procedures
2. Light weight sample filter assembly
3. Use of low residue grade acetone

Accuracy is improved through the minimization of systemic errors associated with sample handling and weighing procedures. High purity reagents, all glass, grease free, sample train components, and light weight filter assemblies and beakers, each contribute to the overall objective of improved precision and accuracy at low particulate concentrations.

* * * * *

8.5.2.2 Care should be taken to maintain the filter box temperature of the paired trains as close as possible to the Method required temperature of 120 ± 5 °C (248 ± 9 °F). If separate ovens are being used for simultaneously operated trains, it is recommended that the oven temperature of

each train be maintained within ± 5 °C (± 9 °F) of each other. Note: After startup of the sampling system, it may take several minutes to equilibrate the system and temperature reading to within the required temperature threshold.

* * * * *

- 14. In appendix A–4 to part 60:
- a. Revise sections 10.1.2 and 11.3 in Method 7.
- b. Redesignate sections 6.1.1.1 through 6.1.1.4 to read as sections 6.1.1.2 through 6.1.1.5 in Method 8.
- c. Add a new section 6.1.1.1 in Method 8.
- d. Revise Figure 8–1 in Method 8.

Appendix A–4 to Part 60—Test Methods 6 Through 10B

* * * * *

Method 7—Determination of Nitrogen Oxide Emissions From Stationary Sources

* * * * *

10.1.2 Determination of Spectrophotometer Calibration Factor K_c . Add 0 ml, 2.0 ml, 4.0 ml, 6.0 ml, and 8.0 ml of the KNO_3 working standard solution (1 ml = 100 μ g NO_2) to a series of five 50-ml volumetric flasks. To each flask, add 25 ml of absorbing solution and 10 ml water. Add 1 N NaOH to each flask until the pH is between 9 and 12 (about 25 to 35 drops). Dilute to the mark with water. Mix thoroughly, and pipette a 25-ml aliquot of each solution into a separate porcelain evaporating dish. Beginning with the evaporation step, follow the analysis

procedure of section 11.2 until the solution has been transferred to the 100-ml volumetric flask and diluted to the mark. Measure the absorbance of each solution at the optimum wavelength as determined in section 10.1.1.2. This calibration procedure must be repeated on each day that samples are analyzed. Calculate the spectrophotometer calibration factor as shown in section 12.2.

* * * * *

11.3 Sample Analysis. Mix the contents of the flask thoroughly, and measure the absorbance at the optimum wavelength used for the standards (Section 10.1.1.2), using the blank solution as a zero reference. Dilute the sample and the blank with equal volumes of water if the absorbance exceeds A_4 , the absorbance of the 400- μ g NO_2 standard (see section 10.1.3).

* * * * *

Method 8—Determination of Sulfuric Acid and Sulfur Dioxide Emissions From Stationary Sources

* * * * *

6.1.1.1 Probe Nozzle. Borosilicate or quartz glass with a sharp, tapered leading edge and coupled to the probe liner using a Teflon union. When the stack temperature exceeds 210 °C (410 °F), a leak-free ground glass fitting or other leak free, non-contaminating fitting must be used to couple the nozzle to the probe liner. It is also acceptable to use a one-piece glass nozzle/liner assembly. The angle of the taper shall be $>30^\circ$, and the taper shall be on the outside to preserve a constant internal diameter. The probe nozzle shall be of the button-hook or elbow design, unless otherwise specified by

the Administrator. Other materials of construction may be used, subject to the approval of the Administrator. A range of nozzle sizes suitable for isokinetic sampling should be available. Typical nozzle sizes range from 0.32 to 1.27 cm ($\frac{1}{8}$ to $\frac{1}{2}$ in) inside diameter (ID) in increments of 0.16 cm ($\frac{1}{16}$ in). Larger nozzle sizes are also available if higher volume sampling trains are used.

6.1.1.2 Probe Liner. Borosilicate or quartz glass, with a heating system to prevent visible condensation during sampling. Do not use metal probe liners.

6.1.1.3 Filter Holder. Borosilicate glass, with a glass frit filter support and a silicone rubber gasket. Other gasket materials (e.g., Teflon or Viton) may be used, subject to the approval of the Administrator. The holder design shall provide a positive seal against leakage from the outside or around the filter. The filter holder shall be placed between the first and second impingers. Do not heat the filter holder.

6.1.1.4 Impingers. Four, of the Greenburg-Smith design, as shown in Figure 8-1. The first and third impingers must have standard

tips. The second and fourth impingers must be modified by replacing the insert with an approximately 13-mm ($\frac{1}{2}$ -in.) ID glass tube, having an unconstricted tip located 13 mm ($\frac{1}{2}$ in.) from the bottom of the impinger. Similar collection systems, subject to the approval of the Administrator, may be used.

6.1.1.5 Temperature Sensor. Thermometer, or equivalent, to measure the temperature of the gas leaving the impinger train to within 1 °C (2 °F).

* * * * *

BILLING CODE 6560-50-P

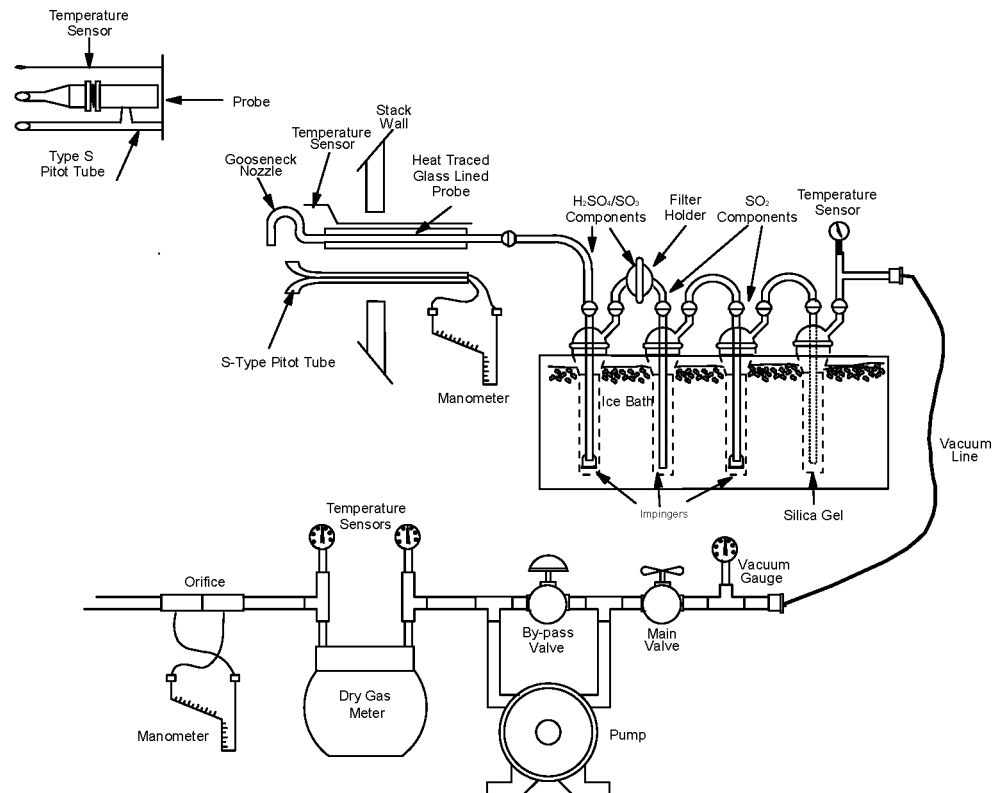


Figure 8-1. Sulfuric Acid Sampling Train

BILLING CODE 6560-50-P

* * * * *

■ 15. Redesignate paragraph (c) as paragraph (b) in section 13.1 in Method 18 of appendix A-6 to part 60 to read as follows:

Appendix A-6 to Part 60—Test Methods 16 Through 18

* * * * *

Method 18—Measurement of Gaseous Organic Compound Emissions by Gas Chromatography

* * * * *

13.1 * * *

(b) Recovery. After developing an appropriate sampling and analytical system for the pollutants of interest, conduct the procedure in section 8.4. Conduct the appropriate recovery study in section 8.4 at each sampling point where the method is being applied. Submit the data and results of the recovery procedure with the reporting of results under section 8.3.

* * * * *

■ 16. In appendix A-7 to part 60:

■ a. Revise sections 11.2.1 and 11.2.2 in Method 22.

■ b. Add section 11.2.3 in Method 22.

The revisions read as follows:

Appendix A-7 to Part 60—Test Methods 19 Through 25E

* * * * *

Method 22—Visual Determination of Fugitive Emissions From Material Sources and Smoke Emissions From Flares

* * * * *

11.2.1 Outdoor Location. Record the following information on the field data sheet (Figure 22-1): Company name, industry, process unit, observer's name, observer's affiliation, and date. Record also the

estimated wind speed, wind direction, and sky condition. Sketch the process unit being observed, and note the observer location relative to the source and the sun. Indicate the potential and actual emission points on the sketch. Alternatively, digital photography as described in Section 11.2.3 may be used for a subset of the recordkeeping requirements of this section.

11.2.2 Indoor Location. Record the following information on the field data sheet (Figure 22–2): Company name, industry, process unit, observer's name, observer's affiliation, and date. Record as appropriate the type, location, and intensity of lighting on the data sheet. Sketch the process unit being observed, and note the observer location relative to the source. Indicate the potential and actual fugitive emission points on the sketch. Alternatively, digital photography as described in Section 11.2.3 may be used for a subset of the recordkeeping requirements of this section.

11.2.3 Digital Photographic Records. Digital photographs, annotated or unaltered, may be used to record and report sky conditions, observer's location relative to the source, observer's location relative to the sun, process unit being observed, potential emission points and actual emission points for the requirements in Sections 11.2.1 and

11.2.2. The image must have the proper lighting, field of view and depth of field to properly distinguish the sky condition (if applicable), process unit, potential emission point and actual emission point. At least one digital photograph must be from the point of the view of the observer. The photograph(s) representing the environmental conditions must be taken within reasonable time of the observation (*i.e.*, 15 mins). Any photographs altered or annotated must be retained in an unaltered format for recordkeeping purposes.

■ 17. In appendix A–8 to part 60:

- a. Revise section 6.2.2 in Method 26.
- b. Revise section 6.2.1 in Method 26A.
- c. Add section 6.2.4 in Method 26A.
- d. Revise equation 8 in section 13.5.1 in Test Method 28WHH.

The revisions read as follows:

Appendix A–8 to Part 60—Test Methods 26 Through 30B

* * * * *

Method 26—Determination of Hydrogen Halide and Halogen Emissions From Stationary Sources Non-Isokinetic Method

* * * * *

6.2.2 Storage Bottles. 100- or 250-ml, high-density polyethylene or glass sample storage containers with Teflon screw cap liners to store impinger samples.

* * * * *

Method 26A—Determination of Hydrogen Halide and Halogen Emissions From Stationary Sources Isokinetic Method

* * * * *

6.2.1 Probe-Liner and Probe-Nozzle Brushes, Wash Bottles, Petri Dishes, Graduated Cylinder and/or Balance, and Rubber Policeman. Same as Method 5, sections 6.2.1, 6.2.2, 6.2.4, 6.2.5, and 6.2.7.

* * * * *

6.2.4 Sample Storage Containers. High-density polyethylene or glass sample storage containers with Teflon screw cap liners to store impinger samples.

Test Method 28WHH for Measurement of Particulate Emissions and Heating Efficiency of Wood-Fired Hydronic Heating Appliances

* * * * *

13.5.1 * * *

$$\sigma_i = (62.56 + (-0.0003413 \times T_{3i}) + (-0.00006225 \times T_{3i}^2)) 0.1337, \text{ lbs/gal} \quad \text{Eq. 8}$$

* * * * *

■ 18. In appendix B to part 60:

- a. Revise sections 2.1, 3.1, 6.1, 8.1(1), 8.1(3)(ii), 8.2(1), 8.2(2), 8.2(3), 9.0, 12.1, 13.1, 13.2, and 16.0 8. in Performance Specification 1.
- b. Revise section 13.2 in Performance Specification 2.
- c. Revise sections 12.0 and 13.2 in Performance Specification 3.
- d. Revise section 13.1 in Performance Specification 11.
- e. Add section 13.0 in Performance Specification 15.
- f. Revise section 11.8.7 and table 1 in Performance Specification 18.
- g. Add section 12.0 to Appendix A of Performance Specification 18.

The revisions read as follows:

Appendix B to Part 60—Performance Specifications

* * * * *

Performance Specification 1—Specifications and Test Procedures for Continuous Opacity Monitoring Systems in Stationary Sources

* * * * *

2.1 ASTM D6216–12 (incorporated by reference, see § 60.17) is the reference for design specifications, manufacturer's performance specifications, and test procedures. The opacity monitor manufacturer must periodically select and test an opacity monitor, that is representative of a group of monitors produced during a specified period or lot, for conformance with

the design specifications in ASTM D6216–12. The opacity monitor manufacturer must test each opacity monitor for conformance with the manufacturer's performance specifications in ASTM D6216–12. Note: If the initial certification of the opacity monitor occurred before January 26, 2018 using D6216–98, D6216–03, or D6216–07, it is not necessary to recertify using D6216–12.

3.1 All definitions and discussions from section 3 of ASTM D6216–12 are applicable to PS–1.

* * * * *

6.1 *Continuous Opacity Monitoring System.* You, as owner or operator, are responsible for purchasing an opacity monitor that meets the specifications of ASTM D6216–12, including a suitable data recorder or automated data acquisition handling system. Example data recorders include an analog strip chart recorder or more appropriately an electronic data acquisition and reporting system with an input signal range compatible with the analyzer output.

* * * * *

8.1 * * *

(1) You must purchase an opacity monitor that complies with ASTM D6216–12 and obtain a certificate of conformance from the opacity monitor manufacturer.

(2) * * *

(3) * * *

(ii) Calibration Error Check. Conduct a three-point calibration error test using three calibration attenuators that produce outlet pathlength corrected, single-pass opacity

values shown in ASTM D6216–12, section 7.5. If your applicable limit is less than 10 percent opacity, use attenuators as described in ASTM D6216–12, section 7.5 for applicable standards of 10 to 19 percent opacity. Confirm the external audit device produces the proper zero value on the COMS data recorder. Separately, insert each calibration attenuators (low, mid, and high-level) into the external audit device. While inserting each attenuator, (1) ensure that the entire light beam passes through the attenuator, (2) minimize interference from reflected light, and (3) leave the attenuator in place for at least two times the shortest recording interval on the COMS data recorder. Make a total of five nonconsecutive readings for each attenuator. At the end of the test, correlate each attenuator insertion to the corresponding value from the data recorder. Subtract the single-pass calibration attenuator values corrected to the stack exit conditions from the COMS responses. Calculate the arithmetic mean difference, standard deviation, and confidence coefficient of the five measurements value using equations 1–3, 1–4, and 1–5. Calculate the calibration error as the sum of the absolute value of the mean difference and the 95 percent confidence coefficient for each of the three test attenuators using equation 1–6. Report the calibration error test results for each of the three attenuators.

* * * * *

8.2 * * *

(1) Conduct the verification procedures for design specifications in section 6 of ASTM D6216–12.

(2) Conduct the verification procedures for performance specifications in section 7 of ASTM D6216–12.

(3) Provide to the owner or operator, a report of the opacity monitor's conformance to the design and performance specifications required in sections 6 and 7 of ASTM D6216–12 in accordance with the reporting requirements of section 9 in ASTM D6216–12.

* * * * *

9.0 What quality control measures are required by PS-1?

Opacity monitor manufacturers must initiate a quality program following the requirements of ASTM D6216–12, section 8. The quality program must include (1) a quality system and (2) a corrective action program.

* * * * *

12.1 Desired Attenuator Values. Calculate the desired attenuator value corrected to the emission outlet pathlength as follows:

$$OP_2 = 1 - (1 - OP_1)^{\frac{L_2}{L_1}} \quad \text{Eq. 1-1}$$

Where:

OP₁ = Nominal opacity value of required low-, mid-, or high-range calibration attenuators.

OP₂ = Desired attenuator opacity value from ASTM D6216–12, section 7.5 at the opacity limit required by the applicable subpart.

L₁ = Monitoring pathlength.

L₂ = Emission outlet pathlength.

* * * * *

13.1 Design Specifications. The opacity monitoring equipment must comply with the design specifications of ASTM D6216–12.

13.2 Manufacturer's Performance Specifications. The opacity monitor must comply with the manufacturer's performance specifications of ASTM D6216–12.

* * * * *

16.0 * * *

8. ASTM D6216–12: Standard Practice for Opacity Monitor Manufacturers to Certify Conformance with Design and Performance Specifications. American Society for Testing and Materials (ASTM). April 1998.

* * * * *

Performance Specification 2—Specifications and Test Procedures for SO₂ and NO_x Continuous Emission Monitoring Systems in Stationary Sources

* * * * *

13.2 Relative Accuracy Performance Specification.

	Calculate . . .	RA criteria (%)
If average emissions during the RATA are ≥50% of emission standard.	Use Eq. 2–6, with RM in the denominator	<20.0
If average emissions during the RATA are <50% of emission standard.	Use Eq. 2–6, emission standard in the denominator	<10.0
For SO ₂ emission standards <130 but> 86 ng/J (0.30 and 0.20 lb/million Btu).	Use Eq. 2–6, emission standard in the denominator	<15.0
For SO ₂ emission standards <86 ng/J (0.20 lb/million Btu)	Use Eq. 2–6, emission standard in the denominator	<20.0

* * * * *

Performance Specification 3—Specifications and Test Procedures for O₂ and CO₂ Continuous Emission Monitoring Systems in Stationary Sources

* * * * *

12.0 Calculations and Data Analysis

Summarize the results on a data sheet similar to that shown in Figure 2.2 of PS2.

$$RA = \frac{[|\bar{d}| + |CC|]}{\overline{RM}} \times 100$$

Eq. 3-1

Where:

$|\bar{d}|$ = Absolute value of the mean of the differences (from Equation 2-3 of Performance Specification 2).

$|CC|$ = Absolute value of the confidence coefficient (from Equation 2-5 of Performance Specification 2).

\overline{RM} = Average Reference Method Value

$$RA = \frac{|\overline{RM} - \overline{CEMS}|}{\overline{RM}} \times 100 \quad \text{Eq. 3 - 2}$$

\overline{RM} = Average Reference Method Value

\overline{CEMS} = Average CEMS Value

* * * * *

13.2 CEMS Relative Accuracy Performance Specification. The RA of the

CEMS must be no greater than 20.0 percent of the mean value of the reference method

(RM) data when calculated using equation 3–1. The results are also acceptable if the result of Equation 3–2 is less than or equal to 1.0 percent O₂ (or CO₂).

* * * * *

Performance Specification 11—Specifications and Test Procedures for Particulate Matter Continuous Emission Monitoring Systems at Stationary Sources

* * * * *

13.1 What is the 7-day drift check performance specification? Your daily PM CEMS internal drift checks must demonstrate that the daily drift of your PM CEMS does not deviate from the value of the reference light, optical filter, Beta attenuation signal, or other technology-suitable reference standard by more than 2 percent of the response range. If your CEMS includes diluent and/or auxiliary monitors (for temperature, pressure, and/or moisture) that are employed as a necessary part of this performance specification, you must determine the calibration drift separately for each ancillary monitor in terms of its respective output (see the appropriate performance specification for the diluent CEMS specification). None of the calibration drifts may exceed their individual specification.

* * * * *

Performance Specification 15—Performance Specification for Extractive FTIR Continuous Emissions Monitor Systems in Stationary Sources

* * * * *

13.0 Method Performance [Reserved]

* * * * *

Performance Specification 18—Performance Specifications and Test Procedures for Gaseous Hydrogen Chloride (HCl) Continuous Emission Monitoring Systems at Stationary Sources

* * * * *

11.8.7 The zero-level and mid-level CD for each day must be less than 5.0 percent of the span value as specified in section 13.2 of this PS. You must meet this criterion for 7 consecutive operating days.

* * * * *

TABLE 1—INTERFERENCE TEST GAS CONCENTRATIONS

Potential interferent gas ¹	Approximate concentration (balance N ₂)
CO ₂	15% ± 1% CO ₂ . ²
CO	100 ± 20 ppm.
CH ₂ O	20 ± 5 ppm.
CH ₄	100 ± 20 ppm.
NH ₃	10 ± 5 ppm (extractive CEMS only).
NO	250 ± 50 ppm.
SO ₂	200 ± 20 ppm.
O ₂	3% ± 1% O ₂ . ²
H ₂ O	10% ± 1% H ₂ O. ²
N ₂	Balance. ²

¹ Any of these specific gases can be tested at a lower level if the manufacturer has provided reliable means for limiting or scrubbing that gas to a specified level in CEMS field installations.

² Gases for short path IP cell interference tests cannot be added above 100 percent stack equivalent concentration. Add these gases at the indicated percentages to make up the remaining cell volume.

* * * * *

PS-18 Appendix A—Standard Addition Procedures

* * * * *

12.0 Reserved

* * * * *

■ 19. Revise sections 5.1.2(1) and 5.1.2(3) in Procedure 1 of appendix F to part 60 to read as follows:

Appendix F to Part 60—Quality Assurance Procedures

Procedure 1—Quality Assurance Requirements for Gas Continuous Emission Monitoring Systems Used for Compliance Determination

* * * * *

5.1.2 Cylinder Gas Audit (CGA). If applicable, a CGA may be conducted in three of four calendar quarters, but in no more than three quarters in succession.

To conduct a CGA: (1) Challenge the CEMS (both pollutant and diluent portions of the CEMS, if applicable) with an audit gas of known concentration at two points within the following ranges:

Audit point	Audit range		
	Pollutant monitors	Diluent monitors for—	
		CO ₂	O ₂
1	20 to 30% of span value	5 to 8% by volume	4 to 6% by volume.
2	50 to 60% of span value	10 to 14% by volume	8 to 12% by volume.

Inject each of the audit gases, three times each for a total of six injections. Inject the gases in such a manner that the entire CEMS is challenged. Do not inject the same gas concentration twice in succession.

Use of separate audit gas cylinder for audit points 1 and 2. Do not dilute gas from audit cylinder when challenging the CEMS.

The monitor should be challenged at each audit point for a sufficient period of time to assure adsorption-desorption of the CEMS sample transport surfaces has stabilized.

(2) * * *

(3) Use Certified Reference Materials (CRM's) (See Citation 1) audit gases that have been certified by comparison to National Institute of Standards and Technology (NIST) Standard Reference Materials (SRM's) or EPA Protocol Gases following the most recent edition of the EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (See Citation 2). Procedures for preparation of CRM's are described in Citation 1. Procedures for preparation of EPA Protocol Gases are

described in Citation 2. In the case that a suitable audit gas level is not commercially available, Method 205 (See Citation 3) may be used to dilute CRM's or EPA Protocol Gases to the needed level. The difference between the actual concentration of the audit gas and the concentration indicated by the monitor is used to assess the accuracy of the CEMS.

* * * * *

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 20. The authority citation for part 63 continues to read as follows:

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

■ 21. In § 63.7, revise paragraphs (g)(2) introductory text and (g)(2)(v) to read as follows:

§ 63.7 Performance testing requirements.

* * * * *

(g) * * *

(2) Contents of a performance test, CMS performance evaluation, or CMS quality assurance test report (electronic or paper submitted copy). Unless otherwise specified in a relevant standard, test method, CMS performance specification, or quality assurance requirement for a CMS, or as otherwise approved by the Administrator in writing, the report shall include the elements identified in paragraphs (g)(2)(i) through (vi) of this section.

* * * * *

(v) Where a test method, CMS performance specification, or on-going quality assurance requirement for a CMS requires you record or report, the following shall be included in your

report: Record of preparation of standards, record of calibrations, raw data sheets for field sampling, raw data sheets for field and laboratory analyses, chain-of-custody documentation, and example calculations for reported results.

* * * * *

■ 22. In § 63.8, revise paragraph (e)(5)(i) to read as follows:

§ 63.8 Monitoring requirements.

* * * * *

(e) * * *

(5) * * * (i) The owner or operator shall furnish the Administrator a copy of a written report of the results of the performance evaluation containing the information specified in § 63.7(g)(2)(i) through (vi) within 60 days of

completion of the performance evaluation, unless otherwise specified in a relevant standard.

* * * * *

Subpart NNN—National Emission Standards for Hazardous Air Pollutants for Wool Fiberglass Manufacturing

■ 23. Revise § 63.1385(a)(5) to read as follows:

§ 63.1385 Test methods and procedures.

(a) * * *

(5) Method 5 or Method 29 (40 CFR part 60, appendix A–3) for the concentration of total PM. When using Method 5, each run must consist of a minimum sample volume of 2 dry standard cubic meters (dscm). When

using Method 29, each run must consist of a minimum sample volume of 3 dscm. When measuring PM concentration using either Method 5 or 29, the probe and filter holder heating system must be set to provide a gas temperature no greater than 120 ± 5 °C (248 ± 9 °F).

* * * * *

Subpart DDDDD—National Emission Standards for Hazardous Air Pollutants for Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters

* * * * *

■ 24. Revise Table 6 to Subpart DDDDD of part 63 to read as follows:

TABLE 6 TO SUBPART DDDDD OF PART 63—FUEL ANALYSIS REQUIREMENTS

[As stated in § 63.7521, you must comply with the following requirements for fuel analysis testing for existing, new or reconstructed affected sources. However, equivalent methods (as defined in § 63.7575) may be used in lieu of the prescribed methods at the discretion of the source owner or operator]

To conduct a fuel analysis for the following pollutant . . .	You must . . .	Using . . .
1. Mercury	<p>a. Collect fuel samples</p> <p>b. Composite fuel samples</p> <p>c. Prepare composited fuel samples.</p> <p>d. Determine heat content of the fuel type.</p> <p>e. Determine moisture content of the fuel type.</p> <p>f. Measure mercury concentration in fuel sample.</p> <p>g. Convert concentration into units of pounds of mercury per MMBtu of heat content.</p>	<p>Procedure in § 63.7521(c) or ASTM D5192,^a or ASTM D7430,^a or ASTM D6883,^a or ASTM D2234/D2234M^a (for coal) or EPA 1631 or EPA 1631E or ASTM D6323^a (for solid), or EPA 821–R–01–013 (for liquid or solid), or ASTM D4177^a (for liquid), or ASTM D4057^a (for liquid), or equivalent.</p> <p>Procedure in § 63.7521(d) or equivalent.</p> <p>EPA SW–846–3050B^a (for solid samples), ASTM D2013/D2013M^a (for coal), ASTM D5198^a (for biomass), or EPA 3050^a (for solid fuel), or EPA 821–R–01–013^a (for liquid or solid), or equivalent.</p> <p>ASTM D5865^a (for coal) or ASTM E711^a (for biomass), or ASTM D5864^a for liquids and other solids, or ASTM D240^a or equivalent.</p> <p>ASTM D3173,^a ASTM E871,^a or ASTM D5864,^a or ASTM D240, or ASTM D95^a (for liquid fuels), or ASTM D4006^a (for liquid fuels), or equivalent.</p> <p>ASTM D6722^a (for coal), EPA SW–846–7471B^a or EPA 1631 or EPA 1631E (for solid samples), or EPA SW–846–7470A^a or EPA SW–846–7471B^a (for liquid samples), or EPA 821–R–01–013 (for liquid or solid), or equivalent.</p> <p>For fuel mixtures use Equation 8 in § 63.7530.</p>
2. HCl	<p>a. Collect fuel samples</p> <p>b. Composite fuel samples</p> <p>c. Prepare composited fuel samples.</p> <p>d. Determine heat content of the fuel type.</p> <p>e. Determine moisture content of the fuel type.</p> <p>f. Measure chlorine concentration in fuel sample.</p> <p>g. Convert concentrations into units of pounds of HCl per MMBtu of heat content.</p>	<p>Procedure in § 63.7521(c) or ASTM D5192,^a or ASTM D7430,^a or ASTM D6883,^a or ASTM D2234/D2234M^a (for coal) or ASTM D6323^a (for coal or biomass), ASTM D4177^a (for liquid fuels) or ASTM D4057^a (for liquid fuels), or equivalent.</p> <p>Procedure in § 63.7521(d) or equivalent.</p> <p>EPA SW–846–3050B^a (for solid samples), ASTM D2013/D2013M^a (for coal), or ASTM D5198^a (for biomass), or EPA 3050^a or equivalent.</p> <p>ASTM D5865^a (for coal) or ASTM E711^a (for biomass), ASTM D5864, ASTM D240^a or equivalent.</p> <p>ASTM D3173^a or ASTM E871,^a or D5864,^a or ASTM D240,^a or ASTM D95^a (for liquid fuels), or ASTM D4006^a (for liquid fuels), or equivalent.</p> <p>EPA SW–846–9250,^a ASTM D6721,^a ASTM D4208^a (for coal), or EPA SW–846–5050^a or ASTM E776^a (for solid fuel), or EPA SW–846–9056^a or SW–846–9076^a (for solids or liquids) or equivalent.</p> <p>For fuel mixtures use Equation 7 in § 63.7530 and convert from chlorine to HCl by multiplying by 1.028.</p>
3. Mercury Fuel Specification for other gas 1 fuels.	<p>a. Measure mercury concentration in the fuel sample and convert to units of micrograms per cubic meter, or.</p>	<p>Method 30B (M30B) at 40 CFR part 60, appendix A–8 of this chapter or ASTM D5954,^a ASTM D6350,^a ISO 6978–1:2003(E),^a or ISO 6978–2:2003(E),^a or EPA–1631^a or equivalent.</p>

TABLE 6 TO SUBPART DDDDD OF PART 63—FUEL ANALYSIS REQUIREMENTS—Continued

[As stated in § 63.7521, you must comply with the following requirements for fuel analysis testing for existing, new or reconstructed affected sources. However, equivalent methods (as defined in § 63.7575) may be used in lieu of the prescribed methods at the discretion of the source owner or operator]

To conduct a fuel analysis for the following pollutant . . .	You must . . .	Using . . .
4. TSM	<p>b. Measure mercury concentration in the exhaust gas when firing only the other gas 1 fuel is fired in the boiler or process heater.</p> <p>a. Collect fuel samples</p> <p>b. Composite fuel samples</p> <p>c. Prepare composited fuel samples.</p> <p>d. Determine heat content of the fuel type.</p> <p>e. Determine moisture content of the fuel type.</p> <p>f. Measure TSM concentration in fuel sample.</p> <p>g. Convert concentrations into units of pounds of TSM per MMBtu of heat content.</p>	<p>Method 29, 30A, or 30B (M29, M30A, or M30B) at 40 CFR part 60, appendix A–8 of this chapter or Method 101A or Method 102 at 40 CFR part 61, appendix B of this chapter, or ASTM Method D6784^a or equivalent.</p> <p>Procedure in § 63.7521(c) or ASTM D5192,^a or ASTM D7430,^a or ASTM D6883,^a or ASTM D2234/D2234M^a (for coal) or ASTM D6323^a (for coal or biomass), or ASTM D4177,^a (for liquid fuels) or ASTM D4057^a (for liquid fuels), or equivalent.</p> <p>Procedure in § 63.7521(d) or equivalent.</p> <p>EPA SW–846–3050B^a (for solid samples), ASTM D2013/D2013M^a (for coal), ASTM D5198^a or TAPPI T266^a (for biomass), or EPA 3050^a or equivalent.</p> <p>ASTM D5865^a (for coal) or ASTM E711^a (for biomass), or ASTM D5864^a for liquids and other solids, or ASTM D240^a or equivalent.</p> <p>ASTM D3173^a or ASTM E871,^a or D5864, or ASTM D240,^a or ASTM D95^a (for liquid fuels), or ASTM D4006^a (for liquid fuels), or ASTM D4177^a (for liquid fuels) or ASTM D4057^a (for liquid fuels), or equivalent.</p> <p>ASTM D3683,^a or ASTM D4606,^a or ASTM D6357^a or EPA 200.8^a or EPA SW–846–6020,^a or EPA SW–846–6020A,^a or EPA SW–846–6010C,^a EPA 7060^a or EPA 7060A^a (for arsenic only), or EPA SW–846–7740^a (for selenium only).</p> <p>For fuel mixtures use Equation 9 in § 63.7530.</p>

^a Incorporated by reference, see § 63.14.

* * * * *

Subpart UUUUU—National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units

■ 25. Revise § 63.10010(h)(7)(i)(1) to read as follows:

§ 63.10010 What are my monitoring, installation, operation, and maintenance requirements?

* * * * *

(h) * * *

(7) * * *

(i) * * *

(1) Install and certify your PM CEMS according to the procedures and requirements in Performance Specification 11—Specifications and Test Procedures for Particulate Matter Continuous Emission Monitoring Systems at Stationary Sources in Appendix B to part 60 of this chapter, using Method 5 at Appendix A–3 to part 60 of this chapter and ensuring that the

front half filter temperature shall be 160° ± 5 °C (320° ± 9 °F). The reportable measurement output from the PM CEMS must be expressed in units of the applicable emissions limit (e.g., lb/MMBtu, lb/MWh).

* * * * *

■ 26. Revise Table 5 to Subpart UUUUU of part 63 to read as follows:

TABLE 5 TO SUBPART UUUUU OF PART 63—PERFORMANCE TESTING REQUIREMENTS

[As stated in § 63.10007, you must comply with the following requirements performance testing for existing, new or reconstructed affected sources: ¹]

To conduct a performance test for the following pollutant . . .	Using . . .	You must perform the following activities, as applicable to your input- or output-based emission limit . . .	Using . . . ²
1. Filterable Particulate matter (PM).	Emissions Testing	<p>a. Select sampling ports location and the number of traverse points.</p> <p>b. Determine velocity and volumetric flow-rate of the stack gas.</p> <p>c. Determine oxygen and carbon dioxide concentrations of the stack gas.</p> <p>d. Measure the moisture content of the stack gas.</p>	<p>Method 1 at appendix A–1 to part 60 of this chapter.</p> <p>Method 2, 2A, 2C, 2F, 2G or 2H at appendix A–1 or A–2 to part 60 of this chapter.</p> <p>Method 3A or 3B at appendix A–2 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981.³</p> <p>Method 4 at appendix A–3 to part 60 of this chapter.</p>

TABLE 5 TO SUBPART UUUUU OF PART 63—PERFORMANCE TESTING REQUIREMENTS—Continued

[As stated in § 63.10007, you must comply with the following requirements performance testing for existing, new or reconstructed affected sources: ¹]

To conduct a performance test for the following pollutant . . .	Using . . .	You must perform the following activities, as applicable to your input- or output-based emission limit . . .	Using . . . ²
2. Total or individual non-Hg HAP metals.	OR PM CEMS	<p>e. Measure the filterable PM concentration</p> <p>f. Convert emissions concentration to lb/MMBtu or lb/MWh emissions rates.</p> <p>OR</p> <p>a. Install, certify, operate, and maintain the PM CEMS.</p> <p>b. Install, certify, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems.</p> <p>c. Convert hourly emissions concentrations to 30 boiler operating day rolling average lb/MMBtu or lb/MWh emissions rates.</p>	<p>Methods 5 and 5I at appendix A–3 to part 60 of this chapter.</p> <p>For positive pressure fabric filters, Method 5D at appendix A–3 to part 60 of this chapter for filterable PM emissions.</p> <p>Note that the Method 5 or 5I front half temperature shall be 160° ±14 °C (320° ±25 °F).</p> <p>Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).</p> <p>Performance Specification 11 at appendix B to part 60 of this chapter and Procedure 2 at appendix F to part 60 of this chapter.</p> <p>Part 75 of this chapter and § 63.10010(a), (b), (c), and (d).</p>
	Emissions Testing	<p>a. Select sampling ports location and the number of traverse points.</p> <p>b. Determine velocity and volumetric flow-rate of the stack gas.</p> <p>c. Determine oxygen and carbon dioxide concentrations of the stack gas.</p> <p>d. Measure the moisture content of the stack gas.</p> <p>e. Measure the HAP metals emissions concentrations and determine each individual HAP metals emissions concentration, as well as the total filterable HAP metals emissions concentration and total HAP metals emissions concentration.</p> <p>f. Convert emissions concentrations (individual HAP metals, total filterable HAP metals, and total HAP metals) to lb/MMBtu or lb/MWh emissions rates.</p>	<p>Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).</p> <p>Method 1 at appendix A–1 to part 60 of this chapter.</p> <p>Method 2, 2A, 2C, 2F, 2G or 2H at appendix A–1 or A–2 to part 60 of this chapter.</p> <p>Method 3A or 3B at appendix A–2 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981.³</p> <p>Method 4 at appendix A–3 to part 60 of this chapter.</p> <p>Method 29 at appendix A–8 to part 60 of this chapter. For liquid oil-fired units, Hg is included in HAP metals and you may use Method 29, Method 30B at appendix A–8 to part 60 of this chapter; for Method 29, you must report the front half and back half results separately. When using Method 29, report metals matrix spike and recovery levels.</p> <p>Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).</p>
3. Hydrogen chloride (HCl) and hydrogen fluoride (HF).	Emissions Testing	<p>a. Select sampling ports location and the number of traverse points.</p> <p>b. Determine velocity and volumetric flow-rate of the stack gas.</p> <p>c. Determine oxygen and carbon dioxide concentrations of the stack gas.</p> <p>d. Measure the moisture content of the stack gas.</p> <p>e. Measure the HCl and HF emissions concentrations.</p>	<p>Method 1 at appendix A–1 to part 60 of this chapter.</p> <p>Method 2, 2A, 2C, 2F, 2G or 2H at appendix A–1 or A–2 to part 60 of this chapter.</p> <p>Method 3A or 3B at appendix A–2 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981.³</p> <p>Method 4 at appendix A–3 to part 60 of this chapter.</p> <p>Method 26 or Method 26A at appendix A–8 to part 60 of this chapter or Method 320 at appendix A to part 63 of this chapter or ASTM 6348–03³ with</p> <p>(1) the following conditions when using ASTM D6348–03:</p> <p>(A) The test plan preparation and implementation in the Annexes to ASTM D6348–03, Sections A1 through A8 are mandatory;</p>

TABLE 5 TO SUBPART UUUUU OF PART 63—PERFORMANCE TESTING REQUIREMENTS—Continued

[As stated in § 63.10007, you must comply with the following requirements performance testing for existing, new or reconstructed affected sources: ¹]

To conduct a performance test for the following pollutant . . .	Using . . .	You must perform the following activities, as applicable to your input- or output-based emission limit . . .	Using . . . ²
			(B) For ASTM D6348–03 Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (see Equation A5.5); (C) For the ASTM D6348–03 test data to be acceptable for a target analyte, %R must be 70% ≥R ≤130%; and

¹ Regarding emissions data collected during periods of startup or shutdown, see §§ 63.10020(b) and (c) and 63.10021(h).

² See Tables 1 and 2 to this subpart for required sample volumes and/or sampling run times.

³ Incorporated by reference, see § 63.14.

3.e.1(D) The %R value for each compound must be reported in the test report and all field measurements corrected with the calculated %R value for that compound using the following equation:

$$\text{Reported Result} = \frac{(\text{Measured Concentration in Stack})}{\%R} \times 100$$

and

To conduct a performance test for the following pollutant . . . (cont'd)	Using . . . (cont'd)	You must perform the following activities, as applicable to your input- or output-based emission limit . . .	Using . . . ² (cont'd)
	OR HCl and/or HF CEMS	OR a. Install, certify, operate, and maintain the HCl or HF CEMS. b. Install, certify, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems. c. Convert hourly emissions concentrations to 30 boiler operating day rolling average lb/MMBtu or lb/MWh emissions rates.	(2) spiking levels nominally no greater than two times the level corresponding to the applicable emission limit. Method 26A must be used if there are entrained water droplets in the exhaust stream. Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)). Appendix B of this subpart. Part 75 of this chapter and § 63.10010(a), (b), (c), and (d). Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
4. Mercury (Hg)	Emissions Testing	a. Select sampling ports location and the number of traverse points. b. Determine velocity and volumetric flow-rate of the stack gas. c. Determine oxygen and carbon dioxide concentrations of the stack gas. d. Measure the moisture content of the stack gas. e. Measure the Hg emission concentration f. Convert emissions concentration to lb/TBtu or lb/GWh emission rates.	Method 1 at appendix A–1 to part 60 of this chapter or Method 30B at Appendix A–8 for Method 30B point selection. Method 2, 2A, 2C, 2F, 2G or 2H at appendix A–1 or A–2 to part 60 of this chapter. Method 3A or 3B at appendix A–1 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981. ³ Method 4 at appendix A–3 to part 60 of this chapter. Method 30B at appendix A–8 to part 60 of this chapter, ASTM D6784, ³ or Method 29 at appendix A–8 to part 60 of this chapter; for Method 29, you must report the front half and back half results separately. Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).

To conduct a performance test for the following pollutant . . . (cont'd)	Using . . . (cont'd)	You must perform the following activities, as applicable to your input- or output-based emission limit . . .	Using . . . ² (cont'd)
5. Sulfur dioxide (SO ₂)	OR Hg CEMS	OR a. Install, certify, operate, and maintain the CEMS. b. Install, certify, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems. c. Convert hourly emissions concentrations to 30 boiler operating day rolling average lb/TBtu or lb/GWh emissions rates.	Sections 3.2.1 and 5.1 of appendix A of this subpart. Part 75 of this chapter and § 63.10010(a), (b), (c), and (d). Section 6 of appendix A to this subpart.
	OR Sorbent trap monitoring system.	OR a. Install, certify, operate, and maintain the sorbent trap monitoring system. b. Install, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems. c. Convert emissions concentrations to 30 boiler operating day rolling average lb/TBtu or lb/GWh emissions rates.	Sections 3.2.2 and 5.2 of appendix A to this subpart. Part 75 of this chapter and § 63.10010(a), (b), (c), and (d). Section 6 of appendix A to this subpart.
	OR LEE testing	OR a. Select sampling ports location and the number of traverse points. b. Determine velocity and volumetric flow-rate of the stack gas. c. Determine oxygen and carbon dioxide concentrations of the stack gas. d. Measure the moisture content of the stack gas. e. Measure the Hg emission concentration f. Convert emissions concentrations from the LEE test to lb/TBtu or lb/GWh emissions rates. g. Convert average lb/TBtu or lb/GWh Hg emission rate to lb/year, if you are attempting to meet the 29.0 lb/year threshold.	Single point located at the 10% centroidal area of the duct at a port location per Method 1 at appendix A–1 to part 60 of this chapter or Method 30B at Appendix A–8 for Method 30B point selection. Method 2, 2A, 2C, 2F, 2G, or 2H at appendix A–1 or A–2 to part 60 of this chapter or flow monitoring system certified per appendix A of this subpart. Method 3A or 3B at appendix A–1 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981, ³ or diluent gas monitoring systems certified according to part 75 of this chapter. Method 4 at appendix A–3 to part 60 of this chapter, or moisture monitoring systems certified according to part 75 of this chapter. Method 30B at appendix A–8 to part 60 of this chapter; perform a 30 operating day test, with a maximum of 10 operating days per run (<i>i.e.</i> , per pair of sorbent traps) or sorbent trap monitoring system or Hg CEMS certified per appendix A of this subpart. Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)). Potential maximum annual heat input in TBtu or potential maximum electricity generated in GWh.
	SO ₂ CEMS	a. Install, certify, operate, and maintain the CEMS. b. Install, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems. c. Convert hourly emissions concentrations to 30 boiler operating day rolling average lb/MMBtu or lb/MWh emissions rates.	Part 75 of this chapter and § 63.10010(a) and (f). Part 75 of this chapter and § 63.10010(a), (b), (c), and (d). Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).

² See Tables 1 and 2 to this subpart for required sample volumes and/or sampling run times.

³ Incorporated by reference, see § 63.14.

* * * * *

■ 27. In appendix A to part 63:

■ a. Revise section 12.4 in Method 303.

■ b. Revise sections 2.0, 7.2.3.3, 8.1.2, 9.1, 11.3.2, and 12.1 in Method 308.

■ c. Remove and reserve section 7.2.2 in Method 308.

■ d. Add sections 12.5 and 13.0 in Method 308.

■ e. Revise section 9.2.3 in Method 320..

■ f. Revise section 12.9 in Method 323.

■ g. Revise section 8.2.1.3, Figure 8.1. and section 8.2.3.2 in Method 325A.

■ h. Add section 8.2.3.3 in Method 325A.

■ i. Revise sections 9.3.2, 9.13, 11.3.2.5, and 12.2.2 and table 17–1 in Method 325B.

■ j. Remove sections 12.2.3 and 12.2.4 in Method 325B.

The revisions read as follows:

Appendix A to Part 63—Test Methods Pollutant Measurement Methods From Various Waste Media

* * * * *

Method 303—Determination of Visible Emissions From By-Product Coke Oven Batteries

* * * * *

12.4 Average Duration of VE from Charging Operations. Use Equation 303–3 to calculate the daily 30-day rolling log average of seconds of visible emissions from the charging operation for each battery using these current day's observations and the 29 previous valid daily sets of observations.

$$\text{logarithmic average} = e^y - 1$$

(Eq. 303-3)

$$\text{where } y = \frac{\ln(X_1 + 1) + \ln(X_2 + 1) + \dots + \ln(X_i + 1)}{A}$$

* * * * *

Method 308—Procedure for Determination of Methanol Emission From Stationary Sources

* * * * *

2.0 Summary of Method

A gas sample is extracted from the sampling point in the stack. The methanol is collected in deionized distilled water and adsorbed on silica gel. The sample is returned to the laboratory where the methanol in the water fraction is separated from other organic compounds with a gas chromatograph (GC) and is then measured by a flame ionization detector (FID). The fraction adsorbed on silica gel is extracted with deionized distilled water and is then separated and measured by GC/FID.

* * * * *

7.2.2 [Reserved].

* * * * *

7.2.3.3 Methanol Standards for Adsorbent Tube Samples. Prepare a series of methanol standards by first pipetting 10 ml of the methanol working standard into a 100-ml volumetric flask and diluting the contents to exactly 100 ml with deionized distilled water. This standard will contain 10 µg/ml of methanol. Pipette 5, 15, and 25 ml of this standard, respectively, into four 50-ml volumetric flasks. Dilute each solution to 50 ml with deionized distilled water. These standards will have 1, 3, and 5 µg/ml of methanol, respectively. Transfer all four standards into 40-ml glass vials capped with Teflon®-lined septa and store under refrigeration. Discard any excess solution.

* * * * *

8.1.2 Leak Check. A leak check before and after the sampling run is mandatory. The leak-check procedure is as follows:

Temporarily attach a suitable (e.g., 0- to 40-ml/min) rotameter to the outlet of the DGM, and place a vacuum gauge at or near the probe inlet. Plug the probe inlet, pull a vacuum of at least 250 mm (10 inch) Hg or the highest vacuum experienced during the sampling run, and note the flow rate as indicated by the rotameter. A leakage rate in excess of 2 percent of the average sampling rate is acceptable.

Note: Carefully release the probe inlet plug before turning off the pump.

* * * * *

9.1 Miscellaneous Quality Control Measures. The following quality control measures are required:

Section	Quality control measure	Effect
8.1.2, 8.1.3, 10.1	Sampling equipment leak check and calibration	Ensures accurate measurement of sample volume.
10.2	GC calibration	Ensures precision of GC analysis.
13.0	Methanol spike recovery check	Verifies all methanol in stack gas is being captured in impinge/adsorbent tube setup.

* * * * *

11.3.2 Desorption of Samples. Add 3 ml of deionized distilled water to each of the stoppered vials and shake or vibrate the vials for 30 minutes.

* * * * *

12.1 Nomenclature.

C_{af} = Concentration of methanol in the front of the adsorbent tube, µg/ml.

C_{ab} = Concentration of methanol in the back of the adsorbent tube, µg/ml.

C_i = Concentration of methanol in the impinger portion of the sample train, µg/ml.

E = Mass emission rate of methanol, µg/hr (lb/hr).

m_s = Total mass of compound measured in impinger and on adsorbent with spiked train (mg).

m_u = Total mass of compound measured in impinger and on adsorbent with unspiked train (mg).

m_v = Mass per volume of spiked compound measured (mg/L).

M_{tot} = Total mass of methanol collected in the sample train, µg.

P_{bar} = Barometric pressure at the exit orifice of the DGM, mm Hg (in. Hg).

P_{std} = Standard absolute pressure, 760 mm Hg (29.92 in. Hg).

Q_{std} = Dry volumetric stack gas flow rate corrected to standard conditions, dscm/hr (dscf/hr).

R = fraction of spiked compound recovered
 s = theoretical concentration (ppm) of spiked target compound

T_m = Average DGM absolute temperature, degrees K (°R).

T_{std} = Standard absolute temperature, 293 degrees K (528 °R).

V_{af} = Volume of front half adsorbent sample, ml.

V_{ab} = Volume of back half adsorbent sample, ml.

V_i = Volume of impinger sample, ml.

V_m = Dry gas volume as measured by the DGM, dry cubic meters (dcm), dry cubic feet (dcf).

$V_{m(std)}$ = Dry gas volume measured by the DGM, corrected to standard conditions, dry standard cubic meters (dscm), dry standard cubic feet (dscf).

* * * * *

12.5 Recovery Fraction (R)

$$m_v = \frac{m_s}{V_s} - \frac{m_u}{V_u}$$

Equation 308-4

$$R = \frac{m_v \times v_s}{s}$$

Equation 308-5

13.0 Method Performance

Since a potential sample may contain a variety of compounds from various sources, a specific precision limit for the analysis of field samples is impractical. Precision in the range of 5 to 10 percent relative standard deviation (RSD) is typical for gas chromatographic techniques, but an experienced GC operator with a reliable instrument can readily achieve 5 percent RSD. For this method, the following combined GC/operator values are required.

(a) Precision. Triplicate analyses of calibration standards fall within 5 percent of their mean value.

(b) Recovery. After developing an appropriate sampling and analytical system for the pollutants of interest, conduct the

following spike recovery procedure at each sampling point where the method is being applied.

i. Methanol Spike. Set up two identical sampling trains. Collocate the two sampling probes in the stack. The probes shall be placed in the same horizontal plane, where the first probe tip is 2.5 cm from the outside edge of the other. One of the sampling trains shall be designated the spiked train and the other the unspiked train. Spike methanol into the impinger, and onto the adsorbent tube in the spiked train prior to sampling. The total mass of methanol shall be 40 to 60 percent of the mass expected to be collected with the unspiked train. Sample the stack gas into the two trains simultaneously. Analyze the impingers and adsorbents from the two trains

utilizing identical analytical procedures and instrumentation. Determine the fraction of spiked methanol recovered (R) by combining the amount recovered in the impinger and in the adsorbent tube, using the equations in section 12.5. Recovery values must fall in the range: $0.70 \leq R \leq 1.30$. Report the R value in the test report.

* * * * *

Method 320—Measurement of Vapor Phase Organic and Inorganic Emissions by Extractive Fourier Transform Infrared (FTIR) Spectroscopy

* * * * *

9.2.3 Calculate the dilution ratio using the tracer gas as follows:

$$DF = \frac{SF_{6(spik)}}{SF_{6(dir)}}$$

Equation 3

Where:

$$CS = DF * Spike_{dir} + Unspike (1 - DF)$$

Equation 4

DF = Dilution factor of the spike gas; this value shall be ≥ 10 .

$SF_{6(dir)}$ = SF_6 (or tracer gas) concentration measured directly in undiluted spike gas.

$SF_{6(spik)}$ = Diluted SF_6 (or tracer gas) concentration measured in a spiked sample.

$Spike_{dir}$ = Concentration of the analyte in the spike standard measured by filling the FTIR cell directly.

CS = Expected concentration of the spiked samples.

Unspike = Native concentration of analytes in unspiked samples.

* * * * *

Method 323—Measurment of Formaldehyde Emissions From Natural Gas-Fired Stationary Sources-Acetyl Acetone Derivitization Method

* * * * *

12.9 Formaldehyde Concentration Corrected to 15% Oxygen

$$C_{form@15\%O_2} = C_{form} \frac{(20.9-15)}{(20.9-O_{2d})}$$

Eq. 323-8

* * * * *

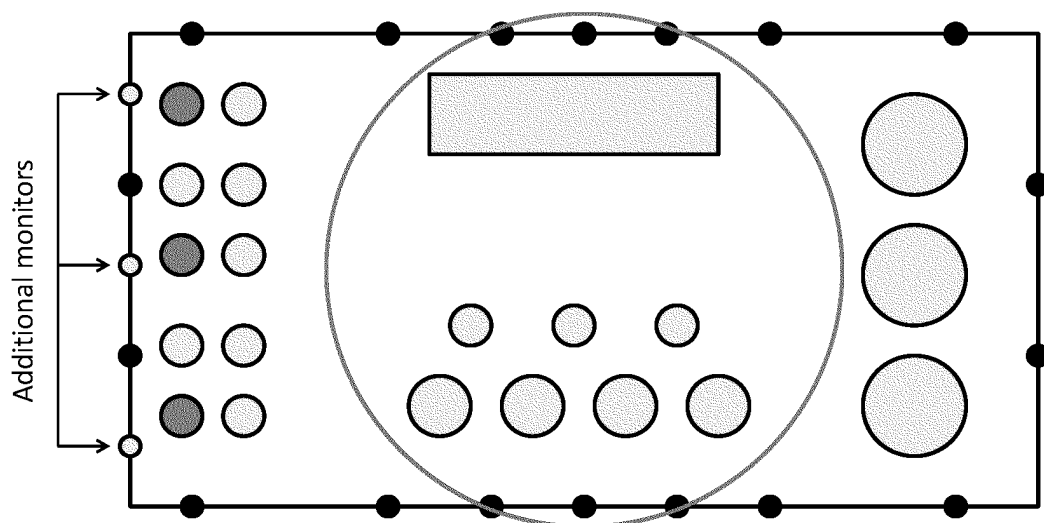
Method 325A—Volatile Organic Compounds From Fugitive and Area Sources: Sampler Deployment and VOC Sample Collection

* * * * *

8.2.1.3 Extra samplers must be placed near known sources of VOCs if the potential

emission source is within 50 meters (162 feet) of the boundary and the source location is between two monitors. Measure the distance (x) between the two monitors and place another monitor approximately halfway between $(x/2 \pm 10 \text{ percent})$ the two monitors. Only one extra sampler is required between two monitors to account for the

known source of VOCs. For example, in Figure 8.1, the facility added three additional monitors (*i.e.*, light shaded sampler locations) and in Figure 8.2, the facility added two additional monitors to provide sufficient coverage of all area sources.



Refinery (20° Angle)

Note: Shaded sources are within 50 meters of the property boundary and are located between two monitors. Additional coverage required by this method was accomplished by placing the monitors halfway between two existing monitors.

Figure 8.1. Facility with a Regular Shape Between 750 and 1,500 Acres in Area

* * * * *

8.2.3.2 For facilities with a monitoring perimeter length greater than or equal to 7,315 meters (24,000 feet), sampling locations are spaced 610 ± 76 meters ($2,000 \pm 250$ feet) apart.

8.2.3.3 Unless otherwise specified in an applicable regulation, permit or other requirement, for small disconnected subareas with known sources within 50 meters (162 feet) of the monitoring perimeter, sampling points need not be placed closer than 152 meters (500 feet) apart as long as a minimum of 3 monitoring locations are used for each subarea.

* * * * *

Method 325B—Volatile Organic Compounds From Fugitive and Area Sources: Sampler Preparation and Analysis

* * * * *

9.3.2 Field blanks must be shipped to the monitoring site with the sampling tubes and must be stored at the sampling location throughout the monitoring exercise. The field blanks must be installed under a protective hood/cover at the sampling location, but the long-term storage caps must remain in place throughout the monitoring period (see Method 325A). The field blanks are then shipped back to the laboratory in the same container as the sampled tubes. Collect at least two field blank samples per sampling period to ensure sample integrity associated with shipment, collection, and storage.

* * * * *

9.13 Routine CCV at the Start of a Sequence. Run CCV before each sequence of analyses and after every tenth sample to ensure that the previous multi-level calibration (see Section 10.0) is still valid.

* * * * *

11.3.2.5 Whenever the thermal desorption—GC/MS analytical method is changed or major equipment maintenance is performed, you must conduct a new five-level calibration (see Section 10.0). System calibration remains valid as long as results from subsequent CCV are within 30 percent of the most recent 5-point calibration (see Section 9.13). Include relevant CCV data in the supporting information in the data report for each set of samples.

* * * * *

12.2.2 Determine the equivalent concentrations of compounds in atmospheres as follows. Correct target compound concentrations determined at the sampling site temperature and atmospheric pressure to standard conditions (25 °C and 760 mm mercury) using Equation 12.5.

$$C_c = \frac{(m_{meas}) * 10^6}{U_{NTP} * \left[\frac{t_{ss}}{298.15} \right]^{\frac{1}{2}} * t}$$

Eq. 12.5

Where:

m_{meas} = The mass of the compound as measured in the sorbent tube (µg).

t = The exposure time (minutes).

t_{ss} = The average temperature during the collection period at the sampling site (K).
 U_{NTP} = The method defined diffusive uptake rate (sampling rate) (mL/min).

Note: Diffusive uptake rates (U_{std}) for common VOCs, using carbon sorbents packed

into sorbent tubes of the dimensions specified in Section 6.1, are listed in Table 12.1. Adjust analytical conditions to keep expected sampled masses within range (see Sections 11.3.1.3 to 11.3.1.5). Best possible method detection limits are typically in the

order of 0.1 ppb for 1,3-butadiene and 0.05 ppb for volatile aromatics such as benzene for 14-day monitoring. However, actual detection limits will depend upon the analytical conditions selected.

* * * * *

TABLE 17.1—SUMMARY OF GC/MS ANALYSIS QUALITY CONTROL PROCEDURES

Parameter	Frequency	Acceptance criteria	Corrective action
Bromofluorobenzene Instrument Tune Performance Check.	Daily ^a prior to sample analysis	Evaluation criteria presented in Section 9.5 and Table 9.2.	(1) Retune and or (2) Perform Maintenance.
Five point calibration bracketing the expected sample concentration.	Following any major change, repair or maintenance or if daily CCV does not meet method requirements. Recalibration not to exceed three months.	(1) Percent Deviation (%DEV) of response factors $\pm 30\%$. (2) Relative Retention Times (RRTs) for target peaks ± 0.06 units from mean RRT.	(1) Repeat calibration sample analysis. (2) Repeat linearity check. (3) Prepare new calibration standards as necessary and repeat analysis.
Calibration Verification (CCV Second source calibration verification check).	Following the calibration curve	The response factor $\pm 30\%$ DEV from calibration curve average response factor.	(1) Repeat calibration check. (2) Repeat calibration curve.
Laboratory Blank Analysis	Daily ^a following bromofluorobenzene and calibration check; prior to sample analysis.	(1) ≤ 0.2 ppbv per analyte or ≤ 3 times the LOD, whichever is greater. (2) Internal Standard (IS) area response $\pm 40\%$ and IS Retention Time (RT) ± 0.33 min. of most recent calibration check.	(1) Repeat analysis with new blank tube. (2) Check system for leaks, contamination. (3) Analyze additional blank.
Blank Sorbent Tube Certification ...	One tube analyzed for each batch of tubes cleaned or 10 percent of tubes whichever is greater.	< 0.2 ppbv per VOC targeted compound or 3 times the LOD, whichever is greater.	Re-clean all tubes in batch and reanalyze.
Samples—Internal Standards	All samples	IS area response $\pm 40\%$ and IS RT ± 0.33 min. of most recent calibration validation.	Flag Data for possible invalidation.
Field Blanks	Two per sampling period	No greater than one-third of the measured target analyte or compliance limit..	Flag Data for possible invalidation due to high blank bias.

^a Every 24 hours.

* * * * *

[FR Doc. 2018–00470 Filed 1–25–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R08–OAR–2017–0698; FRL–9972–54–Region 8]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; North Dakota; Control of Emissions From Existing Commercial and Industrial Solid Waste Incineration Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a Clean Air Act (CAA) section 111(d)/129 plan (the “plan”) submitted by the Division of Air Quality of the North Dakota Department of Health (the “Department”) on June 12, 2014. The plan would allow for the

implementation of emissions guidelines for existing commercial and industrial solid waste incineration (CISWI) units within the jurisdiction of the State of North Dakota. The plan creates new enforceable emissions limits and operating procedures for existing CISWI units within the State of North Dakota in accordance with the requirements established by the revised CISWI new source performance standards (NSPS) and emission guidelines (EG), promulgated by the EPA on March 21, 2011, with subsequent final amendments to the rule promulgated on February 7, 2013. This proposed plan approval rulemaking is being taken in accordance with the requirements of sections 111(d) and 129 of the CAA and the relevant parts and subparts of the Code of Federal Regulations (CFR).

DATES: Written comments must be received on or before February 26, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2017–0698 at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from

www.regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Gregory Lohrke, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado

80202–1129, (303) 312–6396,
lohrke.gregory@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

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

1. *Submitting Confidential Business Information (CBI).* Do not submit CBI to the EPA through <http://www.regulations.gov> or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD-ROM that you mail to the EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** volume, date, and page number);
- Follow directions and organize your comments;
- Explain why you agree or disagree;
- Suggest alternatives and substitute language for your requested changes;
- Describe any assumptions and provide any technical information and/or data that you used;
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced;
- Provide specific examples to illustrate your concerns, and suggest alternatives;
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats; and,
- Make sure to submit your comments by the comment period deadline identified.

II. Background Information

Sections 111 and 129 of the CAA outline the EPA's statutory authority for regulating new and existing solid waste incineration units. Section 111(b) directs the EPA Administrator to publish and periodically revise a list of source categories which significantly cause or contribute to air pollution. This subsection also directs the

Administrator to establish federal standards of performance for new sources within these categories. Section 111(d) grants the EPA statutory authority to require states to submit to the agency implementation plans for establishing performance standards applicable to existing sources belonging to those categories established in section 111(b). Section 129 specifically addresses solid waste combustion and requires that the EPA regulate new and existing waste incineration units pursuant to section 111 of the Act, including the requirement that a state in which existing designated facilities operate submit for approval a state plan for each category of regulated waste incineration units. Section 129(b)(3) requires the EPA to promulgate a federal plan for existing waste incineration units of any designated category located in any state which has not submitted an approvable 111(d)/129 state plan for said category of waste incineration unit. Such federal plans remain in effect until the state in question submits a new or revised state plan and subsequently receives approval and promulgation of the plan under 40 CFR part 62.

State plan submittals under CAA sections 111(d) and 129 must be consistent with the relevant new or revised EG. Section 129(a)(1)(D) of the Act requires the EPA to develop and periodically revise operating standards for new and existing CISWI units. The NSPS and EG for CISWI units were promulgated on December 1, 2000, at 40 CFR part 60, subparts CCCC and DDDD, respectively. Revisions to the CISWI NSPS and EG were subsequently promulgated by the EPA on March 21, 2011 (76 FR 15704), with final actions on reconsideration of the rule published on February 7, 2013 (78 FR 9112), and June 23, 2016 (81 FR 40956). State plan requirements specific to CISWI units, along with a model rule to ease adoption of the EG, are found in subpart DDDD, while more general state plan requirements are found in 40 CFR part 60, subpart B, and part 62, subpart A. The guidelines found in subpart DDDD require that states impose emission limits on designated facilities for those pollutants regulated under section 129, including: Dioxins/furans, carbon monoxide, metals (cadmium, lead and mercury), hydrogen chloride, sulfur dioxide, oxides of nitrogen, opacity and particulate matter. The EG also requires state plans include essential elements pursuant to section 129 requirements, including: Monitoring, operator training and facility permitting requirements.

The current North Dakota state plan was submitted in May 2003 and approved and promulgated on

September 17, 2003 (68 FR 54374), under 40 CFR part 62, subpart JJ in response to the original CISWI rule as it was promulgated on December 1, 2000 (65 FR 75338). Due to the most recent revisions to the CISWI rule, the State of North Dakota is required to revise and resubmit its state plan for the EPA approval with respect to the updated EG requirements. On June 12, 2014, the Department submitted to the EPA revisions to the current North Dakota state plan for existing CISWI units within the state's jurisdiction.

III. Summary of North Dakota's Section 111(d)/129 Plan for Existing CISWI Units

The EPA has completed a review of the revised North Dakota section 111(d)/129 plan submittal in the context of the requirements of 40 CFR part 60, subparts B and DDDD, and part 62, subpart A. The EPA has determined that the plan submittal meets the requirements found in the above-cited subparts. Accordingly, the EPA proposes to approve the submitted state plan. The EPA's proposed approval action is limited to the revised CISWI state plan submittal and the subpart DDDD "Model Rule" addressing CISWI units as it is incorporated by the State of North Dakota in the North Dakota Administrative Code (NDAC) Chapter 33–15–12–02, subpart DDDD. A detailed summary of the submittal's compliance with the requirements found in the CFR is available in the technical support document (TSD) associated with this rulemaking action. The TSD, as well as the complete North Dakota submittal package, will be available in the docket for this rulemaking action and may be found at the www.regulations.gov website.

IV. Proposed Action

The EPA is proposing approval of the North Dakota 111(d)/129 state plan for existing CISWI units because the plan requirements are at least as stringent as the requirements for existing CISWI units found in 40 CFR part 60, subpart DDDD. The state plan was submitted pursuant to 40 CFR part 60, subparts DDDD and B, and part 62, subpart A. Accordingly, the EPA proposes to amend 40 CFR part 62, subpart JJ to reflect the acceptability of the state plan submittal. This proposed approval is limited to the provisions of 40 CFR parts 60 and 62 for existing CISWI units, as found in the emission guidelines of Part 60, subpart DDDD. The EPA Administrator will retain the authorities listed under §§ 60.2542 and 60.2030(c).

V. Statutory and Executive Order Review

Under the CAA, the Administrator is required to approve a section 111(d)/129 plan submission that complies with the provisions of the Act and applicable federal regulations at 40 CFR 62.04. Thus, in reviewing section 111(d)/129 plan submissions, the 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 expected to be an Executive Order 13771 regulatory action because this action is not significant 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,
- Is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

In addition, this proposed rule is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian

country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 62

Environmental protection, Air pollution control, Commercial and industrial solid waste incineration, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: January 22, 2018.

Douglas H. Benevento,

Regional Administrator, Region 8.

[FR Doc. 2018-01492 Filed 1-25-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0006; FRL-9971-46]

Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before February 26, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the pesticide petition number (PP) of interest as shown in the body of this document, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.
- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket,

along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), main telephone number: (703) 305-7090; email address: BPPDFRNotices@epa.gov, Michael Goodis, Registration Division (7505P), main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov. The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT** for the division listed at the end of the pesticide petition summary of interest.

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

1. **Submitting CBI.** Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in

accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the requests before responding to the petitioners. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petitions described in this document contain the data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this document, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is available at <http://www.regulations.gov>.

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of

regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

III. New Tolerances for Non-Inerts

PP 7F8557. (EPA-HQ-OPP-2017-0429). E. I. Du Pont De Nemours and Company, Chestnut Run Plaza, 974 Centre Road, Wilmington, DE 19805, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide picoxystrobin in or on alfalfa, forage at 4 parts per million (ppm); alfalfa, hay at 5 ppm; alfalfa, seed at 9 ppm; almond hulls at 15 ppm; cotton, gin by-products at 40 ppm; cottonseed (Crop Subgroup 20C) at 4 ppm; grass, forage (Grown for Seed) at 40 ppm; grass, hay (Grown for Seed) at 80 ppm; head lettuce at 7 ppm; onion, bulb (Crop Subgroup 3-07A) at 0.8 ppm; onion, green (Crop Subgroup 3-07B) at 15; pea and bean, succulent shelled (Crop Subgroup 6B) at 3 ppm; peanut at 0.1 ppm; peanut, hay at 40 ppm; sunflower (Crop Subgroup 20B) at 3 ppm; tree nut except hulls (Crop Group 14-12) at 0.15 ppm; vegetable, brassica head and stem (Crop Group 5-16) at 5 ppm; vegetable, cucurbit (Crop Group 9) at 0.7 ppm; vegetable, fruiting (Crop Group 8-10) at 1.5 ppm; vegetable, leaf petiole (Crop Subgroup 22B) at 40 ppm; vegetable, leafy except head lettuce (Crop Group 4-16) at 60 ppm; vegetable, leaves of root and tuber (Crop Group 2) at 40 ppm; vegetable, legume, edible podded (Crop Subgroup 6A) at 4 ppm; vegetable, root (Crop Subgroup 1A) at 0.6 ppm; and vegetable, tuberous and corm (Crop Subgroup 1C) at 0.06 ppm. The liquid chromatography/triple quadrupole mass spectrometry (LC/MS/MS) is used to measure and evaluate the chemical picoxystrobin. *Contact:* RD.

IV. Amended Tolerance

1. PP 5F8521. (EPA-HQ-OPP-2015-0787). K-I Chemical USA, Inc., 11 Martine Ave., Suite 970, White Plains, NY 10606, requests to establish tolerances in 40 CFR 180.659 for residues of the herbicide pyroxasulfone (3-[(5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl) pyrazole-4-ylmethyl sulfonyl]-4,5-dihydro-5,5-dimethyl-1,2-oxazole) and its metabolites in or on Crop Subgroup 1C, tuberous and corm vegetables (except granular/flakes and chips) at 0.05 ppm; Crop Group 3-07, bulb vegetables at 0.15 ppm; potatoes, granular/flakes at 0.3 ppm and potato chips at 0.06 ppm. The high performance LC/MS/MS methods has been proposed to enforce the tolerance expression for pyroxasulfone. *Contact:* RD.

2. PP 7E8556. (EPA-HQ-OPP-2017-0224). Interregional Research Project No. 4 (IR-4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540, proposes upon establishment of tolerances referenced in this document under "New Tolerances" for PP 7E8556, to remove existing tolerances in 40 CFR 180.613(a) for the residues of the insecticide flonicamid, including its metabolites and degradates, determined by measuring only the sum of flonicamid, N-(cyanomethyl)-4-(trifluoromethyl)-3-pyridine carboxamide, and its metabolites, TFNA (4-trifluoromethylnicotinic acid), TFNA-AM (4-tri fluoromethylnicotinamide), and TFNG, N-(4-trifluoromethylnicotinoyl)glycine, calculated as the stoichiometric equivalent of flonicamid, in or on vegetable, leafy, except *brassica*, group 4, except spinach at 4.0 ppm, *brassica*, head and stem, subgroup 5A at 1.5 ppm, *brassica*, leafy greens, subgroup 5B at 16 ppm, radish, tops at 16 ppm, turnip, greens at 16 ppm, and cotton, undelinted seed at 0.50 ppm. *Contact:* RD.

3. PP 7E8587. (EPA-HQ-OPP-2017-0465). IR-4, IR-4 Project Headquarters, Rutgers, The State University of NJ, 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to amend 40 CFR 180.368 by removing the tolerances for residues of the herbicide S-metalochlor including its metabolites and degradates in or on Asparagus at 0.10 ppm; beet, garden, leaves at 1.8 ppm; turnip, greens at 1.8 ppm; *brassica*, head and stem, subgroup 5A at 0.60 ppm; *brassica*, leafy greens, subgroup 5B at 1.8 ppm; cotton, undelinted seed at 0.10 ppm; leaf petioles, subgroup 4B at 0.10 ppm. A gas chromatography-nitrogen phosphorus detection (GC/NPD) method has been submitted to the Agency for determining residues in/on crop commodities and is published in PAM Vol. II, Method I. *Contact:* RD.

4. PP 7E8610. (EPA-HQ-OPP-2017-0562). IR-4, IR-4 Project Headquarters, Rutgers, The State University of NJ, 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to amend 40 CFR 180.546 by removing the tolerance for residues of the fungicide mefenoxam, including its metabolites and degradates in or on kiwifruit at 0.10 ppm. The analytical methods cited are the Novartis Crop Protection Method 456-98, "Confirmatory Analytical Method for the Enantioselective Determination of Residues of Parent Metalaxyl (CGA-48988) or Mefenoxam (CGA-329351) in Crop Substrates by Chiral High Performance Liquid

Chromatography with Mass Spectrometric Detection”, and the Ciba-Geigy Corporation Procedure AG-395, “Improved Method for the Determination of Total Residues of Metalaxyl in Crop as 2,6-dimethylaniline”. This total residue method is used for the determination of the combined residues of metalaxyl *N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl) alanine methyl ester and its metabolites which contain the 2,6-dimethylaniline (2,6-DMA) moiety in crop samples.

Contact: RD.

5. *PP 7E8613*. (EPA-HQ-OPP-2017-0587). IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540, proposes upon establishment of tolerances referenced in this document under “New Tolerances” for PP 7E8613, to remove existing tolerances in 40 CFR 180.675 for residues of the insecticide tolfenpyrad, (4-chloro-3-ethyl-1-methyl-*N*-[4-(p-tolyloxy)benzyl]pyrazole-5-carboxamide), including its metabolites and degradates, in or on cotton, undelinted seed at 0.70 ppm; grape at 2.0 ppm; potato at 0.01 ppm; and vegetable, leafy, except brassica, group 4 at 30.0 ppm. The LC/MS/MS method is used to measure and evaluate the chemical. Contact: RD.

V. New Tolerance Exemptions for Non-Inerts (Except PIPS)

1. *PP 6F8504*. (EPA-HQ-OPP-2017-0565). Gowan Company LLC, P.O. Box 5569, Yuma, AZ 85366-5569, requests to establish an exemption from the requirement of a tolerance in 40 CFR part 180 for residues of the biochemical fungicide Extract of *Swinglea glutinosa* in or on all food commodities. The petitioner believes no analytical method is needed because the information supporting the request for exemption indicates limited exposure and no risk. Contact: BPPD.

VI. New Tolerances For Non-Inerts

1. *PP 5F8521*. (EPA-HQ-OPP-2015-0787). K-I Chemical USA, Inc., 11 Martine Ave., Suite 970, White Plains, NY 10606, requests to establish tolerances in 40 CFR 180.659 for residues of the herbicide pyroxasulfone (3-[(5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl) pyrazole-4-yl)methyl sulfonyl]-4,5-dihydro-5,5-dimethyl-1,2-oxazole) and its metabolites in or on Crop Subgroup 1C, tuberous and corm vegetables (except granular/flakes and chips) at 0.05 ppm; Crop Group 3-07, bulb vegetables at 0.15 ppm; potatoes, granular/flakes at 0.3 ppm and potato chips at 0.06 ppm. The high performance LC/MS/MS methods has been proposed to enforce the tolerance

expression for pyroxasulfone. Contact: RD.

2. *PP 7E8556*. (EPA-HQ-OPP-2017-0224). IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for residues of the insecticide flonicamid, including its metabolites and degradates, determined by measuring only the sum of flonicamid, *N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide, and its metabolites, TFNA (4-trifluoromethylnicotinic acid), TFNA-AM (4-trifluoromethylnicotinamide), and TFNG, *N*-(4-trifluoromethylnicotinoyl)glycine, calculated as the stoichiometric equivalent of flonicamid, in or on raw agricultural commodities as follows:

a. Amend 180.613 (a) General. (1) by establishing a tolerance in or on celtuce at 4.0 ppm; Florence fennel at 4.0 ppm; kohlrabi at 1.5 ppm; and Crop Group Expansions/Conversions for *brassica*, leafy greens, subgroup 4-16B at 16 ppm; cottonseed subgroup 20C at 0.60 ppm; leaf petiole vegetable subgroup 22B at 4.0 ppm; leafy greens subgroup 4-16A, except spinach at 4.0 ppm; and vegetable, *brassica*, head and stem, group 5-16 at 1.5 ppm, and

b. Amend 180.613(c) Tolerances with regional registrations, by establishing a tolerance for clover, forage at 0.9 ppm and clover, hay at 4.0 ppm.

Analytical methodology to determine above designated residues of flonicamid for the majority of crops includes an initial extraction with acetonitrile (ACN)/deionized (DI) water, followed by a liquid-liquid partition with ethyl acetate. The residue method for wheat straw is similar, except that a C₁₈ solid phase extraction (SPE) is added prior to the liquid-liquid partition. The final sample solution is quantitated using a liquid chromatograph (LC) equipped with a reverse phase column and a triple quadrupole mass spectrometer (MS/MS). Contact: RD.

3. *PP 7E8587*. (EPA-HQ-OPP-2017-0465). IR-4, IR-4 Project Headquarters, Rutgers, The State University of NJ, 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for residues of the herbicide *S*-metalochlor including its metabolites and degradates in or on the raw agricultural commodities stevia, dried leaves at 15.0 ppm; vegetable, leaves of root and tuber, group 2, except sugar beet at 2.0 ppm; Swiss chard at 0.10 ppm; vegetable, *brassica*, head and stem, group 5-16 at 0.60 ppm; *brassica*, leafy greens, subgroup 4-16B, except Chinese

broccoli at 1.8 ppm; stalk and stem vegetable subgroup 22A, except celtuce, Florence fennel, and kohlrabi at 0.10 ppm; leaf petiole vegetable subgroup 22B at 0.10 ppm; cottonseed subgroup 20C at 0.10 ppm; celtuce at 0.10 ppm; Florence fennel at 0.10 ppm; kohlrabi at 0.60 ppm, and Chinese broccoli at 0.60 ppm. A GC/NPD method has been submitted to the Agency for determining residues in/on crop commodities and is published in PAM Vol. II, Method I. Contact: RD.

4. *PP 7E8610*. (EPA-HQ-OPP-2017-0562). IR-4, IR-4 Project Headquarters, Rutgers, The State University of NJ, 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide mefenoxam, including its metabolites and degradates in or on the raw agricultural commodities cacao bean, bean at 0.2 ppm; wasabi, tops at 6.0 ppm; wasabi, stem at 3.0 ppm; and fruit, small, vine climbing, except grape, crop subgroup 13-07E at 0.10 ppm. The analytical methods cited are the Novartis Crop Protection Method 456-98, “Confirmatory Analytical Method for the Enantioselective Determination of Residues of Parent Metalaxyl (CGA-48988) or Mefenoxam (CGA-329351) in Crop Substrates by Chiral High Performance Liquid Chromatography with Mass Spectrometric Detection”, and the Ciba-Geigy Corporation Procedure AG-395, “Improved Method for the Determination of Total Residues of Metalaxyl in Crop as 2,6-dimethylaniline”. This total residue method is used for the determination of the combined residues of metalaxyl *N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl) alanine methyl ester and its metabolites which contain the 2,6-dimethylaniline (2,6-DMA) moiety in crop samples. Contact: RD.

5. *PP 7E8613*. (EPA-HQ-OPP-2017-0587) from IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to establish tolerances in 40 CFR part 180.675 for residues of the insecticide tolfenpyrad, (4-chloro-3-ethyl-1-methyl-*N*-[4-(p-tolyloxy)benzyl]pyrazole-5-carboxamide), including its metabolites and degradates, in or on arugula at 30.0 ppm; avocado at 1.5 ppm; berry, low growing, subgroup 13-07G, except cranberry and blueberry, lowbush at 3.0 ppm; bushberry, subgroup 13-07B at 7.0 ppm; caneberry, subgroup 13-07A at 7.0 ppm; celtuce at 30.0 ppm; cottonseed, subgroup 20C at 0.70 ppm; Florence fennel at 30.0 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.0 ppm; garden

cress at 30.0 ppm; leafy greens, subgroup 4–16A at 30.0 ppm; leaf petiole vegetable, subgroup 22B at 30.0 ppm; onion, bulb, subgroup 3–07A at 0.09 ppm; onion, green, subgroup 3–07B at 10.0 ppm; upland cress at 30.0 ppm; vegetable, fruiting, group 8–10 at 1.0 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.01 ppm. The LC/MS/MS method is used to measure and evaluate the chemical. *Contact:* RD.

Authority: 21 U.S.C. 346a.

Dated: December 4, 2017.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2018–01498 Filed 1–25–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 22, 24, 27, 30, 74, 80, 90, 95, and 101

[WT Docket No. 10–112; Report No. 3083]

Petitions for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petitions for reconsideration.

SUMMARY: Petitions for Reconsideration & Clarification (Petitions) have been filed in the Commission's rulemaking proceeding by Jeff Chalmers, on behalf of American Messaging Services, LLC; David Alban, on behalf of Sensus USA Inc. and Sensus Spectrum LLC; Kenneth E. Hardman, on behalf of Critical Messaging Association and Mark E. Crosby, on behalf of Enterprise Wireless Alliance.

DATES: Oppositions to the Petitions must be filed on or before February 12, 2018. Replies to an opposition must be filed on or before February 20, 2018.

ADDRESSES: Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Joyce Jones, email: joyce.jones@fcc.gov; phone: (202) 418–1327.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3083, released January 18, 2018. The full texts of the Petitions are available for viewing and copying at the FCC Reference Information Center, 445 12th Street SW, Room CY–A257, Washington, DC 20554. It also may be accessed online via the Commission's Electronic Comment Filing System at: <http://apps.fcc.gov/>

ecfs/. The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA, 5 U.S.C. because no rules are being adopted by the Commission.

Subject: Wireless Radio Services, FCC 17–105, published at 82 FR 41530, September 1, 2017, in WT Docket No. 10–112. This document is being published pursuant to 47 CFR 1.429(e). See also 47 CFR 1.4(b)(1) and 1.429(f), (g).

Number of Petitions Filed: 4.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2018–01407 Filed 1–25–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 17–318; FCC 17–169]

National Television Multiple Ownership Rule

AGENCY: Federal Communications Commission.

ACTION: Proposed rule

SUMMARY: This *Notice of Proposed Rulemaking (NPRM)* initiates a comprehensive review of the national television audience reach cap, including the UHF discount used by broadcasters to determine compliance with the cap. The national cap limits entities from owning or controlling television stations that, together, reach more than 39 percent of the television households in the country. The *NPRM* asks questions about whether a cap is still needed and what public interest goals it would promote, where the cap should be set if still needed, and how compliance with the cap should be calculated, including the question of whether the UHF discount should be eliminated. The Notice also invites comment on the Commission's legal authority to take such actions.

DATES: Comments are due on or before February 26, 2018. Reply Comments are due on or before March 27, 2018.

ADDRESSES: Interested parties may submit comments and replies, identified by MB Docket No. 17–318, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Federal Communications Commission's Website:* <http://www.fcc.gov/ecfs/>.

www.fcc.gov/cgb/ecfs/. Follow the instructions for submitting comments.

- *Mail:* Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

For more detailed filing instructions, see the Procedural Matters section below.

FOR FURTHER INFORMATION CONTACT:

Brendan Holland, Industry Analysis Division, Media Bureau, Brendan.Holland@fcc.gov (202) 418–2757.

SUPPLEMENTARY INFORMATION: This *NPRM* in MB Docket No. 17–318, was adopted December 14, 2017, and released December 18, 2017. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, 445 12th Street SW, Room CY–A257, Washington, DC 20554, or online at https://apps.fcc.gov/edoc_public/attachmatch/FCC-17-169A1.pdf. To request this document in accessible formats for people with disabilities (e.g. braille, large print, electronic files, audio format, etc.) or to request reasonable accommodations (e.g. accessible format documents, sign language interpreters, CART, etc.), send an email to fcc504@fcc.gov or call the FCC's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

1. *Background.* The national television audience reach cap and the related UHF discount are an outgrowth of television ownership restrictions dating back to the earliest days of broadcast television. The Commission first imposed national ownership restrictions for television stations in 1941 by limiting the number of stations that could be commonly owned, operated, or controlled to three. This limit was eventually broadened to seven stations in 1954 and eventually to 12 stations in 1984. In 1985, the Commission also determined that a 25 percent nationwide audience reach cap, in addition to the twelve-station limit, would help prevent a potentially disruptive industry restructuring. Along with the national cap, the Commission also adopted a 50 percent UHF discount to reflect the fact that, in the analog television broadcasting era, UHF signals reached a smaller audience in

comparison with VHF signals. The UHF discount provides that, for purposes of determining compliance with the national audience reach cap, stations broadcasting in the VHF spectrum are attributed with all television households in their Designated Market Areas (DMAs), while UHF stations are attributed with only 50 percent of the households in their DMAs.

2. In the Telecommunications Act of 1996 (1996 Act), Congress directed the Commission to amend its rules to increase the national audience reach cap from 25 percent to 35 percent and eliminate the restriction on owning more than 12 broadcast television stations nationwide. The Commission reaffirmed the 35 percent cap in its *1998 Biennial Review Order*, but the U.S. Court of Appeals for the District of Columbia Circuit (DC Circuit) later remanded that decision, finding that the Commission had failed to demonstrate that the 35 percent national audience reach cap advanced localism, diversity, or competition. In the *2002 Biennial Review Order*, the Commission found that while a national ownership cap was no longer needed to protect diversity and competition, the cap remained necessary to protect localism. The Commission further concluded that raising the cap from 35 percent to 45 percent would strike an appropriate balance between the broadcast networks and the local affiliates by permitting some growth for the owners of the Big Four networks (ABC, CBS, Fox, and NBC) and allowing them to achieve greater economies of scale, while at the same time ensuring that the networks could not reach a larger national audience than their affiliates collectively.

3. Following adoption of the *2002 Biennial Review Order*, and while an appeal of that order was pending, Congress partially rolled back the cap increase by including a provision in the 2004 Consolidated Appropriations Act (CAA) directing the Commission “to modify its rules to set the national cap at 39 percent of national television households.” The CAA further amended Section 202(h) of the 1996 Act to require a quadrennial review of the Commission’s broadcast ownership rules, rather than the previously mandated biennial review. In doing so, however, Congress excluded consideration of “any rules relating to the 39 percent national audience reach limitation” from the quadrennial review requirement. Prior to the enactment of the CAA, several parties had appealed the Commission’s *2002 Biennial Review Order* to the U.S. Court of Appeals for the Third Circuit (Third Circuit). In June

2004, the Third Circuit found that the challenges to the Commission’s actions with respect to the national audience reach cap and the UHF discount were moot as a result of Congress’s action.

4. In August 2016, the Commission eliminated the UHF discount, finding that UHF stations were no longer technically inferior to VHF stations following the digital television transition and that the competitive disparity between UHF and VHF stations had disappeared. Then-Commissioner Pai and Commissioner O’Rielly dissented from this decision. In April 2017, in response to a Petition for Reconsideration, the Commission reinstated the UHF discount, finding that the Commission’s elimination of the discount, effectively tightening the cap without also determining whether the cap remained in the public interest, was arbitrary and capricious and unwise from a public policy perspective. Because the UHF discount is used to determine licensees’ compliance with the national audience reach cap, the Commission concluded that the UHF discount and the cap are inextricably linked, and eliminating the discount without considering the cap itself was in error. In reinstating the UHF discount, the Commission committed to undertake this comprehensive rulemaking to determine whether to modify or eliminate the national cap, including the UHF discount.

5. *Commission Authority To Modify or Eliminate the National Cap.* As an initial matter, the Commission seeks comment on its authority to modify or eliminate the national cap, including authority to modify or eliminate the UHF discount. The Commission previously concluded in the *UHF Discount Elimination Order* that the Commission has authority to modify or eliminate the 39 percent national audience reach cap, including the UHF discount (although it refrained from adjusting the cap). The Commission found that it had such authority based on its broad authority to adopt—and revise or eliminate—all necessary rules under the Communications Act. In contrast, parties opposing reinstatement of the UHF discount on reconsideration argued variously that the Commission lacked authority to modify or eliminate the national cap, the UHF discount, or both.

6. In previously concluding that it has authority to modify or eliminate the national cap, the Commission rejected arguments that, when Congress established the 39 percent national audience reach cap, it precluded the Commission from any adjustment of the cap or the discount. The Commission

reasoned that the 2004 CAA “simply directed the Commission to revise its rules to reflect a 39 percent national audience reach cap and removed the requirement to review the national ownership cap from the Commission’s quadrennial review requirement.” The Commission concluded that the CAA did not impose a statutory national audience reach cap or prohibit the Commission from evaluating the elements of this rule. In addition, although the Third Circuit ultimately concluded in its review of the Commission’s *2002 Biennial Review Order* that questions related to the UHF discount were moot as a result of the CAA, it did not foreclose the Commission’s consideration of its regulation defining the UHF discount in a rulemaking outside the context of section 202(h). Further, Congress elected to use the same language in the 2004 CAA, instructing the Commission to “modify its rules,” as it did when it instructed the Commission to change the cap from 25 to 35 percent as part of the 1996 Act. Both the DC Circuit (in finding it was arbitrary and capricious for the Commission to *retain* that cap as part of the 1998 biennial review) and the Commission itself (in subsequently raising the cap from 35 to 45 percent) interpreted the identical language in the 1996 Act as preserving the Commission’s authority to modify the cap in the future.

7. The Commission further based its finding of authority to modify the cap and discount on its broad authority to adopt rules necessary to carry out the provisions of the Communications Act, and its authority to revisit its rules and revise or eliminate them as appropriate. Given continued questions regarding authority in this area, the Commission seeks further comment on its prior conclusion that it has authority to modify or eliminate the national audience reach cap and the UHF discount. The Commission asks whether Congress’s exclusion of the national cap from the quadrennial review provision merely meant to relieve the Commission of the *obligation* to reconsider the cap every four years (as the Third Circuit concluded), or was it designed to withhold the Commission’s authority to change the cap as set by Congress. The Commission also asks whether Congress’s instruction to the Commission to “modify its rules” in 1996 and 2004, rather than simply mandating a specific national audience reach cap, preserves the Commission’s traditional statutory authority to alter or eliminate the cap in a future rulemaking.

8. *Modification of Elimination of the National Audience Reach Cap.* The Commission seeks comment on whether there is still a need for a national cap that prevents ownership of stations that collectively reach more than a certain percentage of the television households in the country. The Commission asks whether such a cap serves the public interest. The Commission notes at the outset that the video marketplace has changed considerably since it last considered the national cap in the *2002 Biennial Review Order*, and since Congress instructed the Commission to set a 39 percent cap in 2004. The Commission's most recent annual Video Competition Report describes, among other developments, the growth of video programming options available to consumers, including online alternatives to traditional video distribution, reverse compensation fees paid by affiliates to broadcast networks, common ownership of broadcast and cable networks, consolidation among both Multichannel Video Programming Distributors (MVPDs) and non-network owned station groups, and continuing MVPD video subscriber losses. The Commission concluded in the *UHF Order on Reconsideration* that the failure to consider these changes compounded the error of eliminating the UHF discount. Accordingly, the Commission now seeks comment on how these marketplace changes, as well as any other changes not previously mentioned, should be considered in the context of the possible modification or elimination of the national audience reach cap. For instance, the Commission previously found in its *2002 Biennial Review Order* that a national audience reach cap set at some level is necessary in the public interest to promote localism. Specifically, the Commission found that a percentage cap maintains the appropriate balance of power between broadcast networks and their local affiliate groups, in part by preventing the excessive accumulation of audience reach by network-owned groups, which are more likely to hold stations in multiple geographic markets with large populations. The Commission reasoned that a national audience reach cap preserves the leverage necessary for local affiliates to collectively negotiate to influence network programming decisions and exercise their rights to preempt network programming in favor of programming the affiliates feel is better suited to local community needs. In setting a 45 percent cap, the Commission found that a national audience reach cap set at that level would ensure that network-owned

station groups could not achieve a level of direct audience reach that exceeds that of their local affiliates, while at the same time allowing for limited growth by each of the Big Four network owners, allowing them to achieve better economies of scale and scope and remain competitive.

9. The Commission now seeks comment on whether the existing cap is still necessary to promote localism. The Commission asks whether its previously articulated justifications—related to collective influence and preemption by local affiliates—still hold true, and whether localism has increased, decreased, or remained roughly the same over time. The Commission asks whether there are recent examples where local affiliates have influenced network programming to better serve local needs, and how recent affiliate preemption rates compare to those the Commission cited in the *2002 Biennial Review Order*. The Commission asks whether there are other metrics by which it can assess the effect of the national audience reach cap on localism and whether, even if preserving a national audience reach cap at some level would promote localism, would modifying or eliminating the cap nevertheless have offsetting benefits (for example, in promoting competition or diversity).

10. The Commission also asks whether other changes in the marketplace have affected the network/affiliate relationship, such that it would need to adjust assumptions made in previous reviews of the cap. The Commission asks how the growth of independent station groups over the last two decades has changed the dynamic between network-owned station groups and their affiliates. The Commission notes that its interest in preserving a national/local balance between networks and affiliates is predicated upon the Commission's prior conclusion that networks and their affiliates have different economic incentives when it comes to serving local interests. The Commission previously has found that broadcast networks primarily seek to air programming that will appeal to large national audiences, while local affiliates are more attuned to the needs of their local communities. The Commission seeks comment on these prior conclusions, including whether the conclusion that local affiliates are more attuned to local needs is still valid and whether it continues to apply equally to all local affiliates. The Commission also asks whether the size of the station group affects this conclusion.

11. The Commission also seeks comment on whether there are other justifications for a national audience reach cap besides localism. In the *2002 Biennial Review Order*, for example, the Commission noted in its competition discussion that the national cap appeared to encourage innovation in broadcast television by preserving a number of separately-owned station groups and then concluded that a variety of owners had led to innovative programming formats and technical advances. The Commission pointed to new programming formats developed by non-network owned affiliates, such as all-news channels and local news magazines, and the potential for experimentation in the use of digital spectrum as part of the digital television transition. The Commission now seeks comment on whether these prior conclusions have proven true over time and whether they remain true today. The Commission asks whether the variety of owners on a national level produced by the national audience reach cap continues to promote innovation in the marketplace, or whether there are ways in which the national audience reach cap hinders innovation.

12. The Commission previously has found that a national television ownership restriction is not necessary to promote the goals of competition or diversity. The Commission first reached this conclusion in 1984 when, regarding competition, it recognized the relevance of advertising to measuring competition in national and local television markets, and concluded that, for the local spot advertising market, the local television ownership rule rather than a national ownership rule would best address any risk of competitive harm. Regarding diversity, the Commission concluded that national broadcast ownership limits, as opposed to local ownership limits, ordinarily are not pertinent to assuring a diversity of views. The Commission nonetheless set a national audience reach cap to avoid any rapid restructuring of the industry that might be caused by its decision the previous year to raise the numerical cap from seven to twelve stations. The Commission now asks whether these previous conclusions are still valid, and whether any other goals supporting national ownership limits should be considered in this proceeding.

13. In addition, the Commission seeks comment on whether changes in the marketplace warrant a fresh look at the national television ownership rule's impact on competition or diversity at either the local or national level. The Commission asks how marketplace

changes have affected competition in the local broadcast television market or any other relevant markets. The Commission notes that other video distributors, including direct broadcast satellite providers and online video programmers, are not restricted by ownership limits. The Commission asks whether the cap, or the current level of the cap, have any negative impact on competition or diversity, and how any modification of the cap might affect these goals. The Commission asks whether marketplace changes have affected the relationships and business dealings between local broadcasters and other video distributors in ways that would justify retention, modification, or elimination of the national audience reach cap. The Commission notes that it has rules in place related to the distribution of video programming and carriage negotiations between broadcast stations and MVPDs (local exclusivity and retransmission consent negotiation rules) and asks whether the existence of these rules in any way informs the consideration of whether to retain, modify, or eliminate the cap. The Commission asks, for example, whether the rules have affected the relationships and business dealings between local broadcasters and other video distributors in ways that might affect the need for and operation of any national audience reach cap. The Commission also asks whether the cap serves any competition or diversity purpose related to the production or purchase of programming (e.g., syndicated programming).

14. If the Commission concludes that a national audience reach cap remains in the public interest, it asks at what level it should be set. The Commission asks whether a 39 percent cap still makes sense, or whether the cap should be set at a different level. The Commission has not articulated a justification for the cap in well over a decade, and the last time it did, it concluded that the cap should be raised from 35 to 45 percent. Congress subsequently scaled back the Commission's 45 percent cap to the current 39 percent level in 2004. Commenters urging the Commission to retain the 39 percent cap or to adjust it either upward or downward should provide a reasoned basis for any proposed line-drawing. The Commission also seeks comment on whether the national audience reach cap should apply equally to all ownership groups (e.g., groups that are network-owned or affiliated with cable networks versus those that are not). The Commission asks whether audience

reach is the proper measurement to use for the cap (as opposed to some other measurement of a station group's size or influence, such as actual viewership, market share, or amount of advertising revenue). The Commission asks whether it should consider alternatives with some built-in flexibility; for instance, alternatives that might employ the use of a threshold screen that would trigger a more detailed analysis, such as an automatic presumption or a safe harbor, either in lieu of or in addition to a bright line cap. If the Commission were to modify the national audience reach cap, it asks whether this action would affect any barriers to entry (either positively or negatively), including entry by women, minority, or small business owners.

15. *Determining Compliance With a National Cap.* Assuming the Commission retains a national audience reach cap at some level, it seeks comment on how to calculate compliance, including possible modification or elimination of the UHF discount. If the Commission determines that it has authority to adjust the national cap and that a national cap remains necessary in the public interest, it asks what, if any, changes it should make to the rules for determining licensees' compliance with that cap.

16. Initially, the Commission seeks comment on whether to eliminate the UHF discount. Notably, no commenter in the prior UHF discount proceedings presented evidence that the original technical justification for the discount is still valid, and the Commission in the *UHF Discount Order on Reconsideration* did not disturb its earlier conclusion that the UHF discount no longer has a sound technical basis following the digital television transition. The Commission seeks further comment on this prior conclusion, as well as on the importance of any non-technical justifications for the UHF discount that remain relevant. For example, the Commission noted in the *UHF Discount Order on Reconsideration* the industry's reliance on the UHF discount to develop long-term business strategies. Parties seeking reinstatement of the UHF discount described how they used the UHF discount to build new networks that provide innovative, competitive programming. The Commission seeks comment on whether eliminating the UHF discount would, on balance, serve the public interest and whether the current UHF discount causes harm to consumers or presents other drawbacks to retaining it.

17. The Commission also seeks comment on whether the UHF discount should be modified or whether it should be supplemented or replaced with some

other weighting method for determining compliance with any national limit on ownership of broadcast stations. The Commission asks whether there are other station or market characteristics that would warrant discounting or weighting a station's audience reach when determining compliance with a national cap. The Commission previously sought comment on and declined to adopt a VHF discount, acknowledging that UHF spectrum is now generally considered more desirable than VHF spectrum for digital television broadcasting, but finding insufficient evidence to conclude that VHF operations are universally inferior to UHF operations or that VHF stations' economic viability was sufficiently in jeopardy to warrant a VHF discount. The Commission seeks comment on these previous conclusions as well as whether there are other discounts or weights it should consider as part of a national ownership rule. The Commission asks how, if at all, it should account for the fact that many consumers today receive local broadcast stations via an MVPD, rather than over the air, in considering any discount or weight premised on a disparity in over-the-air coverage.

18. The Commission seeks comment on the impact that elimination of the UHF discount would have on the operation or effectiveness of a national audience reach cap. In the *UHF Discount Order on Reconsideration*, the Commission concluded that the elimination of the UHF discount effectively tightened the national cap. Therefore, if the Commission eliminates the UHF discount, the Commission asks whether it should simultaneously raise the national cap and by how much, assuming it finds that it has authority to do so. The Commission asks whether the UHF discount serves the underlying purposes of the national cap, namely, the preservation of a balance of power between broadcast networks and local affiliates, and how, if at all, elimination of the discount would alter that network/affiliate dynamic. The Commission asks whether the UHF discount benefits certain types of station group owners more than others (e.g., non-Big Four networks versus Big Four networks), and how its elimination would affect such owners. The Commission also seeks comment on how eliminating the UHF discount would affect not only the local television market, but the broader video marketplace as a whole.

19. *Benefit-Cost Analysis.* In addition, the Commission seeks comment on how to compare the benefits and costs associated with modifying or

eliminating the national cap, including the UHF discount. The Commission asks commenters supporting modification or elimination of the current 39 percent audience reach cap or the UHF discount to explain the anticipated economic impact of any proposed action and, where possible, to quantify benefits and costs of proposed actions and alternatives. The Commission asks whether the current national audience reach cap creates benefits or costs for any segment of consumers. The Commission asks whether the cap creates benefits or costs for any segment of the industry that should be counted as social benefits or costs rather than transfers from one segment of the industry to another. The Commission asks how the cap creates these benefits and costs, and what evidence supports this explanation. The Commission asks how the value of these benefits and costs can be measured for parties receiving them, what factors create uncertainty about the existence or size of these benefits and costs, and how its economic analysis should take these uncertainties into account.

20. The Commission asks how elimination of the national audience reach cap would alter these benefits and costs, and the comparative benefits and costs of modifying the cap upward rather than eliminating it entirely. The Commission asks whether allowing station groups to exceed the current 39 percent cap leads to any consumer benefits, such as increased competition, choice, innovation, or investment in programming, and what amount of additional scale above the current ownership limit would be required to realize such benefits. The Commission asks the comparative benefits and costs of lowering the cap. Commenters making claims about benefits and costs should support their claims with relevant economic theory and evidence, including empirical analysis and data.

21. Comparison of benefits and costs allows the Commission to identify the most economically efficient policy—that is, the policy that maximizes the value of resources from the perspective of consumers. The Commission asks whether it should seek to preserve a level of localism or other policy outcomes that do not maximize economic efficiency or consumer welfare, what public interest reasons support such actions, and what evidence justifies the elevation of these other public interest considerations over consumer welfare. The Commission asks what limiting principle the Commission should employ to determine when these alternative public interest considerations are satisfied, and

what evidence demonstrates that the commenter's preferred policy alternative is likely to achieve the appropriate level of localism or other desired outcome, as determined by these other public interest considerations.

22. *Relationship to Other Commission Rules.* Prior to 2004, when Congress expressly excluded review of the national audience reach cap from the Commission's quadrennial review process, the national cap typically had been considered in conjunction with the Commission's other media ownership rules. For example, when the Commission raised the limit on the number of stations a broadcaster could own to twelve, it also adopted a limit on the total national audience reach of station groups. To ensure a comprehensive review, the Commission seeks comment on the interplay between the national audience reach cap and other Commission ownership rules affecting television broadcasters. First, the Commission seeks comment on how, if at all, its local television ownership rule, which limits consolidation within local markets, should be taken into account in analyzing whether to modify or eliminate the national cap, which limits consolidation on a national level. Second, the Commission invites comment on how, if at all, it should consider the future decisions of television broadcasters to adopt the "Next Generation" transmission standard (or ATSC 3.0) on a voluntary basis. Finally, the Commission seeks comment on whether it should consider the potential impact on any other Commission rule or action in analyzing whether to modify or eliminate the national cap or UHF discount.

23. *Grandfathering.* To the extent that any rule the Commission adopts as a result of this proceeding causes a station owner to no longer be in compliance with the national audience reach cap or to violate any new limit, the Commission seeks comment on whether it should grandfather such ownership combinations as it has in the past. The Commission further seeks comment as to whether there should be any restrictions on the further transferability of any grandfathered stations. The Commission notes that, in the *UHF Discount Elimination Order*, it grandfathered station combinations that would exceed the 39 percent cap as a result of elimination of the UHF discount, but would have required any grandfathered ownership combination subsequently sold or transferred to comply with the national ownership cap in existence at the time of transfer.

Subsequently, the *UHF Discount Order on Reconsideration* reinstated the UHF discount and dismissed as moot requests to reconsider and modify grandfathering provisions.

24. Given this history, and recognizing broadcaster interest in maintaining the economies of scale and scope achieved through station combinations, if the Commission modifies the cap and/or the UHF discount, the Commission seeks comment on whether it should allow full, intact transferability without divestitures of grandfathered station groups. If the Commission adopts a rule change as a result of this proceeding that necessitates the grandfathering of existing, noncompliant station groups, it seeks comment on the appropriate date for triggering such grandfathering. The Commission also seeks comment on any other alternatives to grandfathering and transferability of non-compliant station groups. Finally, the Commission seeks comment on any new grandfathering issues arising from the questions posed in this *NPRM* or presented in initial comments filed in response.

Procedural Matters

25. *Ex Parte Presentations.* This proceeding 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.

26. *Filing Procedures.* Pursuant to Sections 1.415 and 1.419 of the Commission's rules, 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. 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.

27. *Availability of Documents.* Comments, reply comments, and *ex parte* submissions will be available for public inspection during regular business hours in the FCC Reference Information Center, Federal Communications Commission, 445 12th Street SW, CY-A257, Washington, DC 20554. These documents will also be available via ECFS. Documents will be

available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat.

28. *Additional Information.* For additional information on this proceeding, please contact Brendan Holland of the Media Bureau, Industry Analysis Division, Brendan.Holland@fcc.gov, (202) 418-2757.

29. *Paperwork Reduction Act Notice.* The Commission seeks comment on whether, based on this *NPRM*, it should adopt any new or modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens and pursuant to the Paperwork Reduction Act of 1995 invites the general public and the Office of Management and Budget to comment on any such information collection requirements. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, the Commission seeks specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

30. *Initial Regulatory Flexibility Analysis.* As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared this Initial Regulatory Flexibility Act Analysis (IRFA) of the possible significant economic impact on small entities of the policies and rules proposed in this *NPRM*. The Commission requests written public comments on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments specified above. The Commission will send a copy of this *NPRM*, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

31. *Need for, and Objectives of, the Proposed Rules.* This *NPRM* seeks comment on the Commission's national television audience reach cap, including the discount afforded to UHF stations. Earlier this year, the Commission reinstated the UHF discount, which provides a 50 percent discount to UHF stations for purposes of calculating compliance with the 39 percent audience reach cap. In reinstating the discount, the Commission found that the earlier decision to eliminate the discount had effectively tightened the cap without considering whether the overall cap remained in the public interest, particularly in light of changes to the video marketplace. The Commission found this action to be arbitrary and capricious and unwise from a public policy perspective. This *NPRM* seeks to rectify the Commission's prior error and undertake a broader assessment of the national audience cap,

including the UHF discount. This *NPRM* asks whether the Commission should modify or eliminate the current 39 percent national audience reach cap, and whether to grandfather any newly non-compliant combinations and if so, how.

32. *Legal Basis.* The legal basis for any action that may be taken pursuant to this *NPRM* is contained in Sections 1, 2(a), 4(i), 303(r), 307, 309, and 310 of the Communications Act of 1934, as amended.

33. *Description and Estimate of the Number of Small Entities to Which the Proposed Rules 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 rule revisions, if adopted. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act (SBA). A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA. Below, we provide a description of such small entities, as well as an estimate of the number of such small entities, where feasible.

34. *Television Broadcasting.* This Economic Census category "comprises establishments primarily engaged in broadcasting images together with sound." These establishments operate television broadcast studios and facilities for the programming and transmission of programs to the public. These establishments also produce or transmit visual programming to affiliated broadcast television stations, which in turn broadcast the programs to the public on a predetermined schedule. Programming may originate in their own studio, from an affiliated network, or from external sources. The Small Business Administration has created the following small business size standard for such businesses: those having \$38.5 million or less in annual receipts. The 2012 Economic Census reports that 751 firms in this category operated in that year. Of that number, 656 had annual receipts of \$25,000,000 or less, 25 had annual receipts between \$25,000,000 and \$49,999,999 and 70 had annual receipts of \$50,000,000 or more. Based on this data, the Commission estimates that the majority of commercial television broadcasters are small entities under the applicable size.

35. Additionally, the Commission has estimated the number of licensed commercial television stations to be 1,378. Of this total, 1,263 stations (or about 91 percent) had revenues of \$38.5 million or less, according to Commission staff review of the BIA Kelsey Inc. Media Access Pro Television Database (BIA) on May 9, 2017, and therefore these licensees qualify as small entities under the SBA definition.

36. We note, however, that in assessing whether a business concern qualifies as small under the above definition, business (control) affiliations must be included. Our estimate, therefore, likely overstates the number of small entities that might be affected by our action because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. In addition, an element of the definition of "small business" is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific television station is dominant in its field of operation. Accordingly, the estimate of small businesses to which rules may apply does not exclude any television station from the definition of a small business on this basis and is therefore possibly over-inclusive.

37. *Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements.* If the Commission determines that it should modify or eliminate the current 39 percent national audience reach cap or permanently eliminate or modify the UHF discount, this action could require modification of certain FCC forms and their instructions, possibly including: (1) FCC Form 301, Application for Construction Permit for Commercial Broadcast Station; (2) FCC Form 314, Application for Consent to Assignment of Broadcast Station Construction Permit or License; and (3) FCC Form 315, Application for Consent to Transfer Control of Corporation Holding Broadcast Station Construction Permit or License. The Commission may also have to modify other forms that include in their instructions the media ownership rules or citations to media ownership proceedings, including Form 303-S, Application for Renewal License for AM, FM, TV, Translator, or LPTV Station and Form 323, Ownership Report for Commercial Broadcast Station. The impact of these changes will be the same on all entities, and the Commission does not anticipate that compliance will require the expenditure of any additional resources or place additional burdens on small businesses.

38. *Steps Taken To Minimize Significant Impact on Small Entities and Significant Alternatives Considered.* The RFA requires an agency to describe any significant 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 or reporting requirements under the rule for 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 small entities.

39. The Commission has previously concluded that the national audience reach cap is intended to promote its public interest goal of localism. We seek comment on whether this rule or any modified rule is necessary at this time to serve localism and, if not, whether any rule is necessary to serve our goals of viewpoint diversity and competition in the video marketplace or other goals such as innovation. The *NPRM* seeks comment on the need for, and efficacy of, a national audience reach cap and UHF discount or other type of limit in light of significant changes in the video marketplace since the Commission last reviewed the cap and discount together. Assuming some limit is necessary, the *NPRM* seeks comment on whether the Commission should retain or modify the existing audience reach cap and UHF discount; retain the audience reach cap but adopt a different weighting methodology; adopt a limit based on some other measurement of a station group's size or influence, such as actual viewership, market share, or advertising revenue; or adopt a more flexible alternative such as a threshold screen that would trigger a more detailed analysis, an automatic presumption or safe harbor, either in lieu of or in addition to a bright line cap. The *NPRM* invites comment on the effects of any proposed rule changes on different types of broadcasters (e.g., independent or network-affiliated), the costs and benefits associated with any proposals, and any potential to have significant impact on small entities. The Commission expects to further consider the economic impact on small entities following its review of comments filed in response to the *NPRM* and this IRFA.

40. *Federal Rules that May Duplicate, Overlap, or Conflict With the Proposed Rule.* None.

41. *Ordering Clauses.* Accordingly, it is ordered that, pursuant to the

authority contained in Sections 1, 2(a), 4(i), 303(r), 307, 309, and 310 of the Communications Act of 1934, as amended the *NPRM* is adopted.

42. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this *NPRM*, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2018-01404 Filed 1-25-18; 8:45 am]

BILLING CODE 6712-01-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

Federal Motor Vehicle Safety Standard No. 108; Lamp, Reflective Devices, and Associated Equipment; Denial of Petition for Rulemaking

AGENCY: National Highway Traffic Safety Administration (NHTSA), U. S. Department of Transportation (DOT).

ACTION: Denial of petition for rulemaking.

SUMMARY: This document denies a petition for rulemaking submitted by Mr. William H. Thompson III requesting NHTSA amend Federal Motor Vehicle Safety Standard (FMVSS) No. 108, *Lamps, reflective devices, and associated equipment*. Specifically, Mr. Thompson requested we revise the activation process for red and amber signal warning lamps on school buses to require a new intermediate step during which both colors are activated simultaneously and flash in an alternating pattern and that we decouple the process by which lamps transition to the red-only configuration from the opening of the bus entrance door. NHTSA is denying this petition because Mr. Thompson has not identified a safety need to justify making changes he requested, and Mr. Thompson did not provide persuasive quantitative data to show adopting his requested changes would result in a net benefit to safety.

DATES: The petition is denied as of January 26, 2018.

FOR FURTHER INFORMATION CONTACT: Mr. Wayne McKenzie, Office of Crash Avoidance Standards (Phone: 202-366-1810; Fax: 202-366-7002) or Mr. Daniel Koblenz, Office of the Chief Counsel

(Phone: 202–366–2992; Fax: 202–366–3820). You may mail these officials at: National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

I. The Petition

On October 28, 2012, NHTSA received a letter from Mr. William H. Thompson III containing a petition for rulemaking to amend certain aspects of Federal motor vehicle safety standard (FMVSS) No. 108 relating to school buses equipped with red and amber signal warning lamps.¹ In his petition, Mr. Thompson requested NHTSA add an intermediate lamp configuration to the activation process for signal warning lamps between the existing amber-only and red-only configurations during which the amber and red lamps are both activated and alternate flashing. Additionally, he requested the transition from this intermediate amber-and-red configuration to the red-only configuration be controlled by a timer rather than by the bus door opening mechanism. Mr. Thompson stated adding an intermediate amber-and-red configuration that is activated for a fixed period of time would improve the effectiveness with warning other drivers when the bus is stopping for children as compared to the existing system. According to Mr. Thompson, these changes would reduce confusion regarding the meaning of signal warning lamps, which could in turn reduce the frequency with which other drivers engage in unsafe driving behaviors such as illegally passing school buses while their red signal warning lamps are activated (so-called “stop-arm violations”).

FMVSS No. 108, *Lamps, reflective devices, and associated equipment*, currently requires new school buses be equipped with four red signal warning lamps and allows for the optional installation of four amber signal warning lamps. The red lamps must be placed on the front and rear of the bus cab (two on the front and two on the rear) as high and as far apart as practicable, with optional amber lamps placed inboard of red lamps. Under the existing signal warning lamp activation requirements, a school bus driver manually activates the amber signal

warning lamps by actuating a switch to indicate to other drivers that the bus is preparing to pick up or drop off children. Amber lamps stay activated until the driver opens the bus entrance door, at which time amber lamps automatically deactivate and red lamps automatically activate to indicate children are in the process of boarding or offloading the bus.

Mr. Thompson argued, in his petition, the current signal warning lamp activation process causes uncertainty among other drivers, and this uncertainty constitutes a safety need that justifies amending FMVSS No. 108. Specifically, Mr. Thompson claimed current signal warning lamps do not effectively communicate when the bus will begin the process of picking up or dropping off children because amber lamps do not transition to red until the bus door is actually open (*i.e.*, until boarding or offloading has begun). According to Mr. Thompson, this uncertainty among other drivers leads to “risk factors” in the form of unsafe driving behaviors, such as “passing school buses while the red signal lamps are flashing and stop arm is extended and being cited by law enforcement, making a ‘panic stop’ to avoid passing the school bus as not to break the law and making a sudden stop and having a following motorist caught unaware.” These risk factors, in turn, could lead to injury or death of children and other road users.

To address this perceived safety risk, Mr. Thompson requested NHTSA amend FMVSS No. 108 to revise activation requirements for school bus signal warning lamps so they more clearly indicate the status of the school bus to other drivers. Per his petition, upon approaching a bus stop, the bus driver would activate amber flashing signal lamps by actuating a switch as is done under the existing rule. However, as the bus makes its final approach, the bus driver would actuate the signal warning lamp switch a second time, which would activate an intermediate signal warning lamp configuration during which amber and red signal warning lamps are activated and alternate flashing. This new configuration would be activated for a fixed period (the petition suggests approximately 3 seconds) after which the signal warning lamp system would automatically progress to a red-only configuration and the stop sign would deploy. The transition to the red-only configuration signals other drivers to come to a complete stop and indicates to the bus driver it is safe to open the bus door to pick up or drop off children. According to Mr. Thompson, a 3 second

intermediate step is sufficiently long to warn other drivers that the bus is preparing to stop, which will reduce some of risk factors described above.

II. Agency Analysis

We are denying Mr. Thompson’s petition on two bases. First, we do not believe confusion over the meaning of school bus signal warning lamps is a safety need that must be addressed by amending the lighting standard. Second, Mr. Thomson has not provided data persuasively demonstrating changes he proposed would lead to a net benefit for vehicle safety. We explain our reasoning in more detail below.

a. Mr. Thompson has not demonstrated that uncertainty over the meaning of signal warning lamps is a safety need that must be addressed.

Congress enacted the Motor Vehicle Safety Act of 1966 (the “Safety Act”) for the purpose of “reduc[ing] traffic accidents and deaths and injuries resulting from traffic accidents.”² To accomplish this, the Safety Act authorizes NHTSA to promulgate FMVSSs as well as to engage in other activities such as research and development. Because NHTSA has limited resources with which to accomplish goals of the Safety Act, the agency must make choices about how to most effectively and efficiently allocate resources. Accordingly, we will not take action under our Safety Act authority if we do not believe doing so will further interests of vehicle safety. In the context of petitions for rulemaking filed under 49 CFR part 552, this means we will not grant a petition to amend an FMVSS unless we believe doing so will address a traffic-related safety need.

Mr. Thompson has not shown such a safety need exists in this case. As noted earlier, Mr. Thompson argued in his petition that confusion over the meaning of signal warning lamps is a significant safety risk because it leads to unsafe driving behavior around school buses. To make his case, Mr. Thompson cited several sources, including two NHTSA publications (one survey and one guidance document) and two State-sponsored studies of stop-arm violations.³ While we agree with Mr.

² 49 U.S.C. 30111.

³ In addition to these studies, Mr. Thompson provided other types of evidence. For example, Mr. Thompson stated “expert evidence” indicates drivers who see amber lamps tend to speed up to try and “get past the bus” before red lamps activate. Mr. Thompson asserted signal warning lamp systems could potentially be misused under existing requirements but admitted the sort of misuse he described is “probably not a common occurrence.” However, because this information is unsourced and anecdotal, we cannot use it as a basis in our evaluation for concluding a safety risk exists.

¹ Since Mr. Thompson filed his petition, NHTSA issued a final rule reorganizing almost all aspects of FMVSS No. 108. This final rule did not make any substantive changes to the standard and did not affect our analysis of Mr. Thompson’s petition. However, it did rearrange paragraphs within the standard, and as a result, paragraph numbers Mr. Thompson cited in his petition are no longer accurate.

Thompson that these sources support the conclusion that school bus stop-arm violations are a problem, they do not support Mr. Thompson's assertion that stop-arm violations and other unsafe driving behavior is because of uncertainty over signal warning lamps.

We will first address the two NHTSA publications Mr. Thompson cited. The first NHTSA publication was our 1997 National Survey on Speeding and Unsafe Driving Attitudes and Behaviors, which contains a finding that 99 percent of drivers believed stop-arm violations were the most egregious type of moving violation.⁴ As the title suggests, this is a survey of public opinion; it does not make any conclusions based on empirical data about the frequency or cause of stop-arm violations and does not contain information relevant to evaluating whether these violations are because of uncertainty regarding the meaning of signal warning lamps. The other NHTSA publication Mr. Thompson cited was our 2000 Best Practices Guide on Reducing Illegal Passing of School Buses.⁵ This publication does not include empirical data supporting Mr. Thompson's proposal. Moreover, the policy proposal this document contains focuses on addressing the problem of stop-arm violations through a combination of educational and enforcement initiatives, not changes to FMVSS No. 108.

The two State-sponsored studies Mr. Thompson cited do not support Mr. Thompson's proposition that uncertainty over signal warning lamps is a safety risk. The first study Mr. Thompson cited was conducted by the North Carolina Department of Public Instruction.⁶ That study documented occurrences of stop-arm violations but does not establish their underlying causes.⁷ The second study Mr. Thompson cited was sponsored by the Florida Department of Education.⁸

Unlike the North Carolina study, the Florida study drew conclusions regarding causes of stop-arm violations, stating "while many motorists clearly do not understand the law as it applies to this situation, many more motorists are, in fact, intentionally violating the law."

While the publications Mr. Thompson cited may demonstrate stop-arm violations are a safety problem, they do not support his conclusion that uncertainty over the meaning of signal warning lamps constitutes a safety need that must be addressed through amendments to FMVSS No. 108. None of the publications he cited link uncertainty regarding the meaning of signal warning lamps to unsafe driving behaviors in any significant way, and in fact could be read as supporting the opposite conclusion—drivers understand the signal warning lamps but (at least in some instances) are simply choosing to ignore them.

b. Mr. Thompson has not provided us with data showing persuasive evidence that the change he proposes will provide a positive effect on safety.

As we explained in our 1998 statement of policy on signal lighting, when evaluating petitions to add or amend signal lighting requirements, we look at whether the petitioner has provided data that "show[s] persuasive evidence of a positive safety impact."⁹ If we cannot determine the change will positively affect safety, "NHTSA will not change its regulations to permit the new signal lighting idea, because that would negatively affect standardization of signal lighting." In other words, a petitioner requesting an amendment to an existing signal lighting requirement must provide data persuading us the change will have a benefit to safety outweighing detriments to safety that will occur because of reduced standardization of signal lighting.

Because NHTSA does not have resources to sponsor research on most of the lighting ideas proposed, we rely on petitioners to provide us with data to evaluate whether a requested change to signal lighting requirements will provide a net benefit to vehicle safety. Mr. Thompson's petition did not provide us with such data. Rather, information Mr. Thompson provided falls into one of two categories: Information supporting the general assertion stop-arm violations are a problem (*i.e.*, the studies described in

the previous section), or information explaining how he developed specific aspects of this proposal (*i.e.*, he chose a duration of 3 seconds for the intermediate lamp configuration because that is the duration of the yellow light on a traffic signal for 25 mile-per-hour traffic). Mr. Thompson's petition included no clear data demonstrating the changes he proposed would be beneficial for vehicle safety.

Given that Mr. Thompson did not provide proof of an offsetting safety benefit, we are concerned the changes he proposed may lead to a decrease in vehicle safety because they would disrupt signal light standardization, which could cause driver confusion. As we have explained repeatedly through years of letters of interpretation,¹⁰ as well as our prior responses to other petitions made under Part 552,¹¹ the effectiveness of all signal lamps (including school bus signal warning lamps) is premised on driver familiarity with established lighting schemes. For decades, the knowledge that flashing amber signal warning lamps on a school bus indicate a school bus is preparing to stop and flashing red signal warning lamps indicate children are boarding or offloading, has been ingrained in the mind of the driving public. Changing how school bus warning lamps operate by adding Mr. Thompson's intermediate configuration would disrupt this well-understood scheme. This could increase driver confusion until such time all buses use the new lighting scheme and drivers become familiar with the new lighting scheme.

Relatedly, we are also concerned about Mr. Thompson's other proposal to tie the activation of the red-only signal warning lamp configuration to a 3 second timer rather than to the opening of the bus entrance door. The current standard requires amber signal warning lamps deactivate and red signal warning lamps activate automatically upon the opening of the bus entrance door. Under this system, red lamps are only ever activated when the bus is in the process of picking up or dropping off children. By contrast, under Mr. Thompson's scheme, the red-only configuration necessarily activates before bus doors open. This could confuse drivers who have learned red signal warning lamps are only activated when children are in the process of boarding or offloading.

Finally, we note the Florida-sponsored study discussed in the

⁴ DOT HS 809 688, available at https://one.nhtsa.gov/people/injury/drowsy_driving1/speed_voIII_finding/SpeedVolumelIFindingsFinal.pdf. (Please note that the survey was updated in 2002, but kept the same DOT HS number).

⁵ Available at <https://one.nhtsa.gov/people/injury/buses/2000schoolbus/index.htm>.

⁶ Available at <http://www.ncbussafety.org/StopArmViolationCamera/>.

⁷ In a more recent study conducted in October 2013 by the North Carolina Department of Public Instruction, authors explicitly stated the question of why stop-arm violations occur must be studied further, and confusing signal warning lamps are just one of several possible reasons for this problems. See Pilot Testing of a School Bus Stop Arm Camera System (October 2013), available at http://www.ncbussafety.org/StopArmViolationCamera/documents/2013%2010%2030%20Final%20ITRE_stoparm_Camera_report.pdf.

⁸ University of South Florida College of Engineering, Center for Urban Transportation

Research, *Motorist Comprehension of Florida's School Bus Stop Law and School Bus Signalization Devices: Final Report* (June 1997), available at <https://www.cutr.usf.edu/wp-content/uploads/2012/07/school.pdf>.

⁹ Statement of Policy, 63 FR 59482 (Nov. 4, 1998).

¹⁰ See, e.g., letter to James A. Haigh (April 8, 2008), available at <https://isearch.nhtsa.gov/files/07-005005as.htm>.

¹¹ See, e.g., NovaBUS, Inc.: Denial of Application for Decision of Inconsequential Compliance, 67 FR 31862 (May 10, 2002).

previous section found significant driver confusion over the legal obligations applying to drivers when they encounter a school bus with flashing signal warning lamps. (This is distinct from the confusion Mr. Thompson identifies as a safety risk, which is over the meaning of the signal warning lamps themselves.) Given there is evidence drivers are already confused about laws relating to stop-arm violations, we do not think it would be beneficial for safety to make the signal warning lamp activation sequence more complex than it already is (as would be the case under Mr. Thompson's request).

For these reasons in accordance with 49 CFR part 552, Mr. Thompson's October 28, 2012, petition for rulemaking is denied.

Issued on January 12, 2018, in Washington, DC, under authority delegated in 49 CFR 1.95 and 501.5.

Heidi R. King,

Deputy Administrator.

[FR Doc. 2018-01403 Filed 1-25-18; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 171017999-8036-01]

RIN 0648-BH32

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Modifications to Greater Amberjack Recreational Fishing Year and Fixed Closed Season

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement management measures described in a framework action to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP), as prepared by the Gulf of Mexico Fishery Management Council (Council). If implemented, this proposed rule would change the recreational fishing year and modify the recreational fixed closed season for greater amberjack in the Gulf of Mexico (Gulf) exclusive economic zone (EEZ). The purposes of this proposed rule and the framework action are to constrain recreational

harvest to assist in ending overfishing, and to rebuild the greater amberjack stock in the Gulf, while maximizing optimum yield (OY) of the greater amberjack stock in the Gulf.

DATES: Written comments must be received on or before February 10, 2018.

ADDRESSES: You may submit comments on the proposed rule, identified by "NOAA-NMFS-2017-0149" by any of the following methods:

- **Electronic Submission:** Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2017-0149, click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.

- **Mail:** Submit written comments to Kelli O'Donnell, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

- **Instructions:** Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

Electronic copies of the framework action, which includes an environmental assessment, a regulatory impact review, and a Regulatory Flexibility Act (RFA) analysis may be obtained from the Southeast Regional Office website at http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/reef_fish/2017/GAJ_Fishing%20Year/final_action_modify_rec_fishing_yr.pdf.

FOR FURTHER INFORMATION CONTACT:

Kelli O'Donnell, NMFS SERO, telephone: 727-824-5305, email: Kelli.ODonnell@noaa.gov.

SUPPLEMENTARY INFORMATION: The Gulf reef fish fishery, which includes greater amberjack, is managed under the FMP. The Council prepared the FMP and NMFS implements the FMP under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) through regulations at 50 CFR part 622.

Background

The Magnuson-Stevens Act requires NMFS and regional fishery management councils to prevent overfishing and to

achieve, on a continuing basis, the OY from federally managed fish stocks to ensure that fishery resources are managed for the greatest overall benefit to the nation.

The greater amberjack resource in the Gulf was declared overfished by NMFS on February 9, 2001. The most recent Southeast Data Assessment and Review stock assessment was completed in 2016, and indicated the Gulf greater amberjack stock remained overfished, was undergoing overfishing, and would not be rebuilt by 2019, as was previously estimated. In response to the assessment results, the Council established new annual catch limits (ACLs) and annual catch targets (ACTs) (codified as quotas) that will be effective on January 27, 2018 (82 FR 61485; December 28, 2017). Under these new harvest levels, NMFS estimates the Gulf greater amberjack stock will be rebuilt by 2027. The Council also modified recreational fixed closed season from June through July each year to January through June. The Council intended this change to the fixed closed season to be a short-term measure to protect the Gulf greater amberjack stock during its spawning season (March through April) and allow the Council time to develop this current framework action and proposed rule to establish two separate recreational fishing seasons.

Management Measures Contained in This Proposed Rule

This proposed rule would revise the recreational fishing year and the recreational closed season for greater amberjack in the Gulf.

Greater Amberjack Recreational Fishing Year

The current Gulf recreational fishing year for greater amberjack is January 1 through December 31 and was established in the original FMP (49 FR 39548; October 9, 1984). This proposed rule would revise the Gulf greater amberjack recreational fishing year to be August 1 through July 31. This change would allow for greater amberjack harvest to occur later in the year and provide an opportunity to harvest greater amberjack when harvest of many other reef fish species is prohibited due to in-season quota closures. Starting the fishing year in August, when fishing effort is lower, is also expected to result in enough quota remaining to allow for fishing during May of the following calendar year.

Consistent with the change in the fishing year, this proposed rule would revise the years associated with the greater amberjack recreational ACLs and quotas. Currently, the recreational ACLs

and quotas are defined by the calendar year, which is also the fishing year. With the proposed change to the recreational fishing year, the recreational ACLs and quotas would apply across calendar years. Therefore, this proposed rule would assign the recently implemented 2018 ACL and quota to the remainder of the August 1, 2017, through July 31, 2018, recreational fishing year. The 2019 recreational ACL and quota would correspond to the 2018–2019 recreational fishing year, and the recreational ACL and quota for 2020 and beyond would correspond to all subsequent fishing years.

Greater Amberjack Recreational Closed Season

The final rule for Amendment 35 to the FMP established a greater amberjack recreational closed season from June 1 to July 31 to restrict harvest during times of peak fishing (77 FR 67574; November 13, 2012). This closed season was expected to reduce harvest enough to avoid an in-season closure as a result of the quota being met. However, the recreational sector has closed early each year since 2014. Therefore, the Council decided to modify the recreational closed season. As explained above, NMFS recently published a final rule that changed the closed season from June through July each year to January through June (82 FR 61485; December 28, 2017) to allow the Council the time to further modify the closed season to create two separate recreational fishing seasons.

This proposed rule would modify the recreational fixed closed season for greater amberjack to be from January 1 through April 30, June 1 through July 31, and November 1 through December 31, each year. This means that recreational harvest would be allowed in May and from August through October each calendar year unless an in-season closure was necessary to constrain harvest to the recreational quota. Because this proposed rule would also change the recreational fishing year, NMFS would begin monitoring landings as compared to the applicable quota on August 1 each year and, therefore, any in-season quota closure would occur later in the fall or during May of the following year. The proposed recreational fixed closed season is expected to reduce landings, which would reduce the likelihood of an in-season closure and recreational landings exceeding the recreational ACL. This rulemaking is also expected to protect greater amberjack during peak spawning months in the majority of the Gulf (March through April), thereby contributing to rebuilding the greater

amberjack stock within the rebuilding time period.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the Assistant Administrator has determined that this proposed rule is consistent with the framework action, the FMP, the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

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

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is as follows:

A description of the proposed rule, why it is being considered, and the objectives of, and legal basis for this proposed rule are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, recordkeeping, or other compliance requirements are introduced by this proposed rule. Accordingly, this proposed rule does not implicate the Paperwork Reduction Act.

The proposed rule would modify the recreational greater amberjack fishing year and fixed closed season. As a result, this proposed rule would affect recreational anglers and federally permitted charter vessels and headboats (for-hire) fishing for greater amberjack in the Gulf. Only recreational anglers are directly affected by this proposed rule, and they are not considered business entities under the RFA. For-hire vessels would be affected by this action but only in an indirect way. For-hire businesses (charter vessels and headboats) operate in the recreational sector, but these businesses only sell fishing services to recreational anglers. For-hire vessels provide a platform for the opportunity to fish and not a guarantee to catch or harvest any species, though expectations of successful fishing, however defined, likely factor into the decision by anglers to purchase these services. Because the effects on for-hire vessels would be indirect, they fall outside the scope of the RFA.

The information provided above supports a determination that this

proposed rule would not have a significant economic impact on a substantial number of small entities. Because this proposed rule, if implemented, is not expected to have a significant economic impact on any small entities, an initial regulatory flexibility analysis is not required and none has been prepared.

List of Subjects in 50 CFR Part 622

Commercial, Fisheries, Fishing, Fishing season, Fishing year, Greater amberjack, Gulf, Recreational, Reef fish.

Dated: January 19, 2018.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

■ 2. In § 622.7, add paragraph (h) to read as follows:

§ 622.7 Fishing years.

* * * * *

(h) *Gulf of Mexico greater amberjack recreational sector*—August 1 through July 31. (Note: The fishing year for the commercial sector for greater amberjack is January 1 through December 31).

■ 3. In § 622.34, revise paragraph (c) to read as follows:

§ 622.34 Seasonal and area closures designed to protect Gulf reef fish.

* * * * *

(c) *Seasonal closure of the recreational sector for greater amberjack.* The recreational sector for greater amberjack in or from the Gulf EEZ is closed from January 1 through April 30, June 1 through July 31, and November 1 through December 31, each year. During the closure, the bag and possession limit for greater amberjack in or from the Gulf EEZ is zero.

* * * * *

■ 4. In § 622.39, revise paragraph (a)(2)(ii) to read as follows:

§ 622.39 Quotas.

* * * * *

(a) * * *

(2) * * *

(ii) *Recreational quota for greater amberjack.*

(A) For the 2017–2018 fishing year—716,173 lb (324,851 kg).

(B) For the 2018–2019 fishing year—
902,185 lb (409,224 kg).

(C) For the 2019–2020 fishing year
and subsequent fishing years—
1,086,985 lb (493,048 kg).

* * * * *

■ 5. In § 622.41, revise paragraph
(a)(2)(iii) to read as follows:

**§ 622.41 Annual catch limits (ACLs),
annual catch targets (ACTs), and
accountability measures (AMs).**

(a) * * *

(2) * * *

(iii) The applicable recreational ACL
for greater amberjack, in round weight,
is 862,860 lb (391,387 kg) for the 2017–

2018 fishing year, 1,086,970 lb (493,041
kg) for the 2018–2019 fishing year, and
1,309,620 lb (594,034 kg) for 2019–2020
fishing year and subsequent fishing
years.

* * * * *

[FR Doc. 2018–01374 Filed 1–25–18; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 83, No. 18

Friday, January 26, 2018

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

January 23, 2018.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments are required regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by February 26, 2018 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@OMB.EOP.GOV or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Copies of the submission(s) may be obtained by calling (202) 720-8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs

potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: Volunteer Programs.

OMB Control Number: 0560-0232.

Summary of Collection: Section 1526 of the Food and Agriculture Act of 1981 (7 U.S.C. 2272) permits the Secretary of Agriculture to establish a program to use volunteers to perform a wide range of activities to carry out the programs of or supported by the Department of Agriculture (USDA). Each USDA agency is granted the authority to establish programs designed to provide educationally related work assignments for students in non-pay status. USDA, Departmental Regulation 4230-1 requires documentation of service performed without compensation by persons who do not receive Federal appointment. For this requirement, the information collection request is necessary to continue implementation of the programs, which allows the Farm Service Agency (FSA) and Risk Management Agency (RMA) to use volunteers to perform a wide range of activities to carry out the programs of or supported by the Agency.

Need and Use of the Information: Applicants who are accepted in the program will complete the "Service Agreement and Attendance Record." FSA and RMA will use the reported information to respond to request for information on volunteers from the USDA Office of Human Resources Management. If the information were not collected for each volunteer, FSA and RMA would be unable to document service performed without compensation by persons in the program if this information were not collected for each volunteer.

Description of Respondents: Individuals or households.

Number of Respondents: 20.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 30.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2018-01412 Filed 1-25-18; 8:45 am]

BILLING CODE 3410-05-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Proposed Information Collection; Comment Request; Miscellaneous Short Supply Activities

AGENCY: Bureau of Industry and Security.

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 March 27, 2018.

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 PRAComments@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Mark Crace, BIS ICB Liaison, (202) 482-8093 or at mark.crace@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This information collection is comprised of two rarely used short supply activities: "Registration of U.S. Agricultural Commodities for Exemption from Short Supply Limitations On Export", and "Petitions for The Imposition of Monitoring or Controls On Recyclable Metallic materials; Public Hearings." These activities are statutory in nature and, therefore, must remain a part of BIS's information collection budget authorization.

II. Method of Collection

Submitted in paper form.

III. Data

OMB Control Number: 0694-0102.

Form Number(s): None.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1.
Estimated Time per Response: 201 hours.

Estimated Total Annual Burden Hours: 201.

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; they also will become a matter of public record.

Sheleen Dumas,

Departmental PRA Lead, Office of the Chief Information Officer.

[FR Doc. 2018-01323 Filed 1-25-18; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-583-853]

Certain Crystalline Silicon Photovoltaic Products From Taiwan: Amended Preliminary Results and Preliminary Determination of No Shipments

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is amending the preliminary results of the administrative review of the antidumping duty order on certain crystalline silicon photovoltaic products (solar products) from Taiwan covering the period of review (POR) February 1, 2016, through January 31, 2017.

DATES: January 26, 2018.

FOR FURTHER INFORMATION CONTACT:

Thomas Martin, AD/CVD Operations, Office IV, Enforcement & Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482-3936.

SUPPLEMENTARY INFORMATION:

Background

On April 10, 2017, Commerce published a notice initiating an antidumping administrative review of solar products from Taiwan covering 34 companies for the POR.¹ On December 20, 2017, Commerce published the preliminary results of antidumping duty administrative review and partial rescission of antidumping duty administrative review.² In this notice, Commerce stated incorrectly that 23 of the 34 companies³ listed in the *Initiation Notice* had withdrawn their requests for administrative review, pursuant to 19 CFR 351.213(d)(1).⁴ Actually, neither petitioner nor any of the 23 companies had withdrawn requests for administrative review. Thus, all 23 companies remain under review.

Preliminary Determination of No Shipments

Of the 23 companies at issue, 14 companies filed timely statements reporting that they made no shipments of subject merchandise to the United States during the POR. Based on the certifications submitted by these companies and our analysis of U.S. Customs and Border Protection (CBP) information, we preliminarily determine

¹ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 82 FR 17188, 17189 (April 10, 2017) (*Initiation Notice*).

² See *Certain Crystalline Silicon Photovoltaic Products from Taiwan: Preliminary Results of Antidumping Duty Administrative Review and Partial Rescission of Antidumping Duty Administrative Review; 2016-2017*, 82 FR 60370 (Dec 20, 2017) and accompanying Preliminary Decision Memorandum (*Preliminary Results*).

³ Commerce stated that the following companies had withdrawn requests for administrative review: Baoding Jiasheng Photovoltaic Technology Co Ltd., Baoding Tianwei Yingli New Energy Resources Co., Ltd., Beijing Tianneng Yingli New Energy Resources Co Ltd., Boviet Solar Technology Co., Ltd., Canadian Solar Inc., Canadian Solar International, Ltd., Canadian Solar Manufacturing (Changshu), Inc., Canadian Solar Manufacturing (Luoyang), Inc., Canadian Solar Solution Inc., E-TON Solar Tech. Co., Ltd., Hainan Yingli New Energy Resources Co., Ltd., Hengshui Yingli New Energy Resources Co., Ltd., Inventec Energy Corporation, Lixian Yingli New Energy Resources Co., Ltd., Shenzhen Yingli New Energy Resources Co., Ltd., Sunengine Corporation Ltd., Sunrise Global Solar Energy, Tianjin Yingli New Energy Resources Co., Ltd., Trina Solar (Schweiz) AG, Trina Solar (Singapore) Science and Technology Pte Ltd., Win Win Precision Technology Co., Ltd., Yingli Energy (China) Co., Ltd., and Yingli Green Energy International Trading Company Limited.

⁴ See Letter from AU Optronics et al., "Re: Certain Crystalline Silicon Photovoltaic Products from Taiwan—Comment on Partial Rescission of Administrative Review, dated December 22, 2017; see also Letter from Canadian Solar Inc. et al., "Re: Crystalline Silicon Photovoltaic Products from Taiwan (02/01/2016—01/31/2017): Comments Opposing Decision to Rescind Review for Canadian Solar Entities," dated December 27, 2017.

that these 14 companies had no shipments during the POR.⁵ Given that these companies certified that they made no shipments of subject merchandise to the United States during the POR, and there is no information calling their claims into question, we preliminarily determine that these companies did not have any reviewable transactions during the POR. Commerce will issue a no-shipment inquiry to CBP requesting that it review these no-shipment claims. Consistent with Commerce's practice, we will not rescind the review, but, rather, will complete the review and issue instructions to CBP based on the final results.⁶

Rate for Companies Not Individually Examined

Of the 23 companies at issue, the remaining nine are non-selected respondents. Consistent with our preliminary results and Commerce's practice, we preliminarily assign to these nine companies the Motech Industries Inc.⁷ preliminary rate of 1.07 percent. See table below.

Manufacturer/ exporter	Weighted- average margin (percent)
Canadian Solar Inc	1.07
Canadian Solar International, Ltd	1.07
Canadian Solar Manufacturing (Changshu), Inc	1.07
Canadian Solar Manufacturing (Luoyang), Inc	1.07
Canadian Solar Solution Inc	1.07
Sunrise Global Solar Energy	1.07
Trina Solar (Schweiz) AG	1.07

⁵ See certifications of no shipments filed by Sunengine Corporation Ltd, dated April 24, 2017, and certifications of no shipments filed by Boviet Solar Technology Co., Ltd, Baoding Jiasheng Photovoltaic Technology Co., Ltd., Baoding Tianwei Yingli New Energy Resources Co., Ltd., Beijing Tianneng Yingli New Energy Resources Co., Ltd., Hainan Yingli New Energy Resources Co., Ltd., Hengshui Yingli New Energy Resources Co., Ltd., Lixian Yingli New Energy Resources Co., Ltd., Shenzhen Yingli New Energy Resources Co., Ltd., Tianjin Yingli New Energy Resources Co., Ltd., Yingli Energy (China) Co., Ltd., and Yingli Green Energy International Trading Company Limited, dated May 10, 2017. See also Letter from Inventec Solar Energy Corporation and its affiliates, dated April 24, 2017 (certifying that E-TON Solar Tech. Co., Ltd., and Inventec Energy Corporation had no shipments).

⁶ See, e.g., *Certain Frozen Warmwater Shrimp from Thailand: Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Review, Preliminary Determination of No Shipments; 2012-2013*, 79 FR 15951, 15952 (March 24, 2014), unchanged in *Certain Frozen Warmwater Shrimp from Thailand: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Partial Rescission of Review; 2012-2013*, 79 FR 51306, 51307 (August 28, 2014).

⁷ See *Preliminary Results*, 82 FR at 60371.

Manufacturer/ exporter	Weighted- average margin (percent)
Trina Solar (Singapore) Science and Technology Pte Ltd	1.07
Win Win Precision Technology Co., Ltd	1.07

Assessment Rates

Upon issuance of the final results, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review, in accordance with 19 CFR 351.212(b). Commerce intends to issue assessment instructions to CBP 15 days after the publication date of the final results of review.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of solar products from Taiwan entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies under review will be the rate established in the final results of this review (except, if the rate is zero or *de minimis*, no cash deposit will be required); (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the manufacturer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recently completed segment of the proceeding for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 19.50 percent *ad valorem*, the all-others rate established in the less-than-fair-value investigation.⁸ These cash deposit requirements, when imposed, shall remain in effect until further notice.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

⁸ See *Certain Crystalline Silicon Photovoltaic Products from Taiwan: Final Determination of Sales at Less Than Fair Value*, 79 FR 76966 (December 23, 2014).

Dated: January 18, 2018.

Gary Taverman,

Deputy Assistance Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–01446 Filed 1–25–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–836]

Glycine From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Results of the Antidumping Duty Administrative Review; 2010–2011

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Court of International Trade (CIT or Court) sustained the final remand results pertaining to the administrative review of the antidumping duty order on glycine from the People's Republic of China (China), covering the period of March 1, 2010, through February 28, 2011. The Department of Commerce (Commerce) is notifying the public that the final judgment in this case is not in harmony with Commerce's final results of the administrative review and that Commerce is amending the final results with respect to the dumping margin assigned to Baoding Mantong Fine Chemistry Co. Ltd. (Baoding Mantong).

DATES: Applicable January 26, 2018.

FOR FURTHER INFORMATION CONTACT: Madeline Heeren or Edythe Artman, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9179 or (202) 482–3931, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 18, 2012, Commerce published the *Final Results*,¹ in which it determined Baoding Mantong to have a weight-averaged dumping margin of 453.79 percent for the period under review. On November 3, 2015, the Court remanded these results to Commerce for reconsideration of all aspects of its determination of the margin assigned to

Baoding Mantong in the *Final Results*.² In the final results of redetermination, Commerce relied on surrogate financial information that resulted in a dumping margin of 64.97 percent.³ On April 19, 2017, the Court remanded the revised results to Commerce for reconsideration of the selection of certain surrogate values in its determination of the margin assigned to Baoding Mantong.⁴ In its second final results of redetermination, Commerce revised the surrogate values for three inputs—liquid ammonia, formaldehyde and steam coal—which resulted in a dumping margin of 0.00 percent.⁵ On December 20, 2017, the Court sustained the Second Results of Redetermination.⁶

Timken Notice

In its decision in *Timken*,⁷ as clarified by *Diamond Sawblades*,⁸ the Court of Appeals for the Federal Circuit held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of a court decision that is not “in harmony” with a Commerce determination and must suspend liquidation of entries pending a “conclusive” court decision. The CIT's December 20, 2017, final judgment sustaining the Second Results of Redetermination constitutes a final decision of the Court that is not in harmony with Commerce's *Final Results*. This notice is published in fulfillment of the *Timken* publication requirements. Accordingly, Commerce will continue the suspension of liquidation of the subject merchandise pending a final and conclusive court decision.

Amended Final Results of Review

Because there is now a final court decision, Commerce is amending the *Final Results* with respect to the dumping margin calculated for Baoding Mantong. Based on the Second Results of Redetermination, as sustained by the CIT, the revised dumping margin for Baoding Mantong, for the period March

² See *Baoding Mantong Fine Chemistry Co., Ltd. v. United States*, Court No. 12–00362, Slip Op. 15–123 (CIT November 3, 2015).

³ See “*Final Results of Redetermination Pursuant to Court Remand*,” dated March 29, 2017.

⁴ See *Baoding Mantong Fine Chemistry Co., Ltd. v. United States*, Court No. 12–00362, Slip Op. 17–44 (CIT April 19, 2017).

⁵ See “*Final Results of Redetermination Pursuant to Court Remand*,” dated July 18, 2017 (Second Results of Redetermination).

⁶ See *Baoding Mantong Fine Chemistry Co., Ltd. v. United States*, Court No. 12–00362, Slip Op. 17–169 (CIT December 20, 2017).

⁷ See *Timken Co. v. United States*, 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

⁸ See *Diamond Sawblades Mfrs. Coalition v. United States*, 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

¹ See *Glycine from the People's Republic of China: Final Results of Antidumping Duty Administrative Review*, 77 FR 64100 (October 18, 2012) (*Final Results*).

1, 2010, through February 28, 2011, is as follows:

Producer or exporter	Weighted-average dumping margin (percent)
Baoding Mantong Fine Chemistry Co. Ltd.	0.00

In the event the Court's ruling is not appealed or, if appealed, upheld by a final and conclusive court decision, Commerce will instruct the U.S. Customs and Border Protection to assess antidumping duties on unliquidated entries of subject merchandise with respect to Baoding Mantong.

Cash Deposit Requirements

Since the *Final Results*, Commerce has established a new cash deposit rate for Baoding Mantong.⁹ Therefore, the cash deposit rate for Baoding Mantong will remain the company-specific rate established for it in a subsequent and most recently completed administrative review.¹⁰

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(e)(1), 751(a)(1), and 777(i)(1) of the Act.

Dated: January 17, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, Performing the Non-Exclusive Functions and Duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018-01445 Filed 1-25-18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Meeting of the Renewable Energy and Energy Efficiency Advisory Committee

AGENCY: International Trade Administration, U.S. Department of Commerce

ACTION: Notice of an open meeting

SUMMARY: The Renewable Energy and Energy Efficiency Advisory Committee (REEEAC) will hold a meeting on Thursday, May 10, 2018 at the U.S. Department of Commerce Herbert C. Hoover Building in Washington, DC. The meeting is open to the public with

registration instructions provided below.

DATE: May 10, 2018, from approximately 8:30 a.m. to 5:00 p.m. Eastern Standard Time (EST). Members of the public wishing to participate must register in advance with Victoria Gunderson at the contact information below by 5:00 p.m. EST on Friday, May 4, 2018, in order to pre-register, including any requests to make comments during the meeting or for accommodations or auxiliary aids.

ADDRESSES: To register, please contact Victoria Gunderson, Designated Federal Officer, Office of Energy and Environmental Industries (OEEI), International Trade Administration, U.S. Department of Commerce at (202) 482-7890; email: Victoria.Gunderson@trade.gov.

FOR FURTHER INFORMATION CONTACT:

Victoria Gunderson, Designated Federal Officer, Office of Energy and Environmental Industries (OEEI), International Trade Administration, U.S. Department of Commerce at (202) 482-7890; email: Victoria.Gunderson@trade.gov.

SUPPLEMENTARY INFORMATION:

Background: The Secretary of Commerce established the REEEAC pursuant to discretionary authority and in accordance with the Federal Advisory Committee Act, as amended (5 U.S.C. App.), on July 14, 2010. The REEEAC was re-chartered most recently on June 9, 2016. The REEEAC provides the Secretary of Commerce with consensus advice from the private sector on the development and administration of programs and policies to expand the export competitiveness of the U.S. renewable energy and energy efficiency products and services.

On May 10, the REEEAC will hold the seventh, and final, in-person meeting of its current charter term and hold REEEAC sub-committee working sessions, discuss next steps for each sub-committee (Export Competitiveness, Market Access, and Finance), consider recommendations for approval, and hear from officials from the Department of Commerce and other agencies on major issues affecting the competitiveness of the U.S. renewable energy and energy efficiency industries. An agenda will be made available by May 4 upon request.

The meeting will be open to the public and will be accessible to people with disabilities. All guests are required to register in advance by the deadline identified under the **DATES** caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted, but may be impossible to fill.

A limited amount of time before the close of the meeting will be available for oral comments from members of the public attending the meeting. To accommodate as many speakers as possible, the time for public comments will be limited to two to five minutes per person (depending on number of public participants). Individuals wishing to reserve speaking time during the meeting must contact Ms. Gunderson and submit a brief statement of the general nature of the comments, as well as the name and address of the proposed participant by 5:00 p.m. EST on Friday, May 4, 2018. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a copy of their oral comments by email to Ms. Gunderson for distribution to the participants in advance of the meeting.

Any member of the public may submit written comments concerning the REEEAC's affairs at any time before or after the meeting. Comments may be submitted to the Renewable Energy and Energy Efficiency Advisory Committee, c/o: Victoria Gunderson, Designated Federal Officer, Office of Energy and Environmental Industries, U.S. Department of Commerce; 1401 Constitution Avenue NW; Mail Stop: 4053; Washington, DC 20230. To be considered during the meeting, written comments must be received no later than 5:00 p.m. EST on Friday, May 4, 2018, to ensure transmission to the REEEAC prior to the meeting. Comments received after that date will be distributed to the members but may not be considered at the meeting.

Copies of REEEAC meeting minutes will be available within 30 days following the meeting.

Dated: January 19, 2018.

Man Cho,

Deputy Director, Office of Energy and Environmental Industries.

[FR Doc. 2018-01335 Filed 1-25-18; 8:45 am]

BILLING CODE 3510-DR-P

DEPARTMENT OF COMMERCE

International Trade Administration

Renewable Energy and Energy Efficiency Advisory Committee

AGENCY: International Trade Administration, U.S. Department of Commerce

ACTION: Notice of an open meeting

⁹ See Glycine from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Partial Rescission of Antidumping Duty Administrative Review; 2013-2014, 80 FR 62027 (October 15, 2015).

¹⁰ *Id.* at 62028.

SUMMARY: The Renewable Energy and Energy Efficiency Advisory Committee (REEEAC) will hold a meeting on Thursday, February 22, 2018 at the U.S. Department of Commerce Herbert C. Hoover Building in Washington, DC. The meeting is open to the public with registration instructions provided below.

DATES: February 22, 2018, from approximately 8:30 a.m. to 5:00 p.m. Eastern Standard Time (EST). Members of the public wishing to participate must register in advance with Victoria Gunderson at the contact information below by 5:00 p.m. EST on Friday, February 16, 2018, in order to pre-register, including any requests to make comments during the meeting or for accommodations or auxiliary aids.

ADDRESSES: To register, please contact Victoria Gunderson, Designated Federal Officer, Office of Energy and Environmental Industries (OEI), International Trade Administration, U.S. Department of Commerce at (202) 482-7890; email: Victoria.Gunderson@trade.gov.

FOR FURTHER INFORMATION CONTACT: Victoria Gunderson, Designated Federal Officer, Office of Energy and Environmental Industries (OEI), International Trade Administration, U.S. Department of Commerce at (202) 482-7890; email: Victoria.Gunderson@trade.gov.

SUPPLEMENTARY INFORMATION:

Background: The Secretary of Commerce established the REEEAC pursuant to discretionary authority and in accordance with the Federal Advisory Committee Act, as amended (5 U.S.C. App.), on July 14, 2010. The REEEAC was re-chartered most recently on June 9, 2016. The REEEAC provides the Secretary of Commerce with consensus advice from the private sector on the development and administration of programs and policies to expand the export competitiveness of the U.S. renewable energy and energy efficiency products and services.

On February 22, the REEEAC will hold the sixth in-person meeting of its charter term, hold REEEAC sub-committee working sessions, discuss next steps for each sub-committee (Export Competitiveness, Market Access, and Finance), consider recommendations for approval, and hear from officials from the Department of Commerce and other agencies on major issues affecting the competitiveness of the U.S. renewable energy and energy efficiency industries. Agenda will be made available by February 16 upon request.

The meeting will be open to the public and will be accessible to people with disabilities. All guests are required to register in advance by the deadline identified under the **DATES** caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted, but may be impossible to fill.

A limited amount of time before the close of the meeting will be available for oral comments from members of the public attending the meeting. To accommodate as many speakers as possible, the time for public comments will be limited to two to five minutes per person (depending on number of public participants). Individuals wishing to reserve speaking time during the meeting must contact Ms. Gunderson and submit a brief statement of the general nature of the comments, as well as the name and address of the proposed participant by 5:00 p.m. EST on Friday, February 16, 2018. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a copy of their oral comments by email to Ms. Gunderson for distribution to the participants in advance of the meeting.

Any member of the public may submit written comments concerning the REEEAC's affairs at any time before or after the meeting. Comments may be submitted to the Renewable Energy and Energy Efficiency Advisory Committee, c/o: Victoria Gunderson, Designated Federal Officer, Office of Energy and Environmental Industries, U.S. Department of Commerce; 1401 Constitution Avenue NW; Mail Stop: 4053; Washington, DC 20230. To be considered during the meeting, written comments must be received no later than 5:00 p.m. EST on Friday, February 16, 2018, to ensure transmission to the REEEAC prior to the meeting. Comments received after that date will be distributed to the members but may not be considered at the meeting.

Copies of REEEAC meeting minutes will be available within 30 days following the meeting.

Dated: January 19, 2018.

Man Cho,

Deputy Director, Office of Energy and Environmental Industries.

[FR Doc. 2018-01334 Filed 1-25-18; 8:45 am]

BILLING CODE 3510-DR-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-469-817]

Ripe Olives From Spain: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that ripe olives from Spain are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is April 1, 2016, through March 31, 2017. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable January 26, 2018.

FOR FURTHER INFORMATION CONTACT: Catherine Carstos, Bryan Hansen, or Peter Zukowski, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-1757, (202) 482-3683, or (202) 482-0189, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on July 12, 2017.¹ On November 16, 2017, Commerce postponed the preliminary determination of this investigation and the revised deadline is now January 18, 2017.² For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.³ A list of topics included in the Preliminary Decision Memorandum is included at Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically

¹ See *Ripe Olives from Spain: Initiation of Less-Than-Fair-Value Investigation*, 82 FR 33054 (July 19, 2017) (*Initiation Notice*).

² See *Ripe Olives from Spain: Postponement of Preliminary Determination in the Less-Than-Fair Value Investigation*, 82 FR 53479 (November 16, 2017).

³ See Memorandum, "Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of ripe Olives from Spain," dated concurrently with, and hereby adopted by this notice (Preliminary Decision Memorandum).

via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>, and to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/>. The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is ripe olives from Spain. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,⁴ the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope). Both Aceitunas Guadalquivir S.L. (AG) and Angel Camacho Alimentacion S.L. (Camacho) stated that cocktail mixes are out of the scope. Without any further elaboration, the petitioners commented that AG and Camacho cannot unilaterally decide what is in or outside the scope. For this preliminary determination, Commerce is not modifying the scope and is including cocktail mixes in our analysis. We will further evaluate this issue for purposes of the final determination.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value (NV) is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary determination, see the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established

for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act. In this investigation, Commerce calculated estimated weighted-average dumping margins for AG, Agro Sevilla Aceitunas S.COOP Anndalusia, and Camacho that are not zero, *de minimis*, or based entirely on facts otherwise available. Commerce calculated the all-others rate using a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents using each company's business proprietary data for the merchandise under consideration.⁵

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Aceitunas Guadalquivir S.L.	16.80
Agro Sevilla Aceitunas S.COOP Anndalusia	14.64
Angel Camacho Alimentacion S.L.	19.73
All-Others	17.13

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) The cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit

rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

Commerce normally adjusts cash deposits for estimated antidumping duties by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding, when CVD provisional measures are in effect. Because Commerce preliminarily did not make an affirmative determination for countervailable export subsidies, Commerce has not offset the estimated weighted-average dumping margin by a CVD rate.⁶

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.⁷ Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date

⁴ See *Antidumping Duties; Countervailing Duties, Final Rule*, 62 FR 27296, 27323 (May 19, 1997).

⁵ For a complete analysis of the data, see Memorandum, "Less-Than-Fair-Value Investigation of Ripe Olives from Spain: Calculation of the All-Others Rate," dated concurrently with this notice.

⁶ See *Ripe Olives from Spain: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination With Final Antidumping Duty Determination*, 82 FR 56218 (November 20, 2017).

⁷ See 19 CFR 351.309; see also 19 CFR 351.303 (for general filing requirements).

of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On December 14, 2017, pursuant to 19 CFR 351.210(e), certain exporters of subject merchandise requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.⁸ In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) The preliminary determination is affirmative; (2) the requesting exporters account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later

than 135 days after the date of publication of this preliminary determination.

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: January 18, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The products covered by this investigation are certain processed olives, usually referred to as "ripe olives." The subject merchandise includes all colors of olives; all shapes and sizes of olives, whether pitted or not pitted, and whether whole, sliced, chopped, minced, wedged, broken, or otherwise reduced in size; all types of packaging, whether for consumer (retail) or institutional (food service) sale, and whether canned or packaged in glass, metal, plastic, multi-layered airtight containers (including pouches), or otherwise; and all manners of preparation and preservation, whether low acid or acidified, stuffed or not stuffed, with or without flavoring and/or saline solution, and including in ambient, refrigerated, or frozen conditions.

Included are all ripe olives grown, processed in whole or in part, or packaged in Spain. Subject merchandise includes ripe olives that have been further processed in Spain or a third country, including but not limited to curing, fermenting, rinsing, oxidizing, pitting, slicing, chopping, segmenting, wedging, stuffing, packaging, or heat treating, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in Spain.

Excluded from the scope are: (1) Specialty olives⁹ (including "Spanish-style," "Sicilian-

style," and other similar olives) that have been processed by fermentation only, or by being cured in an alkaline solution for not longer than 12 hours and subsequently fermented; and (2) provisionally prepared olives unsuitable for immediate consumption (currently classifiable in subheading 0711.20 of the Harmonized Tariff Schedule of the United States (HTSUS)).

The merchandise subject to this investigation is currently classifiable under subheadings 2005.70.0230, 2005.70.0260, 2005.70.0430, 2005.70.0460, 2005.70.5030, 2005.70.5060, 2005.70.6020, 2005.70.6030, 2005.70.6050, 2005.70.6060, 2005.70.6070, 2005.70.7000, 2005.70.7510, 2005.70.7515, 2005.70.7520, and 2005.70.7525 HTSUS. Subject merchandise may also be imported under subheadings 2005.70.0600, 2005.70.0800, 2005.70.1200, 2005.70.1600, 2005.70.1800, 2005.70.2300, 2005.70.2510, 2005.70.2520, 2005.70.2530, 2005.70.2540, 2005.70.2550, 2005.70.2560, 2005.70.9100, 2005.70.9300, and 2005.70.9700. Although HTSUS subheadings are provided for convenience and US Customs purposes, they do not define the scope of the investigation; rather, the written description of the subject merchandise is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Period of Investigation
- IV. Scope Comments
- V. Product Characteristics
- VI. Discussion of the Methodology
 - A. Determination of the Comparison Method
 - B. Results of the Differential Pricing Analysis
- VII. Date of Sale
- VIII. Product Comparisons
- IX. Export Price and Constructed Export Price

made from various olive varieties. Most are stuffed with pimento; other popular stuffings are jalapeno, garlic, and cheese. The raw olives that are used to produce Spanish-style green olives are picked while they are unripe, after which they are submerged in an alkaline solution for typically less than a day to partially remove their bitterness, rinsed, and fermented in a strong salt brine, giving them their characteristic flavor.

- "Sicilian-style" green olives. Sicilian-style olives are large, firm green olives with a natural bitter and savory flavor. This style of olive is produced in small quantities in the United States using a Sevillano variety of olive and harvested green with a firm texture. Sicilian-style olives are processed using a brine-cured method, and undergo a full fermentation in a salt and lactic acid brine for 4 to 9 months. These olives may be sold whole unpitted, pitted, or stuffed.

- "Kalamata" olives. Kalamata olives are slightly curved in shape, tender in texture, and purple in color, and have a rich natural tangy and savory flavor. This style of olive is produced in Greece using a Kalamata variety olive. The olives are harvested after they are fully ripened on the tree, and typically use a brine-cured fermentation method over 4 to 9 months in a salt brine.

- Other specialty olives in a full range of colors, sizes, and origins, typically fermented in a salt brine for 3 months or more.

⁸ See Letter from Asociación de Exportadores e Industriales de Aceitunas de Mesa (ASEMESA), Industria Aceyunera Marciense, S.A., DCOOP, S. COOP. AND., Agro Sevilla Aceitunas, SOC. COOP. AND., Plasoliva, S.L., GOYA en Espana, S.A.U., Aceitunas Guadalquivir, S.L., Angel Camacho Alimentación, S.L., Internacional Oliverera S.A., F.J. Sanchez Sucesores, S.A.U., and Aceitunas Sevillanas S.A., "Request to Postpone the Final Antidumping Determination: Ripe Olives from Spain," dated December 14, 2017.

⁹ Some of the major types of specialty olives and their curing methods are:

- "Spanish-style" green olives. Spanish-style green olives have a mildly salty, slightly bitter taste, and are usually pitted and stuffed. This style of olive is primarily produced in Spain and can be

- X. Normal Value
 - A. Comparison Market Viability
 - B. Affiliated Party Transactions and Arm's-Length Test
 - C. Level of Trade
 - D. Cost of Production Analysis
 - 1. Calculation of COP
 - 2. Test of Comparison Market Sales Prices
 - 3. Results of the COP Test
 - E. Calculation of NV Based on Comparison Market Prices
 - F. Calculation of NV Based on Constructed Value
- XI. Currency Conversion
- XII. Conclusion

[FR Doc. 2018-01447 Filed 1-25-18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XF975

Caribbean Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Caribbean Fishery Management Council's (Council) Scientific and Statistical Committee (SSC) will hold a 5-day meeting in February/March to discuss Action 3 of the Island Based FMP, including the ABC control rule and its application to stock complexes, and the items contained in the agenda in the **SUPPLEMENTARY INFORMATION**.

DATES: The meeting will be held from February 26 to March 2, 2018, starting on Monday at 1 p.m. through Friday 12 p.m.

ADDRESSES: The meeting will be held at the Council Office, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico.

FOR FURTHER INFORMATION CONTACT: Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918-1903; telephone: (787) 766-5926.

SUPPLEMENTARY INFORMATION:

—Call to Order

—Adoption of Agenda

—Overview

Review outcomes from previous meeting.

—Action 3: Management Reference Points for Stocks/Stock complexes in each of the Puerto Rico, St. Thomas/ St. John and St Croix FMPs

—Tiered ABC Control Rule

- Finalize process for determining the scalars used in Tiered ABC Control Rule
- Finalize process for determining the buffer from the overfishing limit (OFL) to ABC (scientific uncertainty buffer) used in the Tiered ABC Control Rule.
- Finalize choice of scalar and scientific uncertainty buffer for Tiers 4a and 4b for the applicable stocks.
- Application of Acceptable Biological Catch (ABC) Control Rule Language
- Review and Finalize process developed for the application of ABC CR to Tier 4a species with high CVs
- Southeast Fisheries Science Center (SEFSC) options
- Stocks/stock complexes to which the Tiered ABC CR cannot be applied:
- Recommendations on time series of landings data (year sequences) to establish reference points for the applicable stocks/stock complexes.
- Recommendations on the establishment of the maximum sustainable yield proxy (*e.g.*, mean, median, following the Caribbean Annual Catch Limit Amendments' approach) for the applicable stocks/stock complexes.
- Recommendations on the scientific uncertainty buffer to determine the ABC for the applicable stocks/stock complexes.
- Recommendations to the Caribbean Fishery Management Council
- Other Business

The order of business may be adjusted as necessary to accommodate the completion of agenda items. The meeting will begin on February 26, 2018 at 1 p.m. Other than the start time, interested parties should be aware that discussions may start earlier or later than indicated. In addition, the meeting may be extended from, or completed prior to the date established in this notice.

Special Accommodations

These meetings are physically accessible to people with disabilities. For more information or request for sign language interpretation and other auxiliary aids, please contact Mr. Miguel A. Rolón, Executive Director, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico, 00918-1903, telephone: (787) 766-5926, at least 5 days prior to the meeting date.

Dated: January 23, 2018.

Tracey L. Thompson,

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

[FR Doc. 2018-01427 Filed 1-25-18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XF981

Mid-Atlantic Fishery Management Council (MAFMC); Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Tilefish Monitoring Committee of the Mid-Atlantic Fishery Management Council (Council) will hold a meeting.

DATES: The meeting will be held on Friday, March 16, 2018, beginning at 9 a.m. and conclude by 1 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held via webinar with a telephone-only connection option.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674-2331 or on their website at www.mafmc.org.

FOR FURTHER INFORMATION CONTACT:

Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526-5255.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is for the Tilefish Monitoring Committee to recommend management measures designed to achieve recommended catch limits for the blue line and golden tilefish fisheries.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526-5251, at least 5 days prior to the meeting date.

Dated: January 23, 2018.

Tracey L. Thompson,

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

[FR Doc. 2018-01430 Filed 1-25-18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648–XF950

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting (webinar).

SUMMARY: The Pacific Fishery Management Council (Pacific Council) will hold a webinar meeting to review the 2018 update stock assessment for Pacific sardine. This webinar is open to the public.

DATES: The webinar will be held Tuesday, March 6, 2018, from 1 p.m. to 4 p.m., or until business has been completed.

ADDRESSES: The meeting will be held via webinar. A public listening station is available at the Pacific Council office (address below). To attend the webinar, use this link: <https://www.gotomeeting.com/webinar> (Click “Join a Webinar” in top right corner of page). (1) Enter the Webinar ID: 596–833–451. (2) Enter your name and email address (required). You must use your telephone for the audio portion of the meeting by dialing this TOLL number 1–415–655–0060. (3) Enter the Attendee phone audio access code 376–071–500. (4) Enter your audio phone pin (shown after joining the webinar). NOTE: We have disabled Mic/Speakers as an option and require all participants to use a telephone or cell phone to participate. Technical Information and System Requirements: PC-based attendees are required to use Windows® 7, Vista, or XP; Mac®-based attendees are required to use Mac OS® X 10.5 or newer; Mobile attendees are required to use iPhone®, iPad®, Android™ phone or Android tablet (See the <https://www.gotomeeting.com/webinar/ipad-iphone-android-webinar-apps>). You may send an email to Mr. Kris Kleinschmidt at Kris.Kleinschmidt@noaa.gov or contact him at 503–820–2280, extension 411 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Kerry Griffin, Pacific Council; telephone: (503) 820–2409.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to review the 2018 update stock assessment for Pacific sardine. The Coastal Pelagic Species (CPS) Subcommittee of the Pacific Council’s Scientific and Statistical Committee (SSC) will conduct the review, and will follow the Pacific Council’s Terms of Reference for Stock Assessment Reviews. The Pacific Council will use the 2018 assessment to establish Pacific sardine fishery management measures and harvest specifications for the 2018–19 fishing year, which begins July 1 and ends the following June 30 each year. Representatives of the Council’s CPS Management Team and the CPS Advisory Subpanel will also participate in the review, as advisers.

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

Special Accommodations

The public listening station is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at kris.kleinschmidt@noaa.gov; phone: (503) 820–2411 at least 10 days prior to the meeting date.

Dated: January 23, 2018.

Tracey L. Thompson,

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

[FR Doc. 2018–01422 Filed 1–25–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****Proposed Information Collection; Comment Request; Atlantic Highly Migratory Species Permit Family of Forms**

AGENCY: National Oceanic and Atmospheric Administration, 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 a revised, and continuing information collection described below, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before March 27, 2018.

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 pracomments@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to: Cliff Hutt, phone 301–427–8503 or email Cliff.Hutt@noaa.gov.

SUPPLEMENTARY INFORMATION:**I. Abstract**

This request is for the revision and extension of a current information collection, which includes both vessel and dealer permits.

Under the provisions of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), the National Oceanic and Atmospheric Administration’s National Marine Fisheries Service (NMFS) is responsible for management of the Nation’s marine fisheries. In addition, NMFS must comply with the United States’ obligations under the Atlantic Tunas Convention Act of 1975 (16 U.S.C. 971 *et seq.*). NMFS issues permits to fishing vessels and dealers in order to collect information necessary to comply with domestic and international obligations, secure compliance with regulations, and disseminate necessary information.

Regulations at 50 CFR 635.4 require that vessels participating in commercial and recreational fisheries for Atlantic highly migratory species (HMS) and dealers purchasing Atlantic HMS from a vessel obtain a Federal permit issued by NMFS. This action addresses the renewal of permit applications currently approved under PRA 0648–0327, including both vessel and Atlantic Tunas Dealer permits. Vessel permits include Atlantic Tunas (except Longline permits, which are approved under OMB Control No. 0648–0205), HMS Charter/Headboat, HMS Angling, and Swordfish General Commercial permits. This action also includes the one-time requirement for commercial vessels greater than 20 meters in length to obtain a International Maritime

Organization/Lloyd's Registry (IMO/LR) number.

The primary reason for the revision of this information collection is to reflect that HMS International Trade Permits have been removed from this collection as they were discontinued in 2016, and replaced with the International Fishing Trade Permit (IFTP). The IFTP is covered under OMB Control No. 0648–0732. Thus, the burden and costs associated with renewal and issuance of an initial HMS ITP are no longer applicable to this collection of information.

II. Method of Collection

Methods of submittal include on line, email, and mail.

III. Data

OMB Control Number: 0648–0327.

Form Number(s): None.

Type of Review: Regular submission (request for revision and extension of a current information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 39,571.

Estimated Time per Response:

Renewal of Atlantic Tunas Dealer Permit application, 5 minutes; renewal applications for the following vessel permits—Atlantic Tunas, HMS Charter/Headboat, HMS Angling, and Swordfish General Commercial, 10 minutes; initial Atlantic Tunas Dealer Permit application, 15 minutes; initial applications for the following vessel permits—Atlantic Tunas, HMS Charter/Headboat, HMS Angling, and Swordfish General Commercial, 35 minutes; One-time application for the IMO/LP number, 30 minutes.

Estimated Total Annual Burden Hours: 11,063.

Estimated Total Annual Cost to Public: \$947,844.

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; they also will become a matter of public record.

Dated: January 19, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–01327 Filed 1–25–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF980

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Tilefish Advisory Panel of the Mid-Atlantic Fishery Management Council (Council) will hold a meeting.

DATES: The meeting will be held on Wednesday, February 21, 2018, beginning at 9 a.m. and conclude by 1 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held via webinar with a telephone-only connection option.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331 or on their website at www.mafmc.org.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to create fishery performance reports for blueline and golden tilefish by the Council's Tilefish Advisory Panel. The intent of these reports is to facilitate a venue for structured input from the Advisory Panel members for the Tilefish specifications processes, including recommendations by the Council and its Scientific and Statistical Committee (SSC).

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders,

(302) 526–5251, at least 5 days prior to the meeting date.

Dated: January 23, 2018.

Tracey L. Thompson,

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

[FR Doc. 2018–01429 Filed 1–25–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF911

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

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

ACTION: Notice of change of date for the SEDAR 51 Review Workshop for Gulf of Mexico Gray Snapper.

SUMMARY: The SEDAR 51 assessment of the Gulf of Mexico Gray Snapper will consist of: A Data Workshop; an Assessment Workshop and series of Assessment webinars; and a Review Workshop. This notice is to indicate a change of date for the Review Workshop for SEDAR 51. The original Review Workshop dates were February 13–15, 2018. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 51 Review Workshop will be held from 9 a.m. on March 20, 2018 until 5 p.m. on March 22, 2018. See **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The SEDAR 51 Review Workshop will be held at the Gulf of Mexico Fishery Management Council Office, 2203 N Lois Ave, Suite 1100, Tampa, FL 33607.

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

FOR FURTHER INFORMATION CONTACT: Julie Neer, SEDAR Coordinator; phone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: Julie.neer@safmc.net.

SUPPLEMENTARY INFORMATION: The original notice published in the **Federal Register** on January 22, 2018 (83 FR 2963).

The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data,

Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three step process including: (1) Data Workshop; (2) Assessment Process utilizing workshops and webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Review Workshop agenda are as follows:

1. The Review Panel participants will review the stock assessment reports to determine if they are scientifically sound.

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

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the council office (see ADDRESSES) at least 10 days prior to the meeting.

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

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

Dated: January 23, 2018.

Tracey L. Thompson,

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

[FR Doc. 2018-01453 Filed 1-25-18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XF976

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold public meetings of the Council and its Committees.

DATES: The meetings will be held Tuesday, February 13, 2018 through Thursday, February 15, 2018. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held at: The Hilton Garden Inn Raleigh/Crabtree Valley, 3912 Arrow Drive, Raleigh, NC 27612, telephone: (919) 703-2525.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State St., Suite 201, Dover, DE 19901; telephone: (302) 674-2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D. Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526-5255. The Council's website, www.mafmc.org also has details on the meeting location, proposed agenda, webinar listen-in access, and briefing materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's website when possible).

Tuesday, February 13, 2018

Risk Policy Framework and MSE

Council discussion on integration of more comprehensive social and economic analyses into MAFMC MSE model developed to evaluate Council risk policy and ABC Framework and risk policy and butterfly specifications.

Climate Change and Fisheries

Trends in average commercial fishing locations over time in response to shifts in species distribution and discuss future direction of Rutgers/MAFMC Climate Velocity COCA project.

Wednesday, February 14, 2018

Ricks E Savage Award

Black Sea Bass Recreational Management Measures

Adopt 2018 Federal waters management measures (tabled motion from December 2017 meeting); review state proposals for 2018 February fishery; and, discuss progress on LOA Framework.

Summer Flounder, Scup, and Black Sea Bass Commercial Accountability Measures Framework—Meeting 2

Review and approve preferred alternatives.

Council Habitat Update

Progress towards a Regional Fish Habitat Assessment; Council engagement on Offshore Wind Energy Planning; and, habitat projects of interest (GARFO/Habitat Conservation update).

North Atlantic Right Whale 5-Year Review and Reinitiation of Endangered Species Act (ESA) Section 7 Fishery Biological Opinions

Update on the status of right whales and a summary of recent research; overview of consultation on commercial fisheries under Section 7 of the ESA; and, update on planned activities of the Atlantic Large Whale Take Reduction Team under the Marine Mammal Protection Act in 2018.

Thursday, February 15, 2018

Business Session

Committee Reports; Executive Director's Report; Science Report (review final draft of EAFM Risk Assessment); Law Enforcement Reports; Organization Reports; and, Liaison Reports.

Continuing and New Business

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency

action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526-5251, at least 5 days prior to the meeting date.

Dated: January 23, 2018.

Tracey L. Thompson,

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

[FR Doc. 2018-01428 Filed 1-25-18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Council Coordination Committee Meeting

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

ACTION: Notice of a public meeting; information regarding the agenda.

SUMMARY: NMFS will host a meeting of the Council Coordination Committee (CCC), consisting of the Regional Fishery Management Council chairs, vice chairs, and executive directors on February 27–February 28, 2018. The intent of this meeting is to discuss issues of relevance to the Councils and NMFS, including issues related to the implementation of the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act. Agenda items include discussions on budget allocations for FY2018 and budget planning for FY2019; an update on current joint science initiatives, including Ecosystem Based Fisheries Management; the FY2018 legislative outlook; updates on aquaculture initiatives, Council Member voting recusals, the NMFS National Standard 1 implementation, Marine Recreational Information Program updates; and other topics related to implementation of the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act. All sessions are open to the public.

DATES: The meeting will begin at 8:30 a.m. on Tuesday, February 27, 2018, recess at 5 p.m. or when business is complete; and reconvene at 8:30 a.m. on

Wednesday, February 28, 2018, and adjourn by 4:30 p.m. or when business is complete.

ADDRESSES: The meeting will be held at the Holiday Inn Capitol Hill, 550 C Street SW, Washington, DC 20024, telephone 202-479-4000, fax 202-288-4627.

FOR FURTHER INFORMATION CONTACT:

Brian Fredieu: telephone 301-427-8505 or email at Brian.Fredieu@noaa.gov.

SUPPLEMENTARY INFORMATION:

The Magnuson-Stevens Fishery Conservation and Management Reauthorization Act established the CCC by amending Section 302 (16 U.S.C. 1852) of the MSA. The committee consists of the chairs, vice chairs, and executive directors of each of the eight Regional Fishery Management Councils authorized by the MSA or other Council members or staff. Updates to this meeting and additional information will be posted on <http://www.nmfs.noaa.gov/sfa/management/councils/ccc/ccc.htm> when available.

Proposed Agenda

Tuesday, February 27, 2018

8:30 a.m.—Morning session begins

- Welcome/Introductions
- NMFS Update & FY17 Priorities
- Aquaculture Initiative Updates
- Legislative Outlook
- MSA Reauthorization & CCC Comments
- Regulatory Reform Update
- Management and Budget Update
- Council Member Conflict of Interest and Recusal working group update
- FOIA Guidance

5:15 p.m.—Adjourn for the day

Wednesday, February 28, 2018

9 a.m.—Morning Session Begins

- EBFM Regional Implementation
- Electronic Monitoring Policy Development
- MRIP Transition Implementation
- BSIA Guidance Update
- NS1 Technical Guidance Update
- Other Business

4:15 p.m.—Adjourn for the day

The order in which the agenda items are addressed may change. The CCC will meet as late as necessary to complete scheduled business.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Brian Fredieu at 301-427-8505 at least five working days prior to the meeting.

Dated: January 22, 2018.

Samuel D. Rauch, III,

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

[FR Doc. 2018-01389 Filed 1-25-18; 8:45 am]

BILLING CODE 3510-22-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

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

ACTION: Additions to and deletions from the Procurement List.

SUMMARY: This action adds services to the Procurement List that will be provided by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products from the Procurement List previously furnished by such agencies.

DATES: *Date added to the Procurement List:* February 25, 2018.

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: Amy B. Jensen, Telephone: (703) 603-7740, Fax: (703) 603-0655, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION:

Additions

On 12/15/2017 (82 FR 240) and 12/22/2017 (82 FR 245), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the services and impact of the additions on the current or most recent contractors, the Committee has determined that the services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501-8506 and 41 CFR 51-2.4.

Regulatory Flexibility Act Certification

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

1. The action will not result in any additional reporting, recordkeeping or

other compliance requirements for small entities other than the small organizations that will provide the services to the Government.

2. The action will result in authorizing small entities to provide the services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following services are added to the Procurement List:

Services

Service Type: Grounds Maintenance Service

Mandatory for: U.S. Coast Guard Station

Atlantic City, 900 Beach Thorofare,
Atlantic City, NJ

Mandatory Source of Supply: Fedcap
Rehabilitation Services, Inc., New York,
NY

Contracting Activity: U.S. Coast Guard,
TRACEN CAPE MAY (00042)

Service Type: Custodial Service

Mandatory for: U.S. Customs and Border
Protection, 6604 E. Rutter Ave., Hangar
32, Spokane, WA

Mandatory Source of Supply: Good Works,
Inc., Spokane, WA

Contracting Activity: U.S. Customs and
Border Protection, Air and Marine CTR
Div

Service Type: Mail and Supply Center
Operations Service

Mandatory for: DARPA Headquarters, 675
North Randolph Street, Arlington, VA

Mandatory Source of Supply: Linden
Resources, Inc., Arlington, VA

Contracting Activity: Defense Advanced
Research Projects Agency (DARPA)

Deletions

On 12/22/2017 (82 FR 245), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

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

Regulatory Flexibility Act Certification

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

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

2. The action may result in authorizing small entities to furnish the products to the Government.

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

End of Certification

Accordingly, the following products are deleted from the Procurement List:

Products

NSN—Product Name: PSIN TO12M—Kit,
Wee-Deliver Starter

Mandatory Source of Supply: New Horizons
Rehabilitation Services, Inc., Auburn
Hills, MI

Contracting Activity: U.S. Postal Service

NSNs—Product Names:

7920–01–512–4960—Mop Head, Wet,
Looped-End, Anti-Microbial, 32 oz.,
Yellow

7920–01–512–8967—Mop Head, Wet,
Looped-End, Anti-Microbial, 32 oz.,
White

7920–01–512–8970—Mop Head, Wet,
Looped-End, Anti-Microbial, 32 oz., Red

7920–01–512–8971—Mop Head, Wet,
Looped-End, Anti-Microbial, 32 oz.,
Orange

7920–01–512–9340—Mop Head, Wet,
Looped-End, Anti-Microbial, 22 oz., Red

7920–01–512–9341—Mop Head, Wet,
Looped-End, Anti-Microbial, 22 oz.,
Yellow

7920–01–512–9342—Mop Head, Wet,
Looped-End, Anti-Microbial, 22 oz.,
Orange

7920–01–512–9344—Mop Head, Wet,
Looped-End, Anti-Microbial, 22 oz.,
White

7920–01–512–9346—Mop Head, Wet,
Looped-End, Anti-Microbial, 20 oz.,
Yellow

7920–01–513–4767—Mop Head, Wet,
Looped-End, Anti-Microbial, 24 oz.,
Yellow

7920–01–513–4769—Mop Head, Wet,
Looped-End, Anti-Microbial, 16 oz.,
Yellow

Mandatory Source of Supply: Alphapointe,
Kansas City, MO

Contracting Activities: Department of
Veterans Affairs, Strategic Acquisition
Center, General Services Administration,
Fort Worth, TX

Patricia Briscoe,

*Deputy Director, Business Operations,
(Pricing and Information Management).*

[FR Doc. 2018–01439 Filed 1–25–18; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

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

ACTION: Proposed deletions from the
Procurement List.

SUMMARY: The Committee is proposing
to delete a product and a service from
the Procurement List that was
previously furnished by nonprofit
agencies employing persons who are
blind or have other severe disabilities.

DATES: Comments must be received on
or before: February 25, 2018.

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: Amy B. Jensen,
Telephone: (703) 603–7740, 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.

Deletion

The following product and service are
proposed for deletion from the
Procurement List:

Product

NSN—Product Name: 8415–01–494–4605—
Cover, Parachutists' and Ground Troops'
Helmet, All Services, Snow Camouflage,
ML

Mandatory Source of Supply: Mount Rogers
Community Services Board, Wytheville,
VA

Contracting Activity: Defense Logistics
Agency Troop Support

Service

Service Type: Custodial Service

Mandatory for: GSA PBS Region 5, Federal
Building and U.S. Courthouse, 201 N
Vermilion Street, Danville, IL

Mandatory Source of Supply: Challenge
Unlimited, Inc., Alton, IL

Contracting Activity: Public Buildings
Service, Acquisition Management
Division

Patricia Briscoe,

*Deputy Director, Business Operations,
(Pricing and Information Management).*

[FR Doc. 2018–01444 Filed 1–25–18; 8:45 am]

BILLING CODE 6353–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION**[Docket No. CFPB–2018–0001]****Request for Information Regarding Bureau Civil Investigative Demands and Associated Processes****AGENCY:** Bureau of Consumer Financial Protection.**ACTION:** Notice and request for information.**SUMMARY:** The Bureau of Consumer Financial Protection (Bureau) is seeking comments and information from interested parties to assist the Bureau in assessing potential changes that can be implemented to the Bureau's Civil Investigative Demand (CID) processes, consistent with law, to consider whether any changes to the processes would be appropriate.**DATES:** Comments must be received by March 27, 2018.**ADDRESSES:** You may submit responsive information and other comments, identified by Docket No. CFPB–2018–0001, by any of the following methods:

- *Electronic:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Email:* FederalRegisterComments@cfpb.gov. Include Docket No. CFPB–2018–0001 in the subject line of the message.
- *Mail:* Monica Jackson, Office of the Executive Secretary, Consumer Financial Protection Bureau, 1700 G Street NW, Washington, DC 20552.
- *Hand Delivery/Courier:* Monica Jackson Office of the Executive Secretary, Consumer Financial Protection Bureau, 1700 G Street NW, Washington, DC 20552.

Instructions: The Bureau encourages the early submission of comments. All submissions must include the document title and docket number. Because paper mail in the Washington, DC area and at the Bureau is subject to delay, commenters are encouraged to submit comments electronically. In general, all comments received will be posted without change to <http://www.regulations.gov>. In addition, comments will be available for public inspection and copying at 1700 G St NW, Washington, DC 20552, on official business days between the hours of 10 a.m. and 5 p.m. eastern standard time. You can make an appointment to inspect the documents by telephoning 202–435–7275.

All submissions in response to this request for information, including attachments and other supporting materials, will become part of the public

record and subject to public disclosure. Sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: For general inquiries and submission process questions, please call Monica Jackson at (202) 435–7275.

SUPPLEMENTARY INFORMATION: In the course of its investigatory activities, and as authorized by 12 U.S.C. 5562 and 12 CFR 1080.6, the Bureau issues CIDs to entities and persons whom the Bureau has reason to believe may have information relevant to a violation of the laws the Bureau enforces. These demands require recipients to provide the Bureau with information in varying forms: Most frequently some combination of written answers to interrogatories, written reports, documents, tangible things, and testimony. Recipients are required to produce the requested information to the Bureau, which uses such information to further investigations of potential violations of Federal consumer financial laws.

To assess the efficiency and effectiveness of its existing CID processes, the Bureau is, as described below, issuing this request for information seeking public comment on how best to achieve meaningful burden reduction or other improvement to the CID processes while continuing to achieve the Bureau's statutory and regulatory objectives.

Overview of This Request for Information

The Bureau is using this request for information to seek public input regarding the exercise of its authority to issue CIDs, including from entities who have received one or more CIDs from the Bureau, or members of the bar who represent these entities.

The issuance of CIDs is an essential tool for fulfilling the Bureau's statutory mission of enforcing Federal consumer financial law. The Bureau issues CIDs in accordance with the law and in furtherance of its investigatory objectives. The Bureau understands, however, that responding to a CID can impose burdens on the recipients. Entities who have received one or more CIDs, members of the bar who represent these entities, and members of the public are likely to have useful information and perspectives on the benefits and burdens of the Bureau's existing processes related to CIDs. The Bureau is especially interested in better

understanding how its processes related to CIDs may be updated, streamlined, or revised to better achieve the Bureau's statutory and regulatory objectives, while minimizing burdens, consistent with applicable law, and how to align the Bureau's CID processes with those of other agencies with similar authorities. Interested parties may also be well-positioned to identify those parts of the Bureau's processes related to CIDs that are most in need of improvement, and, thus, assist the Bureau in prioritizing and properly tailoring its review process. In short, engaging CID recipients, potential CID recipients, and the public in an open, transparent process will help inform the Bureau's review of its processes related to CIDs.

Questions for Commenters

To allow the Bureau to more effectively evaluate suggestions, the Bureau requests that, where possible, comments include:

- Specific suggestions regarding any potential updates or modifications to the Bureau's practices regarding the formulation, issuance, or modification of CIDs consistent with the Bureau's regulatory and statutory objectives, including, in as much detail as possible, the potential update or modification, supporting data or other information such as cost information or information concerning alignment with the processes of other agencies with similar authorities; and
- Specific identification of any aspects of the Bureau's CID processes that should not be modified, including supporting data or other information such as cost information or information concerning alignment with the processes of other agencies with similar authorities.

The following list of questions represents a preliminary attempt by the Bureau to identify elements of Bureau processes related to CIDs on which it should immediately focus. This non-exhaustive list is meant to assist in the formulation of comments and is not intended to restrict the issues that may be addressed. In addressing these questions or others, the Bureau requests that commenters identify with specificity the Bureau regulations or practices at issue, providing legal citations where appropriate and available.

The Bureau is seeking feedback on all aspects of its civil investigative demand process, including but not limited to:

1. The Bureau's processes for initiating investigations, including 12 CFR 1080.4's delegation of authority to initiate investigations to the Assistant Director of the Office of Enforcement

and the Deputy Assistant Directors of the Office of Enforcement;

2. The Bureau's processes for the issuance of CIDs, including the non-delegable authority of the Director, Assistant Director of the Office of Enforcement, and the Deputy Assistant Directors of the Office of Enforcement to issue CIDs;

3. Specific steps that the Bureau could take to improve CID recipients' understanding of investigations, whether through the notification of purpose included in each CID or through other avenues, including facilitating a better understanding of the specific types of information sought by the CID;

4. The nature and scope of requests included in Bureau CIDs, including whether topics, questions, or requests for written reports effectively achieve the Bureau's statutory and regulatory objectives, while minimizing burdens, consistent with applicable law, and the extent to which the meet and confer process helps achieve these objectives;

5. The timeframes associated with each step of the Bureau's CID process, including return dates, and the specific timeframes for meeting and conferring, and petitioning to modify or set aside a CID;

6. The Bureau's taking of testimony from an entity, including whether 12 CFR 1080.6(a)(4)(ii), and/or the Bureau's processes should be modified to make expressly clear that the standards applicable to Federal Rule of Civil Procedure 30(b)(6) also apply to the Bureau's taking of testimony from an entity;

7. The Bureau's processes for handling the inadvertent production of privileged information, including whether 12 CFR 1080.8(c) and/or the Bureau's processes should be modified in order to make expressly clear that the standards applicable to Federal Rule of Evidence 502 also apply to documents inadvertently produced in response to a CID;

8. The rights afforded to witnesses by 12 CFR 1080.9, including limitations on the role of counsel described in 12 CFR 1080.9(b) in light of the statutory delineation of objections set forth in 12 U.S.C. 5562(c)(13)(D)(iii);

9. The Bureau's processes concerning meeting and conferring with recipients of CIDs, including, for example, negotiations regarding modifications and the delegation of authority to the Assistant Director of the Office of Enforcement and Deputy Assistant Directors of the Office of Enforcement to negotiate and approve the terms of satisfactory compliance with civil

investigative demands and extending the time for compliance;

10. The Bureau's requirements for responding to CIDs, including certification requirements, and the Bureau's CID document submission standards; and

11. The Bureau's processes concerning CID recipients' petitions to modify or set aside Bureau CIDs, including:

a. Whether it is appropriate for Bureau investigators to provide the Director with a statement setting out a response to the petition without serving that response on the petitioner;

b. Whether petitions and the Director's orders should be made public, consistent with applicable laws; and

c. The costs and benefits of the petition to modify or set aside process, vis-à-vis direct adjudication in Federal court, in light of the statutory requirement for the petition process and the fact that CIDs are not self-enforcing.

Authority: 12 U.S.C. 5511(c).

Dated: January 18, 2018.

Mick Mulvaney,

Acting Director, Bureau of Consumer Financial Protection.

[FR Doc. 2018-01435 Filed 1-25-18; 8:45 am]

BILLING CODE 4810-AM-P

DEPARTMENT OF DEFENSE

Department of the Air Force

Acceptance of Group Application Under Public Law and Department of Defense Directive

AGENCY: Department of the Air Force, DoD Civilian/Military Service Review Board, DoD.

ACTION: Notice.

Under the provisions of Section 401, Public Law 95-202 and DoD Directive 100.20, the Department of Defense Civilian/Military Service Review Board has accepted an application on behalf of a group known as "Department of the Navy (DON) Civilian Special Agents who Served in Direct Support and Under Control of the DON within the Republic of Vietnam During the Period January 9, 1962 through May 7, 1975 (Vietnam War)." Persons with information or documentation pertinent to the determination of whether service of this group should be considered active military service to the Armed Forces of the United States are encouraged to submit such information or documentation within 60 days to the DoD Civilian/Military Service Review Board (DoD C/MSRB), 1500 West

Perimeter Road, Suite 3700, Joint Base Andrews NAF, MD 20762-7002.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas R. Uiselt, Deputy Executive Secretary, DoD C/MSRB, at 240-612-5409, thomas.r.uiselt.civ@mail.mil. Copies of documents or other materials submitted cannot be returned.

Henry Williams,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2018-01308 Filed 1-25-18; 8:45 am]

BILLING CODE 5001-10-P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS-2016-0033; OMB Control Number 0704-0332]

Submission for OMB Review; Comment Request

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

ACTION: Notice.

SUMMARY: The Defense Acquisition Regulations System has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by February 26, 2018.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Appendix I, DoD Pilot Mentor-Protege Program; OMB Control Number 0704-0332.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Type of Request: Revision of a currently approved collection.

Reporting Frequency: On occasion.

Number of Respondents: 127.

Responses per Respondent: 2, approximately.

Annual Responses: 255.

Average Burden per Response: 2.3 hours, approximately.

Annual Burden Hours: 595.

Needs and Uses: DoD needs this information to ensure that participants in the Mentor-Protege Program ("the Program") are fulfilling their obligations under the mentor-protege agreements and that the Government is receiving value for the benefits it provides through the Program. DoD uses the information as source data for reports to

Congress required by section 811(d) of the National Defense Authorization Act for Fiscal Year 2000 (Pub. L. 106–65). Participation in the Program is voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

Comments and recommendations on the proposed information collection should be sent to Ms. Jasmeet Seehra, DoD Desk Officer, at *Oira_submission@omb.eop.gov*. Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments, identified by docket number and title, by the following method:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

DoD Clearance Officer: Mr. Frederick C. Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at: WHS/ESD Directives Division, 4800 Mark Center Drive, 2nd Floor, East Tower, Suite 03F09, Alexandria, VA 22350–3100.

Jennifer L. Hawes,
Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2018–01478 Filed 1–25–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 17–61]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT:

Pamela Young, (703) 697–9107, *pamela.a.young14.civ@mail.mil* or Kathy Valadez, (703) 697–9217, *kathy.a.valadez.civ@mail.mil*; DSCA/DSA–RAN.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 17–61 with attached Policy Justification and Sensitivity of Technology.

Dated: January 23, 2018.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P



DEFENSE SECURITY COOPERATION AGENCY

201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

JAN 17 2018

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 17-61, concerning the Army's proposed Letter(s) of Offer and Acceptance to Saudi Arabia for defense articles and services estimated to cost \$500 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:

1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified document provided under separate cover)



Transmittal No. 17–61

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser*: Kingdom of Saudi Arabia

(ii) *Total Estimated Value*:

Major Defense Equipment *	\$ 0 million
Other	\$500 million
Total	\$500 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase*:

Major Defense Equipment (MDE):

None

Non-MDE:

Continued participation, technical assistance, and support in the Patriot Legacy Field Surveillance Program (FSP); the Patriot Advanced Capability 3 (PAC–3) FSP; and the Patriot Engineering Services Program (ESP). Also included are Patriot and HAWK Missile System spare parts and repair and return management services and component repairs, and other related elements of logistics and program support.

(iv) *Military Department*: Army (SR–B–ZAT, ZAS, BDN A2, WAK A5, and subsequent cases)

(v) *Prior Related Cases, if any*: SR–B–UAJ A1

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid*: None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold*: See Attached Annex

(viii) *Date Report Delivered to Congress*: January 17, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Saudi Arabia—Continuation of Missile System Support Services

The Government of the Kingdom of Saudi Arabia has requested a possible purchase for continued participation, technical assistance, and support in the Patriot Legacy Field Surveillance Program (FSP); the Patriot Advanced Capability 3 (PAC–3) FSP; and the Patriot Engineering Services Program (ESP). Also included are Patriot and HAWK Missile System spare parts and repair and return management services and component repairs, and other related elements of logistics and program support. The total estimated program cost is \$500 million.

This proposed sale will support U.S. foreign policy and national security objectives by helping to improve the security of a friendly country which has

been, and continues to be, an important force for political stability and economic growth in the Middle East. This potential sale is a continuation of current support. Saudi Arabia will have no difficulty absorbing this equipment and support into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractors are Lockheed Martin, Bethesda, MD for the FSP and Raytheon Company, Andover, MA for the ESP. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the permanent assignment of any U.S. Government or contractor representatives to Saudi Arabia. Support teams of 4–10 people will travel to the country on a temporary basis for 1–3 weeks at a time.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 17–61

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology*:

1. The Patriot Legacy and PAC–3 FSP programs assist international customers to maintain the readiness of their systems. These programs include the shared programs and country unique costs such as the Stockpile Reliability Test (SRT) and Missile Recertification programs. Services include the storage and aging program, surveillance firing program, the Patriot PAC–3 Missile Support Center (P3MSC), program support and a parts library.

2. As a participating international partner in the Patriot Engineering Services Program (ESP), Saudi Arabia is granted access to information such as engineering changes in development and under consideration, schedules for important events such as procurement and fielding of Patriot system improvements, development of Post Deployment Build (PDB) software, and a comprehensive program to address the issue of loss of sources of supply and advanced technology and their impact on availability of components. The program provides funding for the publication effort to incorporate country specific changes to Technical Manuals (TM). Preparation of all necessary Country specific TM change pages based on the latest version of the USG Department of Army Technical Manuals (DATMs) that support PDB

requirements and the existing Repair Parts and Special Tools Lists (RPSTLs). Tasks include technical writing, illustrating, editing and quality review of all changes in accordance with Technical Information Operating Procedures (TIOPS). Organizational Maintenance, Intermediate maintenance and repair parts are covered. Preparation of change pages documenting any upgrades to the existing manuals. These manuals shall include and document any configuration changes as identified resulting in a new manual. Examples of country specific tasks include country unique communication studies and analysis, specialized training for operations and maintenance personnel for new versions (builds) of system software, power generation trade studies, country unique publications, and in country technical and logistical support for system modifications.

3. Increasing Patriot and Hawk spares support provides Saudi Arabia the capability to sustain and bolster missile system operations through the purchase of spares, consumable repair parts, support equipment, supplies, and maintenance. Included is support for the procurement and transportation of classified parts that are part of Saudi Arabia's current Patriot and Hawk Missile System configurations, with a highest classification of CONFIDENTIAL.

4. If a technologically advanced adversary obtains knowledge of the specific hardware and software source code in this proposed sale, the information could be used to develop countermeasures or equivalent systems that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

5. A determination has been made that Saudi Arabia can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

6. All defense articles and services listed in this transmittal are authorized for release and export to the Kingdom of Saudi Arabia.

[FR Doc. 2018–01426 Filed 1–25–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE**Office of the Secretary****National Intelligence University Board of Visitors; Notice of Federal Advisory Committee Meeting; Cancellation**

AGENCY: Under Secretary of Defense for Intelligence, Department of Defense.

ACTION: Notice; cancellation.

SUMMARY: On Thursday, January 18, 2018 (83 FR 2625–2626), the Department of Defense (DoD) published a notice announcing a meeting of the National Intelligence University Board of Visitors that was to take place on Tuesday, January 23, 2018 and Wednesday, January 24, 2018. Due to a lapse in appropriations for the Department of Defense, the DoD is cancelling the January 23, 2018 and January 24, 2018 meeting.

FOR FURTHER INFORMATION CONTACT: Dr. Susan Studds, (301) 243–2121 (Voice), (301) 277–7067 (Facsimile), susan.studds@dodiis.mil (Email). Mailing address is President, DIA National Intelligence University, 7400 Pentagon, Washington, DC 20301–7400. website: <http://ni-u.edu/wp/about-niu/leadership-2/board-of-visitors/>.

SUPPLEMENTARY INFORMATION: Due to the lapse in appropriations for the DoD, the

Designated Federal Officer for the National Intelligence University Board of Visitors along with the DoD was unable to provide public notification required by 41 CFR 102–3.150(a) concerning the cancellation of its previously announced meeting on January 23, 2018 and January 24, 2018 of the National Intelligence University Board of Visitors that published on Thursday, January 18 2018. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

Dated: January 23, 2018.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–01507 Filed 1–25–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE**Office of the Secretary**

[Transmittal No. 17–80]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT:

Pamela Young, (703) 697–9107, pamela.a.young14.civ@mail.mil or Kathy Valadez, (703) 697–9217, kathy.a.valadez.civ@mail.mil; DSCA/DSA–RAN.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 17–80 with attached Policy Justification and Sensitivity of Technology.

Dated: January 23, 2018.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P



DEFENSE SECURITY COOPERATION AGENCY

201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5406

JAN 18 2018

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 17-80, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of Belgium for defense articles and services estimated to cost \$6.53 billion. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:

1. Transmittal
2. Policy Justification
3. Sensitivity of Technology



BILLING CODE 5001-06-C

Transmittal No. 17-80

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Belgium

(ii) *Total Estimated Value:*

Major Defense Equipment *	\$4.53 billion
Other	\$2.00 billion
Total	\$6.53 billion

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

Thirty-four (34) F-35 Joint Strike Fighter Conventional Take Off and Landing (CTOL) Aircraft

Thirty-eight (38) Pratt & Whitney F-135 Engines (34 installed, 4 spares)

Non-MDE:

Also included are Electronic Warfare Systems; Command, Control, Communications, Computer and

Intelligence/Communications, Navigational, and Identification (C4I/CNI); Autonomic Logistics Global Support System (ALGS); Autonomic Logistics Information System (ALIS); Full Mission Trainer; Weapons Employment Capability, and other Subsystems, Features, and Capabilities; F-35 unique infrared flares; Reprogramming center; F-35 Performance Based Logistics; software development/integration; aircraft ferry and tanker support; support equipment; tools and test equipment; communications equipment; spares and repair parts; personnel training and training equipment; publications and technical documents; U.S. Government and contractor engineering and logistics personnel services; and other related elements of logistics and program support.

(iv) *Military Department:* Air Force (BE-D-SAD)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* January 18, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Belgium—F-35 Joint Strike Fighter Aircraft

The Government of Belgium has requested to buy thirty-four (34) F-35 Joint Strike Fighter Conventional Take Off and Landing (CTOL) aircraft, and thirty-eight (38) Pratt & Whitney F-135 engines (34 installed, 4 spares). Also included are Electronic Warfare Systems; Command, Control, Communications, Computer and Intelligence/Communications, Navigational, and Identification (C4I/CNI); Autonomic Logistics Global Support System (ALGS); Autonomic Logistics Information System (ALIS); Full Mission Trainer; Weapons Employment Capability, and other Subsystems, Features, and Capabilities; F-35 unique infrared flares; Reprogramming center; F-35 Performance Based Logistics; software development/integration; aircraft ferry and tanker support; support equipment; tools and test equipment; communications equipment; spares and repair parts; personnel training and training equipment; publications and technical documents; U.S. Government and contractor engineering and logistics personnel services; and other related

elements of logistics and program support. The estimated total case value is \$6.53 billion.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of an ally and partner nation which has been, and continues to be, an important force for political and economic stability in Western Europe.

This proposed sale of F-35s will provide Belgium with a credible defense capability to deter aggression in the region and ensure interoperability with U.S. forces. The proposed sale will augment Belgium's operational aircraft inventory and enhance its air-to-air and air-to-ground self-defense capability. Belgium will have no difficulty absorbing these aircraft into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractors will be Lockheed Martin Aeronautics Company, Fort Worth, TX; and Pratt & Whitney Military Engines, East Hartford, CT. This proposal is being offered in the context of a competition. If the proposal is accepted, it is expected that offset agreements will be required. All offsets are defined in negotiations between the Purchaser and the contractor.

Implementation of this proposed sale will require multiple trips to Belgium involving U.S. Government and contractor representatives for technical reviews/support, program management, and training over the life of the program. U.S. contractor representatives will be required in Belgium to conduct Contractor Engineering Technical Services (CETS) and Autonomic Logistics and Global Support (ALGS) for after-aircraft delivery.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 17-80

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The F-35 Conventional Take-Off and Landing (CTOL) Block 3 aircraft is classified SECRET, except as noted below. It contains current technology representing the F-35 low observable airframe/outer mold line, Pratt & Whitney engine, radar, integrated core processor central computer, mission systems/electronic warfare suite, a multiple sensor suite, operational flight

and maintenance trainers, technical data/documentation, and associated software. As the aircraft and its subsystems are under development, many specific identifying equipment/system nomenclatures have not been assigned to date. Sensitive and classified elements of the F-35 CTOL Block 3 aircraft include hardware, accessories, components, and associated software for the following major subsystems:

a. The Propulsion system is classified SECRET and contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET. The single 40,000-lb thrust class engine is designed for low observability and has been integrated into the aircraft system. Pratt & Whitney, with the F-135, is developing and producing engine turbo machinery compatible with the F-35 and assures highly reliable, affordable performance. The engine is designed to be utilized in all F-35 variants, providing unmatched commonality and supportability throughout the worldwide base of F-35 users. The CTOL propulsion configuration consists of a main engine, diverterless supersonic inlet, and a Low Observable Axisymmetric Nozzle (LOAN).

b. The AN/APG-81 Active Electronically Scanned Array (AESA) provides mission systems with air-to-air and air-to-ground tracks which the mission system uses as a component to sensor fusion. The AESA allows the radar to direct RF energy in a way that does not expose the F-35, allowing it to maintain low observability in high-threat environments. The radar subsystem supports integrated system performance for air-to-air missions by providing search, track, identification, and AIM-120 missile data link functionality. The radar also provides synthetic aperture radar mapping for locating surface targets and weather mapping for weather avoidance. The radar functions are tightly integrated, interleaved, and managed by an interface to sensor management functions within mission software. The hardware and software are classified SECRET.

c. The Electro Optical Targeting System (EOTS) contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET. The EOTS subsystem to the sensor suite provides long-range

detection and tracking, Infrared Search and Track (IRST) capability, a Forward-Looking Infrared (FLIR) sensor for precision tracking, and Bomb Damage Indication (BDI) capability. EOTS replaces multiple separate internal or podded systems typically found on legacy aircraft. The functionality of the EOTS employs the following modes: Targeting FLIR; Laser Range-Finding and Target Designation; E.O. DAS and EOTS Performance.

d. The Electro-Optical Distributed Aperture System (EODAS) is a subsystem to the sensor suite and provides full spherical coverage for air-to-air and air-to-ground detection and Navigation Forward Looking Infrared (NFLIR) imaging. The system contains both SECRET and UNCLASSIFIED elements and contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET. The NFLIR capability provides infrared (IR) imagery directly to the pilot's Helmet-Mounted Display (HMD) for navigation in total darkness, including takeoff and landing, and provides a passive IR input to the F-35's sensor fusion algorithms. The all-aspect missile warning function provides time-critical warnings of incoming missiles and cues other subsystems to provide effective countermeasure employment. EODAS also provides an IRST function that can create and maintain Situational Awareness-quality tracks (SAIRST). EODAS is a mid-wave Infrared (IR) system consisting of six identical sensors distributed around the F-35 aircraft. Each sensor has a corresponding airframe window panel integrated with the aircraft structure to meet aerodynamic and stealth requirements.

e. The Electronic Warfare (EW) system contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET. Sensitive elements include: apertures; radio frequency (RF) and infrared (IR) countermeasures; and Electronic Countermeasures (ECM) techniques and features. The reprogrammable, integrated system provides radar warning and electronic support measures (ESM) along with a fully integrated countermeasures (CM) system. The EW system is the primary subsystem used to enhance situational awareness, targeting support and self defense through the search, intercept, location and identification of in-band emitters and to automatically counter IR

and RF threats. The IR and RF countermeasures are classified SECRET. This system uses low signature-embedded apertures, located in the aircraft control surface edges, to provide direction finding and identification of surface and airborne emitters and the geo-location of surface emitters. The system is classified SECRET.

f. The Command, Control, Communications, Computers and Intelligence/Communications, Navigation, and Identification (C4I/CNI) system provides the pilot with unmatched connectivity to flight members, coalition forces, and the battlefield. It is an integrated subsystem designed to provide a broad spectrum of secure, anti-jam, covert voice and data communications, precision radio navigation and landing capability, self-identification, beyond visual range target identification, and connectivity with off-board sources of information. The functionality is tightly integrated within the mission system for enhanced efficiency and effectiveness in the areas of communications, navigation, identification, and sensor fusion. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET. The CNI function includes both SECRET and UNCLASSIFIED elements. Sensitive elements of the CNI subsystems include:

(1) The VHF/UHF Voice and Data (Plain and Secure) Communication functionality includes air-to-air UHF/VHF voice and data, both clear and secure, to provide communications with other friendly and coalition aircraft, air-to-ground UHF voice to provide communications with ground sites, and intercommunication voice and tone alerts to provide communications between the avionics system and the pilot. UHF/VHF downlink of air vehicle status and maintenance information is provided to notify the ground crews of the amounts and types of stores, fuel, and other supplies or equipment needed to quickly turn the aircraft for the next mission. The system contains both SECRET and UNCLASSIFIED elements and contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET.

(2) The Tactical Air Navigation (TACAN) functionality provides operational modes to identify ground station and to provide bearing-to-station, slant range-to-ground station, bearing-to-airborne station and slant range to the nearest airborne station or aircraft. TACAN is not unique to the F-

35 aircraft but is standard on most U.S. Air Force aircraft. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET.

(3) The Identification Friend or Foe Interrogator and Transponder Identification functionality consists of integrated Mark XII Identification Friend or Foe (IFF) transponder capability to provide identification of other friendly forces. The CNI system supports sensor fusion by supplying data from IFF interrogations and off-board sources through the intra-flight data link. The system contains both SECRET and UNCLASSIFIED elements and contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET.

(4) The Global Positioning System Navigation functionality includes the Global Positioning System (GPS) aided inertial navigation to provide high-quality positional navigation, and the Instrument Landing System (ILS)/Tactical Air Control and Navigation (TACAN) to provide navigation and landing cues within controlled airspace. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET.

(5) The Multi-Function Advanced Data Link (MADL) is used specifically for communications between F-35 aircraft and has a very low probability of intercept, contributing to covert operations. The system contains both SECRET and UNCLASSIFIED elements and contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET.

(6) The Inertial Navigation System is an all-attitude, Ring Laser Gyro-based navigation system providing outputs of linear and angular acceleration, velocity, body angular rates, position, altitude (roll, pitch, and platform azimuth), magnetic and true heading, altitude, and time tags. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET.

(7) The Radar Altimeter functionality is a module provided in the CNI system rack 3A and uses separate transmit and receive antennae. It measures and reports altitude, and altitude rate of change. Control data is transferred over to a configurable avionics interface card

which translates the information to the F-35 aircraft computers. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET.

(8) The Instrument Landing System (ILS) measures, and reports azimuth course and alignment, elevation course alignment, and distance to the runway. Data from the ILS is used to drive visual flight instrumentation. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET.

(9) The Tactical Data Link is a secure broadcast Tactical Digital Information Link (TADIL) used for real-time voice/data exchange for command and control, relative navigation, and Precise Position Location Identification (PPLI), providing Link-16 type capabilities. The system contains both SECRET and UNCLASSIFIED elements and contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is classified SECRET.

g. The F-35 Autonomic Logistics Global Sustainment (ALGS) includes both SECRET and UNCLASSIFIED elements. It provides a fully integrated logistics management solution. ALGS integrates a number of functional areas, including supply chain management, repair, support equipment, engine support, and training. The ALGS infrastructure employs a state-of-the-art information system that provides real-time, decision-worthy information for sustainment decisions by flight line personnel. Prognostic health monitoring technology is integrated with the air system and is crucial to the predictive maintenance of vital components.

h. The F-35 Autonomic Logistics Information System (ALIS) includes both SECRET and UNCLASSIFIED elements. The ALIS provides an intelligent information infrastructure that binds all of the key concepts of ALGS into an effective support system. ALIS establishes the appropriate interfaces among the F-35 Air Vehicle, the warfighter, the training system, government information technology (IT) systems, JSF operations, and supporting commercial enterprise systems. Additionally, ALIS provides a comprehensive tool for data collection and analysis, decision support, and action tracking.

i. The F-35 Training System includes both SECRET and UNCLASSIFIED elements. The Training System includes several types of training devices, to

provide for integrated training of both pilots and maintainers. The pilot training device includes a Full Mission Simulator (FMS). The maintainer training devices include an Aircraft Systems Maintenance Trainer (ASMT), Ejection System Maintenance Trainer (ESMT), and Weapons Loading Trainer (WLT). The F-35 Training System can be integrated, where both pilots and maintainers learn in the same Integrated Training Center (ITC). Alternatively, the pilots and maintainers can train in separate facilities (Pilot Training Center and Maintenance Training Center).

j. Weapons employment capability is SECRET and contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is SECRET. Software (object code) is classified SECRET. Sensitive elements include co-operative targeting.

k. Other Subsystems, Features, and Capabilities:

(1) The Low Observable Air Frame is SECRET and contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is classified SECRET. Software (object code) is SECRET. Sensitive elements include: the Radar Cross Section and its corresponding plots, construction materials and fabrication.

(2) The Integrated Core Processor (ICP) Central Computer is SECRET and contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is SECRET. Software (object code) is classified SECRET. Sensitive elements include: F-35 Integrated Core Processor utilizing Commercial Off-the-Shelf (COTS) Hardware and Module Design to maximize growth and allow for efficient management of DMS and Technology Insertion, if additional processing is needed, a second ICP will be installed in the space reserved for that purpose, more than doubling the current throughput and memory capacity.

(3) The F-35 Helmet Mounted Display System (HMDS) is SECRET and contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is SECRET. Software (object code) is SECRET. Sensitive elements include: HMDS consists of the Display Management Computer-Helmet, a helmet shell/display module, a quick disconnect integrated as part of the ejection seat, helmet trackers and tracker processing, day- and night-vision camera functions, and dedicated

system/graphics processing. The HMDS provides a fully sunlight readable, bi-ocular display presentation of aircraft information projected onto the pilot's helmet visor. The use of a night vision camera integrated into the helmet eliminates the need for separate Night Vision Goggles (NVG). The camera video is integrated with EO and IR imaging inputs and displayed on the pilot's visor to provide a comprehensive night operational capability.

(4) The Pilot Life Support System is SECRET and contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is SECRET. Software (object code) is SECRET. Sensitive elements include: a measure of Pilot Chemical, Biological, and Radiological Protection through use of an On-Board Oxygen Generating System (OBOGS); and an escape system that provide additional protection to the pilot. OBOGS takes the Power and Thermal Management System (PTMS) air and enriches it by removing gases (mainly nitrogen) by adsorption, thereby increasing the concentration of oxygen in the product gas and supplying breathable air to the pilot.

(5) The Off-Board Mission Support System is SECRET and contains technology representing the latest state-of-the-art in several areas. Information on performance and inherent vulnerabilities is SECRET. Software (object code) is SECRET. Sensitive elements include: mission planning, mission briefing, maintenance/intelligence/tactical debriefing, sensor/algorithm planning, EW system reprogramming, data debrief, etc.

1. Publications: Manuals are considered SECRET as they contain information on aircraft/system performance and inherent vulnerabilities.

2. The JSF Reprogramming Center is classified SECRET and contains technology representing the latest state-of-the-art in several areas. This hardware/software facility is located in the U.S. and provides F-35 customers a means to update JSF electronic warfare databases. Sensitive elements include: EW software databases and tools to modify these databases.

3. (U) If a technologically advanced adversary were to obtain knowledge of specific hardware, the information could be used to develop countermeasures which might reduce weapons system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. (U) A determination has been made that Belgium can provide substantially

the same degree of protection for sensitive technology being released as the U.S. Government. This proposed sustainment program is necessary to the furtherance of the U.S. foreign policy and national security objectives outlined in the policy justification.

5. (U) All defense articles and services listed on this transmittal are authorized for release and export to the Government of Belgium.

[FR Doc. 2018-01432 Filed 1-25-18; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Military Family Readiness Council; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the Department of Defense Military Family Readiness Council will take place. This meeting is not a Town Hall meeting but is open to the public for the purpose of observing Council proceedings, guest speaker presentations, and Council deliberations.

DATES: Tuesday, March 6, 2018 from 1:00 p.m. to 3:00 p.m.

ADDRESSES: 1155 Defense Pentagon PLC2 Pentagon Library and Conference Center, Room B6, Washington, DC 20301.

FOR FURTHER INFORMATION CONTACT: Dr. Randy Eltringham, (571) 372-5315 (Voice), (571) 372-0884 (Facsimile), OSD Pentagon OUSD P-R Mailbox Family Readiness Council, osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil (Email). Mailing address is Office of the Deputy Assistant Secretary of Defense (Military Community & Family Policy), Office of Family Readiness Policy, 4800 Mark Center Drive, Alexandria, VA 22350-2300, Room 3G15. Website: <http://www.militaryonesource.mil/those-who-support-mfrc>. The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the

Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102-3.140 and 102-3.150.

Purpose of the Meeting: This is the second meeting of the Council for Fiscal Year 2018 (FY2018). During this meeting, Council members will receive status updates on three FY2017 Recommendations for Immediate Action. They will also review and deliberate about two FY2018 focus areas: (1) Child and Youth Well-being; and (2) Spouse Licensure.

Agenda: Opening Remarks, Administrative Announcements, Review of Written Public Submissions, Status Updates on FY2017 Recommendations for Immediate Action: Interstate Compact on Educational Opportunity for Military Children; Integration and Coordination of Medical, Education and Family Support Services for Special Needs Families; and Blended Retirement System and Financial Literacy. FY2018 Focus Areas: Child and Youth Well-being; and Spouse Licensure. Closing Remarks. **Note:** Exact order may vary.

Meeting Accessibility: This meeting is open to the public, subject to the availability of space. Members of the public who are entering the Pentagon should arrive at the Pentagon Visitors Center waiting area (Pentagon Metro Entrance) no later than 12:00 p.m. on the day of the meeting to allow time to pass through security check points and be escorted to the meeting location. Members of the public are asked to email their RSVP to the Council at osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil no later than 5:00 p.m. on Monday, February 26, 2018 to confirm seating availability and to request an escort or handicapped accessible transportation from the Pentagon Visitors Center to the meeting location.

Written Statements: Persons interested in providing a written statement for review and consideration by Council members attending the March 6, 2018 meeting must do so no later than close of business Monday, February 12, 2018, through the Council mailbox at osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil. Any written statements received after this date will be provided to Council members in preparation for the final Council meeting of FY2018. The DFO will review all timely submissions and ensure submitted written statements are provided to Council members two weeks prior to the meeting that is subject to this notice. Written statements must not be longer than two type-written pages and should address the following details: Issue or

concern, discussion, and a recommended course of action. Those who make submissions are requested to avoid including personal identifiable information (PII) such as names of adults and children, phone numbers, addresses, social security numbers, and other contact information within the body of the written statement. Links or brief summaries of supplemental supporting documentation may also be included, if needed, to provide appropriate historical context and background information.

Dated: January 23, 2018.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018-01465 Filed 1-25-18; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD-2017-OS-0040]

Submission for OMB Review; Comment Request

AGENCY: Defense Security Service, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by February 26, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at Oira_submission@omb.eop.gov. Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571-372-0493, or whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: National Industrial Security System (NISS); OMB Control Number 0704-XXXX.

Type of Request: New.
Number of Respondents: 11,671.
Responses per Respondent: 1.
Annual Responses: 11,671.
Average Burden per Response: 60 minutes.
Annual Burden Hours: 11,671.

Needs and Uses: The information collection requirement is necessary for DSS to oversee the National Industrial Security Program (NISP) pursuant to Executive Order 12829. The National Industrial Security System (NISS) will become the repository of records related to the maintenance of information pertaining to contractor facility security clearances (FCL) and contractor capabilities to protect classified information in its possession.

Affected Public: Cleared contractor companies participating in the NISP.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 03F09, Alexandria, VA 22350-3100.

Dated: January 23, 2018.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018-01450 Filed 1-25-18; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF ENERGY

Charter Renewal: Environmental Management Advisory Board

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of charter renewal.

SUMMARY: Pursuant to the Federal Advisory Committee Act and in accordance with Title 41 of the Code of Federal Regulations, and following consultation with the Committee Management Secretariat, General Services Administration, notice is

hereby given that the Environmental Management Advisory Board (Board) will be renewed for a two-year period beginning January 19, 2018.

The Board provides the Assistant Secretary for Environmental Management (EM) with information and strategic advice on a broad range of corporate issues affecting the EM program. These corporate issues include, but are not limited to, project management and oversight activities, cost/benefit analyses, program performance, human capital development, and contracts and acquisition strategies.

Additionally, the renewal of the Board has been determined to be essential to conduct DOE's business and to be in the public interest in connection with the performance of duties imposed on DOE by law and agreement. The Board will operate in accordance with the provisions of the Federal Advisory Committee Act, and rules and regulations issued in implementation of that Act.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer McCloskey, Designated Federal Officer, at (301) 903-7427 or email: jennifer.mccloskey@em.doe.gov.

Issued at Washington, DC on January 19, 2018.

Wayne D. Smith,

Committee Management Officer.

[FR Doc. 2018-01438 Filed 1-25-18; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP18-49-000]

Columbia Gas of Pennsylvania, Inc.; Notice of Application

Take notice that on January 16, 2018, Columbia Gas of Pennsylvania, Inc. (CPA), 121 Champion Way, Suite 100, Canonsburg, Pennsylvania 15317, filed in Docket No. CP18-49-000 an application pursuant to section 7(f) of the Natural Gas Act (NGA) requesting a service area determination within which CPA may, without further Commission authorization, enlarge or expand its facilities. CPA states that this determination will allow it to transport natural gas from a delivery point in Ohio for distribution to consumers in Pennsylvania. CPA asserts that it recently discovered that one of the Columbia Gas Transmission, LLC points of delivery that serves CPA is located in Columbiana County, Ohio, approximately 679 feet from the

Pennsylvania border. CPA avers that it further discovered that there is a Columbia Gas of Ohio, Inc. customer in Ohio being serviced from the CPA pipeline. CPA does not contemplate any change in its operations and does not plan to serve any customers in Ohio. CPA additionally requests that the Commission determine that CPA qualifies as a local distribution company for the purposes of transportation under section 311 of the Natural Gas Policy Act and that it be granted waiver of all reporting and accounting requirements, as well as other rules and regulations that are normally applicable to natural gas companies subject to the Commission's jurisdiction, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website web at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208-3676 or TTY, (202) 502-8659.

Any questions concerning this application may be directed to Brooke E Wancheck, Assistant General Counsel, 290 W Nationwide Blvd., Columbus, Ohio 43215, by telephone at (614) 460-5558 or Kenneth W Christman, Assistant General Counsel, 121 Champion Way, Suite 100, Canonsburg, Pennsylvania 15317, by telephone at (724) 416-6315.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to

obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit seven copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at <http://www.ferc.gov>. Persons unable to file electronically

should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on February 12, 2018.

Dated: January 22, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018-01503 Filed 1-25-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2058-098]

Avista Corporation; Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Comments, Recommendations, Terms and Conditions, and Fishway Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

- a. *Application Type:* Amendment of License.
- b. *Project No.:* 2058-098.
- c. *Date Filed:* November 13, 2017.
- d. *Applicant:* Avista Corporation (licensee).
- e. *Name of Project:* Clark Fork Hydroelectric Project No. 2058.
- f. *Location:* The project is located on the Clark Fork River in Bonner County, Idaho and Sanders County, Montana.
- g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)-825(r).
- h. *Applicant Contact:* Nate Hall, License Manager, Avista Corporation, 94 Avista Power Road, P.O. Box 1469, Noxon, MT 59853; telephone (406) 847-1281; email nate.hall@avistacorp.com.
- i. *FERC Contact:* Marybeth Gay; telephone: (202) 502-6125; email address: Marybeth.gay@ferc.gov.
- j. *Deadline for filing motions to intervene and protests, comments, recommendations, terms and conditions, and fishway prescriptions is* 60 days from the issuance date of this notice by the Commission.

All documents may be filed electronically via the internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's website at <http://www.ferc.gov/docs-filing/efiling.asp>. The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, recommendations, terms and conditions and fishway

prescriptions using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P-2058-098.

k. *Description of Request:* On

November 13, 2017, the licensee filed an application to amend its license to construct and operate a permanent upstream fish passage facility at the Cabinet Gorge Hydroelectric Development at the Clark Fork Project in Bonner County, Idaho. The licensee would use this facility to capture and transport native migratory salmonids, with a focus on the federally-listed as threatened bull trout. The proposed fishway would allow the licensee to collect target species at the dam, transport them to an existing fish handling and holding facility for processing, and transport them to tributaries in Montana upstream of the Cabinet Gorge Dam or return them to the Lower Clark Fork River based on genetic assignments or size of the fish. The new facility would be located on the south bank of the Clark Fork River, immediately downstream of the Cabinet Gorge Dam.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE, Room 2A, Washington, DC 20426, or by calling (202) 502-8371. This filing may also be viewed on the Commission's website at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1-866-208-3676 or email FERCOnlineSupport@ferc.gov, for TTY, call (202) 502-8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should

so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to Intervene: Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the title PROTEST, MOTION TO INTERVENE, COMMENTS, RECOMMENDATIONS, TERMS AND CONDITIONS, or FISHWAY PRESCRIPTIONS; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, recommendations, terms and conditions, or prescriptions should relate to the proposed amendment application. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: January 22, 2018.

Kimberly D. Bose,
Secretary.

[FR Doc. 2018-01506 Filed 1-25-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. FA15-16-000]

Dominion Energy Transmission, Inc.; Notice of Paper Hearing Procedure

Take notice that on December 8, 2017, Dominion Energy Transmission, Inc. (Dominion) filed a request for Commission review of certain findings and recommendations in the November 8, 2017 audit report¹ issued in this docket by the Director of the Office of Enforcement under authority delegated to him by section 375.311 of the Commission's regulations (Audit Report).² In accordance with section 158.3 of the Commission's regulations,³ Dominion notified the Commission that it requested review of contested issues by means of a shortened procedure. Pursuant to section 158.3, we direct the commencement of a paper hearing.

The Audit Report summarizes Enforcement's review, first announced in this docket on April 15, 2015, of Dominion's compliance with the Uniform System of Accounts, the reporting requirements of the FERC Form No. 2, and Dominion's own gas tariff. The Audit Report states that, while Dominion agreed not to contest certain of Enforcement's findings and recommendations in the report, it does contest the Audit Report's findings and recommendations pertaining to the Allowance for Funds Used During Construction (AFUDC). The scope of the paper hearing is limited to these challenged findings and recommendations.

In accordance with section 158.3, Dominion and any other interested entity, including the Commission staff, shall file, within 45 days of this notice, an initial memorandum that addresses the relevant facts and applicable law that support the position or positions taken regarding the matters at issue. Reply memoranda may be filed by participants who filed initial memoranda. Reply memoranda must be filed within 20 days of the due date for initial memoranda. Pursuant to section 158.3, subpart T of Part 385 of the Commission's regulations shall apply to

¹ *Audit of Dominion Energy Transmission, Inc.'s compliance with its FERC Gas Tariff; the accounting requirements of the Uniform System of Accounts Prescribed for Natural Gas Companies; and the reporting requirements of the FERC Form No. 2, Annual Report*, Commission Office of Enforcement Division of Audits and Accounting (filed Nov. 8, 2017) (Audit Report).

² 18 CFR 375.311 (2017).

³ 18 CFR 158.3 (2017).

all filings. Further, pursuant to section 158.4, each entity's memorandum should set out the facts and argument as prescribed for briefs in Rule 706 of the Commission's Rules of Practice and Procedure.⁴ Section 158.5 also requires that the facts stated in the memorandum must be sworn to by persons having knowledge thereof, which latter fact must affirmatively appear in the affidavit.⁵

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: January 22, 2018.

Kimberly D. Bose,
Secretary.

[FR Doc. 2018-01504 Filed 1-25-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC18-7-000]

Commission Information Collection Activities (FERC-725I); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC-725L, Mandatory Reliability Standards for the Bulk-Power System: MOD Reliability Standards.

DATES: Comments on the collection of information are due March 27, 2018.

ADDRESSES: You may submit comments (identified by Docket No. IC18-7-000) by either of the following methods:

- *eFiling at Commission's website:*
<http://www.ferc.gov/docs-filing/efiling.asp>.

- *Mail/Hand Delivery/Courier:*
Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with

⁴ 18 CFR 158.4 (2017) (citing 18 CFR 385.706 (2017)).

⁵ 18 CFR 158.5 (2017).

submission guidelines at: <http://www.ferc.gov/help/submission-guide.asp>. For user assistance contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at: (866) 208-3676 (toll-free), or (202) 502-8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at <http://www.ferc.gov/docs-filing/docs-filing.asp>.

FOR FURTHER INFORMATION CONTACT:

Ellen Brown may be reached by email at DataClearance@FERC.gov, telephone at (202) 502-8663, and fax at (202) 273-0873.

SUPPLEMENTARY INFORMATION:

Title: FERC-725L, Mandatory Reliability Standards for the Bulk-Power System: MOD Reliability Standards.

OMB Control No.: 1902-0261.

Type of Request: Three-year extension of the FERC-725L information

collection requirements with no changes to the current reporting requirements.

Abstract: MOD Reliability Standards ensure that generators remain in operation during specified voltage and frequency excursions, properly coordinate protective relays and generator voltage regulator controls, and ensure that generator models accurately reflect the generator's capabilities and equipment performance.

Reliability Standards MOD-025-2, MOD-026-1, and MOD-027-1 "address generator verifications needed to support Bulk-Power System reliability and will ensure that accurate data is verified and made available for planning simulations." NERC explains that Bulk-Power System reliability benefits from "good quality simulation models of power system equipment," and that "model validation ensures the proper performance of the control systems and validates the computer models used for stability analysis." ¹ NERC further states that the proposed Reliability Standards will enhance reliability because the tests

performed to obtain model data may reveal latent defects that could cause inappropriate unit response during system disturbances.

Reliability Standards MOD-032-1 and MOD-033-2 are designed to replace, consolidate and improve upon" existing MOD standards, in addressing system-level modeling data and validation requirements necessary for developing planning models and the Interconnection-wide cases that are integral to analyzing the reliability of the Bulk-Power System.

Type of Respondents: NERC-registered entities including generator owners, transmission planners, planning authorities, balancing authorities, resource planners, transmission service providers, reliability coordinators, and transmission operators.²

Estimate of Annual Burden ³: The Commission estimates the annual public reporting burden ⁴ for the information collection as:

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden and cost per response	Total annual burden hours and total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
MOD-025-2 (Verification and Data Reporting of Generator Real and Reactive Power Capability and Synchronous Condenser Reactive Power Capability)						
Attachment 2	933 (GO)	1	933	6 hrs.; \$448.92 ⁵	5,598 hrs.; \$418,842	448.92
Evidence Retention ..	933 (GO)	1	933	1 hr.; \$32.74 ⁶	933 hrs.; \$30,546	32.74
Total	6,531 hrs.; \$449,388
MOD-026-1 (Verification of Models and Data for Generator Excitation Control System or Plant Volt/Variance Control Functions)						
Instructions for obtaining excitation control system or plant voltage/variance control function model.	185 (TP)	1	185	8 hrs.; \$598.56 ⁴	1,480 hrs.; \$110,734	598.56
Documentation on generator verification.	466 (GO)	1	466	8 hrs.; \$598.56 ⁴	3,728 hrs.; \$278,929	598.56
Evidence Retention ..	651 (GO and TOP) ..	1	651	1 hr.; \$32.74 ⁵	651 hrs.; \$21,314	32.74
Total	5,859 hrs.; \$410,977

¹ NERC Petition for Approval of Five Proposed Reliability Standards MOD-025-2, MOD-026-1, MOD-027-1, PRC-019-1, and PRC-024-1 issued on 5/30/2013.

² In subsequent portions of this notice, the following acronyms will be used: PA = Planning Authority, GO = Generator Owner, TP = Transmission Planner, BA = Balancing Authority, RP = Resource Planner, TSP = Transmission Service Provider, RC = Reliability Coordinator, TOP = Transmission Operator.

³ Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

⁴ Each of the five MOD standards in the FERC-725L information collection previously contained "one-time" components to their respondent burden. These one-time burden categories consisted

primarily of activities related to establishing industry practices and developing data validation procedures tailored toward these reliability standards and their reporting requirements. None of the one-time burdens apply any longer, so they are being removed from the FERC-725L information collection.

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden and cost per response	Total annual burden hours and total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
MOD-027-1 (Verification of Models and Data for Turbine/Governor and Load Control or Active Power/Frequency Control Functions)						
Instructions for obtaining excitation control system or plant voltage/variance control function model.	185 (TP)	1	185	8 hrs.; \$598.56 ⁴	1,480 hrs.; \$110,734	598.56
Documentation on generator verification.	466 (GO)	1	466	8 hrs.; \$598.56 ⁴	3,728 hrs.; \$278,929	598.56
Evidence Retention.	651 (GO and TP)	1	651	1 hr.; \$32.74 ²	651 hrs.; \$21,314	32.74
Total	5,859 hrs.; \$410,977
MOD-032-1 (Verification of Models and Data for Turbine/Governor and Load Control or Active Power/Frequency Control Functions)						
Data Submittal	1,197 (BA, GO, PA, RP, TO, TP, and TSP).	1	1,197	8 hrs.; \$544.96 ⁷	9,576 hrs.; \$652,317	544.96
Evidence Retention ..	1,197 (BA, GO, PA, RP, TO, TP, and TSP).	1	1,197	1 hr.; \$32.74 ²	1,197 hrs.; \$39,190 ..	32.74
Total	10,773 hrs.; \$691,507.
MOD-033-1 (Steady-State and Dynamics System Model Validation)						
Data Submittal	188 (RC and TOP) ..	1	188	8 hrs.; \$544.96 ⁶	1,504 hrs.; \$102,452	544.96
Evidence Retention ..	194 (PA, RC, and TOP).	1	194	1 hr.; \$32.74 ²	194 hrs.; \$6,352	32.74
Total	1,698 hrs.; \$108,804

The total annual estimated burden and cost for the FERC-725L information collection is 27,544 hours and \$2,071,653 respectively.

Comments: Comments are invited on:

- (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility;
- (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used;
- (3) ways to enhance the quality, utility

and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: January 22, 2018.

Kimberly D. Bose,
Secretary.

[FR Doc. 2018-01505 Filed 1-25-18; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2017-0008; FRL-9971-42]

Pesticide Product Registration; Receipt of Applications for New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before February 26, 2018.

ADDRESSES: Submit your comments, identified by the Docket Identification (ID) Number and the File Symbol of interest as show in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

⁵ This wage figure uses the weighted hourly average wage (plus benefits) for electrical engineers (Occupation Code: 17-2071) and managers (Occupation Code: 11-0000) obtained from the Bureau of Labor Statistics: \$74.82/hour. The average used the following calculation: [\$68.12/hour + \$81.52/hour] ÷ 2 = \$74.82/hour. \$68.12/hour is the wage for engineers. \$81.52 is the wage for manager.

⁶ Uses the hourly average wage (plus benefits) for file clerks obtained from the Bureau of Labor Statistics: \$32.74/hour (BLS Occupation Code: 43-4071).

⁷ Uses the hourly average wage (plus benefits) for electrical engineers obtained from the Bureau of Labor Statistics: \$68.12/hour (BLS Occupation Code: 17-2071).

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Michael Goodis, Registration Division (7505P), main telephone number: (703) 305-7090; email address: RDfRNtices@epa.gov. The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each application summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

1. *Submitting CBI.* Do not submit this information to EPA through www.regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in

accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

III. Notice of Receipt—New Uses

1. *PP 5F8521.* (EPA-HQ-OPP-2015-0787). K-I Chemical USA, Inc., 11 Martine Ave., Suite 970, White Plains, NY 10606, requests to establish tolerances in 40 CFR 180.659 for residues of the herbicide pyroxasulfone (3-[(5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl) pyrazole-4-yl)methylsulfonyl]-4,5-dihydro-5,5-dimethyl-1,2-oxazole) and its metabolites in or on Crop Subgroup 1C, tuberous and corm vegetables (except granular/flakes and chips) at 0.05 part per million (ppm); Crop Group 3-07, bulb vegetables at 0.15 ppm; potatoes, granular/flakes at 0.3 ppm and potato chips at 0.06 ppm. The high performance liquid chromatography/triple quadrupole mass spectrometry (LC/MS/MS) methods has been proposed to enforce the tolerance expression for pyroxasulfone. *Contact:* RD.

2. *File Symbol:* 88144-R. *Docket ID number:* EPA-HQ-OPP-2017-0581. *Applicant:* Armed Forces Pest Management Board, U.S. Army Garrison-Forest Glen, 2460 Linden Ln., Silver Spring, MD 20910. *Active ingredient:* Permethrin. *Product type:* Insecticide. *Proposed use:* Disinsection of Military Aircraft Only. *Contact:* RD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: December 4, 2017.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2018-01500 Filed 1-25-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2017-0602; FRL-9972-27]

FIFRA Scientific Advisory Panel; Nominations to the FIFRA Scientific Advisory Panel; Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice provides the names, addresses, and professional affiliations of persons recently nominated by the National Institutes of Health (NIH) and the National Science Foundation (NSF) to serve on the Scientific Advisory Panel (SAP) established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Brief biographical sketches for the nominees are posted on the EPA website at <https://www.epa.gov/sap>. The Panel was created on November 28, 1975, and converted from a discretionary to a statutory Panel by amendment to FIFRA, dated October 25, 1988. The Agency, at this time, anticipates selecting four new members to serve on the panel as a result of membership terms that will expire in 2018. Public comments on the current nominations are invited, as these comments will be used to assist the Agency in selecting the new chartered Panel members.

DATES: Comments identified by docket ID number EPA-HQ-OPP-2017-0602, must be received on or before February 26, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2017-0602, by one of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/contacts.html>.

FOR FURTHER INFORMATION CONTACT:

Tamue L. Gibson, M.S., DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave, NW,

Washington, DC 20460-0001; telephone number: (202) 564-7642; email address: gibson.tamue@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) and FIFRA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Submitting CBI.* Do not submit CBI information to EPA through [regulations.gov](https://www.epa.gov) or email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/comments.html>.

II. Background

Purpose of FIFRA SAP

The FIFRA SAP serves as a scientific peer review mechanism of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide independent scientific advice, information and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on health and the environment. FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act (5 U.S.C. Appendix 2, FIFRA Statutory Requirement). The FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the NIH and the NSF. FIFRA established a Science Review Board (SRB) consisting of at least 60 scientists who are available to FIFRA SAP on an ad hoc basis to assist in reviews conducted by FIFRA SAP. As a scientific peer review mechanism,

FIFRA SAP provides comments, evaluations, and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendations to the Agency.

The Agency, at this time, anticipates selecting four new members to serve on the panel as a result of membership terms that will expire in 2018. The Agency requested that NIH and NSF nominate experts for selection from the fields of human health risk assessment, including expertise in human exposure and physiologically-based pharmacokinetic (PBPK) modeling, and expertise in toxicology and veterinary pathology; specifically, carcinogenicity, reproductive and developmental toxicology, and neurotoxicity. The Agency also noted that experts with specific experience in risk assessment and dose response analysis are preferred.

Nominees should be well published and current in their fields of expertise. FIFRA further stipulates that the Agency publish the name, address and professional affiliation of the nominees in the **Federal Register**.

III. Charter

A Charter for the FIFRA Scientific Advisory Panel, dated October 17, 2016, was issued in accordance with the requirements of the Federal Advisory Committee Act, Public Law 92-463, 86 Stat. 770 (5 U.S.C. Appl. I).

A. Qualifications of Members

Members are scientists who have sufficient professional qualifications, including training and experience, to provide expert comments on the impact of pesticides on human health and the environment. No persons shall be ineligible to serve on the Panel by reason of their membership on any other advisory committee to a Federal department or agency, or their employment by a Federal department or agency (except the EPA). The Administrator appoints individuals to serve on the Panel for staggered terms of up to 3 years. Panel members are subject to the provisions of 5 CFR part 2635, Standards of Ethical Conduct for Employees of the Executive Branch, which include rules regarding conflicts of interest. Each nominee selected by the Administrator, before being formally appointed, is required to submit a confidential statement of employment and financial interest, which shall fully disclose, among other financial

interests, the nominee's sources of research support, if any.

In accordance with section 25(d)(1) of FIFRA, the Administrator shall require nominees to the Panel to furnish information concerning their professional qualifications, including educational background, employment history, and scientific publications.

B. Applicability of Existing Regulations

With respect to the requirements of section 25(d) of FIFRA that the Administrator promulgate regulations regarding conflicts of interest, the Charter provides that EPA's existing regulations applicable to Special Government Employees, which include advisory committee members, will apply to the members of the Scientific Advisory Panel. These regulations appear in 5 CFR part 2635. In addition, the Charter provides for open meetings with opportunities for public participation.

C. Process of Obtaining Nominees

In accordance with the provisions of section 25(d) of FIFRA, EPA on April 17, 2017, requested that the NIH and the NSF nominate scientists to fill vacancies occurring on the Panel. The Agency requested nominations of experts in the fields of human health risk assessment, including expertise in human exposure and physiologically-based pharmacokinetic (PBPK) modeling, and expertise in toxicology and veterinary pathology; specifically, carcinogenicity, reproductive and developmental toxicology, and neurotoxicity. The Agency also noted that experts with specific experience with risk assessment and dose response analysis are preferred. NIH and NSF responded providing the Agency with a total of 37 nominees. Copies of the responses, with the listed nominees, are available in the public docket referenced in unit I.B.1. of this notice. Of the 37 nominees, 17 are interested and available to actively participate in SAP meetings (see Section IV. Nominees). One nominee, Dr. David Jett of NIH, is currently serving as a member of the FIFRA SAP and therefore is not listed. Of the current 37 nominees, the following 19 individuals are not available:

1. John Balmes, M.D., University of California-Berkeley, San Francisco, CA
2. David Bellinger, Ph.D., Harvard Medical School, Boston, MA
3. Nora Besansky, Ph.D., University of Notre Dame, Notre Dame, IN
4. Kim Brouwer, Pharm.D., Ph.D., University of North Carolina at Chapel Hill, Chapel Hill, NC
5. David Crews, Ph.D., University of Texas at Austin, Austin, TX
6. David Eaton, Ph.D., University of

- Washington, Seattle, WA
7. Mary Beth Genter, Ph.D., University of Cincinnati College of Medicine, Cincinnati, OH
 8. Robyn Gilden, Ph.D., RN, University of Maryland School of Nursing, Baltimore, MD
 9. John Groopman, Ph.D., Johns Hopkins University, Baltimore, MD
 10. Ramesh Gupta, D.V.M., Ph.D., D.A.B.T., Murray State University, Murray, KY
 11. Bruce Hammock, Ph.D., University of California-Davis, Davis, CA
 12. Paul Howard, Ph.D., (Retired), Food and Drug Administration, Chardon, OH
 13. Germaine Buck Louis, Ph.D. M.S., Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, MD
 14. Melissa Perry, Sc.D., M.H.S., George Washington University, Washington, DC
 15. Lisa Peterson, Ph.D., University of Minnesota, Minneapolis, MN
 16. Frank Raushel, Ph.D., Texas A&M University, College Station, TX
 17. Rick Relyea, Ph.D., Rensselaer Polytechnic Institute, Troy, NY
 18. Justin Teeguarden, Ph.D., Pacific Northwest Laboratories, Richland, WA
 19. Sarah Woodley, Ph.D., Duquesne University, Pittsburgh, PA

IV. Nominees

Following are the names, addresses, and professional affiliations of current nominees being considered for membership on the FIFRA SAP. The Agency anticipates selecting four individuals to fill vacancies occurring in 2018. Brief biographical sketches for the nominees are posted on the EPA website at <https://www.epa.gov/sap>.

1. Jonathan W. Boyd, Ph.D., West Virginia University, Morgantown, WV
2. Robert E. Chapin, Ph.D., Pfizer Global Research and Development, Groton, CT
3. Weihsueh A. Chiu, Ph.D., Texas A&M University, College Station, TX
4. George B. Corcoran, Ph.D., Wayne State University, Detroit, MI
5. Nikolay M. Filipov, Ph.D., University of Georgia, Athens, GA
6. Paul M. Foster, Ph.D., National Institutes of Health, Durham, NC
7. John T. Greenamyre, M.D., Ph.D., University of Pittsburgh, Pittsburgh, PA
8. William C. Griffith, Ph.D., University of Washington, Seattle, WA
9. William K. Karasov, Ph.D., University of Wisconsin-Madison, Madison, WI
10. Francisco J. Leyva, M.D., Ph.D., Sc.M., National Institutes of Health, Rockville, MD
11. Michael A. Malfatti, Ph.D., Lawrence Livermore National Laboratory, Livermore, CA
12. Daniel K. Nomura, Ph.D., University of California-Berkeley, Berkeley, CA
13. David Peden, Ph.D., University of North Carolina School of Medicine, Chapel Hill, NC
14. Beate R. Ritz, M.D., Ph.D., University of California-Los Angeles, Los Angeles, CA
15. Christopher P. Weis, Ph.D., National

- Institutes of Health, Bethesda, MD
16. Clifford P. Weisel, Ph.D., Rutgers University, Piscataway, NJ
17. Raymond S.H. Yang, Ph.D., Colorado State University, Fort Collins, CO

Authority: 7 U.S.C. 136 *et seq.*; 21 U.S.C. 301 *et seq.*

Dated: January 11, 2018.

Stanley Barone Jr.,

Acting Director, Office of Science Coordination and Policy.

[FR Doc. 2018-01496 Filed 1-25-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2017-0693; FRL-9972-65]

FIFRA Scientific Advisory Panel; Notice of Public Meeting and Nominations of Ad Hoc Panel Members

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 3-day in-person meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review Methods for Efficacy Testing of Premises and Soil Treatment for Fire Ant Pesticides. There will also be a 3-hour preparatory virtual meeting of the FIFRA SAP to be conducted via webcast using Adobe Connect and telephone conferencing. Registration will be required to attend this virtual meeting. The date and registration instructions for the virtual meeting will be available on the FIFRA SAP website <http://www.epa.gov/sap> by late February to mid-March.

DATES: The virtual preparatory meeting will be announced in a future **Federal Register** Notice and on <http://www.epa.gov/sap>. The in-person meeting will be held on May 8 to May 10, 2018, from approximately 9 a.m. to 5 p.m.

Comments. Written comments on all docketed materials should be submitted on or before March 19, 2018. FIFRA SAP may not be able to fully consider written comments submitted after March 19, 2018. Requests to make oral comments should be submitted on or before April 16, 2018 by contacting the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**. For additional instructions, see Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

Nominations. Nominations of candidates to serve as ad hoc members of FIFRA SAP for this meeting should be provided on or before February 26, 2018.

Webcast. The in-person meeting may be webcast. Please refer to the FIFRA SAP website at <http://www.epa.gov/scipoly/sap> for information on how to access the webcast. Please note that the webcast is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the meeting will continue as planned.

Special accommodations. For information on access or services for individuals with disabilities, and to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to allow EPA time to process your request.

ADDRESSES:

Meeting: The meeting will be held at the Environmental Protection Agency, Conference Center, Lobby Level, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202.

Comments. Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2017-0693, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

Nominations, requests to present oral comments, and requests for special accommodations. Submit nominations to serve as ad hoc members of FIFRA SAP, requests for special accommodations, or requests to present oral comments to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Dr. Marquee D. King, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: 202-564-3626; email address: king.marquee@epa.gov. You may also subscribe to the following listservs to be notified when notices regarding this and

other SAP related activities are published.

https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic_id=USAEPAPPT_101
<https://public.govdelivery.com/accounts/USAEPAPPT/subscribers/qualify>

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action may be of interest to the public in general and those who are or may be required to conduct testing of chemical substances and provide submissions to the EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), FIFRA and/or Toxic Substances Control Act (TSCA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

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

1. *Submitting CBI.* Do not submit CBI information to EPA through [regulations.gov](http://www.regulations.gov) or email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

C. How may I participate in this meeting?

You may participate in this meeting by following the instructions in this unit. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA-HQ-OPP-2017-0693 in the subject line on the first page of your request.

1. *Written comments.* Written comments should be submitted, using the instructions in **ADDRESSES** and Unit I.B., on or before March 19, 2018, to provide FIFRA SAP the time necessary to consider and review the written comments. FIFRA SAP may not be able to fully consider written comments submitted after March 19, 2018.

2. *Oral comments.* The Agency encourages each individual or group wishing to make brief oral comments to FIFRA SAP to submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before April 16, 2018, in order to be included on the meeting agenda. Requests to present oral

comments will be accepted until the date of the meeting and, to the extent that time permits, the Chair of FIFRA SAP may permit the presentation of oral comments at the meeting by interested persons who have not previously requested time. Oral comments before FIFRA SAP are limited to approximately 5 minutes unless arrangements have been made prior to April 16, 2018. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment. In addition, each speaker should bring 20 copies of their oral remarks and presentation slides (if required) for distribution to FIFRA SAP at the meeting by the DFO.

3. *Seating at the meeting.* Seating at the meeting will be open and on a first-come basis.

4. *Request for nominations to serve as ad hoc expert members of FIFRA SAP for this meeting.* As part of a broader process for developing a pool of candidates for each meeting, FIFRA SAP staff routinely solicits the stakeholder community for nominations of prospective candidates for service as ad hoc members of FIFRA SAP. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates for a specific meeting. Individuals nominated for this meeting should have expertise in one or more of the following areas:

Entomologists and other scientists who are generally familiar with pesticide efficacy testing and application methods for public health pests including those who are specifically familiar with premises pesticide efficacy testing for flies, cockroaches, yellow jackets, mosquitoes, and/or ticks; and those who are familiar with pesticide efficacy testing for control of field populations of red imported fire ants.

Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the scientific issues for this meeting. Nominees should be identified by name, occupation, position, address, email address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before February 26, 2018. The Agency will consider all nominations of prospective candidates for this meeting that are received on or before that date. However, final selection of ad hoc members for this meeting is a discretionary function of the Agency.

The selection of scientists to serve on FIFRA SAP is based on the function of the Panel and the expertise needed to address the Agency's charge to the Panel. No interested scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a Federal department or agency or their employment by a Federal department or agency, except EPA. Other factors considered during the selection process include availability of the potential Panel member to fully participate in the Panel's review, absence of any conflicts of interest or appearance of lack of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of lack of impartiality, lack of independence, and bias may result in disqualification, the absence of such concerns does not assure that a candidate will be selected to serve on FIFRA SAP. Numerous qualified candidates are identified for each Panel. Therefore, selection decisions involve carefully weighing a number of factors including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives on the Panel. In order to have the collective breadth of experience needed to address the Agency's peer review charge for this meeting, the Agency anticipates selecting approximately 12 ad hoc scientists.

FIFRA SAP members are subject to the provisions of 5 CFR part 2634—Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture, as supplemented by EPA in 5 CFR part 6401. In anticipation of this requirement, prospective candidates for service on FIFRA SAP will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of research support. EPA will evaluate the candidate's financial disclosure form to assess whether there are financial conflicts of interest, appearance of a lack of impartiality, or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service on FIFRA SAP. Those who are selected from the pool of prospective candidates will be asked to attend the public meetings and to participate in the discussion of key issues and assumptions at these meetings. In addition, they will be asked

to review and to help finalize the meeting minutes and the final meeting report. The list of FIFRA SAP members participating at this meeting will be posted on the FIFRA SAP website at <http://www.epa.gov/scipoly/sap> or may be obtained from the OPP Docket at <http://www.regulations.gov>.

II. Background

A. Purpose of FIFRA SAP

FIFRA SAP serves as a primary scientific peer review mechanism of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide scientific advice, information and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on health and the environment. FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act (5 U.S.C. Appendix). FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health and the National Science Foundation. The FIFRA SAP is assisted in their reviews by ad hoc participation from members of the Science Review Board (SRB). As a scientific peer review mechanism, FIFRA SAP provides comments, evaluations, and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. The FIFRA SAP is not required to reach consensus in its recommendations to the Agency but consensus is a preferred outcome and possible under FACA.

B. Public Meeting

EPA-registered pesticide products are an important part of pest management programs to accomplish control of invertebrate pests. The Agency has a number of guidelines intended to assist in the development of appropriate protocols to test product efficacy. EPA Product Performance Test Guidelines OPPTS 810.3100 Soil Treatment for Imported Fire Ants and OPPTS 810.3500 Premises Treatments were published in March 1998. To increase clarity and consistency in efficacy testing and to include current scientific standards, the Agency is revising these product performance guidelines. The Agency will be seeking advice and recommendations from the SAP on scientific issues associated with the two proposed revised EPA guidelines.

The proposed premises treatment guideline contains recommended test

methodologies for a wide range of products intended to kill, control, flush, and/or knockdown invertebrate premises pests, such as cockroaches, ticks, mosquitoes, flies, and wasps. The guideline does not cover treatment of livestock or pets, wide area-mosquito control, or bed bug products. In addition to guidance for testing efficacy of direct pesticide application to pests, residual treatments, and cockroach and fly baits in the laboratory, the proposed guideline also includes field testing methods for outdoor misting systems, Hymenoptera nest treatments, and outdoor foggers. Finally, methods for resistance ratio determination and characterization of pest population strain susceptibility are described.

The proposed red imported fire ant treatment guideline contains recommended test methodologies for evaluating the performance of pesticide products for the treatment and control of red imported fire ant colonies/mounds. The guideline does not cover premises treatments for red imported fire ant workers/foragers, such as direct application to pests. Field tests for both mound- and area-applied pesticide products are proposed, along with accompanying laboratory studies for baits, barrier treatments, and insect growth regulators.

C. FIFRA SAP Documents and Meeting Minutes

EPA's background paper, draft charge questions to FIFRA SAP, and related supporting materials will be available on or before January 22, 2018. In addition, a list of candidates under consideration as prospective ad hoc panelists for this meeting will be available for a 15-day public comment period in early to mid-March. You may obtain electronic copies of most meeting documents, including FIFRA SAP composition (*i.e.*, members and ad hoc members for this meeting) and the meeting agenda, at <http://www.regulations.gov> and the FIFRA SAP website at <http://www.epa.gov/scipoly/sap>.

FIFRA SAP will prepare the meeting minutes and final report summarizing its recommendations to the Agency approximately 90 days after the meeting. The meeting minutes and final report will be posted on the FIFRA SAP website or may be obtained from the OPP Docket at <http://www.regulations.gov>.

Authority: 7 U.S.C. 136 *et. seq.*; 21 U.S.C. 301 *et seq.*

Dated: January 9, 2018.

Stanley Barone, Jr.,

Acting Director, Office of Science Coordination and Policy.

[FR Doc. 2018-01495 Filed 1-25-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9973-38-OW]

Reopening of Comment Period on the Notice of Availability of the Deepwater Horizon Oil Spill Louisiana Trustee Implementation Group Draft Restoration Plan and Environmental Assessment #2: Provide and Enhance Recreational Opportunities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability; reopening of comment period.

SUMMARY: On December 20, 2017, the Environmental Protection Agency (EPA) published a Notice of Availability of the Deepwater Horizon Oil Spill Louisiana Trustee Implementation Group (Louisiana TIG) Draft Restoration Plan and Environmental Assessment #2: Provide and Enhance Recreational Opportunities (Draft RP/EA) and requested comments from the public. The EPA is reopening the comment period on the Notice of Availability of the Draft RP/EA that was scheduled to close on January 19, 2018, until February 2, 2018. The Louisiana TIG will consider public comments received from December 20, 2017, through February 2, 2018. The EPA is making this change to provide the public with additional time to provide comments.

DATES: The public comment period for the Notice of Availability published in the **Federal Register** on December 20, 2017 (82 FR 60397), is being reopened. Written comments must be received on or before February 2, 2018.

ADDRESSES: *Obtaining Documents:* You may download the Draft RP/EA at any of the following sites:

- <http://www.gulfspillrestoration.noaa.gov>
- <http://www.la-dwh.com>
- <https://www.doi.gov/deepwaterhorizon/adminrecord>.

Alternatively, you may request a CD of the Draft RP/EA (see **FOR FURTHER INFORMATION CONTACT**). You may also view the document at any of the public facilities listed at <http://www.gulfspillrestoration.noaa.gov>.

Submitting Comments: You may submit comments on the Draft RP/EA by one of following methods:

• *Via the Web:* <http://www.gulfspillrestoration.noaa.gov/restoration-areas/louisiana>.

• *Via U.S. Mail:* U.S. Fish and Wildlife Service, P.O. Box 49567, Atlanta, GA 30345; or Louisiana Coastal Protection & Restoration Authority, ATTN: Joann Hicks, P.O. Box 44027, Baton Rouge, LA 70804.

Once submitted, comments cannot be edited or withdrawn. The Louisiana TIG may publish any comment received on the document. 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 Louisiana TIG 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). Please be aware that your entire comment, including your personal identifying information, will become part of the public record. Please note that mailed comments must be postmarked on or before the comment deadline of 7 days following publication of this notice to be considered.

FOR FURTHER INFORMATION CONTACT:

• Louisiana—Joann Hicks at LATIGPublicComments@la.gov or 225-342-5477.

• EPA—Tim Landers at landers.timothy@epa.gov or 202-566-2231.

SUPPLEMENTARY INFORMATION:

Next Steps

To allow additional time for the public to provide comments, the EPA is reopening the public comment period until February 2, 2018. The public is encouraged to review and comment on the Draft RP/EA. After the public comment period ends, the Louisiana TIG will consider the comments received before issuing a Final RP/EA. A summary of comments received and the Louisiana TIG's responses and any revisions to the document, as appropriate, will be included in the final document.

Authority

The authority for this action is the Oil Pollution Act of 1990 (33 U.S.C. 2701 *et seq.*), its implementing NRDA regulations found at 15 CFR part 990, and NEPA (42 U.S.C. 4321 *et seq.*).

Dated: January 19, 2018.

John Goodin,

Acting Director, Office of Wetlands, Oceans and Watersheds, Office of Water.

[FR Doc. 2018-01517 Filed 1-25-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-9037-3]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564-7146 or <http://www2.epa.gov/nepa/>.

Weekly receipt of Environmental Impact Statements

Filed 01/15/2018 Through 01/19/2018 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-nepa-public/action/eis/search>.

EIS No. 20180006, Draft, BLM, WY, Converse County Oil and Gas Project Draft EIS, Comment Period Ends: 03/12/2018, Contact: Mike Robinson (307) 261-7520

EIS No. 20180007, Draft, USFS, CO, Berlaimont Estates Road Improvement Project, Comment Period Ends: 03/12/2018, Contact: Matthew Klein 941-400-4452

EIS No. 20180008, Final, BLM, CA, Abbreviated Final Environmental Impact Statement Proposed Land Exchange between Bureau of Land Management and Agua Caliente Band of Cahuilla Indians, Review Period Ends: 03/12/2018, Contact: Ashley Adams 760-833-7100

Dated: January 22, 2018.

Kelly Knight,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2018-01391 Filed 1-25-18; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0647]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before March 27, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email PRA@fcc.gov and to Cathy.Williams@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418-2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0647.

Title: Annual Survey of Cable

Industry Prices, FCC Form 333.

Form Number: FCC Form 333.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; State, local or Tribal Government.

Number of Respondents and Responses: 728 respondents and 728 responses.

Estimated Time per Response: 7 hours.

Frequency of Response: Annual reporting requirement.

Total Annual Burden: 5,096 hours.

Total Annual Cost: None.

Obligation To Respond: Mandatory.

The statutory authority for this information collection is in Sections 4(i) and 623(k) of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality:

If individual respondents to this survey wish to request confidential treatment of any data provided in connection with this survey, they can do so upon written request, in accordance with Sections 0.457 and 0.459 of the Commission's rules. To request confidential treatment of their data, respondents must describe the specific information they wish to protect and provide an explanation of why such confidential treatment is appropriate. If a respondent submits a request for confidentiality, the Commission will review it and make a determination.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The Cable Television Consumer Protection and Competition Act of 1992 ("Cable Act") requires the Commission to publish annually a report on average rates for basic cable service, cable programming service, and equipment. The report must compare the prices charged by cable operators subject to effective competition and those that are not subject to effective competition. The Annual Cable Industry Price Survey is intended to collect the data needed to prepare that report. The data from these questions are needed to complete this report.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2018-01406 Filed 1-25-18; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0812]

Information Collection Approved by the Office of Management and Budget (OMB)

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for a revision of a currently approved information collection pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). An

agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number, and no person is required to respond to a collection of information unless it displays a currently valid control number. Comments concerning the accuracy of the burden estimates and any suggestions for reducing the burden should be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section below.

FOR FURTHER INFORMATION CONTACT:

Nicole Ongele, Office of the Managing Director, at (202) 418-2991, or email: Nicole.Ongele@fcc.gov.

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

OMB Control Number: 3060-0812.

OMB Approval Date: December 4, 2017.

OMB Expiration Date: December 31, 2020.

Title: Regulatory Fee True-Up, Waiver or Exemption.

Form Nos.: N/A.

Respondents: Business or other for-profit and Not-for-profit institutions.

Number of Respondents and Responses: 19,674 respondents; 19,774 responses.

Estimated Time per Response: 0.25 hours-1 hour.

Frequency of Response: Annual, on occasion and one-time reporting requirements; recordkeeping requirement.

Total Annual Burden: 10,016 hours.

Total Annual Cost: No Cost.

Obligation To Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 158 and 47 U.S.C. 159.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: Licensees or regulatees concerned about disclosure of sensitive information in any submissions to the Commission may request confidential treatment pursuant to 47 CFR 0.459 of the Commission's rules.

Needs and Uses: This information collection consolidates and revises the previously approved information collection requirements under OMB Control Numbers 3060-0655 and 3060-1064 into 3060-0812. The purpose of the information collection requirements are to:

(a) The Commission uses the "true-up" feedback received from regulatees to adjust the regulatee's fee obligations accordingly.

(b) The Commission will use the information that is submitted in support

of requests for a waiver or deferral of the payment of an application fee and the waiver, deferral, or reduction of an annual regulatory fee to determine if the applicant has met the statutory and regulatory legal standards to warrant relief.

(c) The Commission will use the information that is submitted in support of requests for an exemption of the payment of an application fee to facilitate the statutory provision that non-profit entities be exempt from payment of regulatory fees; and facilitate the FCC's ability to audit regulatory fee payment compliance.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2018-01408 Filed 1-25-18; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0214]

Information Collection Being Submitted to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to

comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before February 26, 2018.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email Nicholas.A.Fraser@omb.eop.gov; and to Cathy Williams, FCC, via email PRA@fcc.gov and to Cathy.Williams@fcc.gov. Include in the comments the Title as shown in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418-2918.

SUPPLEMENTARY INFORMATION: To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page <http://www.reginfo.gov/public/do/PRAMain>, (2) look for the section of the web page called "Currently Under Review," (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, (6) when the list of Commission ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the Commission's submission to OMB will be displayed.

OMB Control Number: 3060-0214.

Title: Sections 73.3526 and 73.3527, Local Public Inspection Files; Sections 73.1212, 76.1701 and 73.1943, Political Files.

Form Number: None.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for profit entities; Not for profit institutions; State, Local or Tribal government; Individuals or households.

Number of Respondents and Responses: 24,013 respondents; 63,261 responses.

Estimated Time per Response: 1-52 hours.

Frequency of Response: On occasion reporting requirement, Recordkeeping requirement, Third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority that covers this information collection is contained in Sections 151, 152, 154(i), 303, 307 and 308 of the Communications Act of 1934, as amended.

Total Annual Burden: 2,067,853 Hours.

Total Annual Cost: \$27,168.

Privacy Impact Assessment: The Commission prepared a system of records notice (SORN), FCC/MB-2, "Broadcast Station Public Inspection Files," that covers the PII contained in the broadcast station public inspection files located on the Commission's website. The Commission will revise appropriate privacy requirements as necessary to include any entities and information added to the online public file in this proceeding.

Nature and Extent of Confidentiality: Most of the documents comprising the public file consist of materials that are not of a confidential nature. Respondents complying with the information collection requirements may request that the information they submit be withheld from disclosure. If confidentiality is requested, such requests will be processed in accordance with the Commission's rules, 47 CFR 0.459.

In addition, the Commission has adopted provisions that permit respondents subject to the information collection requirement for Shared Service Agreements to redact confidential or proprietary information from their disclosures.

Needs and Uses: The information collection requirements included under this OMB Control Number 3060-0214, requires commercial broadcast stations to maintain for public inspection a file containing the material set forth in 47 CFR 73.3526.

This collection is being revised to reflect the burden associated with the Shared Service Agreement disclosure requirements adopted in the 2014 Quadrennial Regulatory Review (81 FR 76220, Nov. 1, 2016, FCC 16-107, rel. Aug. 25, 2016) (Second Report and Order) and affirmed in the 2014 Quadrennial Regulatory Review Order on Reconsideration (83 FR 733, Jan. 8, 2018, FCC 17-156, rel. Nov. 20, 2017) (Order on Reconsideration). The collection requires commercial television stations to place in their online public inspection file a copy of every Shared Service Agreement for the station (with the substance of oral agreements reported in writing), regardless of whether the agreement involves commercial television stations in the same market or in different markets, with confidential or proprietary information redacted where appropriate. For purposes of this collection, a Shared Service Agreement is any agreement or series of agreements in which (1) a station provides any station-related services, including, but

not limited to, administrative, technical, sales, and/or programming support, to a station that is not directly or indirectly under common de jure control permitted under the Commission's regulations; or (2) stations that are not directly or indirectly under common de jure control permitted under the Commission's regulations collaborate to provide or enable the provision of station-related services, including, but not limited to, administrative, technical, sales, and/or programming support, to one or more of the collaborating stations. For purposes of this collection, the term "station" includes the licensee, including any subsidiaries and affiliates, and any other individual or entity with an attributable interest in the station.

In the Order on Reconsideration, the Commission upheld the definition of SSAs and the disclosure requirements that were adopted in the Second Report and Order, finding that they were supported by the record. Specifically, the Commission found in the Order on Reconsideration that the Commission in the Second Report and Order adopted a clear definition of SSAs based on the record before it. Furthermore, the FCC found that the Commission in the Second Report and Order provided a sufficient justification for requiring the disclosure of SSAs in order to help the Commission obtain information relevant to its statutory responsibilities.

The information collection requirements contained under 47 CFR 73.1212, 73.3527, 73.1943 and 76.1701 are still a part of the information collection and remain unchanged since last approved by OMB.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2018-01405 Filed 1-25-18; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0584]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or

the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before March 27, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email PRA@fcc.gov and to Nicole.Ongele@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418-2991.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents,

including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control Number: 3060-0584.

Title: Administration of U.S. Certified Accounting Authorities in Maritime Mobile and Maritime Mobile-Satellite Radio Services, FCC Forms 44 and 45.

Form Nos.: FCC Forms 44 and 45.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit organizations.

Number of Respondents and Responses: 19 respondents; 59 responses.

Estimated Time per Response: 1-3 hours.

Frequency of Response: Recordkeeping; on occasion, semi-annual, and annual reporting requirements; and third-party disclosure requirements.

Obligation To Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C 154(i) and 303(r).

Total Annual Burden: 79 hours.

Total Annual Cost: \$475,000.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality. However, respondents may request materials or information submitted to the Commission be withheld from public inspection pursuant to 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission has standards for accounting authorities in the maritime mobile and maritime-satellite radio services under 47 CFR part 3. The Commission uses these standards to determine the eligibility of applicants for certification as a U.S. accounting authority, to ensure compliance with the maritime mobile and maritime-satellite radio services, and to identify accounting authorities to the International Telecommunications Union (ITU). Respondents are entities seeking certification or those already certified to be accounting authorities.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2018-01472 Filed 1-25-18; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of Intent To Terminate the Receivership of 4663, Guaranty National Bank of Tallahassee, Tallahassee, Florida

Notice is hereby given that the Federal Deposit Insurance Corporation (FDIC or Receiver) as Receiver for Guaranty National Bank of Tallahassee, Tallahassee, Florida, intends to terminate its receivership for said institution. The FDIC was appointed Receiver of Guaranty National Bank of Tallahassee on March 12, 2004. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: January 23, 2018.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2018-01502 Filed 1-25-18; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meeting

January 23, 2018.

TIME AND DATE: 10:00 a.m., Thursday, February 15, 2018.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW, Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Secretary*

of *Labor v. Mach Mining, LLC*, Docket Nos. LAKE 2014–77, et al. (Issues include whether the Judge erred by ruling that the operator did not violate a standard requiring that electrical protection devices on high voltage longwall equipment be properly maintained.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and § 2706.160(d).

CONTACT PERSON FOR MORE INFO:

Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

PHONE NUMBER FOR LISTENING TO

MEETING: 1–(866) 867–4769, Passcode: 678–100.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2018–01529 Filed 1–24–18; 11:15 am]

BILLING CODE 6735–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–18–1046; Docket No. CDC–2018–0008]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Monitoring Activities. CDC is requesting a revision to this information collection project to include a redesigned survey and a new clinic-level data collection.

DATES: CDC must receive written comments on or before March 27, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0008 by any of the following methods:

- **Federal eRulemaking Portal:** *Regulations.gov*. Follow the instructions for submitting comments.
- **Mail:** Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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.

5. Assess information collection costs.

Proposed Project

National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Monitoring Activities—(OMB No. 0920–1046, exp. 01/31/2018)—Reinstatement with Change—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting a revision of the information collection with the OMB Control Number 0920–1046, formerly entitled “Annual Survey of the National Breast and Cervical Cancer Early Detection Program Grantees’ Program Implementation”. We are proposing a new title, “National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Monitoring Activities.” In the previous OMB approval period, information collection consisted of an annual grantee survey. In the next OMB approval period, information collection will consist of a redesigned survey and a new clinic-level data collection. The number of respondents will increase from 67 to 70, and the total estimated annualized burden will increase from 45 to 683.

Breast and cervical cancers are prevalent among women in the United States. In 2014, more than 236,000 women were diagnosed with breast cancer, and more than 12,000 women were diagnosed with cervical cancer. Evidence shows that deaths from both breast and cervical cancers can be avoided by increasing screening services among women. However, screening is typically underutilized among women who are under- or uninsured, have no regular source of healthcare, or who recently immigrated to the U.S. As a longstanding priority within chronic disease prevention, CDC focuses on increasing access to these cancer screenings, particularly among women who may be at increased risk.

To improve access to cancer screening, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Pub. L. 101–354), which directed CDC to create the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The NBCCEDP currently provides

funding to 70 grantees under “Cancer Prevention and Control Programs for State, Territorial, and Tribal Organizations (DP17–1701).” NBCCEDP grantees include states or their bona fide agents; U.S. territories; and tribes or tribal organizations. The purpose of NBCCEDP is to increase breast and cervical cancer screening rates among women residing within defined geographical locations (as determined by the funded program) who are at or below 250% of the federal poverty level; aged 40–64 years for breast cancer services, and aged 21–64 years for cervical cancer services; and under- or uninsured.

The NBCCEDP was significantly redesigned in 2017 to expand its focus on direct service provision to include implementation of evidence-based

interventions (EBIs) intended to increase breast and cervical cancer screening at the population level. Based on the redesigned NBCCEDP, the information collection plan has also been redesigned. CDC is required to monitor and evaluate processes and outcomes related to the NBCCEDP.

CDC proposes two forms of information collection. First, the NBCCEDP Grantee Survey was reconstructed to reflect the focus of the redesigned program under DP17–1701. The grantee survey will be submitted to CDC annually. Second, CDC proposes to collect clinic-level data to assess EBI implementation and the NBCCEDP’s primary outcome of interest—breast and cervical screening rates within partner health system clinics. NBCCEDP grantees will collect and report baseline

and annual clinic-level data for all partnering health system clinic sites—an estimated 6 clinics per grantee for breast cancer data and 6 clinics per grantee for cervical cancer data. All information will be reported to CDC electronically.

The proposed information collections will allow CDC to gauge progress in meeting NBCCEDP program goals and monitor implementation activities, evaluate outcomes, and identify grantee technical assistance needs. In addition, findings will inform program improvement and help identify successful activities that need to be maintained, replicated, or expanded.

CDC seeks a three-year OMB approval. Participation is required for NBCCEDP grantees. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
NBCCEDP Grantees	NBCCEDP Grantee Survey	70	1	45/60	53
NBCCEDP Grantees	NBCCEDP Clinic-level Information Collection Instrument—Breast.	70	6	45/60	315
NBCCEDP Grantees	NBCCEDP Clinic-level Information Collection Instrument—Cervical.	70	6	45/60	315
Total	683

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–01381 Filed 1–25–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

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 Centers for Disease Control and Prevention (CDC), announces the following meeting for the Subcommittee on Dose Reconstruction Review (SDRR)

of the Advisory Board on Radiation and Worker Health (ABRWH). This meeting is open to the public, but without a public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference at the USA toll-free, dial-in number at 1–866–659–0537; the pass code is 9933701. The conference line has 150 ports for callers.

DATES: The meeting will be held on March 13, 2018, 10:30 a.m. to 4:30 p.m. EDT.

ADDRESSES: Audio Conference Call via FTS Conferencing. The USA toll-free dial-in number is 1–866–659–0537; the pass code is 9933701.

FOR FURTHER INFORMATION CONTACT: Theodore Katz, MPA, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road, Mailstop E–20, Atlanta, Georgia 30333, Telephone (513) 533–6800, Toll Free 1 (800) CDC–INFO, Email ocas@cdc.gov.

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board as established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, rechartered on March 22, 2016,

pursuant to Executive Order 13708, and will expire on March 22, 2018.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. SDRR was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

Matters To Be Considered: The agenda will include discussions on the following dose reconstruction program quality management and assurance activities: Dose reconstruction cases under review from Sets 19–24, including Iowa Ordinance Plant, Sandia-Albuquerque, Sandia National Laboratory, Pacific Proving Grounds, Nevada Test Site, Los Alamos National Laboratory, Feeds Material Production Center (Fernald), Pantex, Weldon Spring, Rocky Flats Plant, W.R. Grace, Mallinckrodt Chemical Company, and potentially other Department of Energy and Atomic Weapons Employers facilities.

The Director, Management Analysis and Services Office, 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.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2018–01387 Filed 1–25–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–18–18EW; Docket No. CDC–2018–0010]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, 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. This notice invites comment on a proposed information collection project titled “Fatigued Driving among Oil and Gas Extraction workers: Risks and Interventions”—a study examining the determinants of fatigue among oil and gas well service operators, and the effectiveness of fatigue detection devices.

DATES: CDC must receive written comments on or before March 27, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0010 by any of the following methods:

- **Federal eRulemaking Portal:** *Regulations.gov.* Follow the instructions for submitting comments.
- **Mail:** Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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.
5. Assess information collection costs.

Proposed Project

Fatigued Driving among Oil and Gas Extraction workers: Risks and Interventions—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention. The Occupational Safety and Health Act of 1970, Public Law 9–596 (Section 20) [a][1] authorizes NIOSH to conduct research to advance the health and safety of workers.

Transportation incidents are the leading cause of death in the U.S. Oil & Gas extraction (OGE) industry, resulting in over 40% of all workplace fatalities.

The motor vehicle fatality rate in this industry (7.6 fatalities/100,000 workers) was almost nine times that for all industries, and second only to that in the transportation, warehousing, and utilities industry (9.3 fatalities/100,000 workers) during 2003–2009. Nearly every worker in the OGE industry drives as part of their job.

Well sites are often in remote locations, requiring workers to drive on rural roads which may lack safety features such as lighting, guard rails, and adequate road grading. Workers travel long distances from their homes to work sites and between work sites, putting them at increased risk of fatigue and motor vehicle crashes. In addition, OGE work is physically demanding, repetitive, and often conducted in all weather conditions. Long hours and shiftwork are typical; 12-hour shifts for two or more consecutive weeks are

common. While it is speculated that these factors (*i.e.*, commuting practices, job tasks, time on task, working hours, consecutive shifts, seasonal effects) may increase the risk for fatigue and motor vehicle crashes, limited research has examined this among OGE workers.

NIOSH is seeking a one-year approval from OMB to conduct three surveys of U.S. land-based OGE workers who drive light-duty vehicles. The surveys will provide detailed information about determinants of fatigued driving and perceptions of fatigue monitoring devices among OGE workers, not available elsewhere. The study will take place among OGE field operations in collaboration with NIOSH industry partners who will provide access to their vehicles and data from trip records and accelerometers and allow installation of 2 fatigue-detection

devices in their vehicles as intervention strategies.

Information gathered from this study will be used to identify evidence-based best practices in fatigue risk management, and highlight improvements that may be targeted to improve OGE worker safety. The surveys will be administered online or with hard copies to a sample of 45 workers. We estimate that 90% of workers (40) will complete the three surveys electronically and the others will opt to complete a hard copy version. The main questionnaire will take approximately 15 minutes to complete. The post-intervention survey will take approximately five minutes to complete, and the end of shift survey will take two minutes to complete.

The total estimated burden hours is 27. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Oil and Gas Extraction Workers who drive light-duty trucks.	Determinants of fatigued driving and perceptions of fatigue monitors (Tablet Version).	40	1	15/60	10
Oil and Gas Extraction Workers who drive light-duty trucks.	Determinants of fatigued driving and perceptions of fatigue monitors (Hardcopy).	5	1	15/60	2
Oil and Gas Extraction Workers who drive light-duty trucks.	End of shift survey (Tablet Version)	40	6	2/60	8
Oil and Gas Extraction Workers who drive light-duty trucks.	End of shift survey (Hardcopy)	5	6	2/60	1
Oil and Gas Extraction Workers who drive light-duty trucks.	Post-intervention survey (Tablet Version).	40	1	5/60	5
Oil and Gas Extraction Workers who drive light-duty trucks.	Post-intervention survey (Hardcopy)	5	1	5/60	1
Oil and Gas Extraction Workers who drive light-duty trucks.	Non-response survey	1	1	3/60	1
Total	27

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–01380 Filed 1–25–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10305]

Agency Information Collection Activities: Submission for OMB Review; 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by February 26, 2018.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs; Attention: CMS Desk Officer; Fax Number: (202) 395-5806 OR Email: OIRA_submission@omb.eop.gov.

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 Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(g)); *Use:*

Medicare Part C and Part D sponsoring organizations (Medicare Advantage Organizations), must submit Medicare Part C, Medicare Part D, or Medicare Part C and Part D data (depending on the type of contracts they have in place with CMS). In order for the reported data to be useful for monitoring and performance measurement, the data must be reliable, valid, complete, and comparable among sponsoring organizations. To maintain the independence of the validation process, sponsoring organizations are responsible for hiring external, independent data validation contractors (DVCs) who meet a minimum set of qualifications and credentials. For the retrospective review in 2018, the DVCs will review data submitted by sponsoring organizations for CY2017. The main changes for the 2018 DV are to eliminate the Part C/D reporting section Sponsor Oversight of Agents and adding the Part D reporting section Improving Drug Utilization Review Controls. *Form Number:* CMS-10305 (OMB control number: 0938-1115); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 574; *Total Annual Responses:* 574; *Total Annual Hours:* 24,050. (For policy questions regarding this collection contact Maria Sotirelis at 410-786-0552.)

Dated: January 23, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018-01459 Filed 1-25-18; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1703-N]

Medicare Program; Request for Nominations to the Advisory Panel on Hospital Outpatient Payment

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is requesting nominations to fill vacancies on the Advisory Panel (the Panel) on Hospital Outpatient Payment (HOP). The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Centers for

Medicare & Medicaid Services (the Administrator) on the clinical integrity of the Ambulatory Payment Classification (APC) groups and their associated weights, and supervision of hospital outpatient therapeutic services.

DATES: The agency will receive nominations on a continuous basis.

ADDRESSES: Please submit nominations electronically to the following email address: APCPanel@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Persons wishing to nominate individuals to serve on the Panel or to obtain further information may submit an email to the following email address: APCPanel@cms.hhs.gov.

News Media: Representatives should contact the CMS Press Office at (202) 690-6145.

Website: For additional information on the HOP Panel, updates to the Panel's activities, and submission of nominations to the HOP Panel, we refer readers to our website at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act (the Act), and allowed by section 222 of the Public Health Service Act (PHS Act) to consult with an expert outside panel, that is, the Advisory Panel (the Panel) on Hospital Outpatient Payment (HOP) regarding the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights that are components of the Medicare Hospital Outpatient Prospective Payment System (OPPS), and the appropriate supervision level for hospital outpatient therapeutic services. The Panel is governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92-463), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory panels. The Panel may consider data collected or developed by entities and organizations (other than the Department of Health and Human Services) as part of their deliberations.

We consider the technical advice provided by the Panel as we prepare both the proposed and final rulemaking to update the OPPS for the following calendar year (CY).

On May 20, 2016, we published a notice in the **Federal Register** that announced the August 2016 summer

panel meeting and the transition to one meeting of the panel per year (81 FR 31941).

II. Request for Nominations; Criteria for Nominees

The Panel shall consist of a chair and up to 15 members who are full-time employees of hospitals, hospital systems, or other Medicare providers that are subject to the OPPTS. For supervision deliberations, the Panel shall also include members that represent the interests of Critical Access Hospitals (CAHs), who advise the Centers for Medicare & Medicaid Services (CMS) only regarding the level of supervision for hospital outpatient therapeutic services. (For purposes of the Panel, consultants or independent contractors are not considered to be full-time employees in these organizations.)

The HOP Panel currently consists of 13 panel members. Two additional vacancies will occur in CY 2018. The list of HOP Panel members is located in the FACA database, Advisory Panel on Hospital Outpatient Payment Committee page, on the FACA database website at: <https://www.facadatabase.gov/committee/committee.aspx?cid=1791&aid=76>.

Panel members serve on a voluntary basis, without compensation, according to an advance written agreement; however, for the meetings, CMS reimburses travel, meals, lodging, and related expenses in accordance with standard Government travel regulations. CMS has a special interest in ensuring, while taking into account the nominee pool, that the Panel is diverse in all respects of the following: Geography; rural or urban practice; race, ethnicity, sex, and disability; medical or technical specialty; and type of hospital, hospital health system, or other Medicare provider subject to the OPPTS. Appointment to the HOP Panel shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Based upon either self-nominations or nominations submitted by providers or interested organizations, the Secretary, or his or her designee, appoints new members to the Panel from among those candidates determined to have the required expertise. New appointments are made in a manner that ensures a balanced membership under the FACA guidelines. This notice requests nominations for HOP Panel members on a continuous basis. Nominations for a person not serving on the committee may be reconsidered as committee vacancies arise, but should be updated

and resubmitted no later than 3 years after the original nomination submittal to continue to be considered for committee vacancies. CMS will consider the nominations submitted in response to the notice published in the **Federal Register** on December 23, 2016, entitled "Medicare Program; Renewal of the Advisory Panel on Hospital Outpatient Payment and Solicitation of Nominations to the Advisory Panel on Hospital Outpatient Payment" (81 FR 94378), unless they are withdrawn or the nominees' qualifications have changed. Nominations will be considered as vacancies occur.

The Panel must be balanced in its membership in terms of the points of view represented and the functions to be performed. Each panel member must be employed full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPPTS (except for the CAH members, since CAHs are not paid under the OPPTS). All members must have technical expertise to enable them to participate fully in the Panel's work. Such expertise encompasses hospital payment systems; hospital medical care delivery systems; provider billing systems; APC groups; Current Procedural Terminology codes; and alpha-numeric Health Care Common Procedure Coding System codes; and the use of, and payment for, drugs, medical devices, and other services in the outpatient setting, as well as other forms of relevant expertise. For supervision deliberations, the Panel shall have members that represent the interests of CAHs, who advise CMS only regarding the level of supervision for hospital outpatient therapeutic services.

It is not necessary for a nominee to possess expertise in all of the areas listed, but each must have a minimum of 5 years of experience and currently have full-time employment in his or her area of expertise. Generally, members of the Panel serve overlapping terms up to 4 years, based on the needs of the Panel and contingent upon the rechartering of the Panel. A member may serve after the expiration of his or her term until a successor has been sworn in.

Any interested person or organization may nominate qualified individuals. Self-nominations will also be accepted. Each nomination must include the following:

- Letter of Nomination stating the reasons why the nominee should be considered.
- Curriculum vitae or resume of the nominee that includes an email address where the nominee can be contacted.
- Written and signed statement from the nominee that the nominee is willing

to serve on the Panel under the conditions described in this notice and further specified in the Charter.

- The hospital or hospital system name and address, or CAH name and address, as well as all Medicare hospital and or Medicare CAH billing numbers of the facility where the nominee is employed.

Future updates or changes to the panel nomination process may be published in the **Federal Register** or posted on the CMS Advisory Panel for Hospital Outpatient Payment website, referenced in section II, "Request for Nominations; Criteria for Nominees," of this notice.

IV. Copies of the Charter

To obtain a copy of the Panel's Charter, we refer readers to our website at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: January 12, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018-01474 Filed 1-25-18; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9106-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—October Through December 2017

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from October through December 2017, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone No.
I. CMS Manual Instructions	Ismael Torres	(410) 786-1864
II. Regulation Documents Published in the Federal Register	Terri Plumb	(410) 786-4481
III. CMS Rulings	Tiffany Lafferty	(410) 786-7548
IV. Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786-7491
V. FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI. Collections of Information	William Parham	(410) 786-4669
VII. Medicare-Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786-2749
VIII. American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786-2749
IX. Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786-7205
X. One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786-7205
XI. National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
XII. Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Linda Gousis, JD	(410) 786-8616
XIII. Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XIV. Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XV. Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786-8564
All Other Information	Annette Brewer	(410) 786-6580

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue

various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and “real time”

accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

III. How to Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at <http://www.cms.gov/manuals>.

Dated: January 17, 2018.

Kathleen Cantwell,

Director, Office of Strategic Operations and Regulatory Affairs.

BILLING CODE 4120-01-P

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: February 23, 2017 (82 FR 11456), May 5, 2017 (82 FR 21241), August 4, 2017 (82 FR 36404) and October 27, 2017 (82 FR 49819). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (October through December 2017)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: <http://cms.gov/manuals>.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have

arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at <http://www.gpo.gov/libraries/>

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for January 2018 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files use (CMS-Pub. 100-04) Transmittal No. 3878.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
108	Transition Workload Handbook Fee-for-Service Contractor Workload Transitions Transition Handbooks
109	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
110	Affordable Care Act Bundled Payments for Care Improvement Initiative – Recurring File Updates Models 2 and 4 April 2018 Updates
111	Update to Medicare Deductible, Coinsurance and Premium Rates for 2018 Basis for Determining the Part A Coinsurance Amounts Part B Annual Deductible Part B Premium
Medicare Benefit Policy (CMS-Pub. 100-02)	
228	Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct Errors and Omissions (SNF Requirements - General Medicare SNF PPS Overview Medicare SNF Coverage Guidelines Under PPS Hospital Providers of Extended Care Services

	<p>Three-Day Prior Hospitalization</p> <p>Three-Day Prior Hospitalization - Foreign Hospital</p> <p>Effect on Spell of Illness</p> <p>Medical Service of an Intern or Resident-in-Training</p> <p>Medical and Other Health Services Furnished to SNF Patients</p> <p>Services Furnished Under Arrangements With Providers</p> <p>Definition of Durable Medical Equipment</p>
229	<p>Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2017</p>
230	<p>Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Updates</p> <p>Table of Contents</p> <p>Index of Acronyms</p> <p>RHC General Information</p> <p>FQHC General Information</p> <p>RHC Staffing Requirements</p> <p>RHC Temporary Staffing Waivers</p> <p>RHC and FQHC Visits</p> <p>Multiple Visits on Same Day</p> <p>3-Day Payment Window</p> <p>RHC Services</p> <p>FQHC Services</p> <p>Emergency Services</p> <p>Non RHC/FQHC Services</p> <p>Description of Non RHC/FQHC Services</p> <p>RHC Payment Rate</p> <p>RHC Payment Limit and Exceptions</p> <p>Payment Codes for FQHCs Billing Under the PPS</p> <p>FQHC PPS Payment Rate and Adjustments</p> <p>FQHC Payment Codes</p> <p>RHC and FQHC Cost Report Requirements</p> <p>RHC and FQHC Cost Report Forms</p> <p>RHC and FQHC Charges, Coinsurance, Deductible, and Waivers</p> <p>Comminglin</p> <p>Dental, Podiatry, Optometry, and Chiropractic Services</p> <p>Graduate Medical Education</p> <p>Transitional Care Management (TCM) Services</p> <p>Chronic Care Management (CCM) Services</p> <p>Services and Supplies Furnished "Incident to" Physician's Services</p> <p>Provision of Incident to Services and Supplies</p> <p>Incident to Services and Supplies Furnished in the Patient's Home or Location Other than the RHC or FQHC</p> <p>Payment to Physician Assistants</p> <p>Services and Supplies Furnished Incident to NP, PA, and CNM Services</p> <p>Services and Supplies Incident to CP Services</p> <p>Mental Health Visits</p> <p>Physical Therapy, Occupational Therapy, and Speech Language Pathology Service</p> <p>Requirements for Visiting Nursing Services</p>

	<p>Treatment Plans</p> <p>Hospice Services</p> <p>Hospice Attending Practitioner</p> <p>Provision of Services to Hospice Patients in a RHC or FQHC</p> <p>Preventive Health Services</p> <p>Preventive Health Services in RHCs</p> <p>Preventive Health Services in FQHCs</p> <p>Copayment for FQHC Preventive Health Services</p>
231	<p>Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2017</p>
232	<p>January 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS)</p> <p>Covered Inpatient Hospital Services Covered Under Part A</p>
233	<p>Clarification of Payment Policy Changes for Negative Pressure Wound Therapy (NPWT) Using a Disposable Device and the Outlier Payment Methodology for Home Health Services</p> <p>Table of Contents</p> <p>National 60-Day Episode Rate</p> <p>Outlier Payments</p> <p>Consolidated Billing</p> <p>Patient Confined to the Home</p> <p>Sequence of Qualifying Services and Other Medicare Covered Home Health Services</p> <p>Needs Skilled Nursing Care on an Intermittent Basis (Other than Solely Venipuncture for the Purposes of Obtaining a Blood Sample), Physical Therapy, Speech-Language Pathology Services, or Has Continued Need for Occupational Therapy</p> <p>Physician Certification</p> <p>Supporting Documentation Requirements</p> <p>Wound Care</p> <p>Medical Supplies (Except for Drugs and Biologicals Other Than Covered Osteoporosis Drugs), the Use of Durable Medical Equipment and Furnishing Negative Pressure Wound Therapy Using a Disposable Device</p> <p>Negative Pressure Wound Therapy Using a Disposable Device</p> <p>Coinsurance, Copayments, and Deductibles</p>
234	<p>Clarification of Admission Order and Medical Review Requirements</p> <p>Table of Contents</p> <p>Covered Inpatient Hospital Services Covered Under Part A</p> <p>Hospital Inpatient Admission Order and Certification</p>
235	<p>Removal of Contractor Requirement to Submit Opt Out Data into the Contractor Reporting of Operational and Workload Data (CROWD) System (Form 8)</p>
236	<p>Medicare Benefit Policy Manual - Chapter 10, Ambulance Locality and Advanced Life Support (ALS) Assessment Locality</p> <p>Ground Ambulance Services</p>
237	<p>Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2018</p>

238	Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Medicare Benefit Policy Manual Chapter 13 Update Treatment Plans or Home Care Plans Graduate Medical Education Services and Supplies Furnished "Incident to" Physician's Services Provision of Incident to Services and Supplies Incident to Services and Supplies Furnished in the Patient's Home or Location Other than the RHC or FQHC Payment for Incident to Services and Supplies Nurse Practitioner, Physician Assistant, and Certified Nurse Midwife Services Payment to Physician Assistants Services and Supplies Furnished Incident to NP, PA, and CNM Services Clinical Psychologist and Clinical Social Worker Services Services and Supplies Incident to CP Services Mental Health Visits Physical Therapy, Occupational Therapy, and Speech Language Pathology Services Description of Visiting Nursing Services Requirements for Visiting Nursing Services Home Health Agency Shortage Area Treatment Plans Telehealth Services Hospice Attending Practitioner Provision of Services to Hospice Patients in an RHC or FQHC Preventive Health Services in RHCs Copayment and Deductible for RHC Preventive Health Services Preventive Health Services in FQHCs Copayment for FQHC Preventive Health Service Care Management Services Transitional Care Management Services General Care Management Services – Chronic Care Management and General Behavioral Health Integration Services Psychiatric Collaborative Care Model Services
Medicare National Coverage Determination (CMS-Pub. 100-03)	
203	Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Application of Oxygen) Hyperbaric Oxygen Therapy
Medicare Claims Processing (CMS-Pub. 100-04)	
3872	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2018
3873	Place of Service Codes
3874	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3875	Internet Only Manual Update to Pub. 100-04, Chapter 16, to Update Clinical Lab Fee Schedule Layout
3876	Decommission the MCS Maintained HBCRB081 Report ("Correct Coding Quarterly Savings Report") Savings Report Savings Record Format

3877	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3878	January 2018 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
3879	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3880	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3881	Clinical Laboratory Fee Schedule Not Otherwise Classified, Not Otherwise Specified, or Unlisted Service or Procedure Code Data Collection
3882	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3883	Payment for Services Furnished by Qualified Nonphysician Anesthetists Qualified Nonphysician Anesthetist Services Entity or Individual to Whom Fee Schedule is Payable for Qualified Nonphysician Anesthetists Anesthesia Fee Schedule Payment for Qualified Nonphysician Anesthetists Conversion Factors Used for Qualified Nonphysician Anesthetists Conversion Factors for Anesthesia Services of Qualified Nonphysician Anesthetists Furnished on or After January 1, 1992.
3884	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3885	Fiscal Year (FY) 2018 Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS Changes
3886	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3887	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3888	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3889	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3890	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3891	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3892	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3893	Ambulance Inflation Factor for CY 2018 and Productivity Adjustment Ambulance Inflation Factor (AIF)
3894	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
3895	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3896	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3897	Pulmonary Rehabilitation (PR) Services Addition to Chapter 19, Indian Health Services (IHS) Pulmonary Rehabilitation, Physical Therapy, Occupational Therapy,

	Speech-Language Pathology and Diagnostic Audiology Services - Payment Policy Pulmonary Rehabilitation Services - Claims Processing
3898	Correction to Prevent Payment on Inpatient Information Only Claims for Beneficiaries Enrolled in Medicare Advantage Plans Claims Processing Requirements for TAVR Services for Medicare Advantage (MA) Plan Participants Claims Processing Requirements for TMVR for MR Services for Medicare Advantage (MA) Plan Participants
3899	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3900	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3901	Update to Pub 100-04, Chapter 18 Preventive and Screening Services - Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)
3902	New Waived Tests
3903	Annual Medicare Physician Fee Schedule (MPFS) Files Delivery and Implementation and Medicare Physician Fee Schedule Database (MPFSDB) 2018 File Layout Manual Addendum
3904	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3905	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3906	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3907	October 2017 Integrated Outpatient Code Editor (IOCE) Specifications Version 18.3
3908	Influenza Vaccine Payment Allowances - Annual Update for 2017-2018 Season
3909	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - January 2018
3910	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
3911	New Positron Emission Tomography (PET) Radiopharmaceutical/Tracer Unclassified Codes
3912	Off-Cycle Update to the Long Term Care Hospital (LTCH) Prospective Payment System (PPS) Fiscal Year (FY) 2018 Pricer
3913	Common Edits and Enhancements Modules (CEM) Code Set Update
3914	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3915	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE)
3916	Claim Status Category and Claim Status Codes Update
3917	Calendar Year (CY) 2018 Participation Enrollment and Medicare Participating Physicians and Suppliers Directory (MEDPAR) Procedures

3918	Therapy Cap Values for Calendar Year (CY) 2018
3919	Update to Rural Health Clinic (RHC) All Inclusive Rate (AIR) Payment Limit for Calendar Year (CY) 2018
3920	Qualified Medicare Beneficiary Indicator in the Medicare Fee-For-Service Claims Processing System
3921	Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Application of Oxygen)
3922	Update to the Federally Qualified Health Center (FQHC) Prospective Payment System (PPS) for Calendar Year (CY) 2018 - Recurring File Update
3923	Quarterly Update of HCPCS Codes Used for Home Health Consolidated Billing Enforcement
3924	2018 Annual Update to the Therapy Code List
3925	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2018
3926	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3927	Instructions for Downloading the Medicare ZIP Code File for April 2018
3928	Off-Cycle Update to the Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Fiscal Year (FY) 2018 Pricer
3929	Elimination of the GT Modifier for Telehealth Services
3930	Hospice Manual Update Only for Section 30.3 Data Required on the Institutional Claim to A/B MAC (HHH) Hospice Pricer Program Input/Output Record Layout
3931	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3932	Special Requirements for Immunosuppressive Drugs
Medicare Secondary Payer (CMS-Pub. 100-05)	
	None
Medicare Financial Management (CMS-Pub. 100-06)	
295	Notice of New Interest Rate for Medicare Overpayments and Underpayments -1st Qtr. Notification for FY 2018
Medicare State Operations Manual (CMS-Pub. 100-07)	
171	Revisions to State Operations Manual (SOM), Appendix U - Survey Procedures and Interpretive Guidelines for Responsibilities of Medicare Participating Religious Nonmedical Healthcare Institutions
172	Revision to State Operations Manual (SOM) Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals
173	Revisions to State Operation Manual (SOM), Appendix PP Guidance to Surveyors for Long Term Care Facilities
174	Revisions to the State Operations Manual (SOM) Appendix P
175	Revisions to State Operations Manual (SOM) Appendix J, Part II – Interpretive Guidelines – Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities
176	Revisions to State Operations Manual (SOM) Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

Medicare Program Integrity (CMS-Pub. 100-08)	
747	Update to Reporting Requirements Reconsideration Requests – Non-certified Providers/Suppliers External Reporting Requirements
748	Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings Election of Status Coordination of the ALJ Hearing Party in the ALJ Hearing The ALJ Hearing
749	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
750	Proof of Delivery Documentation Requirements Supplier Proof of Delivery Documentation Requirements Proof of Delivery and Delivery Methods Proof of Delivery Requirements for Recently Eligible Medicare FFS Beneficiaries Supplier Documentation
751	Clarifying Signature Requirements
752	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
753	Certificates of Medical Necessity (CMN) and Durable Medical Equipment (DME) Information Forms (DIF)
754	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
755	Tracking Medicare Contractors' Prepayment and Postpayment Reviews
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
	None
Medicare Quality Improvement Organization (CMS-Pub. 100-10)	
	None
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None
Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
	None
Medicare Managed Care (CMS-Pub. 100-16)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Demonstrations (CMS-Pub. 100-19)	
180	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
181	Next Generation ACO Model - Weekly AIPBP Reduction File Change
182	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
183	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
184	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
185	Demonstration: Payment Update for 2018

186	IVIG Demonstration: Payment Update for 2018
187	Next Generation Accountable Care Organization (NGACO) Year Three Benefit Enhancements
One Time Notification (CMS-Pub. 100-20)	
1928	Multi-Carrier System (MCS), Fiscal Intermediary Shared System (FISS) and VIPS Medicare Shared System (VMS) Automation of Prior Authorization (PA) Requests/Pre-Claim Reviews (PCR) and their Responses with Multiple Services (for programs like Home Health (HH)) via the Electronic Submission of Medical Documentation (esMD) System
1929	CMS Approved Review Topics for Durable Medical Equipment, Prosthetic, Orthotics, Supplies (DMEPOS)
1930	National Provider Identification Crosswalk System (NPICS) Retirement Analysis Only - Engage Shared Systems Maintainers (SSMs) and Medicare Administrative Contractors (MACs) in Meetings and Correspondence Related to the NPICS Retirement with the Integrated Data Repository (IDR) Team
1931	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1932	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects within the Fiscal Intermediary Shared System - Removing/Archiving demonstration codes 38, 42 and 43)
1933	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects within the Fiscal Intermediary Shared System - Removing/Archiving demonstration codes 38, 42 and 43)
1934	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1935	FISS Process Enhancements – Analysis Only
1936	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
1937	Provider Education and Referral Reporting
1938	Archiving National Provider Identifier Crosswalk System (NPICS) System Logic in the Durable Medical Equipment (DME) Claims Processing System
1939	Fiscal Intermediary Shared Systems (FISS) Enhancements to the Mass Adjustment of Process Recovery Audit Contractor (RAC) Claims
1940	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1941	Transitional Drug Add-on Payment Adjustment (TDAPA) for patients with Acute Kidney Injury (AKI)
1942	Common Working File (CWF) to Medicare Beneficiary Database (MBD) Extract File Changes for Detailed Skilled Nursing Facility Data to Support HIPAA Eligibility Transaction System (HETS)
1943	Assign the Correct 935 Indicator on Adjustment Claims Submitted through the Provider Portal
1944	MCS Analysis Only: Undeliverable Medicare Summary Notices (UMSNs) – Beneficiary Do Not Forward Process
1945	Add Date of Receipt to the Beneficiary Data Streamlining (BDS) Part A Claims Layout
1946	Shared System Enhancement 2015: Removing/Archiving Obsolete Reports within the Multi-Carrier System (MCS)

1947	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front End Updates for April 2018
1948	Archiving National Provider Identifier Crosswalk System (NPICS) System Logic in the Multi-Carrier System (MCS)
1949	Remove Obsolete Edits from the Fiscal Intermediary Shared Systems (FISS)
1950	Fiscal Intermediary Shared System (FISS) and VIPS Medicare Shared System (VMS) to Update Records Based on the Automation of Prior Authorization (PA) Requests/Pre-Claim Reviews (PCR) and their Responses with Multiple Services (for programs like Home Health (HH))
1951	Shared System Enhancement 2015: Removing/Archiving Obsolete On Request Jobs within the Multi-Carrier System (MCS)
1952	Calculating Interim Rates for Graduate Medical Education (GME) Payments to New Teaching Hospitals
1953	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete On-Request Jobs - Phase 1
1954	New Common Working File (CWF) Medicare Secondary Payer (MSP) Type for Liability Medicare Set-Aside Arrangements (LMSAs) and No-Fault Medicare Set-Aside Arrangements (NFMSAs)
1955	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1956	Analysis and Design Working Sessions for the Development of a Pre-Payment Common Additional Documentation Request (ADR) Letter
1957	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects Within the Common Working File (CWF) - Removing/Archiving Demonstration codes 51 and 56
1958	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete Financial and Expert Claims Processing System (ECPS) Reports - Phase 1
1959	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete Financial and Expert Claims Processing System (ECPS) Reports - Phase 1
1960	Implementation of the Award for the Jurisdiction Part A and Part B Medicare Administrative Contractor (JJ A/B MAC)
1961	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1962	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete Core Reports - Phase 1
1963	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1964	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete Core Reports - Phase 1
1965	Shared System Enhancement 2015: Resolve Operating Report (ORPT) Issues – Development and Implementation
1966	Out-of-Jurisdiction Providers (OJP) and Qualified Chain Providers (QCP) Move to Correct A/B MAC Jurisdiction - Analysis CR Only
1967	CICS Region Merge(s) for A/B MACs - Analysis Only
1968	Tracking Status of Claims Adjustments
1969	Partial Settlement of 2-Midnight Policy Court Cases
1970	Establish an Automated Process For Creating Mass Adjustments Utilizing

	Expert Claims Processing System (ECPS) - Analysis Only
1971	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
1972	Analysis Only: Develop Enhanced Claims Search Reporting in Fiscal Intermediary Shared System (FISS)
1973	Multi-Carrier System (MCS) Modernization Proof of Concept Number 8
1974	Revision of PWK (Paperwork) Fax/Mail Cover Sheets
1975	ICD-10 and Other Coding Revisions to National Coverage Determinations (NCDs)
1976	Common Working File (CWF) to Modify CWF Provider Queries to Only Accept National Provider Identifier (NPI) as valid Provider Number
1977	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1978	Implementation of Changes to Certificate of Medical Necessity (CMN) and CMN DME Information Form (CMN DIF) as a result of the New Medicare Card Project
1979	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects Within the Common Working File (CWF)
1980	Shared System Enhancement 2015: Removing/Archiving Obsolete On Request Jobs within the Multi-Carrier System (MCS)
1981	Fiscal Year (FY) 2014 and 2015 Worksheet S-10 Revisions: Further Extension for All Inpatient Prospective Payment System (IPPS) Hospitals
1982	Line Level versus Claim Level Reporting – Analysis Only
1983	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects within the Fiscal Intermediary Shared System - Removing/Archiving demonstration codes 38, 42 and 43)
1984	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
70	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
71	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
72	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (October through December 2017)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at <http://www.gpoaccess.gov/fr/index.html>. The following website <http://www.archives.gov/federal-register/> provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at:
<http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-4Q17QPU.pdf>

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings (October through December 2017)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings>. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (October through December 2017)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the

title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Application of Oxygen)	NCD 20.29	203	11/17/2017	04/03/2017

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (October through December 2017)

Addendum V includes listings of the FDA-approved investigational device exemption (IDE) numbers that the FDA assigns. The listings are organized according to the categories to which the devices are assigned (that is, Category A or Category B), and identified by the IDE number. For the purposes of this quarterly notice, we list only the specific updates to the Category B IDEs as of the ending date of the period covered by this notice and a contact person for questions or additional information. For questions or additional information, contact John Manlove (410-786-6877).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more information about the classes or categories, please refer to the notice published in the April 21, 1997 **Federal Register** (62 FR 19328).

IDE	Device	Start Date
G170177	Medtronic IN.PACT Admiral Drug-Coated Balloon	10/04/2017
G170229	Gel-Bead embolization spheres	10/04/2017
G170226	Strattice Reconstructive Tissue Matrix	10/05/2017
G170227	DiamondTemp Ablation System	10/06/2017
G170232	LC Bead LUMI	10/13/2017
G170237	Exablate Model 4000 Type 1	10/20/2017
G170051	Left Gastric Artery Embolization for Glycemic Control	10/24/2017
G170100	Axonics Sacral Neuromodulation System	10/27/2017
G170240	Doctormate Renqiao Remote Ischemic Conditioning Device Type IPC-906X	10/27/2017
G170242	A High-Performance ECoG-based Neural Interface for Communication and Neuroprosthetic Control	10/27/2017
G170247	HiResolution Bionic Ear System	11/02/2017
G160196	Neovase Reducer System	11/03/2017
G170248	ClonoSEQ in-vitro assay, laboratory developed test	11/07/2017
G170252	TraceIT Tissue Spacer	11/07/2017
G170251	Wingman Crossing Catheter	11/08/2017
G170179	SYNERGY Everolimus-Eluting Platinum Chromium Coronary Stent System	11/09/2017
G170261	AXIOS Stent and Electrocautery Enhanced Delivery System 10mmx10mm; AXIOS Stent and Electrocautery Enhanced Delivery System 15mmx10mm; AXIOS Stent and Electrocautery Enhanced Delivery System 20mmx10mm	11/09/2017
G170189	Contour PVA, Embosphere and Embosphere	11/14/2017
G170254	Wallstent	11/16/2017
G170257	SPRINT PNS System for the Treatment of Back Pain	11/17/2017
G170258	CardioMEMS HF System	11/17/2017
G170083	PQ Bypass System	11/20/2017
G170219	Cardio Flow Orbital Atherectomy System	11/21/2017
G170205	Brown Glaucoma Implant	11/22/2017
G170268	Activa PC+S Neurostimulation System; Neurostimulation Systems for Deep Brain Stimulation	11/24/2017
G170270	SurgiMed Meshed Collagen Matrix	11/29/2017
G170273	Medtronic Arctic Front Advance Cardiac Cryoballoon catheter	11/30/2017
G170272	Study of Left Main Coronary Artery Healing after PCI with Boston Scientific Synergy Bioabsorbable Polymer Stent (SOLEMN)	12/01/2017
G170126	MMS MicroStent System	12/08/2017
G170279	Aries 2 Device	12/08/2017
G170282	SYNERGY Everolimus-Eluting Platinum Chromium Coronary Stent System	12/13/2017
G170283	Cardioblate BP2, Cardioblate LP, Cardioblate Pen, Cardioblate XL Pen, Cardioblate MAPs; Cardioblate Generator; Cardioblate CryoFlex Probes and Clamp; Cardioblate CryoFlex Console	12/13/2017

IDE	Device	Start Date
G150231	Mayo Clinic Nerve Scaffold #1 (MCNS1)	12/14/2017
G160258	REZUM SYSTEM	12/15/2017
G170286	Transmural Transcaval Closure Device (Delivery System & Implant); Guidewire for use with Transcaval Closure Device	12/15/2017
G170287	Invisalign Palatal Expander	12/15/2017

Addendum VI: Approval Numbers for Collections of Information (October through December 2017)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact William Parham (410-786-4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities, (October through December 2017)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: <http://www.cms.gov/MedicareApprovedFacilities/CASF/list.asp#TopOfPage>. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
Good Samaritan Hospital Medical Center 1000 Montauk Highway West Islip, NY 11795	1902865355	10/20/2017	NY
Salt Lake Regional Medical Center 1050 E. South Temple Salt Lake City, UT 84102	1417988833	12/11/2017	UT
The following facilities have editorial changes (in bold).			
FROM: SSM St. Mary's Health Center TO: SSM Health St Mary's Hospital - St. Louis 6420 Clayton Road Richmond Heights, MO 63117	26-0091	01/12/2012	MO
FROM: DePaul Health Center TO: SSM Health DePaul Hospital - St. Louis 12303 DePaul Drive St. Louis, MO 63044-2588	26-0104	10/30/2009	MO
FROM: SSM St. Clare Health Center TO: SSM Health St. Clare Hospital – Fenton 1015 Bowles Avenue Fenton, MO 63026	26-0081	01/23/2006	MO
FROM: SSM St. Joseph Health Center TO: SSM Health St. Joseph Hospital - St Charles 300 First Capitol Drive St. Charles, MO 63301	26-0005	04/26/2005	MO
FROM: Saint Louis University Hospital TO: SSM Health Saint Louis University Hospital 3635 Vista at Grand Boulevard St. Louis, MO 63110 P.O. Box 15250 SSM-SLUH, INC	26-0105	05/17/2005	MO
FROM: St Mary's Medical Center TO: St. Vincent Evansville 3700 Washington Avenue Evansville, IN 47740	15-0100	05/17/2005	IN
FROM: Provena Mercy Medical Center TO: Presence Mercy Medical Center 1325 North Highland Avenue	140174	07/15/2005	IL

Facility	Provider Number	Effective Date	State
Aurora, IL 60506			
FROM: Resurrection Medical Center TO: Presence Resurrection Medical Center 35 West Talcott Avenue Chicago, IL 60631	140117	04/12/2005	IL
FROM: Provena Saint Joseph Hospital TO: Presence Saint Joseph Hospital 77 North Airlite Street Elgin, IL 60123-4912	140217	05/11/2005	IL
FROM: Provena Saint Joseph Medical Center TO: Presence Saint Joseph Medical Center 333 North Madison Street Joliet, IL 60435-6595	140007	09/06/2005	IL
FROM: Provena St. Mary's Hospital TO: Presence St. Mary's Hospital 500 West Court Street Kankakee, IL 60901	140155	06/01/2005	IL
FROM: Tenet Hospital Limited TO: Baylor Scott & White Medical Center-White Rock 9440 Poppy Drive Dallas, TX 75218	450678	09/07/2007	TX
FROM: Foote Hospital TO: Henry Ford Allegiance Health 205 North East Avenue Jackson, MI 49201	230092	11/03/2005	MI
FROM: Rogue Valley Medical Center TO: Asante Rogue Regional Medical Center 2825 East Barnett Road Medford, OR 97504	380018	05/05/2005	OR
The following facilities have been removed.			
Facility	Provider Number	Effective Date	State
Lee's Summit Medical Center 2100 SE Blue Parkway Lee's Summit, MO 64063	260190	05/17/2005	MO

Addendum VIII:**American College of Cardiology's National Cardiovascular Data Registry Sites (October through December 2017)**

Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators (ICDs) for certain clinical indications, as long as information about the procedures is reported to a central registry. Detailed descriptions of the covered indications are available in the NCD. In January 2005, CMS established the ICD Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals needed to transition to the ACC-NCDR ICD Registry by April 2006.

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS website at <http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961>

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the ACC-NCDR ICD registry. Therefore, for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC-NCDR ICD registry. The entire list of facilities that participate in the ACC-NCDR ICD registry can be found at www.ncdr.com/webncdr/common

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available by accessing our website and clicking on the link for the

American College of Cardiology's National Cardiovascular Data Registry at: www.ncdr.com/webncdr/common. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	City	State
The following facilities are new listings for this quarter.		
Our Lady of the Lake Ascension Community	Gonzales	LA

Facility	City	State
Hospital		
Newton Wellesley Hospital	Newton	MA
Gerald Champion Regional Medical	Alamogordo	NM
The following facilities are terminations for this quarter.		
Forest Hills Hospital Termination Requested	Forest Hills	NY
Central Maine Medical Center Termination Requested--Please see case 00325173. We have consolidated ICD to PID 288750.	Lewiston	ME
Forrest General Hospital Service/Facility Closed--This facility had duplicate accounts. The ICD Registry was merged with PID 266955. Access to the ICD Registry for PID 656089 will cease 12/31/17.	Hattiesburg	MS
Nicholas H. Noyes Memorial Hospital Termination Requested	Dansville	NY
University Campus of CHI Health CUMC-Bergan Mercy Termination Requested	Omaha	NE
St. Joseph Regional Medical Center - South Bend Termination Requested-- Please see case 00325200. We have consolidated the ICD registry to PID 663672.	Mishawaka	IN
Willis Knighton Pierremont Termination Requested	Shreveport	LA
Union Hospital Termination Requested	Elkton	MD
Melbourne Same Day Surgery Termination Requested	Melbourne	FL
Integrus Grove Hospital Termination Requested--Please see case 00325232. We are consolidating the ICD Account to PID 334434 so all registries are under one account.	Grove	OK

Addendum IX: Active CMS Coverage-Related Guidance Documents (October through December 2017)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the

national coverage determination process. The document is available at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27>. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum X:

List of Special One-Time Notices Regarding National Coverage Provisions (October through December 2017)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at www.cms.hhs.gov/coverage. For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (October through December 2017)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography (PET)** scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage>. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (October through December 2017)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in

order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage>. For questions or additional information, contact Linda Gousis, JD, (410-786-8616).

Facility	Provider Number	Date Approved	State
The following facilities are new listings for this quarter.			
Lovelace Medical Center 601 Dr. Martin Luther King Jr. Ave. NE Albuquerque, NM 87102	320009	10/09/2017	NM
JFK Medical Center 5301 South Congress Avenue Atlantis, FL 33462	100080	01/25/2017	FL
Pitt County Memorial Hospital, Inc. d/b/a Vidant Medical Center 2100 Stantonsburg Road Greenville, NC 27834	340040	09/27/2017	NC
CHI St. Vincent Heart Clinic 2 St. Vincent Circle Little Rock, AR 72205	040007	11/22/2017	AR
Hillcrest Medical Center 1120 S. Utica Tulsa, OK 74104	370001	12/04/2017	OK
The following facilities have editorial changes (in bold).			
FROM: Inova Fairfax Hospital TO: Inova Fairfax Medical Campus 3300 Gallows Road Falls Church, VA 22042 Joint Commission # 6351	490063	07/26/2017	VA
Delray Medical Center, Inc 5352 Linton Boulevard Delray Beach, FL 33484 Joint Commission # 5215	100258	08/17/2017	FL

Facility	Provider Number	Date Approved	State
UT Southwestern Medical Center/William P. Clements Jr. University Hospital 6201 Harry Hines Boulevard Dallas, TX 75390 Joint Commission #9013. Hospital previously listed as St. Paul Medical Center.	450044	08/09/2017	TX
New York Presbyterian – Columbia University Medical Center 622 West 168th Street New York, NY 10032 Joint Commission # 5838	330101	09/24/2015	NY
University of Utah Hospital 50 N Medical Drive Salt Lake City, UT 84132 Joint Commission # 9544	460009	08/09/2017	UT
Northwestern Memorial Hospital 251 E Huron Street Chicago, IL 60611 Joint Commission # 7267	140281	08/19/2017	IL
Texas Heart Hospital of the Southwest DBA The Heart Hospital Baylor Plano 1100 Allied Drive Plano, TX 75093 Joint Commission # 440319	670025	08/23/2017	TX
North Carolina Baptist Hospital DBA Wake Forest Baptist Medical Center Medical Center Boulevard Winston Salem, NC 27157 Joint Commission # 6571	340047	08/19/2017	NC
Mayo Clinic 4500 San Pablo Road Jacksonville, FL 32224 Joint Commission # 369946	100151	10/04/2017	FL
Baylor University Medical Center at Dallas 3500 Gaston Avenue Dallas, TX 75246 Joint Commission # 8993	450021	11/01/2017	TX
Seton Medical Center Austin 1201 W 38th Street Austin, TX 78705 Joint Commission # 8939	450056	10/04/2017	TX
Emory University Hospital 1364 Clifton Road Atlanta, GA 30322 Joint Commission # 6689	110010	09/27/2017	GA
Thomas Jefferson University Hospital 111 South 11th Street Philadelphia, PA 19107 Joint Commission # 6132	390174	09/21/2017	PA
FROM: Albert Einstein Medical	390142	09/20/2017	PA

Facility	Provider Number	Date Approved	State
Center TO: Einstein Medical Center Philadelphia 5501 Old York Road Philadelphia, PA 19141 Joint Commission # 6118			
Lancaster General Hospital 555 North Duke Street Lancaster, PA 17602 Joint Commission # 6086	390100	10/04/2017	PA

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (October through December 2017)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (October through December 2017)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21,

[FR Doc. 2018-01475 Filed 1-25-18; 8:45 am]
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2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS's minimum facility standards

for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (October through December 2017)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Children and Families****Submission for OMB Review; Comment Request**

Title: Medical Complaint Form, Contact Investigation Form: Non-TB Illness, and Contact Investigation Form: Active/Suspect TB.

OMB No.: 0970–NEW.

The Administration for Children and Families' Office of Refugee Resettlement (ORR) places unaccompanied minors in their custody in licensed care provider facilities until reunification with a qualified sponsor. Pursuant to Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al.*,

v. Janet Reno, Attorney General of the United States, et al., Case No. CV 85–4544–RJK (C.D. Cal. 1996), care provider facilities, on behalf of ORR, shall arrange for appropriate routine medical and dental care, family planning services, and emergency healthcare services, including a complete medical examination within 48 hours of admission to ORR, screening for infectious diseases, appropriate immunizations in accordance with the U.S. Public Health Service (PHS), Center for Disease Control, administration of prescribed medication and special diets, and appropriate mental health interventions for each minor in care.

The Medical Complaint and Contact Investigation forms are to be used as worksheets for healthcare providers and health departments to compile

information that would otherwise have been collected during a medical evaluation. Once completed, the forms will be given to care provider facility staff for data entry into ORR's electronic data repository known as 'The UAC Portal'. Entered data will be used to record and monitor health conditions/illnesses including infectious diseases, document preventative services, develop care plans, ensure serious illnesses/conditions receive appropriate post-release follow-up care, and to track interventions taken to prevent the spread of infectious diseases.

Respondents: Office of Refugee Resettlement Grantee staff.

Annual Burden Estimates

Estimated Respondent Burden for Responding:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Medical Complaint Form	120	836	.13	13,042
Contact Investigation Form: Non-TB Illness	120	4	.08	38
Contact Investigation Form: Active/Suspect TB	120	2	.08	19

Estimated Total Annual Burden Hours: 13,099.

Estimated Respondent Burden for Recordkeeping:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Medical Complaint Form	120	836	0.08	8,026
Contact Investigation Form: Non-TB Illness	120	4	0.08	38
Contact Investigation Form: Active/Suspect TB	120	2	0.08	19

Estimated Total Annual Burden: 8,083.

Additional Information: 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. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: 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. 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–01390 Filed 1–25–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Children and Families****Proposed Information Collection Activity; Comment Request****Proposed Projects**

Title: Supplemental Nutrition Assistance Program (SNAP) Matching Program Performance Outcomes.
OMB No.: 0970–0464.

Description: State agencies administering the Supplemental

Nutrition Assistance Program (SNAP) are mandated to participate in a computer matching program with the federal Office of Child Support Enforcement (OCSE). The matching program compares SNAP applicant and recipient information with employment and wage information maintained in the National Directory of New Hires (NDNH). The outcomes of the compared information help state SNAP agencies with administering the program and verifying and determining an individual's benefit eligibility. To receive NDNH information, state agencies enter into a computer matching agreement and adhere to its terms and conditions, including providing OCSE with annual performance outcomes attributable to the use of NDNH information.

The Office of Management and Budget (OMB) requires OCSE to periodically report performance measurements demonstrating how the use of

information in the NDNH supports OCSE's strategic mission, goals, and objectives. OCSE will provide the annual SNAP performance outcomes to OMB.

The information collection activities for the SNAP performance outcomes reports are authorized by: (1) Subsection 453 (j)(10) of the Social Security Act (42 U.S.C. 653(j)(10)), which allows the

Secretary of the U.S. Department of Health and Human Services to disclose information maintained in the NDNH to state agencies administering SNAP under the Nutrition Act of 2008, as amended by the Agriculture Act of 2014; (2) the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988 (5 U.S.C. 552a), which sets forth the terms

and conditions of a computer matching program; and, (3) the Government Performance and Results Modernization Act of 2010 (Pub. L. 111–352), which requires agencies to report program performance outcomes to the Office of Management and Budget and for the reports to be available to the public.

Respondents: State SNAP Agencies.

ANNUAL BURDEN ESTIMATES

Information collection title	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
SNAP Matching Program Performance Outcomes	53	1	1.92	101.76
Estimated Total Annual Burden Hours:	101.76

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–01388 Filed 1–25–18; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–2475]

Determination of Regulatory Review Period for Purposes of Patent Extension; VARUBI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VARUBI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by March 27, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 25, 2018. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 27,

2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of March 27, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-E-2475 for "Determination of Regulatory Review Period for Purposes of Patent Extension; VARUBI." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.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.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product VARUBI (rolapitant). VARUBI is indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Subsequent to this approval, the USPTO received a patent term restoration application for VARUBI (U.S. Patent No. 7,049,320) from OPKO Health, Inc., and the USPTO

requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 2, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VARUBI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for VARUBI is 3,070 days. Of this time, 2,708 days occurred during the testing phase of the regulatory review period, while 362 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* April 8, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 8, 2007.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* September 5, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for VARUBI (NDA 206500) was initially submitted on September 5, 2014.

3. *The date the application was approved:* September 1, 2015. FDA has verified the applicant's claim that NDA 206500 was approved on September 1, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,716 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of

§ 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01373 Filed 1–25–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0073]

Agency Information Collection Activities; Proposed Collection; Comment Request; Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our requirements for food irradiation processors.

DATES: Submit either electronic or written comments on the collection of information by March 27, 2018.

ADDRESSES: You may submit comments as follows: Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 27,

2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of March 27, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2018–N–0073 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Irradiation in the Production, Processing, and Handling of Food.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential

Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **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.

FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests

or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Irradiation in the Production, Processing, and Handling of Food

OMB Control Number 0910-0186—Extension

This information collection supports FDA regulations. Specifically, under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the FD&C Act. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To ensure safe use of a radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum (or minimum and maximum) energy of the emitted radiation. Section 179.21(b)(2) requires that the label or accompanying labeling bear adequate directions for installation and use and a statement supplied by us that indicates maximum dose of radiation allowed. Section 179.26(c) requires that the label or

accompanying labeling bear a logo and a radiation disclosure statement. Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (e.g., the food treated, lot identification, scheduled process, etc.). The records required by § 179.25(e) are used by our inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. We cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

Description of respondents: Respondents to the information collection are businesses engaged in the irradiation of food.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
179.25(e), large processors	4	300	1,200	1	1,200
179.25(e), small processors	4	30	120	1	120
Total					1,320

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Upon review of the information collection we have retained the currently approved burden estimate. Our estimate of the recordkeeping burden under § 179.25(e) is based on our experience regulating the safe use of radiation as a direct food additive. The number of firms who process food using irradiation is extremely limited. We estimate that there are four irradiation plants whose business is devoted primarily (i.e., approximately 100 percent) to irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. We estimate that this irradiation accounts for no more than 10 percent of the business for each of these firms. Therefore, the average estimated burden is based on four facilities devoting 100 percent of their business to food irradiation (4 × 300 hours = 1,200 hours

for recordkeeping annually), and four facilities devoting 10 percent of their business to food irradiation (4 × 30 hours = 120 hours for recordkeeping annually).

No burden has been estimated for the labeling requirements in §§ 179.21(b)(1), 179.21(b)(2), and 179.26(c) because the disclosures are supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not subject to review by the OMB under the PRA.

Dated: January 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-01470 Filed 1-25-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6878]

Hypertension: Developing Fixed-Dose Combination Drugs for Treatment; 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 “Hypertension: Developing Fixed-Dose Combination Drugs for Treatment.” The purpose of this guidance is to assist sponsors in the clinical development of

fixed-dose combination drugs for the treatment of hypertension. The guidance focuses on development of two-drug combinations of previously approved drugs.

DATES: Submit either electronic or written comments on the draft guidance by March 27, 2018 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-2017-D-6878 for "Hypertension: Developing Fixed-Dose Combination Drugs for Treatment; Draft Guidance for Industry." Received comments will be placed in the docket and, except for

those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **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:

Naomi Lowy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 22, Rm. 4204, Silver Spring, MD 20993-0002, 301-796-0692.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Hypertension: Developing Fixed-Dose Combination Drugs for Treatment." The purpose of this guidance is to assist sponsors in the clinical development of fixed-dose combination drugs for the treatment of hypertension. The guidance focuses on development of two-drug combinations of previously approved drugs.

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 developing fixed-dose combination drugs for treatment of hypertension. 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. 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: January 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-01352 Filed 1-25-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6903]

Advisory Committee; Pharmaceutical Science and Clinical Pharmacology Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Pharmaceutical Science

and Clinical Pharmacology Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Pharmaceutical Science and Clinical Pharmacology Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until January 22, 2020.

DATES: Authority for the Pharmaceutical Science and Clinical Pharmacology Advisory Committee will expire on January 22, 2020, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Jay Fajiculay, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: PSCP@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates scientific, clinical, and technical issues related to the safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have, and as required, any other product for which FDA has regulatory responsibility, and makes appropriate recommendations to the Commissioner. The Committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

The Committee shall consist of a core of 14 voting members including two Chairpersons. Members and Chairpersons are selected by the

Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical sciences (pharmaceutical manufacturing, bioequivalence research, laboratory analytical techniques, pharmaceutical chemistry, physiochemistry, biochemistry, molecular biology, immunology, microbiology) and clinical pharmacology (dose-response, pharmacokinetics-pharmacodynamics, modeling and simulation, pharmacogenomics, clinical trial design, pediatrics, and special populations and innovative methods in drug development), biostatistics, related biomedical and pharmacological specialties, current good manufacturing practices, and quality systems implementation. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include up to three non-voting members who are identified with industry interests.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AdvisoryCommitteeForPharmaceuticalScienceandClinicalPharmacology/default.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: January 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-01377 Filed 1-25-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2016-E-2443 and FDA-2016-E-2444]

Determination of Regulatory Review Period for Purposes of Patent Extension; VRAYLAR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VRAYLAR and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by March 27, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 25, 2018. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 27, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of March 27, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket Nos. FDA-2016-E-2443 and FDA-2016-E-2444 for "Determination of Regulatory Review Period for Purposes of Patent Extension; VRAYLAR." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available

for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product.

Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product VRAYLAR (cariprazine). VRAYLAR is indicated for the treatment of schizophrenia and acute treatment of manic or mixed episodes associated with bipolar I disorder. Subsequent to this approval, the USPTO received a patent term restoration application for VRAYLAR (U.S. Patent Nos. 7,737,142 and 7,943,621) from Forest Laboratories, LLC, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 7, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VRAYLAR represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for VRAYLAR is 3,742 days. Of this time, 2,709 days occurred during the testing phase of the regulatory review period, while 1,033 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* June 21, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 21, 2005.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* November 19, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for VRAYLAR (NDA 204370) was initially submitted on November 19, 2012.

3. *The date the application was approved:* September 17, 2015. FDA has verified the applicant's claim that NDA 204370 was approved on September 17, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 905 or 275 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01368 Filed 1–25–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5570]

Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability that appeared in the **Federal Register** of November 29, 2017. In the notice of availability, FDA requested comments on draft guidance for industry and FDA staff entitled “Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices.” The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published November 29, 2017 (82 FR 56607). Submit either electronic or written comments on the draft guidance by March 30, 2018, 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–2017–D–5570 for “Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability.” 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT:

Marina Kondratovich, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4672, Silver Spring, MD 20993-0002, 301-796-6036; or Peter Tobin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5657, Silver Spring, MD 20993-0002, 240-402-6169.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 29, 2017, FDA published a notice of availability with a 60-day comment period to request comments on draft guidance for industry and FDA staff entitled "Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices."

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 the FDA on the guiding principles and recommended approach for FDA staff and industry to facilitate consistent application of least burdensome principles to the activities pertaining to products meeting the statutory definition of a device regulated under the Federal Food, Drug, and Cosmetic

Act. 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 draft guidance is not subject to Executive Order 12866.

The Agency has received a request for a 60-day extension of the comment period. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response.

FDA has considered the request and is extending the comment period for the notice of availability for 60 days, until March 30, 2018. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying guidance on these important issues.

II. 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: January 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-01349 Filed 1-25-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-5625]

Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments Waiver by Application Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability that appeared in the **Federal Register** of November 29, 2017. In the notice of availability, FDA requested comments on draft guidance for industry and FDA staff entitled "Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application Studies." The Agency is

taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published November 29, 2017 (82 FR 56610). Submit either electronic or written comments on the draft guidance by March 30, 2018, 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-2017-D-5625 for "Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments (CLIA)

Waiver by Application Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability.” 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Recommendations

for Dual 510(k) and Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Peter Tobin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 5657, Silver Spring, MD 20993–0002, 240–402–6169.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 29, 2017, FDA published a notice of availability with a 60-day comment period to request comments on draft guidance for industry and FDA staff entitled “Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application Studies.”

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 the guiding principles and recommended approach for FDA staff and industry to facilitate consistent application of least burdensome principles to the activities pertaining to products meeting the statutory definition of a device regulated under the Federal Food, Drug, and Cosmetic Act. 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 draft guidance is not subject to Executive Order 12866.

The Agency has received a request for a 60-day extension of the comment period. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response.

FDA has considered the request and is extending the comment period for the notice of availability for 60 days, until March 30, 2018. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying guidance on these important issues.

II. 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: January 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01350 Filed 1–25–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0181]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Carfentanil; 4-fluoroamphetamine (4-FA) and Ten Other Substances; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is providing interested persons with the opportunity to submit written comments concerning recommendations by the World Health Organization (WHO) to impose international manufacturing and distributing restrictions, under international treaties, on certain drug substances. The comments received in response to this notice will be considered in preparing the United States’ position on these proposals for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria, in March 2018. This notice is issued under the Controlled Substances Act (CSA).

DATES: Submit either electronic or written comments by February 26, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 26, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of February 26, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery

service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-0181 for "International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Carfentanil; 4-fluoroamphetamine (4-FA) and Ten Other Substances; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **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.

FOR FURTHER INFORMATION CONTACT: James R. Hunter, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5150, Silver Spring, MD 20993-0002, 301-796-3156, james.hunter@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (Psychotropic Convention). Section 201(d)(2)(B) of the CSA (21 U.S.C. 811(d)(2)(B)) provides that when the United States is notified under Article 2 of the Psychotropic Convention that the CND proposes to decide whether to add a drug or other substance to one of the schedules of the

Psychotropic Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State must transmit notice of such information to the Secretary of Health and Human Services (Secretary of HHS). The Secretary of HHS must then publish a summary of such information in the **Federal Register** and provide opportunity for interested persons to submit comments. The Secretary of HHS must then evaluate the proposal and furnish a recommendation to the Secretary of State that shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

As detailed in the following paragraphs, the Secretary of State has received notification from the Secretary-General of the United Nations (the Secretary-General) regarding six substances to be considered for control under the Psychotropic Convention. This notification reflects the recommendation from the 39th WHO Expert Committee for Drug Dependence (ECDD), which met in November 2017. In the **Federal Register** of August 14, 2017 (82 FR 37866), FDA announced the WHO ECDD review and invited interested persons to submit information for WHO's consideration.

The full text of the notification from the Secretary-General is provided in section II of this document. Section 201(d)(2)(B) of the CSA requires the Secretary of HHS, after receiving a notification proposing scheduling, to publish a notice in the **Federal Register** to provide the opportunity for interested persons to submit information and comments on the proposed scheduling action.

The United States is also a party to the 1961 Single Convention on Narcotic Drugs (1961 Single Convention). The Secretary of State has received a notification from the Secretary-General regarding six substances to be considered for control under this convention. The CSA does not require HHS to publish a summary of such information in the **Federal Register**. Nevertheless, to provide interested and affected persons an opportunity to submit comments regarding the WHO recommendations for narcotic drugs, the notification regarding these substances is also included in this **Federal Register** notice. The comments will be shared with other relevant Agencies to assist the Secretary of State in formulating the position of the United States on the control of these substances. The HHS recommendations are not binding on the representative of the United States in discussions and negotiations relating to

the proposal regarding control of substances under the 1961 Single Convention.

The short 30-day time period for the submission of comments is needed to ensure that Health and Human Services may, in a timely fashion, carry out the required action and be responsive to the United Nations.

II. United Nations Notification

The formal notification from the United Nations that identifies the drug substances and explains the basis for the recommendations is reproduced as follows (non-relevant text removed):

Reference:

NAR/CL.4/2017

WHO/ECDD39; 1961C–Art.3; 1971C–Art.2
CU 2017/437/DTA/SGB

The Secretary-General of the United Nations presents his compliments to the Secretary of State of the United States of America and has the honour to inform the Government that the Director-General of the World Health Organization (WHO), pursuant to article 3, paragraphs 1 and 3 of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol (1961 Convention) and article 2, paragraphs 1 and 4 of the Convention on Psychotropic Substances of 1971 (1971 Convention) notified the Secretary-General of the following recommendations:

Substances recommended to be placed in Schedules I and IV of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol:

Carfentanil

Chemical name: Methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl) amino]piperidine-4-carboxylate

Substances recommended to be placed in Schedule I of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol:

Ocfentanil

Chemical name: N-(2-Fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide

Furanyl fentanyl

Chemical name: N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide

Acryloylfentanyl (Acryl fentanyl)

Chemical name: N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide

4-Fluoroisobutyl fentanyl (4-FIBF, pFIBF)

Chemical name: N-(4-Fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide

Tetrahydrofuranylfentanyl (THF-F)

Chemical name: N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]oxolane-2-carboxamide

Substances recommended to be placed in Schedule II of the Convention on Psychotropic Substances (1971):

AB-CHMINACA

Chemical name: N-[(2S)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-

(cyclohexylmethyl)-1H-indazole-3-carboxamide

5F-ADB (5F-MDMB-PINACA)

Chemical name: Methyl (2S)-2-[[1-(5-fluoropentyl)-1H-indazole-3-carbonyl]amino]-3,3-dimethylbutanoate
AB-PINACA

Chemical name: N-[(2S)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-pentyl-1H-indazole-3-carboxamide

UR-144

Chemical name: (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone

5F-PB-22

Chemical name: Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate
4-Fluoroamphetamine (4-FA)

Chemical name: 1-(4-Fluorophenyl)propan-2-amine

In addition, in the letter from the Director-General of the World Health Organization to the Secretary-General, reference is also made to the recommendations by the thirty-ninth meeting of the WHO Expert Committee on Drug Dependence (ECDD) for carrying out a critical review of preparations containing almost exclusively cannabidiol (CBD), Pregabalin, and Tramadol at a subsequent Expert Committee meeting, as well as for Etizolam to remain under surveillance. Furthermore, the letter also makes reference to the recommendation by the Expert Committee with regard to cannabis and its component substances.

In accordance with the provisions of Article 3, paragraph 2 of the 1961 Convention and article 2, paragraph 2 of the 1971 Convention, the Secretary-General hereby transmits the notification as Annex I to the present note. Also in accordance with the same provisions, the notification from WHO will be brought to the attention of the sixty-first session of the Commission on Narcotic Drugs (12–16 March 2018).

In connection with the notification, WHO has also submitted the relevant extract from the report of the thirty-ninth meeting of the WHO Expert Committee on Drug Dependence which is hereby transmitted as Annex II.

In order to assist the Commission in reaching a decision, it would be appreciated if the Government could communicate any economic, social, legal, administrative or other factors that it considers relevant to the possible scheduling of the afore-mentioned substances that are recommended by WHO to be placed under international control under the 1961 Convention (namely: Carfentanil, Ocfentanil, Furanyl fentanyl, Acryloylfentanyl (Acryl fentanyl), 4-Fluoroisobutyl fentanyl (4-FIBF, pFIBF), and Tetrahydrofuranylfentanyl (THF-F)) and the 1971 Convention (namely: AB-CHMINACA, 5F-ADB (5F-MDMB-PINACA), AB-PINACA, UR-144, 5F-PB-22 and 4-Fluoroamphetamine (4-FA)).

Communications are to be sent at the latest by 2 February 2018 to the Executive Director of the United Nations Office on Drugs and Crime, c/o Secretary, Commission on Narcotic Drugs, P.O. Box 500, 1400 Vienna, Austria, fax: +43-1-26060-5885, e-mail: sgb@unodc.org.

28 December 2017

His Excellency

Mr. Rex Tillerson

Secretary of State of the United States of America

Annex I

Letter Addressed to the Secretary-General of the United Nations From the Director-General of the World Health Organization

“The Thirty-Ninth meeting of the WHO Expert Committee on Drug Dependence convened from 6 to 10 November 2017, at WHO headquarters in Geneva. The objective of this meeting was to carry out an in-depth evaluation of psychoactive substances in order to determine whether or not WHO should recommend these substances to be placed under international control.

With reference to Article 2, paragraphs 1 and 4 of the Convention on Psychotropic Substances (1971) and Article 3, paragraphs 1 and 3 of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol, I am pleased to submit recommendations of the World Health Organization as follows:

To be placed in Schedules I and IV of the Single Convention on Narcotic Drugs (1961):

—Carfentanil

chemical name: Methyl 1-(2-phenylethyl)-4-[phenyl(propionoyl) amino]piperidine-4-carboxylate

To be placed in Schedule I of the Single Convention on Narcotic Drugs (1961):

—Ocfentanil

chemical name: N-(2-Fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide

—Furanyl fentanyl

chemical name: N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide

—Acryloylfentanyl (Acryl fentanyl)

chemical name: N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide

—4-Fluoroisobutyl fentanyl (4-FIBF, pFIBF)

chemical name: N-(4-Fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide

—Tetrahydrofuranylfentanyl (THF-F)

chemical name: N-Phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]oxolane-2-carboxamide

To be placed in Schedule II of the Convention on Psychotropic Substances (1971):

—AB-CHMINACA

chemical name: N-[(2S)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide

—5F-ADB (5F-MDMB-PINACA)

chemical name: Methyl (2S)-2-[[1-(5-fluoropentyl)-1H-indazole-3-carbonyl] amino]-3,3-dimethylbutanoate

—AB-PINACA

chemical name: N-[(2S)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-pentyl-1H-indazole-3-carboxamide

—UR-144

chemical name: (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone

—5F-PB-22

chemical name: Quinolin-8-yl 1-(5-fluoropentyl)-1-*H*-indole-3-carboxylate
—4-Fluoroamphetamine (4-FA)

chemical name: 1-(4-Fluorophenyl)propan-2-amine

In addition, the Expert Committee recommended to carry out a critical review at a subsequent Expert Committee meeting for:

—Preparations containing almost exclusively cannabidiol (CBD)

chemical name: (1'*R*,2'*R*)-5'-Methyl-4-pentyl-2'-(prop-1-en-2-yl)-1',2',3',4'-tetrahydro-[1,1'*b*]biphenyl]-2,6-diol

—Pregabalin

chemical name: (3*S*)-3-(Aminomethyl)-5-methylhexanoic acid

—Tramadol

chemical name: rac-(1*R*,2*R*)-2-[(Dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexan-1-ol

It also recommended that the following substance remain under surveillance:

—Etizolam (INN)

chemical name: 4-(2-Chlorophenyl)-2-ethyl-9-methyl-6*H*-thieno[3,2-*c'*][1,2,4]triazolo[4,3-*a*][1,4]diazepine

The recommendations and the assessments and findings on which they are based are set out in detail in the Report of the 39th Expert Committee on Drug Dependence, which is the Committee that advises me on these issues. An extract of the Committee's Report is attached in Annex 1 to this letter.

I am very pleased with the ongoing collaboration among the United Nations Office on Drugs and Crime (UNODC), International Narcotics Control Board (INCB) and WHO, in particular, how this collaboration has supported the work of the WHO Expert Committee on Drug Dependence, and more generally, the implementation of operational recommendations from the United Nations General Assembly Special Session (UNGASS) 2016.

I would like to take this opportunity to inform you that the 40th Expert Committee on Drug Dependence will take place in May 2018 and will be specifically dedicated to the pre review of cannabis and its major component substances."

Annex II

Extract From the Report of the 39th Expert Committee on Drug Dependence

Substances recommended to be scheduled in Schedule I and Schedule IV of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol:

Carfentanil

Chemically, carfentanil is Methyl 1-(2-phenylethyl)-4-[phenyl(propionoyl)amino]piperidine-4-carboxylate. Carfentanil has no stereoisomers.

Carfentanil has not been previously pre-reviewed or critically reviewed. A notification was received from a Party to the Conventions thus initiating a critical review.

Carfentanil is convertible into sufentanil and alfentanil, two very potent opioid analgesics controlled as Schedule I drugs under the Single Convention on Narcotic

Drugs of 1961. It is a μ -opioid receptor agonist, and its pharmacodynamic and clinical effects are similar to fentanyl but it is about 100 times more potent. It binds to opioid receptors, and produces respiratory depression, decreased consciousness, antinociception, and miosis. The substance has been associated with hundreds of deaths and nonfatal intoxications globally, and it has created significant concerns in a number of countries. Due to the extremely small doses that induce lethal effects, it poses a particularly serious threat to public health.

Carfentanil is a compound liable to similar abuse and with similar ill effects to controlled opioids such as fentanyl that are included in Schedule I of the Single Convention on Narcotic Drugs of 1961. There is sufficient evidence that it is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, because it meets the required condition of similarity, it is recommended that carfentanil (Methyl 1-(2-phenylethyl)-4-[phenyl(propionoyl)amino]piperidine-4-carboxylate) be placed in Schedule I of the Single Convention on Narcotic Drugs of 1961, as consistent with Article 3, paragraph 3 (iii) of that Convention in that the substance is liable to similar abuse and productive of similar ill effects to drugs in Schedule I.

The Committee considered and recognized the impact that international scheduling could have on veterinary access to carfentanil in relation to its therapeutic use in large animals. However, the Committee was particularly concerned regarding the extreme potency of the substance and serious risk to public health. The Committee felt that the therapeutic advantages did not offset the severe threat to human health. As such, and with consideration that substances in Schedule IV afford Parties the opportunity to adopt special measures for drugs with particularly dangerous properties, the Committee recommended that carfentanil (Methyl 1-(2-phenylethyl)-4-[phenyl(propionoyl)amino]piperidine-4-carboxylate) be also placed in Schedule IV of the Single Convention on Narcotic Drugs of 1961.

Substances recommended to be placed in Schedule I of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol:

Ocfentanil

Chemically, ocfentanil is *N*-(2-Fluorophenyl)-2-methoxy-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide. It has no stereoisomers.

Ocfentanil has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to the attention of WHO that ocfentanil is clandestinely manufactured, poses a risk to public health and society, and has no recognized therapeutic use by any party.

Ocfentanil is an opioid that is structurally related to fentanyl that is regulated under Schedule I of the Single Convention on Narcotic Drugs of 1961, and produces opioid effects including analgesia, euphoria,

sedation, and potentially serious respiratory depression. Ocfentanil-related deaths have been reported, and it has come under national control in several countries in different regions of the world.

Ocfentanil is a compound liable to similar abuse and with similar ill effects to controlled opioids such as fentanyl that are included in Schedule I of the Single Convention on Narcotic Drugs of 1961. It has no recorded therapeutic use, and its use has been associated with fatalities. There is sufficient evidence that it is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, because it meets the required condition of similarity, it is recommended that ocfentanil (*N*-(2-Fluorophenyl)-2-methoxy-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide) be placed in Schedule I of the Single Convention on Narcotic Drugs of 1961, as consistent with Article 3, paragraph 3 (iii) of that Convention in that the substance is liable to similar abuse and productive of similar ill effects to drugs in Schedule I.

Furanyl fentanyl

Chemically, furanyl fentanyl is *N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide. Furanyl fentanyl has no stereoisomers.

Furanyl fentanyl has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that furanyl fentanyl is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

Furanyl fentanyl is a compound liable to similar abuse and with similar ill effects to controlled opioids such as fentanyl that are included in Schedule I of the Single Convention on Narcotic Drugs of 1961. It has no recorded therapeutic use and its use has been associated with fatalities. There is sufficient evidence that it is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, because it meets the required condition of similarity, it is recommended that furanyl fentanyl (*N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide) be placed in Schedule I of the Single Convention on Narcotic Drugs of 1961, as consistent with Article 3, paragraph 3 (iii) of that Convention in that the substance is liable to similar abuse and productive of similar ill effects to drugs in Schedule I.

Acryloylfentanyl (Acryl fentanyl)

Chemically, acryloylfentanyl is *N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide. It has no stereoisomers.

Acryloylfentanyl has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that acryloylfentanyl is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

Acryloylfentanyl is a compound liable to similar abuse and with similar ill effects to

controlled opioids such as fentanyl that are included in Schedule I of the Single Convention on Narcotic Drugs of 1961. It has no recorded therapeutic use, and its use has been associated with fatalities. There is sufficient evidence that it is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, because it meets the required condition of similarity, it is recommended that acryloylfentanyl (*N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide) be placed in Schedule I of the Single Convention on Narcotic Drugs of 1961, as consistent with Article 3, paragraph 3 (iii) of that Convention in that the substance is liable to similar abuse and productive of similar ill effects to drugs in Schedule I.

4-Fluoroisobutyryl fentanyl (4-FIBF, pFIBF)

Chemically, 4-fluoroisobutyryl fentanyl (4-FIBF, pFIBF) is *N*-(4-Fluorophenyl)-2-methyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]propanamide.

4-Fluoroisobutyryl fentanyl has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that it is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

4-Fluoroisobutyryl fentanyl is a compound liable to similar abuse and with similar ill effects to controlled opioids such as fentanyl that are included in Schedule I of the Single Convention on Narcotic Drugs of 1961. It has no recorded therapeutic use, and its use has been associated with fatalities. There is sufficient evidence that it is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, because it meets the required condition of similarity, it is recommended that 4-fluoroisobutyryl fentanyl (*N*-(4-Fluorophenyl)-2-methyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]propanamide) be placed in Schedule I of the Single Convention on Narcotic Drugs of 1961, as consistent with Article 3, paragraph 3 (iii) of that Convention in that the substance is liable to similar abuse and productive of similar ill effects to drugs in Schedule I.

Tetrahydrofuranylfentanyl (THF-F)

Chemically, tetrahydrofuranylfentanyl is *N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]oxolane-2-carboxamide. Tetrahydrofuranylfentanyl contains a stereogenic centre allowing for the existence of a pair of enantiomers, (S)-tetrahydrofuranylfentanyl and (R)-tetrahydrofuranylfentanyl. There is no information on the actual enantiomers found on the illicit drug market at the time of the report.

Tetrahydrofuranylfentanyl has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that tetrahydrofuranylfentanyl is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

Tetrahydrofuranylfentanyl is a compound liable to similar abuse and with similar ill effects to controlled opioids such as fentanyl that are included in Schedule I of the Single Convention on Narcotic Drugs of 1961. It has no recorded therapeutic use, and its use has been associated with fatalities. There is sufficient evidence that it is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, because it meets the required condition of similarity, it is recommended that tetrahydrofuranylfentanyl (*N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]oxolane-2-carboxamide) be placed in Schedule I of the Single Convention on Narcotic Drugs of 1961, as consistent with Article 3, paragraph 3 (iii) of that Convention in that the substance is liable to similar abuse and productive of similar ill effects to drugs in Schedule I.

Substances recommended to be scheduled in Schedule II of the Convention on Psychotropic Substances (1971):

AB-CHMINACA

Chemically, AB-CHMINACA is *N*-[(2S)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide. AB-CHMINACA contains a chiral centre, so that two enantiomers exist: (R)-ABCHMINACA and (S)-AB-CHMINACA. Based on the literature and the most likely precursors to be used in manufacture, an (S)-configuration of the stereocenter should be expected.

AB-CHMINACA has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that AB-CHMINACA is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

AB-CHMINACA is a synthetic cannabinoid receptor agonist. It is clandestinely manufactured and sold under a variety of brand names. Its mode of action suggests also the potential for dependence and likelihood of misuse. Effects of AB-CHMINACA are consistent with those of synthetic cannabinoid receptor agonists and include relaxation, euphoria, depersonalization, distorted perception of time, impaired motor performance, hallucinations, paranoia, confusion, fear, anxiety, tachycardia, and nausea and vomiting. Its cannabimimetic effects are more potent than those of THC, which is listed in Schedule II in the Convention on Psychotropic Substances of 1971. There is evidence of an increase in number of persons using AB-CHMINACA in many countries that have included fatal and non-fatal cases. This substance causes substantial harm and has no therapeutic usefulness. AB-CHMINACA has similar abuse and similar ill effects as other synthetic cannabinoids receptor agonists already scheduled in Schedule II of the Convention on Psychotropic Substances of 1971. The Committee recommended that AB-CHMINACA (*N*-[(2S)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide) be placed in Schedule II under the Convention on Psychotropic Substances of 1971.

5F-ADB/5F-MDMB-PINACA

Chemically, 5F-ADB (also known as 5F-MDMB-PINACA) is Methyl (2*S*)-2-[[1-(5-fluoropentyl)-1*H*-indazole-3-carbonyl]amino]-3,3-dimethylbutanoate. 5F-ADB contains a chiral centre, so that two enantiomers exist: (R)-5F-ADB and (S)-5F-ADB.

5F-ADB has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that 5F-ADB is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

5F-ADB is a synthetic cannabinoid receptor agonist. It has cannabimimetic effects that are more potent than those of THC and MDMB-CHMICA, substances which are listed in Schedule II of the Convention on Psychotropic Substances of 1971. Its mode of action suggests the potential for dependence and likelihood of abuse. There is evidence of an increase in number of persons using 5F-ADB in many countries that have included fatal and non-fatal cases. This substance causes substantial harm and has no therapeutic usefulness. The Committee recommended that 5F-ADB, also known as 5F-MDMB-PINACA, (Methyl (2*S*)-2-[[1-(5-fluoropentyl)-1*H*-indazole-3-carbonyl]amino]-3,3-dimethylbutanoate) be placed in Schedule II under the Convention on Psychotropic Substances of 1971.

AB-PINACA

Chemically, AB-PINACA is *N*-[(2*S*)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-pentyl-1*H*-indazole-3-carboxamide. AB-PINACA has stereoisomers.

AB-PINACA has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that AB-PINACA is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

The Committee considered that the degree of risk to public health and society associated with the abuse of AB-PINACA is substantial. Therapeutic usefulness has not been recorded. It recognized that AB-PINACA has similar abuse and similar ill-effects to other synthetic cannabinoids receptor agonists in Schedule II of the Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that AB-PINACA is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. The Committee recommended that AB-PINACA (*N*-[(2*S*)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-pentyl-1*H*-indazole-3-carboxamide) be placed in Schedule II under the Convention on Psychotropic Substances of 1971.

UR-144

Chemically, UR-144 is (1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone. It has no stereoisomers.

UR-144 was previously critically reviewed by the 36th ECDD in 2014. The Committee

recommended that UR-144 not be placed under international control at that time but be kept under surveillance.

Of particular significance to the Committee was the lack of analytically confirmed cases of non-fatal and fatal intoxications at the time involving solely UR-144. Subsequent data collected from the literature and from different countries indicating that this substance may cause substantial harm and that it has no medical use, warranted an updated critical review.

The Committee considered that the degree of risk to public health and society associated with the abuse of UR-144 is substantial. Therapeutic usefulness has not been recorded. It recognized that UR-144 has similar abuse and similar ill-effects to other synthetic cannabinoids receptor agonists in Schedule II of the Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that UR-144 is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. The Committee recommended that UR-144 ((1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone) be placed in Schedule II under the Convention on Psychotropic Substances of 1971.

5F-PB-22

Chemically, 5F-PB-22 is Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate. It has no stereoisomers.

5F-PB-22 has not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that 5F-PB-22 is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party.

The Committee considered that the degree of risk to public health and society associated with the abuse of 5F-PB-22 is substantial. Therapeutic usefulness has not been recorded. It recognized that 5F-PB-22 has similar abuse and similar ill-effects to other synthetic cannabinoids receptor agonists in Schedule II of the Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that 5F-PB-22 is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. The Committee recommended that 5F-PB-22 (Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate) be placed in Schedule II under the Convention on Psychotropic Substances of 1971.

4-Fluoroamphetamine (4-FA)

The chemical name of 4-FA is 1-(4-Fluorophenyl)propan-2-amine. The presence of a chiral centre gives rise to the enantiomeric pair of (S)-4-FA and (R)-4-FA, respectively. 4-FA is most likely to be available as the racemic mixture.

4-FA underwent a critical review in 2015. At that time, the committee recommended that 4-FA not be placed under international control due to insufficient evidence regarding dependence, abuse, and risks to public

health. However, it was kept under surveillance. Preliminary information collected from various sources indicated that this substance may cause substantial harm and that it has no medical use, thereby warranting an updated critical review.

4-FA is a ring-substituted derivative of amphetamine that is listed in Schedule II of the Convention on Psychotropic Substances of 1971. The clinical features associated with 4-FA intoxications include agitation, tachycardia, hypertension, hyperthermia, cardiovascular toxicity and cerebrovascular complications such as severe headaches and cerebral hemorrhage. Some severe adverse reactions required hospitalizations and others resulted in death.

The Committee considered that the degree of risk to public health and society associated with the abuse of 4-FA is substantial. Therapeutic usefulness has not been recorded. It recognized that 4-FA has similar abuse and similar ill-effects to substances in Schedule II of the Convention on Psychotropic Substances of 1971.

The Committee considered that there is sufficient evidence that 4-FA is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. The Committee recommended that 4-FA (1-(4-Fluorophenyl)propan-2-amine) be placed in Schedule II under the Convention on Psychotropic Substances of 1971.

Substances recommended for critical review:

Preparations Containing Almost Exclusively Cannabidiol (CBD)

Chemically, cannabidiol is (1*R*,2*R*)-5'-Methyl-4-pentyl-2'-(prop-1-en-2-yl)-1',2',3',4'-tetrahydro-[1,1'-biphenyl]-2,6-diol. Cannabidiol (CBD) is normally taken to refer to the naturally occurring (-)- enantiomer.

Cannabidiol has not been previously pre-reviewed or critically reviewed by the Expert Committee on Drug Dependence (ECDD). The current review was based on the recommendation from the 38th ECDD that pre-review documentation on cannabis-related substances, including cannabidiol, be prepared and evaluated at a subsequent committee meeting.

CBD is not specifically listed in the schedules of the 1961, 1971 or 1988 International Drug Control Conventions. There is no evidence that CBD as a substance is liable to similar abuse and similar ill-effects as substances in the 1961 or 1971 Conventions (including cannabis and dronabinol (THC), respectively). The purpose of the pre-review was to determine whether current information justifies an Expert Committee critical review whereby the Committee finds that information may justify the scheduling or a change in the scheduling of the substance in the 1961 or 1971 Conventions. As CBD is not currently a scheduled substance in its own right (only as a component of cannabis extracts), current information does not justify a change in this scheduling position and does not justify scheduling of the substance.

However, CBD is produced for pharmaceutical purposes as an extract of

cannabis, and cannabis extracts and tinctures are included in the Single Convention on Narcotic Drugs of 1961. The pre-review of Cannabis Extracts and Tinctures will be held at the 40th ECDD meeting in May 2018. Therefore it is also recommended that extracts or preparations containing almost exclusively CBD (cannabidiol; (1*R*,2*R*)-5'-Methyl-4-pentyl-2'-(prop-1-en-2-yl)-1',2',3',4'-tetrahydro-[1,1'-biphenyl]-2,6-diol) be subject to critical review at that meeting.

Pregabalin

Chemically, pregabalin is (3*S*)-3-(Aminomethyl)-5-methylhexanoic acid. Pregabalin is the (S)-(+)-isomer of 3-isobutyl-GABA.

Pregabalin has not been previously pre-reviewed or critically reviewed. A pre-review at the 39th ECDD was proposed based on information received by the WHO Secretariat regarding the misuse of pregabalin.

Pregabalin, a gabapentinoid, is an analogue of gamma amino butyric acid (GABA), but does not act at GABA receptors or synapses or bind to benzodiazepine receptors. While pregabalin has therapeutic uses, the increasing evidence of its misuse and abuse in many countries is becoming a growing cause for concern.

Pregabalin has been shown to have the capacity to produce a state of dependence. On this basis, the Committee recommended that pregabalin ((3*S*)-3-(Aminomethyl)-5-methylhexanoic acid) proceed to a future critical review. The Committee requested that the Secretariat collect further data to support the critical review.

Tramadol

Chemically, tramadol is rac-(1*R*,2*R*)-2-[(Dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexan-1-ol. Tramadol has two chiral centres and consequently, four different stereoisomers exist: (1*R*,2*R*), (1*S*,2*S*), (1*R*,2*S*), and (1*S*,2*R*).

Pre-reviews of Tramadol have been carried out by the ECDD in 1992, 2000, 2006, and 2014 and a critical review in 2002. The Committee most recently at its 36th meeting in 2014, and based on the evidence available regarding dependence, abuse and risks to public health, recommended that a critical review of tramadol was not warranted at that time. On the basis of information received by the WHO Secretariat regarding the misuse of tramadol, it was recommended that a pre-review of tramadol be carried out at the 39th ECDD in November 2017.

Tramadol is used as a medication for controlling moderate acute and chronic painful conditions, and it is listed in several national essential medicines lists. It produces opioid-like effects predominately through the conversion of tramadol into its active metabolite. There is growing evidence of abuse of tramadol in many countries, accompanied by adverse reactions, and tramadol-associated deaths. The Committee recommended that tramadol ((rac-(1*R*,2*R*)-2-[(Dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexan-1-ol) proceed to a critical review at a subsequent meeting. The Committee requested the Secretariat to collect additional data for the critical review, including engagement with Member States to

obtain information on the extent of problems associated with tramadol misuse. Also, the Committee asked for information on the medical use of tramadol including the extent that low income countries, countries facing conflicts and aid and relief agencies use and possibly rely on tramadol for provision of analgesia.

Substance recommended to remain under surveillance:

Etizolam (INN)

Chemically, etizolam is 4-(2-Chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine. It does not have stereoisomers.

The ECDD reviewed etizolam at the 26th meeting (1989) and the 27th meeting (1990). At the 37th ECDD in 2015, the committee pre-reviewed etizolam and recommended that a critical review of etizolam was warranted for a future meeting. The Committee noted deficiencies in information and suggested several potential sources that could be helpful in the preparation of the critical review, including those from traffic accident reports, seizure data, user forums, and pharmacovigilance data.

Owing to the lack of significantly more information since the pre-review conducted by the 37th ECDD in 2015, and considering the current insufficiency of data regarding dependence, abuse and risks to public health, the Committee recommended that etizolam (4-(2-Chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine) be kept under surveillance. The Committee asked the Secretariat to request more data from Member States that may be affected by the misuse of etizolam, and which could facilitate a future review.

III. Discussion

Although WHO has made specific scheduling recommendations for each of the drug substances, the CND is not obliged to follow the WHO recommendations. Options available to the CND for substances considered for control under the Psychotropic Convention include the following: (1) Accept the WHO recommendations; (2) accept the recommendations to control, but control the drug substance in a schedule other than that recommended; or (3) reject the recommendations entirely.

Carfentanil, also known as 4-carbomethoxyfentanyl, is an extremely potent synthetic opioid that is similar in structure to and approximately 100 times more potent than fentanyl as an analgesic. At one time legitimately produced, carfentanil is no longer manufactured, marketed, or used in the United States; it is approved by FDA for use under restricted conditions by veterinarians as an immobilizing agent for certain large animals. Illicitly produced carfentanil is a particularly harmful fentanyl analogue that is also being laced into heroin or sold by itself

and trafficked in the United States. It is not approved for human use. Drug seizure data indicate that carfentanil is typically used in small doses to cut heroin and other illicitly abused drugs. The significant risk to public health associated with carfentanil use stems from its respiratory depressive effects with very small amounts. Several fatalities have been reported as the result of carfentanil overdoses. On October 28, 1988, the Drug Enforcement Administration (DEA) published a Final Rule that placed carfentanil in Schedule II of the CSA (53 FR 43684). As such, no additional controls will be necessary to fulfill U.S. obligations if carfentanil is placed in Schedules I and IV of the Single Convention on Narcotic Drugs (1961).

Ocfentanil is a synthetically produced opioid that is structurally related to fentanyl and approximately equipotent in effect. Reported risks associated with use of ocfentanil include development of opioid use disorder, overdose, and fatal overdose. It has no approved medical use in the United States. The DEA initiated the temporary placement of this substance under Schedule I by publishing a notification of intent in the **Federal Register** on December 13, 2017 (82 FR 58575). As such, additional controls will be necessary to fulfill U.S. obligations if ocfentanil is placed in Schedules I of the Single Convention on Narcotic Drugs (1961).

Furanyl fentanyl (Fu-F) is a potent clandestinely produced synthetic opioid that is an analog of fentanyl. Evidence suggests that the pattern of abuse of fentanyl analogues, including furanyl fentanyl, parallels that of heroin and prescription opioid analgesics. Fu-F produces typical opioid effects that include respiratory depression and loss of consciousness. Seizures of Fu-F have been encountered in powder form. Fu-F has been connected to fatal overdoses, in which intravenous routes of administration are documented. It has no approved medical use in the United States. On November 29, 2016, the DEA issued a final order to temporarily schedule Fu-F and its isomers, esters, ethers, salts and salts of isomers, esters and ethers into Schedule I pursuant to the temporary scheduling provisions of the CSA (81 FR 85873). As such, additional permanent controls will be necessary to fulfill U.S. obligations if Fu-F is controlled under Schedule I of the 1961 Single Convention.

Acryloylfentanyl (Acryl fentanyl) belongs to the 4-anilidopiperidine class of synthetic opioids and is similar in structure to fentanyl. Acryloylfentanyl is a clandestinely produced analog of fentanyl and sold illegally as a research

chemical on several websites.

Acryloylfentanyl has also been associated with adverse events typically associated with opioid use such as respiratory depression, anxiety, constipation, tiredness, hallucinations, and withdrawal. The use of acryloylfentanyl has also been linked to the development of opioid use disorder, overdose, and fatal overdose.

Acryloylfentanyl has no commercial or medical uses. On July 14, 2017, the DEA issued a temporary order to temporarily schedule acryloylfentanyl, its isomers, esters, ethers, salts and salts of isomers, esters and ethers into Schedule I pursuant to the temporary scheduling provisions of the CSA (82 FR 32453). As such, additional permanent controls will be necessary to fulfill U.S. obligations if Fu-F is controlled under Schedule I of the 1961 Single Convention.

4-fluoroisobutyryl fentanyl (4-FIBF) is a clandestinely produced synthetic opioid that is an analog of fentanyl. It has m-receptor agonist activity similar to that of fentanyl. This would result in effects associated with opioid agonists such as analgesia, respiratory depression, anxiety, constipation, tiredness, hallucinations, withdrawal, development of opioid use disorder, overdose, and fatal overdose. The use of 4-FIBF has been implicated in several cases of overdose and fatal overdoses. 4-FIBF has not been approved for medical use in the United States. On May 3, 2017, the DEA issued a temporary order to temporarily schedule 4-FIBF, its isomers, esters, ethers, salts and salts of isomers, esters and ethers into Schedule I pursuant to the temporary scheduling provisions of the CSA (82 FR 20544). As such, additional permanent controls will be necessary to fulfill U.S. obligations if 4-FIBF is controlled under Schedule I of the 1961 Single Convention.

AB-CHMINACA is a clandestinely produced synthetic cannabinoid agonist that is approximately 16 times more potent than delta-9-tetrahydrocannabinol. Adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, organ failure, anxiety, acute psychosis, and death. AB-CHMINACA has been detected in illicit synthetic cannabinoid substances and found in cases of overdose and hospitalizations. On October 16, 2017, the DEA published a Final Rule to permanently control AB-CHMINACA as a Schedule I substance under the CSA (82 FR 47971). As such, additional permanent controls will be not necessary to fulfill U.S. obligations if AB-CHMINACA is controlled under

Schedule I of the 1961 Single Convention.

5F-ADB is a clandestinely produced synthetic cannabinoid agonist. In general, adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, anxiety, and acute psychosis. 5F-ADB has been identified in overdose and/or cases involving death attributed to their abuse. Adverse health effects reported from incidents involving 5F-ADB and other synthetic cannabinoids have included: nausea, persistent vomiting, agitation, altered mental status, seizures, convulsions, loss of consciousness, and/or cardio toxicity. On April 10, 2017, the DEA issued a temporary scheduling order to temporarily schedule 5F-ADB, its isomers, esters, ethers, salts and salts of isomers, esters, and ethers into Schedule I pursuant to the temporary scheduling provisions of the CSA (82 FR 17119). As such, additional permanent controls will be necessary to fulfill U.S. obligations if 5F-ADB is controlled under Schedule II of the 1971 Convention on Psychotropic Substances.

AB-PINACA is a clandestinely produced synthetic cannabinoid agonist approximately 1.5 times as potent as delta-9-tetrahydrocannabinol. Adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, anxiety, acute psychosis, and death. AB-PINACA has been detected in illicit synthetic cannabinoid substances, and reported in cases of overdose and hospitalizations. It has not been approved for medical use in the United States. On October 16, 2017, the DEA published a Final Rule to permanently control AB-PINACA as a Schedule I substance under the CSA (82 FR 47971). As such, additional permanent controls will not be necessary to fulfill U.S. obligations if AB-PINACA is controlled under Schedule II of the 1971 Convention on Psychotropic Substances.

UR-144 is a clandestinely produced synthetic cannabinoid agonist. In general, adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, anxiety, acute psychosis, and death. UR-144 has been detected in herbal smoking blends that are sold as herbal incense. On May 11, 2016, the DEA issued a Final Rule to permanently schedule UR-144 into Schedule I of the CSA (81 FR 29142). As such, additional permanent controls will not be necessary to fulfill U.S. obligations if UR-144 is controlled under Schedule II of the 1971

Convention on Psychotropic Substances.

5F-PB-22 is a synthetic cannabinoid agonist with similar effects to delta-9-tetrahydrocannabinol, one of the main psychoactive components of cannabis. Adverse effects produced by cannabinoid agonists include tachycardia, agitation, hallucination, chest pain, seizure, anxiety, acute psychosis, and death. 5F-PB-22 is clandestinely produced. It has been found laced on plant material and marketed as herbal products, and is smoked for its psychoactive effects. According to the WHO, 5F-PB-22 has been associated with fatal intoxications. On September 6, 2016, the DEA issued a Final Rule to permanently place 5F-PB-22 into Schedule I of the CSA (81 FR 61130). As such, additional permanent controls will not be necessary to fulfill U.S. obligations if 5F-PB-22 is controlled under Schedule II of the 1971 Convention on Psychotropic Substances.

4-Fluoroamphetamine (4-FA) is a psychoactive substance of the phenethylamine and substituted amphetamine chemical classes and produces stimulant effects. WHO reports that 4-FA is clandestinely produced, and its use is associated with fatal and non-fatal intoxications. 4-FA is not approved for medical use in the United States and it is not controlled under the CSA. As such, additional permanent controls will be necessary to fulfill U.S. obligations if 4-FA is controlled under Schedule II of the 1971 Convention on Psychotropic Substances.

FDA, on behalf of the Secretary of HHS, invites interested persons to submit comments on the notifications from the United Nations concerning these drug substances. FDA, in cooperation with the National Institute on Drug Abuse, will consider the comments on behalf of HHS in evaluating the WHO scheduling recommendations. Then, under section 201(d)(2)(B) of the CSA, HHS will recommend to the Secretary of State what position the United States should take when voting on the recommendations for control of substances under the Psychotropic Convention at the CND meeting in March 2018.

Comments regarding the WHO recommendations for control of carfentanil, ocfentanil, furanyl fentanyl (Fu-F), acryloylfentanyl (acryl fentanyl), 4-fluoroisobutyl fentanyl (4-FIBF), and tetrahydrofuranylfentanyl (THF-F), under the 1961 Single Convention, will also be forwarded to the relevant Agencies for consideration in

developing the U.S. position regarding narcotic substances at the CND meeting.

Dated: January 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees from the Idaho National Laboratory in Scoville, Idaho, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 1090 Tusculum Avenue, MS C-46, Cincinnati, OH 45226-1938, Telephone 877-222-7570. Information requests can also be submitted by email to DCAS@CDC.GOV.

SUPPLEMENTARY INFORMATION:

Authority: 42 U.S.C. 7384q(b). 42 U.S.C. 7384l(14)(C).

On November 22, 2017, as provided for under 42 U.S.C. 7384l(14)(C), the Acting Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Idaho National Laboratory (INL) in Scoville, Idaho, and who were monitored for external radiation at the Idaho Chemical Processing Plant (CPP) (e.g., at least one film badge or TLD dosimeter from CPP) between January 1, 1975, and December 31, 1980, for a number of work days aggregating at least 250 work days, occurring solely under this employment, or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation became effective on December 22, 2017. Therefore, beginning on December 22, 2017, members of this class of employees,

defined as reported in this notice, became members of the SEC.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2018–01449 Filed 1–25–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).

Date: February 20, 2018.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Brenda Lange-Gustafson, Ph.D., Scientific Review Officer, NIAID/NIH/DHHS, Scientific Review Program, 5601 Fishers Lane, Room 3G13, Rockville, MD 20852, 240–669–5047, bgustafson@niaid.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).

Date: February 21–23, 2018.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892.

Contact Person: Priti Mehrotra, Ph.D., Chief, Immunology Review Branch, Scientific Review Program, Division of Extramural Activities, Room #3G40, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–7616, 240–669–5066, pmehrotra@niaid.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; PHS 2018–1 Topic 54 & 55:

Adjuvant Discovery & Development for Allergic Diseases.

Date: February 23, 2018.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Dharmendar Rathore, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G30, National Institutes of Health/NIAID, 5601 Fishers Lane Drive, MSC 9823, Bethesda, MD 20892–9823, 240–669–5058, rathored@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 23, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–01486 Filed 1–25–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Mentored Career Development (K) and Conference (R13) Award Application Review, (2018/05).

Date: March 2, 2018.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Plaza, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John P. Holden, Ph.D., Scientific Review Officer, 6707 Democracy Boulevard, Room 920, Democracy Two, Bethesda, MD 20892, (301) 496–8775, john.holden@mail.nih.gov.

Dated: January 23, 2018.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–01488 Filed 1–25–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Fellowships in Digestive Diseases and Nutrition.

Date: February 15–16, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, yangj@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–16–034: NIDDK Ancillary Studies to Major Ongoing Clinical Studies in Digestive Sciences (R01).

Date: February 15, 2018.

Time: 2:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Najma S. Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, begumn@niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases

Special Emphasis Panel; Fellowships in Diabetes, Endocrinology and Metabolic Diseases.

Date: February 22–23, 2018.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7021, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–3993, tathamt@mail.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R13 Conference Grant Applications.

Date: February 22, 2018.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, yangj@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Drug-Induced Liver Injury Network (DILIN) Review.

Date: March 1, 2018.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, yangj@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; MoTrPAC Ancillary Studies.

Date: March 1, 2018.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, barnardm@extra.niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 23, 2018.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–01489 Filed 1–25–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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: National Institute on Alcohol Abuse and Alcoholism Initial Review Group; Neuroscience Review Subcommittee.

Date: March 1, 2018.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Terrace Level Conference Room T508, Rockville, MD 20852.

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2081, Rockville, MD 20852. 301–443–0800, bbuzas@mail.nih.gov.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group; Biomedical Research Review Subcommittee.

Date: March 6, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Terrace Level Conference Room T508, 5635 Fishers Lane, Rockville, MD 20852.

Contact Person: Philippe Marmillot, Ph.D., Scientific Review Officer, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2017,

Bethesda, MD 20892, 301–443–2861, marmillotp@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: January 23, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–01485 Filed 1–25–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Coordinating Center Network.

Date: February 16, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20892.

Contact Person: Alicja L. Markowska, Ph.D., DSC, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–496–9666, markowsa@nia.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 23, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–01484 Filed 1–25–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the NHLBI Special Emphasis Panel.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; KKO1: Career Development Program to Promote Diversity in Health Research.

Date: March 2, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger, Center 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Lindsay M. Garvin, Ph.D., Scientific Review Officer, Office of Scientific Review, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Suite 7189, Bethesda, MD 20892, 301-827-7911, lindsay.garvin@nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Preparing for Effectiveness-Implementation Trials (U01).

Date: March 2, 2018.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger, Center 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: YingYing Li-Smerin, MD, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7184, Bethesda, MD 20892-7924, 301-827-7942, lismerein@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Maximizing the Scientific Value of the NHLBI Biorepository: Scientific Opportunities for Exploratory Research (R21).

Date: March 2, 2018.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn, Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Tony L. Creazzo, Ph.D., Scientific Review Officer, Office of Scientific

Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892-7924, 301-827-7913, creazzotl@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 19, 2018.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-01370 Filed 1-25-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting 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/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: February 26–27, 2018.

Closed: February 26, 2018, 3:00 p.m. to adjournment.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, 45 Center Drive, Building 45 (Natcher), Conference Rooms E1 and E2, Bethesda, MD 20892.

Open: February 27, 2018, 8:00 a.m. to 3:00 p.m.

Agenda: The agenda will include opening remarks, administrative matters, Director's report, NIH Health Disparities update, and other business of the Council.

Place: National Institutes of Health, 45 Center Drive, Building 45 (Natcher), Conference Rooms E1 and E2, Bethesda, MD 20892.

Contact Person: Dr. Joyce A. Hunter, Deputy Director, NIMHD, National Institutes of Health, National Institute on Minority Health and Health Disparities, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 402-1366, hunterj@nih.gov.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles, will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

January 18, 2018.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-01371 Filed 1-25-18; 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: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Biology Structure and Regeneration Study Section.

Date: February 15–16, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

Contact Person: Yanming Bi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–451–0996, ybi@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Metabolic Reprogramming to Improve Immunotherapy.

Date: February 20, 2018.

Time: 11:00 a.m. to 4:00 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: Malaya Chatterjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, (301) 806–2515, chatterm@csr.nih.gov.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Molecular Oncogenesis Study Section.

Date: February 21–22, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Nywana Sizemore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6204, MSC 7804, Bethesda, MD 20892, 301–435–1718, sizemoren@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Cancer, Heart, and Sleep Epidemiology B Study Section.

Date: February 22–23, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Hotel, 1500 New Hampshire Avenue NW, Washington, DC 20036.

Contact Person: Gniesha Yvonne Dinwiddie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3137, Bethesda, MD 20892, dinwiddiegy@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated

Review Group; Neurogenesis and Cell Fate Study Section.

Date: February 22–23, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Serrano Hotel, 405 Taylor Street, San Francisco, CA 94102.

Contact Person: Joanne T Fujii, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, (301) 435–1178, fujij@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neural Oxidative Metabolism and Death Study Section.

Date: February 22–23, 2018.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton La Jolla Hotel, 3299 Holiday Court, La Jolla, CA 92037.

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213–9887, hamelinc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurodegeneration and Neuroprotection.

Date: February 22, 2018.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton La Jolla Hotel, 3299 Holiday Court, La Jolla, CA 92037.

Contact Person: Carole L. Jelsema, Ph.D., Chief and Scientific Review Administrator, MDCN Scientific Review Group, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7850, Bethesda, MD 20892, (301) 435–1248, jelsemac@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Chronic Disease in the Caribbean.

Date: February 23, 2018.

Time: 10:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Hotel, 1500 New Hampshire Avenue NW, Washington, DC 20036.

Contact Person: Gniesha Yvonne Dinwiddie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3137, Bethesda, MD 20892, dinwiddiegy@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: January 19, 2018.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–01369 Filed 1–25–18; 8:45 am]

BILLING CODE 4140–01–PFebruary 23, 2018

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: Population Sciences and Epidemiology Integrated Review Group; Cancer, Heart, and Sleep Epidemiology A Study Section.

Date: February 20–21, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marines' Memorial Club & Hotel, 609 Sutter Street, San Francisco, CA 94102.

Contact Person: Denise Wiesch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7770, Bethesda, MD 20892, (301) 437–3478, wieschd@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurotoxicology and Alcohol.

Date: February 22, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Argonaut Hotel, 495 Jefferson Street, San Francisco, CA 94109.

Contact Person: Nicholas Gaiano, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5178, MSC 7844, Bethesda, MD 20892–7844, 301–435–1033, gaianonr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Learning, Memory, and Cognition.

Date: February 22, 2018.

Time: 11:30 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: Ying-Yee Kong, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5185, Bethesda, MD 20892, ying-ye.kong@nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Molecular Genetics A Study Section.

Date: February 26, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn-Denver Downtown, 1400 Welton Street, Denver, CO 80202.

Contact Person: Richard A Currie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892, (301) 435-1219, currieri@csr.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Drug Discovery and Mechanisms of Antimicrobial Resistance Study Section.

Date: February 26–27, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

Contact Person: Guangyong Ji, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3188, MSC 7808, Bethesda, MD 20892, 301-435-1146, jig@csr.nih.gov.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Tumor Microenvironment Study Section.

Date: February 26–27, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Angela Y. Ng, MBA, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6200, MSC 7804, Bethesda, MD 20892, 301-435-1715, ngan@mail.nih.gov.

Name of Committee: Vascular and Hematology Integrated Review Group; Hemostasis and Thrombosis Study Section.

Date: February 26, 2018.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: JW Marriott New Orleans, 614 Canal Street, New Orleans, LA 70130.

Contact Person: Bukhtiar H Shah, DVM, Ph.D., Scientific Review Officer, Vascular and Hematology IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, (301) 806-7314, shahb@csr.nih.gov.

Name of Committee: Cell Biology Integrated Review Group; Biology of the Visual System Study Section.

Date: February 26–27, 2018.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Kabuki, 1625 Post Street, San Francisco, CA 94115.

Contact Person: Michael H. Chaitin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7850, Bethesda, MD 20892, (301) 435-0910, chaitinm@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Pregnancy and Neonatology Study Section.

Date: February 26–27, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Clara M Cheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, 301-435-1041, chengc@csr.nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Diseases and Pathophysiology of the Visual System Study Section.

Date: February 26–27, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

Contact Person: Nataliya Gordiyenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7846, Bethesda, MD 20892, 301-435-1265, gordiyenkon@csr.nih.gov.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Cancer Genetics Study Section.

Date: February 26–27, 2018

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW, Washington, DC 20015.

Contact Person: Juraj Bies, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301-435-1256, biesj@mail.nih.gov

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Virology—B Study Section.

Date: February 26–27, 2018.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marines' Memorial Club & Hotel, 609 Sutter Street, San Francisco, CA 94102.

Contact Person: John C. Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892, (301) 435-2398, pughjohn@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Biobehavioral Mechanisms of Emotion, Stress and Health Study Section.

Date: February 26–27, 2018.

Time: 8:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marines' Memorial Club & Hotel, 609 Sutter Street, San Francisco, CA 94102.

Contact Person: Samantha Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, 301-827-5491, samanthasmith@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: January 23, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-01482 Filed 1-25-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Pepper Centers.

Date: February 15–16, 2018.

Time: 5:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20892.

Contact Person: Alicja L. Markowska, Ph.D., DSC, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-496-9666, markowsa@nia.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 23, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-01483 Filed 1-25-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

Date: March 19–20, 2018.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Plaza, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John Hayes, Ph.D., Scientific Review Officer, 6707 Democracy Boulevard, Suite 959, Democracy Two, Bethesda, MD 20892, (301) 451–3398, hayesj@mail.nih.gov.

Dated: January 18, 2018.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–01372 Filed 1–25–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; 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 materials, and personal information concerning

individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; Research Centers in Minority Institutions (RCMI) (U54).

Date: March 7–9, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites by Hilton, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Deborah Ismond, Ph.D., Scientific Review Officer, Division of Scientific Programs, National Institute on Minority Health and Health Disparities, National Institutes of Health, 7201 Wisconsin Ave., Suite 525, Bethesda, MD 20814, (301) 594–2704, ismondrr@mail.nih.gov.

Dated: January 23, 2018.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–01491 Filed 1–25–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of PRAT Fellowship applications.

Date: March 26, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda Downtown, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: John J. Laffan, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18J, Bethesda, MD 20892, 301–594–2773, laffanjo@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: January 23, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–01490 Filed 1–25–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2017–0954]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0085

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval for reinstatement, without change, of the following collection of information: 1625–0085, Streamlined Inspection Program. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before February 26, 2018.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2017–0954] to the Coast Guard using the Federal eRulemaking Portal at <http://www.regulations.gov>. Alternatively, you may submit comments to OIRA using one of the following means:

(1) *Email:* dhsdeskofficer@omb.eop.gov.

(2) *Mail:* OIRA, 725 17th Street NW, Washington, DC 20503, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the internet at <http://www.regulations.gov>.

www.regulations.gov. Additionally, copies are available from: Commandant (CG-612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593-7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202-475-3532, or fax 202-372-8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection. The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG-2017-0954], and must be received by February 26, 2018.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public

comments, are in our online docket at <http://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at <http://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625-0085.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (82 FR 52315, November 13, 2017) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments. Accordingly, no changes have been made to the Collections.

Information Collection Request

Title: Streamlined Inspection Program.

OMB Control Number: 1625-0085.

Summary: The Coast Guard established an optional Streamlined Inspection Program (SIP) to provide owners and operators of U.S. vessels an alternative method of complying with inspection requirements of the Coast Guard.

Need: The SIP regulations under 46 CFR part 8, subpart E, offer owners and operators of inspected vessels an alternative to traditional Coast Guard inspection procedures. Title 46 U.S.C. 3306 of authorizes the Coast Guard to prescribe regulations necessary to carry out the inspections of vessels required to be inspected under 46 U.S.C. 3301, and 46 U.S.C. 3103 allows the Coast Guard to rely on reports, documents, and records of other persons who have been determined to be reliable, and other methods that have been determined to be reliable to ensure compliance with vessels and seamen requirements under 46 U.S.C. subtitle II.

Forms: None.

Respondents: Owners and operators of vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 2,334 hours to 8,254 hours a year due to an increase in the number of SIP participants (*i.e.*, companies and vessels).

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: January 18, 2018.

James D. Roppel,

U.S. Coast Guard, Acting Chief, Office of Information Management.

[FR Doc. 2018-01443 Filed 1-25-18; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2017-0901]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625-0036

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval for reinstatement, without change, of the following collection of information: 1625-0036, Plan Approval and Records for U.S. and Foreign Tank Vessels Carrying Oil in Bulk. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before February 26, 2018.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2017-0901] to the Coast Guard using the Federal eRulemaking Portal at <http://www.regulations.gov>. Alternatively, you may submit comments to OIRA using one of the following means:

(1) **Email:** dhsdeskofficer@omb.eop.gov.

(2) **Mail:** OIRA, 725 17th Street NW, Washington, DC 20503, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the internet at <http://www.regulations.gov>. Additionally, copies are available from: Commandant

(CG-612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr Ave SE, Stop 7710, Washington, DC 20593-7710.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Anthony Smith, Office of Information Management, telephone 202-475-3532, or fax 202-372-8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection. The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG-2017-0901], and must be received by February 26, 2018.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <http://www.regulations.gov> and can be

viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at <http://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625-0036.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (82 FR 49640, October 26, 2017) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments. Accordingly, no changes have been made to the Collections.

Information Collection Request

Title: Plan Approval and Records for U.S. and Foreign Tank Vessels Carrying Oil in Bulk.

OMB Control Number: 1625-0036.

Summary: This information collection aids the Coast Guard in determining if a vessel complies with certain safety and environmental protection standards. Plans, to include records, for construction or modification of U.S. or foreign vessels submitted and maintained on board are required for compliance with these standards.

Need: Title 46 U.S.C. 3703 provides the Coast Guard with the authority to regulate design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of vessels carrying oil in bulk. See e.g., 33 CFR part 157, Rules for the Protection of the Marine Environment Relating to Tank Vessels Carrying Oil in Bulk, and 46 CFR chapter I, subchapter D, Tank Vessels.

Forms: None.

Respondents: Owners and operators of Vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 2,033 hours to 2,106 hours a year due to an increase in the estimated number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: January 18, 2018.

James D. Roppel,

Acting Chief, U.S. Coast Guard, Office of Information Management.

[FR Doc. 2018-01440 Filed 1-25-18; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2017-0953]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625-0029

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval for reinstatement, without change, of the following collection of information: 1625-0029, Self-propelled Liquefied Gas Vessels. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before February 26, 2018.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2017-0953] to the Coast Guard using the Federal eRulemaking Portal at <http://www.regulations.gov>. Alternatively, you may submit comments to OIRA using one of the following means:

(1) *Email:* dhsdeskofficer@omb.eop.gov.

(2) *Mail:* OIRA, 725 17th Street NW, Washington, DC 20503, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the internet at <http://www.regulations.gov>. Additionally, copies are available from: Commandant (CG-612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593-7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202-475-3532, or fax 202-372-8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:**Public Participation and Request for Comments**

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection. The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2017–0953], and must be received by February 26, 2018.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <http://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have

provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at <http://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0029.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (82 FR 49636, October 26, 2017) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Self-propelled Liquefied Gas Vessels.

OMB Control Number: 1625–0029.

Summary: The information is needed to ensure compliance with our rules for the design and operation of liquefied gas carriers.

Need: Title 46 U.S.C. 3703 and 9101 authorizes the Coast Guard to establish regulations to protect life, property, and the environment from the hazards associated with the carriage of dangerous liquid cargo in bulk. Title 46 CFR part 154 prescribes the rules for the carriage of liquefied gases in bulk on self-propelled vessels by governing the design, construction, equipment, and operation of these vessels and the safety of personnel aboard them.

Forms: None.

Respondents: Owners and operators of self-propelled vessels carrying liquefied gas.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 7,890 hours to 8,169 hours a year due to an increase in the estimated number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: January 18, 2018.

James D. Roppel,

U.S. Coast Guard, Acting Chief, Office of Information Management.

[FR Doc. 2018–01442 Filed 1–25–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard**

[Docket No. USCG–2015–0694]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0040

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval for reinstatement, without change, of the following collection of information: 1625–0040, Application for Merchant Mariner Credential (MMC), Application for Merchant Mariner Medical Certificate, Applications for Merchant Mariner Medical Certificate for Entry Level Ratings, Small Vessel Sea Service Form, DOT/USCG Periodic Drug Testing Form, Disclosure Statement for Narcotics, DWI/DUI, and/or Other Convictions, Merchant Mariner Medical Certificates, Recognition of Foreign Certificate. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before February 26, 2018.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2015–0694] to the Coast Guard using the Federal eRulemaking Portal at <http://www.regulations.gov>. Alternatively, you may submit comments to OIRA using one of the following means:

(1) *Email:* dhsdeskofficer@omb.eop.gov.

(2) *Mail:* OIRA, 725 17th Street NW, Washington, DC 20503, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the internet at <http://www.regulations.gov>. Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information

Management, telephone 202-475-3532, or fax 202-372-8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request [USCG-2015-0694], and must be received by February 26, 2018.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION**

CONTACT section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <http://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at <http://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625-0040.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (80 FR 62079, December 14, 2015) required by 44 U.S.C. 3506(c)(2). That Notice elicited one comment.

We did receive one comment on the earlier submission of this ICR. The commenter requested that we provide more detail on the progress of an application while it is being processed. Although this is not a comment directed at the collection, we do provide the following response.

Accordingly, no changes have been made to the Collections. The Coast Guard provides process guides and general requirements to assist with the applications required for a Merchant Mariner. These are available upon the National Maritime Center (NMC) website at www.uscg.mil/nmc.

These guides detail the processes that are followed for the evaluation of merchant mariners. Furthermore, during the mariner evaluation process, the applicants are provided email updates (if email address is provided) detailing the status of their application(s).

The Coast Guard published a second 60-day Notice (82 FR 49639, October 26, 2017) required by 44 U.S.C. 3506(c)(2). This was done due to the length of time that elapsed since posting of the initial 60-day Notice. That Notice elicited no comment. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Application for Merchant Mariner Credential (MMC), Application for Merchant Mariner Medical Certificate, Application for Merchant Mariner Medical Certificate for Entry Level Ratings, Small Vessel Sea Service Form, DOT/USCG Periodic Drug Testing Form, Disclosure Statement for Narcotics, DWI/DUI, and/or Other Convictions, Merchant Mariner Medical

Certificate, Recognition of Foreign Certificate.

OMB Control Number: 1625-0040.

Summary: The Application for Merchant Mariner Credential (MMC), Application for Merchant Mariner Medical Certificate, Application for Merchant Mariner Medical Certificate for Entry Level Ratings, Small Vessel Sea Service Form, DOT/USCG Periodic Drug Testing Form, Disclosure Statement for Narcotics, DWI/DUI, and/or Other Convictions, contains the following information: Signature of applicant and supplementary material required to show that the mariner meets the mandatory requirements for the credential or medical certificate sought; proof of applicant passing all applicable vision, hearing, medical, and/or physical exams; negative chemical test for dangerous drugs; discharges or other documentary evidence of sea service indicating the name, tonnage, propulsion mode and power of the vessels, dates of service, capacity in which the applicant served, and on what waters; and disclosure documentation for narcotics, DWI/DUI, and/or other convictions.

Need: Title 46 United States Code (U.S.C.) Subtitle II, part E, Title 46 Code of Federal Regulation (CFR) part 10, Subpart B, and International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, as amended (STCW Convention) and the STCW Code, including the STCW Final Rule (Docket No. USCG-2004-17914) published on December 24, 2013, requires MMC and Medical Certificate applicants to apply at one of the Coast Guard's seventeen Regional Examination Centers located nationwide. MMCs are established for individuals who are required to hold a credential under Subtitle II. The Coast Guard has the responsibility of issuing MMCs and Medical Certificates to applicants found qualified as to age, character, habits of life, experience, professional qualifications, and physical fitness. The instruments contained within OMB Control No. 1625-0040 serve as a means for the applicant to apply for a MMC and Medical Certificate.

Forms: CG-719B, Application for Merchant Mariner Credential (MMC); CG-719C, Disclosure Statement for Narcotics, DWI/DUI, and/or Other Convictions; CG-719K, Application for Merchant Mariner Medical Certificate; CG-719K/E, Application for Merchant Mariner Medical Certificate for Entry Level Ratings; CG-719S, Small Vessel Sea Service Form; CG-719P, DOT/USCG Periodic Drug Testing Form.

Respondents: Applicants for MMC, whether original, renewal, duplicate, raise of grade, or a new endorsement on a previously issued MMC. Applicants for Medical Certificates to include National and STCW credentialed mariners, and first-class pilots.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden remains 47,444 hours a year (CG-719B = 8,475, CG-719K = 16,440 hours, CG-719K/E = 2,283 hours, CG-719-S = 14, 125 hours, CG-719P = 4,708 hours, and CG-719C = 1,413).

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: January 11, 2018.

James D. Roppel,

Acting Chief, U.S. Coast Guard, Office of Information Management.

[FR Doc. 2018-01448 Filed 1-25-18; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2017-0899]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625-0058

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval for reinstatement, without change, of the following collection of information: 1625-0058, Application for Permit to Transport Municipal and Commercial Waste. Our ICR describe the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before February 26, 2018.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2017-0899] to the Coast Guard using the Federal eRulemaking Portal at <http://www.regulations.gov>. Alternatively, you may submit comments to OIRA using one of the following means:

(1) *Email:* dhsdeskofficer@omb.eop.gov.

(2) *Mail:* OIRA, 725 17th Street NW, Washington, DC 20503, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the internet at <http://www.regulations.gov>. Additionally, copies are available from: Commandant (CG-612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593-7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202-475-3532, or fax 202-372-8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection. The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG-2017-0899], and must be received by February 26, 2018.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>.

www.regulations.gov. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <http://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at <http://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625-0058.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (82 FR 49638, October 26, 2017) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments. Accordingly, no changes have been made to the Collections.

Information Collection Request

Title: Application for Permit to Transport Municipal and Commercial Waste.

OMB Control Number: 1625-0058.

Summary: This information collection provides the basis for issuing or denying a permit, required under 33 U.S.C. 2601 and 33 CFR 151.1009, for the transportation of municipal or commercial waste in the coastal waters of the United States.

Need: In accordance with 33 U.S.C. 2601, the U.S. Coast Guard issued regulations requiring an owner or operator of a vessel to apply for a permit to transport municipal or commercial waste in the United States and to display an identification number or other marking on their vessel.

Forms: None.

Respondents: Owners and operators of vessels.

Frequency: Every 18 months.

Hour Burden Estimate: The estimated burden remains at 13 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: January 18, 2018.

James D. Roppel,

U.S. Coast Guard, Acting Chief, Office of Information Management.

[FR Doc. 2018–01441 Filed 1–25–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4352–DR; Docket ID FEMA–2018–0001]

Pueblo of Acoma; 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 Pueblo of Acoma (FEMA–4352–DR), dated December 20, 2017, and related determinations.

DATES: The declaration was issued December 20, 2017.

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 December 20, 2017, 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 to the lands associated with the Pueblo of Acoma resulting from severe storms and flooding during the period of October 4–6, 2017, 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 for the Pueblo of Acoma.

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 and Hazard Mitigation for the Pueblo of Acoma. Direct Federal assistance is authorized. 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, Gerard Stolar, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas have been designated as adversely affected by this major disaster:

The Pueblo of Acoma for Public Assistance.

The Pueblo of Acoma is eligible to apply 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. 2018–01460 Filed 1–25–18; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4337–DR; Docket ID FEMA–2018–0001]

Florida; Amendment No. 14 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the

State of Florida (FEMA–4337–DR), dated September 10, 2017, and related determinations.

DATES: This amendment was issued January 10, 2018.

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: The notice of a major disaster declaration for the State of Florida is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of September 10, 2017.

Hamilton County for Individual Assistance (already designated for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance 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. 2018–01456 Filed 1–25–18; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2018–0002; Internal Agency Docket No. FEMA–B–1801]

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 Title 44, Part 65 of the Code of 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.")

Dated: January 9, 2018.

Roy E. Wright,

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.
Arizona:						
Maricopa	City of Buckeye (17-09-1137P).	The Honorable Jackie A. Meck, Mayor, City of Buckeye, 530 East Monroe Avenue, Buckeye, AZ 85326.	Engineering Department, 530 East Monroe Avenue, Buckeye, AZ 85326.	https://msc.fema.gov/portal/advanceSearch .	Apr. 20, 2018	040039
Maricopa	City of Peoria (17-09-2535P).	The Honorable Cathy Carlat, Mayor, City of Peoria, 8401 West Monroe Street, Peoria, AZ 85345.	City Hall, 8401 West Monroe Street, Peoria, AZ 85345.	https://msc.fema.gov/portal/advanceSearch .	Mar. 30, 2018	040050
Maricopa	Unincorporated Areas of Maricopa County (17-09-2169P).	The Honorable Denny Barney, Chairman, Board of Supervisors, Maricopa County, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009.	https://msc.fema.gov/portal/advanceSearch .	Apr. 20, 2018	040037
Mohave	City of Kingman (16-09-2824P).	The Honorable Monica Gates, Mayor, City of Kingman, 310 North 4th Street, Kingman, AZ 86401.	City Hall, 310 North 4th Street, Kingman, AZ 86401.	https://msc.fema.gov/portal/advanceSearch .	Apr. 2, 2018	040060

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.
Yavapai	City of Prescott (17-09-2254P).	The Honorable Greg Mengarelli, Mayor, City of Prescott, 201 South Cortez Street, Prescott, AZ 86303.	Public Works Department, 201 South Cortez Street, Prescott, AZ 86303.	https://msc.fema.gov/portal/advanceSearch .	Apr. 20, 2018	040098
Yavapai	City of Prescott (17-09-2793P).	The Honorable Greg Mengarelli, Mayor, City of Prescott, 201 South Cortez Street, Prescott, AZ 86303.	Public Works Department, 201 South Cortez Street, Prescott, AZ 86303.	https://msc.fema.gov/portal/advanceSearch .	Apr. 2, 2018	040098
Florida: Bay	City of Panama City Beach (17-04-6419P).	Mr. Mario Gisbert, City Manager, City of Panama City Beach, 110 South Arnold Road, Panama City Beach, FL 32413.	City Hall, 110 South Arnold Road, Panama City Beach, FL 32413.	https://msc.fema.gov/portal/advanceSearch .	Mar. 29, 2018	120013
Idaho:						
Ada	City of Boise (17-10-0818P).	The Honorable David Bieter, Mayor, City of Boise, City Hall, 150 North Capitol Boulevard, Boise, ID 83702.	Planning and Development Services, City Hall, 150 North Capitol Boulevard, Boise, ID 83702.	https://msc.fema.gov/portal/advanceSearch .	Apr. 6, 2018	160002
Bonneville	City of Swan Valley (17-10-1626P).	The Honorable Janice Duncan, Mayor, City of Swan Valley, P.O. Box 105, Swan Valley, ID 83449.	City Building, 15 Highway 31, Swan Valley, ID 83449.	https://msc.fema.gov/portal/advanceSearch .	Mar. 13, 2018	160154
Bonneville	Unincorporated Areas of Bonneville County (17-10-1626P).	Mr. Roger Christensen, Chairman, Bonneville County Commissioner, 605 North Capital Avenue, Idaho Falls, ID 83402.	Bonneville County Courthouse, 605 North Capital Avenue, Idaho Falls, ID 83402.	https://msc.fema.gov/portal/advanceSearch .	Mar. 13, 2018	160027
Kansas:						
Johnson	City of Olathe (17-07-1722P).	The Honorable Michael Copeland, Mayor, City of Olathe, P. O. Box 768, Olathe, KS 66051.	City Hall, Olathe Planning Office, 100 West Santa Fe Drive, Olathe, KS 66061.	https://msc.fema.gov/portal/advanceSearch .	Apr. 12, 2018	200173
Seward	City of Liberal (17-07-1561P).	The Honorable Joe Denoyer, Mayor, City of Liberal, City Hall, 324 North Kansas Avenue, Liberal, KS 67905.	City Hall, 324 North Kansas Avenue, Liberal, KS 67905.	https://msc.fema.gov/portal/advanceSearch .	Apr. 13, 2018	200330
Minnesota:						
Dakota	City of Burnsville (17-05-5338P).	The Honorable Elizabeth Kautz, Mayor, City of Burnsville, 100 Civic Center Parkway, Burnsville, MN 55337.	City Hall, 100 Civic Center Parkway, Burnsville, MN 55337.	https://msc.fema.gov/portal/advanceSearch .	Apr. 9, 2018	270102
Scott	City of Savage (17-05-5338P).	The Honorable Janet Williams, Mayor, City of Savage, City Hall, 6000 McColl Drive, Savage, MN 55378.	City Hall, 6000 McColl Drive, Savage, MN 55378.	https://msc.fema.gov/portal/advanceSearch .	Apr. 9, 2018	270433
Missouri: New Madrid.	Unincorporated Areas of New Madrid County (17-07-1570P).	Mr. Mark Baker, New Madrid County Commissioner, P.O. Box 68, New Madrid, MO 63869.	Courthouse Square, 450 Main Street, New Madrid, MO 63869.	https://msc.fema.gov/portal/advanceSearch .	Apr. 20, 2018	290849
Nevada:						
Clark	City of Henderson (17-09-0674P).	The Honorable Debra March, Mayor, City of Henderson, 240 South Water Street, Henderson, NV 89015.	Public Works Department, 240 South Water Street, Henderson, NV 89015.	https://msc.fema.gov/portal/advanceSearch .	Mar. 27, 2018	320005
Clark	Unincorporated Areas of Clark County (17-09-0674P).	The Honorable Steve Sisolak, Chairman, Board of Supervisors, Clark County, 500 South Grand Central Parkway, 6th Floor, Las Vegas, NV 89106.	Clark County, Office of the Director of Public Works, 500 South Grand Central Parkway, Las Vegas, NV 89155.	https://msc.fema.gov/portal/advanceSearch .	Mar. 27, 2018	320003
Clark	Unincorporated Areas of Clark County (17-09-2785P).	The Honorable Steve Sisolak, Chairman, Board of Supervisors, Clark County, 500 South Grand Central Parkway, 6th Floor, Las Vegas, NV 89106.	Clark County, Office of the Director of Public Works, 500 South Grand Central Parkway, Las Vegas, NV 89155.	https://msc.fema.gov/portal/advanceSearch .	Apr. 9, 2018	320003
Oregon:						

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.
Benton	City of Philomath (17-10-1546P).	The Honorable Rocky Sloan, Mayor, City of Philomath, 980 Applegate Street, Philomath, OR 97370.	City Hall, 980 Applegate Street, Philomath, OR 97370.	https://msc.fema.gov/portal/advanceSearch .	Mar. 29, 2018	410011
Benton	Unincorporated Areas of Benton County (17-10-1546P).	Ms. Annabelle Jaramillo, Chair, Benton County Board of Commissioners, 205 Northwest 5th Street, Corvallis, OR 97339.	Benton County Sherriff's Office, 180 Northwest 5th Street, Corvallis, OR 97333.	https://msc.fema.gov/portal/advanceSearch .	Mar. 29, 2018	410008
Washington: King ..	City of North Bend (17-10-1428P).	The Honorable Kenneth G. Hearing, Mayor, City of North Bend, 211 Main Avenue North, North Bend, WA 98045.	Planning Department, 126 East 4th Street, North Bend, WA 98045.	https://msc.fema.gov/portal/advanceSearch .	Apr. 13, 2018	530085
Wisconsin: Brown	Unincorporated Areas of Brown County (17-05-5248P).	Mr. Patrick Moynihan, Jr., Chair, Brown County, 305 East Walnut Street, Green Bay, WI 54301.	Zoning Office, 305 East Walnut Street, Green Bay, WI 54301.	https://msc.fema.gov/portal/advanceSearch .	Apr. 4, 2018	550020

[FR Doc. 2018-01455 Filed 1-25-18; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA-2017-0028; OMB No. 1660-0058]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Fire Management Assistance Grant Program

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before February 26, 2018.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency

Management Agency, and sent via electronic mail to dhsdeskofficer@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 500 C Street SW, Washington, DC 20472, email address FEMA-Information-Collections-Management@fema.dhs.gov or Allen Wineland, FMAG Program Manager, Office of Response & Recovery, FEMA, (202) 702-1472.

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on October 12, 2017 at 82 FR 47562 with a 60 day public comment period. FEMA received 58 comments. The comments were unrelated to the collection. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Fire Management Assistance Grant Program.

Type of Information Collection: Reinstatement, with change, of a currently approved information collection.

OMB Number: 1660-0058.

Form Titles and Numbers: FEMA Form 078-0-1, Request for Fire Management Assistance Declaration; FEMA Form 089-0-24, Request for Fire Management Sub-grant; FEMA Form 078-0-2, Principal Advisor's Report.

Abstract: The information collection is required to make grant eligibility determinations for the Fire Management Assistance Grant Program (FMAGP). These eligibility-based grants and

subgrants provide assistance to any eligible State, Indian tribal government, or local government for the mitigation, management, and control of a fire on public or private forest land or grassland that is threatening such destruction as would constitute a major disaster. The data/information gathered in the forms is used to determine the severity of the threatening fire, current and forecast weather conditions, and associated factors related to the fire and its potential threat as a major disaster.

Affected Public: State, local, or Tribal Government.

Estimated Number of Respondents: 178.

Estimated Number of Responses: 553.

Estimated Total Annual Burden Hours: 811.

Estimated Total Annual Respondent Cost: The estimated annual cost to respondents for the hour burden is \$56,281.

Estimated Respondents' Operation and Maintenance Costs: There are no annual costs to respondents operations and maintenance costs for technical services.

Estimated Respondents' Capital and Start-Up Costs: There is no annual start-up or capital costs.

Estimated Total Annual Cost to the Federal Government: The cost to the Federal Government is \$612,370.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (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.

William Holzerland,

Director, Information Management Division, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2018-01457 Filed 1-25-18; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-6068-D-01]

Delegation of Authority to the Assistant Secretary for Administration

AGENCY: Office of the Deputy Secretary, HUD.

ACTION: Notice of delegation of authority.

SUMMARY: Through this notice, the Deputy Secretary delegates to the Assistant Secretary for Administration all authority and responsibility for the coordination, management and supervision for the following offices: Chief Human Capital Officer, Chief Procurement Officer, and Chief Administrative Officer.

DATES: *Applicable:* January 5, 2018.

FOR FURTHER INFORMATION CONTACT: John B. Shumway, Assistant General Counsel for Administrative Law, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 9262, Washington, DC 20410-0500, telephone number 202-402-5190. (This is not a toll-free number.) Individuals with speech or hearing impairments may access this number through TTY by calling 1-800-877-8339.

SUPPLEMENTARY INFORMATION: The Deputy Secretary hereby delegates to the Assistant Secretary for Administration authority to coordinate, manage and supervise the activities of the offices of the Chief Human Capital Officer, the Chief Procurement Officer, and the Chief Administrative Officer.

Section A. Authority

The Deputy Secretary of Housing and Urban Development hereby delegates to the Assistant Secretary for

Administration the authority to coordinate, manage and supervise the activities of the following offices and functions:

1. *Office of the Chief Human Capital Officer:* This office is responsible for employee performance management; executive resources; human capital field support; human capital policy; planning and training; recruitment and staffing; personnel security; employee assistance program; health and wellness; employee and labor relations; pay; benefits and retirement; and human capital information systems. More detailed information can be found in the delegation of authority notice for the Chief Human Capital Officer, posted at https://www.hud.gov/sites/documents/5562-D-01_DELEGATION.PDF.

2. *Office of the Chief Procurement Officer:* This office is responsible for obtaining all contracted goods and services required by the Department efficiently and in the most cost-effective manner possible to enable the Department to meet its strategic objectives. The office provides logistical support to HUD's program offices and other support offices in meeting their mission needs and provides leadership on developing fundamentally sound business practices. More detailed information can be found in the designation of the Chief Acquisition Officer and Senior Procurement Officer notice published elsewhere in today's **Federal Register**.

3. *Office of the Chief Administrative Officer:* This office is responsible for field support services, Executive Secretariat and compliance functions (including privacy, records, and Freedom of Information Act compliance), facilities management, disaster management and national security, communication support services, including digital and multimedia. More detailed information can be found in the delegation of authority notice for the Chief Administrative Officer, posted at <https://www.hud.gov/sites/documents/DOADMIN071814.PDF>.

Section B. Authority to Redelegate

The Assistant Secretary for Administration is authorized to redelegate to employees of HUD any of the authority delegated under Section A above.

Section C. Authority Superseded

This Delegation supersedes Sections A.1 and A.2 (delegating authority to the Chief Operations to supervise the Office of Chief Human Capital Officer and the Office of Chief Administrative Officer) of the May 11, 2015, Delegation of

Authority to the Chief Operations Officer, which was published in the **Federal Register** at 80 FR 26946.

Authority: Section 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: January 5, 2018.

Pamela H. Patenaude,

Deputy Secretary.

[FR Doc. 2018-01508 Filed 1-25-18; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-6080-D-01]

Revocation of Delegation of Authority to the Chief Operations Officer

AGENCY: Office of the Deputy Secretary, HUD.

ACTION: Notice of revocation of delegation of authority.

SUMMARY: Through this notice, the Deputy Secretary revokes authority previously delegated to the Chief Operations Officer in a notice published in the **Federal Register** on May 11, 2015.

DATES: *Applicable Date:* January 5, 2018.

FOR FURTHER INFORMATION CONTACT: John B. Shumway, Assistant General Counsel for Administrative Law, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 9262, Washington, DC 20410-0500, telephone number 202-402-5190. (This is not a toll-free number.) Individuals with speech or hearing impairments may access this number through TTY by calling 1-800-877-8339.

SUPPLEMENTARY INFORMATION: Offices previously supervised by the Chief Operations Officer are supervised by the Assistant Secretary for Administration and the Deputy Secretary. By separate notice, the Deputy Secretary has delegated to the Assistant Secretary for Administration authority to coordinate, manage and supervise the activities of the offices of the Chief Human Capital Officer, the Chief Procurement Officer, and the Chief Administrative Officer. The Chief Information Officer reports directly to the Deputy Secretary.

Authority Superseded

This Delegation revokes the May 11, 2015 Delegation of Authority to the Chief Operations Officer, which was published in the **Federal Register** at 80 FR 26946.

Authority: Section 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: January 5, 2018.

Pamela H. Patenaude,
Deputy Secretary.

[FR Doc. 2018-01499 Filed 1-25-18; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-6079-D-01]

Designations of Chief Acquisition Officer and Senior Procurement Executive

AGENCY: Office of the Deputy Secretary, HUD.

ACTION: Notice of designations.

SUMMARY: The Department of Housing and Urban Development Act, as amended, authorizes the Secretary to delegate functions, powers, and duties as the Secretary deems necessary. In this notice, the Deputy Secretary of HUD designates the Assistant Secretary for Administration as the Chief Acquisition Officer and designates the Chief Procurement Officer as the Senior Procurement Executive.

DATES: January 5, 2018.

FOR FURTHER INFORMATION CONTACT: Office of the Chief Procurement Officer, Department of Housing and Urban Development, 451 7th Street SW, Room 5276, Washington, DC 20410-3000; telephone number 202-708-0294 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION: This notice includes the Department's designations of the Chief Acquisition Officer and Senior Procurement Executive. Previously, the designations were set forth in a **Federal Register** notice published on July 30, 2013 (78 FR 46240). Accordingly, the Secretary hereby revokes the July 30, 2013, designations and designates as follows:

Section A. Designation of Chief Acquisition Officer

1. The Assistant Secretary for Administration is designated to serve as the Department's Chief Acquisition Officer. Functions of the Chief Acquisition Officer are outlined at 41 U.S.C. 414. If the Assistant Secretary for Administration position is vacant, the Senior Procurement Executive will perform all the duties and functions of the Chief Acquisition Officer.

2. The authority of the Chief Acquisition Officer includes the authority to delegate any of the duties and functions of the Chief Acquisition Officer to the Senior Procurement Executive. On July 30, 2013 (78 FR 46240), the Deputy Secretary delegated to the Senior Procurement Executive certain authority to perform the functions of the Chief Acquisition Officer. The July 30, 2013, delegation of authority is affirmed by this notice, with the exception of any references to the Deputy Secretary as Chief Acquisition Officer. Any functions not delegated to the Senior Procurement Executive remain with the Chief Acquisition Officer.

Section B. Designation of Senior Procurement Executive

1. The Chief Procurement Officer is designated as the Department's Senior Procurement Executive.

2. The Senior Procurement Executive shall report directly to the Assistant Secretary for Administration, who has been designated as the Chief Acquisition Officer, without intervening authority, for all procurement-related matters.

3. The authority of the Senior Procurement Executive includes the authority to redelegate the duties and functions of the Senior Procurement Executive.

Section C. Authority Superseded

This designation revokes all previous designations concerning the Chief Acquisition Officer and Senior Procurement Executive, including the designations notice published in the **Federal Register** on July 30, 2013 (78 FR 46240). As noted herein, the July 30, 2013 (78 FR 46240), delegation of authority to the Senior Procurement Executive is affirmed by this notice, with the exception of any references to the Deputy Secretary as Chief Acquisition Officer.

Authority: 41 U.S.C. 414; section 7(d) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: January 5, 2018.

Pamela H. Patenaude,
Deputy Secretary.

[FR Doc. 2018-01501 Filed 1-25-18; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO310000.L13100000.PP0000.18X; OMB Control Number 1004-0034]

Agency Information Collection Activities; Oil and Gas, or Geothermal Resources: Transfers and Assignments

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Land Management (BLM), are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before March 27, 2018.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to the U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW, Room 2134LM, Washington, DC 20240, Attention: Jean Sonneman; by email to jesonnem@blm.gov. Please reference OMB Control Number 1004-0034 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Jennifer Spencer by email at j35spenc@blm.gov, or by telephone at 202-912-7146.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the BLM; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the BLM enhance the quality, utility, and clarity of the information to be collected; and (5) how might the BLM minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: This collection of information enables the BLM to process assignments of record title interest and transfers of operating rights in a lease for oil and gas or geothermal resources. Each assignment or transfer is a contract between private parties but, by law, must be approved by the Secretary. The BLM uses information about assignments and transfers to prevent unlawful extraction of mineral resources, to ensure prompt payment of rentals and royalties for the rights obtained under a Federal lease, and to ensure that leases are not encumbered with agreements that cause the minerals to be uneconomical to produce, resulting in lost revenues to the Federal Government. The information also enables the BLM to ensure the assignee or transferee is in compliance with the bonding requirements, when necessary, before approval of the transfer or assignment.

Title of Collection: Oil, Gas, and Geothermal Resources: Transfers and Assignments.

OMB Control Number: 1004-0034.

Form Numbers: 3000-3 and 3000-3a.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Assignors and assignees of record title interest in a lease for oil and gas or geothermal resources; and transferors and transferees of operating rights (sublease) in a lease for oil and gas or geothermal resources.

Total Estimated Number of Annual Respondents: 17,626.

Total Estimated Number of Annual Responses: 17,626.

Estimated Completion Time per Response: 30 minutes.

Total Estimated Number of Annual Burden Hours: 8,813.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: \$1,674,470.

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 authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Jean Sonneman,

Senior Regulatory Analyst, Bureau of Land Management.

[FR Doc. 2018-01436 Filed 1-25-18; 8:45 am]

BILLING CODE 4310-01-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCAD06800.L17110000.KD0000.16X]

Notice of Availability of Final Environmental Impact Statement and Notice of Decision for Proposed Land Exchange Between the Bureau of Land Management and Agua Caliente Band of Cahuilla Indians, California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability and decision.

SUMMARY: In accordance with the National Environmental Policy Act (NEPA) of 1969, as amended, and pursuant to Section 206 of the Federal Land Policy and Management Act (FLPMA) of 1976, as amended, the Bureau of Land Management (BLM)-Palm Springs-South Coast Field Office announces the availability of an abbreviated Final Environmental Impact Statement (EIS) and Record of Decision (ROD) for the proposed land exchange between the BLM and the Agua Caliente Band of Cahuilla Indians (Tribe). The BLM will issue the ROD concurrently with the Final EIS, but will not implement the ROD until after the 45-day protest period (43 CFR 2201.7-1). The Environmental Protection Agency's 30-day "cooling off" period will run concurrently with the protest period. The Decision approving the land exchange was issued by Douglas J. Herrema, Field Manager, BLM-Palm Springs-South Coast Field Office on January 18, 2018.

DATES: A Decision to complete an exchange is subject to protest for 45 days beginning on the first day of publication of this Notice. Thereby, all protests must be written and received by the BLM at the address below, no later than March 12, 2018. Protests related to NEPA documentation or other content of the decision document will be

considered by the BLM. Verbal protests will not be accepted.

ADDRESSES: You may submit a protest of the proposed ROD by either of the following methods:

- **Email:** AguaCalienteExchange@blm.gov.

- **Mail:** Field Manager, BLM Palm Springs-South Coast Field Office, 1201 Bird Center Dr., Palm Springs, CA, 92262.

Copies of the proposed ROD and Final EIS for the proposed land exchange are available for public review in the Palm Springs-South Coast Field Office at the above address, during regular business hours (8 a.m. to 4 p.m.) Monday through Friday (except holidays), or on the internet at <https://goo.gl/qyjNJa>.

FOR FURTHER INFORMATION CONTACT:

Ashley Adams, Monument Manager, telephone 760-833-7100; address BLM Palm Springs-South Coast Field Office, 1201 Bird Center Drive, Palm Springs CA 92262; email amadams@blm.gov. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1-800-877-8339 to contact the above individual during normal business hours. The Service is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Approval of the proposed land exchange transfers 2,560 acres of Federal lands, appraised in the amount of \$795,000, to the Tribe in exchange for 1,471.24 acres of tribally-owned properties, appraised in the amount of \$845,000. Since the appraised value of the offered Tribal lands exceeds the appraised value of the selected Federal lands, the BLM will make a cash payment of \$50,000 to the Tribe in order to equalize values. The selected Federal lands and offered Tribal lands all occur within the Santa Rosa and San Jacinto Mountains National Monument (Monument).

Federal land to be patented to the Tribe:

San Bernardino and Base Meridian, California

T. 5 S., R. 4 E.

Sections 16, 21, 27, and 29.

The area described aggregates 2,560 acres.

The patent that conveys the Federal lands will reserve a Right-of-Way for ditches and canals constructed by the authority of the United States pursuant to the Act of August 30, 1890 (43 U.S.C. 945).

Non-Federal land to be conveyed to the United States:

San Bernardino and Base Meridian, California

T. 5 S., R. 5 E.,

Section 7,

Section 19,

Section 20, W1/2W1/2.

The area described aggregates 1,471.24 acres.

The purpose of the land exchange is to reduce the extent of “checkerboard” land ownership, thereby providing the BLM and the Tribe with more effective and efficient land management responsibilities within the Monument. The public interest will be well served by making this exchange.

Lands acquired by the BLM will be managed in accordance with applicable statutes and regulations, as well as the California Desert Conservation Area Plan, as amended, and the Santa Rosa and San Jacinto Mountains National Monument Management Plan. Lands acquired by the Tribe will be managed in accordance with its Land Use Ordinance, Indian Canyons Master Plan, and Tribal Habitat Conservation Plan.

In 2008, the proposed land exchange was announced in a Notice of Exchange Proposal (NOEP), which included a 45-day public comment period. In 2010, an Environmental Assessment was released for public review, which allowed for a 30-day comment period. Based on their findings, the BLM determined that preparation of an EIS was necessary.

In 2012, the BLM initiated a public scoping process and subsequently released a Draft EIS with a 90-day public comment period, which concluded on March 29, 2015. Comments on the Draft EIS received from the public and internal BLM review were considered and incorporated as appropriate into the Final EIS. The BLM concluded that changes to the Draft EIS were minor, and as a result, an abbreviated Final EIS was completed. Those changes were primarily related to the exchange value equalization efforts based on a current appraisal. As a result, the amount of trails that were identified for disposal by the BLM were reduced.

Before including your phone number, email address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask the BLM in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 2200

Douglas J. Herrema,

Field Manager, Palm Springs—South Coast Field Office.

[FR Doc. 2018–01437 Filed 1–25–18; 8:45 am]

BILLING CODE 4310–40–P**DEPARTMENT OF THE INTERIOR****Bureau of Land Management****[LLWYP06000.LL13100000.DB0000.17X]**

Notice of Availability of the Draft Environmental Impact Statement for the Converse County Oil and Gas Project, Converse County, Wyoming

AGENCIES: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), the Bureau of Land Management (BLM) as the lead Federal agency, and the United States Forest Service (USFS), participating as a cooperating agency, have prepared a Draft Environmental Impact Statement (Draft EIS) that evaluates, analyzes, and discloses to the public direct, indirect, and cumulative environmental impacts of a proposal to develop oil and natural gas in Converse County, Wyoming. This notice announces a 45-day public comment period to meet the requirements of NEPA and section 106 of the National Historic Preservation Act.

DATES: To ensure that comments will be considered, the BLM must receive written comments on the Converse County Oil and Gas Project Draft EIS within 45 days following the date the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**. The BLM will announce future meetings and any other public involvement activities at least 15 days in advance through public notices, media releases, mailings, and/or at the BLM website <http://bit.ly/2oxHxeq>.

ADDRESSES: Comments on the Converse County Oil and Gas Project may be submitted by any of the following methods:

- *Website:* <http://bit.ly/2oxHxeq>.
- *Email:* blm_wy_casper_wymail@blm.gov.
- *Fax:* 307–261–7587.
- *Mail or hand delivery:* Converse County Oil and Gas Project EIS, BLM Casper Field Office, Attn: Mike Robinson, Project Manager, 2987 Prospector Drive, Casper, WY 82604.

Documents pertinent to this proposal may be examined at the following offices:

- BLM Casper Field Office, 2987 Prospector Drive, Casper, WY 82604;
- USFS Douglas Ranger District Office, 2250 East Richards Street, Douglas, WY 82633; and
- BLM Wyoming State Office, 5353 Yellowstone Road, Cheyenne, WY 82009.

Interested persons may also view the documents online at: <http://bit.ly/2oxHxeq>.

FOR FURTHER INFORMATION CONTACT:

Mike Robinson, Project Manager, telephone: 307–261–7520; address: 2987 Prospector Drive, Casper, WY 82604; email: blm_wy_casper_wymail@blm.gov. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above person during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: An Operator Group (OG) comprised of Anadarko Petroleum Company, Chesapeake Energy Corporation, Devon Energy, EOG Resources, Inc., and SM Energy, proposes to develop oil and gas leases within the Converse County Project Area (CCPA) in Converse County, Wyoming.

The CCPA encompasses approximately 1.5 million acres of land, of which approximately 88,466 surface acres (6 percent of the CCPA) are public lands administered by the BLM and approximately 63,911 surface acres (4 percent of the CCPA) are administered by the USFS. The remaining surface estate consists of approximately 101,012 surface acres (7 percent) administered by the State of Wyoming and approximately 1,247,477 surface acres (83 percent) that are privately owned. The BLM administers approximately 964,525 acres of mineral estate (64 percent) within the CCPA. Split estate lands, lands with private surface and Federal mineral ownership, comprise approximately 812,189 acres of those 964,525 acres (54 percent of the 64 percent) of the Federal mineral ownership of land within the CCPA.

The Draft EIS describes and analyzes the impacts of the OG's Proposed Action (Alternative B) and two alternatives, the No Action Alternative (Alternative A) and Alternative C. Additional alternatives were considered, but eliminated from detailed analysis. All alternatives incorporate best management practices

for oil and gas development and other measures necessary to address impacts to air quality, cultural resources, historic trails, public safety, recreational opportunities, threatened and endangered species, socioeconomic, transportation, vegetation, visual resources, water, wildlife habitats including Greater Sage-grouse and Greater Sage-grouse Priority Habitat Management Areas, and other relevant issues. The following is a summary of the alternatives:

1. Alternative A: The No Action Alternative assumes that approval of the OG's proposed Project would be denied and new drilling would continue under approval of the appropriate permitting agency.

2. Alternative B: The Proposed Action Alternative, which is also the Agency Preferred Alternative, consists of the OG's proposal to explore and develop potentially productive subsurface formations underlying the CCPA by drilling up to approximately 5,000 oil and natural gas wells on 1,500 single and multi-well pads within the CCPA over a period of 10 years. The production life of each well is estimated to be approximately 30 years. The OG would develop the CCPA using directional, vertical, horizontal, and other drilling techniques, as well as to develop infrastructure to support oil and gas production in the CCPA, including: Well pads, roads, pipelines, power lines, compressor stations, electrical substations, and ancillary facilities such as water supply wells and water disposal facilities. The total estimated new surface disturbance for development under Alternative B would be approximately 52,667 acres. This alternative includes requesting full-season exceptions, excluding USFS Administered lands (*i.e.* year-round drilling), to multiple timing limitation stipulations which serve to protect several wildlife species in the project area.

3. Alternative C: This alternative would reduce the surface disturbance and related impacts from oil and gas development based on assumptions that a higher average number of wells would be drilled from each pad. Specifically, 55 percent of well pads in the CCPA would have up to 4 wells, 35 percent of well pads in the CCPA would have 5 to 8 wells, and 10 percent of well pads in the CCPA would have 9 to 16 wells. This would provide for drilling the same number of wells (5,000) under the same drilling rate (500 wells per year) as Alternative B. Furthermore, this would reduce the total number of well pads to 938, which would reduce the miles of access roads, gas gathering

pipelines, water pipelines, and overhead electrical lines needed, as well as the acreage encumbered by the proposed project. The total estimated new surface disturbance for development under Alternative C would be approximately 37,267 acres. This alternative would require that multiple timing stipulations be applied as outlined in the BLM RMP and the USFS LRMP, thus not allowing for year-round drilling.

The BLM NEPA Handbook (H-1790-1) calls for expression of the BLM's preferred alternative in the Draft EIS if one exists (BLM 2008c). The BLM selected Alternative B, the Proposed Action, as a preferred alternative for the Converse County Oil and Gas Development Project. The BLM believes that the Proposed Action has the necessary elements that would address the purpose and need for the Draft EIS and will review public comments on the Draft before the preferred alternative is identified in the Final EIS.

The No Action Alternative (Alternative A) and each of the action alternatives (Alternative B and C) are discussed in terms of alternative-specific activities and schedule, design features, and surface disturbance summaries. Alternatives considered, but eliminated from detailed analysis also are discussed. The analysis of each alternative focuses on the new disturbance that would occur under each alternative and would be in addition to existing and permitted disturbance.

The Notice of Intent to prepare an EIS was published in the **Federal Register** on May 16, 2014 (79 FR 28538). Key issues identified during scoping included: Potential impacts on private landowners over Federal mineral estate; socioeconomic impacts on local communities and residents, including new jobs and economic activity in the community, as well as increased noise, traffic, and population growth; potential impacts on air quality and climate change; potential impacts to groundwater and surface water supply and quality; potential impacts to historic trails; enforcement of reclamation and other mitigation on non-Federal lands; impacts to area recreation, grazing, and hunting; the potential to impact Greater Sage-grouse, migratory birds, big game and other wildlife; and adequate analysis of cumulative impacts.

The public is encouraged to comment on any and all portions of the document. The BLM and the USFS ask that those submitting comments make them as specific as possible with reference to chapters, page numbers,

and paragraphs in the Draft EIS document.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Comments that contain only opinions or preferences will not receive a formal response; however, they will be considered and included as part of the BLM and the USFS decision-making process. The most useful comments are those that include new technical or scientific information, identification of data gaps in the impact analysis, or technical or scientific rationale for opinions or preference.

Authority: 40 CFR 1506.6, 40 CFR 1506.10)

Mary Jo Rugwell,

State Director, Wyoming.

[FR Doc. 2018-01320 Filed 1-25-18; 8:45 am]

BILLING CODE 4310-22-P

INTERNATIONAL TRADE COMMISSION

[USITC SE-18-005]

Change to Date and Time of Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

ORIGINAL TIME AND DATE: January 25, 2018 at 2:00 p.m.

NEW DATE AND TIME: January 26, 2018 at 2:30 p.m.

PLACE: Room 100, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205-2000.

STATUS: Open to the public.

In accordance with 19 CFR 201.35(d)(2)(i), the Commission hereby gives notice that the Commission has determined to change the date and time of the meeting originally scheduled for January 25, 2018 at 2:00 p.m. to January 26, 2018 at 2:30 p.m. to consider Inv. Nos. 701-TA-578 and 731-TA-1386 (Final) (100- to 150-Seat Large Civil Aircraft from Canada).

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission:

Issued: January 24, 2018.

William R. Bishop,
Supervisory Hearings and Information
Officer.

[FR Doc. 2018–01626 Filed 1–24–18; 4:15 pm]

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 Programmable Logic Controllers (PLCS), Components Thereof, and Products Containing Same, DN 3289*; 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 Radwell International Inc. on January 19, 2018. 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 programmable logic controllers (PLCS), components thereof, and products containing same. The complaint names as respondent: Rockwell Automation, Inc. of Milwaukee, WI. The complainant requests that the Commission issue an exclusion order, a cease and desist order.

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 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.

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. 3289) in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures¹). 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 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.

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>.

Issued: January 23, 2018.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2018-01425 Filed 1-25-18; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1098]

Certain Subsea Telecommunication Systems and Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 22, 2017, under section 337 of the Tariff Act of 1930, as amended, on behalf of Neptune Subsea Acquisitions Ltd. of the United Kingdom; Neptune Subsea IP Ltd. of the United Kingdom; and Xtera, Inc. of Allen, Texas. Supplements to the complaint were filed on January 4 and 8, 2018. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain subsea telecommunication systems and components thereof by reason of infringement of one or more of U.S. Patent No. 8,380,068 ("the '068 Patent"); U.S. Patent No. 7,860,403 ("the '403 Patent"); U.S. Patent No. 8,971,171 ("the '171 Patent"); U.S. Patent No. 8,351,798 ("the '798 Patent"); and U.S. Patent No. 8,406,637 ("the '637 Patent"). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The amended complaint, except for any confidential information contained therein, is 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, Room 112, Washington, DC 20436, telephone (202) 205-2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special

assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

FOR FURTHER INFORMATION CONTACT:

Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2017).

Scope of Investigation: Having considered the amended complaint, the U.S. International Trade Commission, on January 19, 2018, *Ordered That*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain subsea telecommunication systems and components thereof by reason of infringement of one or more of claims 1-15 of the '068 Patent; claims 1-14 of the '403 Patent; claims 1-10 of the '171 Patent; claims 13-20 of the '798 Patent; and claims 1-6 of the '637 Patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties or other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1);

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:
Neptune Subsea Acquisitions Ltd., Bates House, Church Road, Harold Wood, Essex, RM3 0SD, UK

Neptune Subsea IP Ltd., Bates House, Church Road, Harold Wood, Essex, RM3 0SD, UK
Xtera, Inc., 500 West Bethany Drive, Allen, TX 75013

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Nokia Corporation, Karaportti 3, 02610 Espoo, Finland
Nokia Solutions and Networks B.V., Antareslaan 1, 2132JE Hoofddorp, The Netherlands
Nokia Solutions and Networks Oy, Karaportti 3, 02610 Espoo, Finland
Alcatel-Lucent Submarine Networks SAS, 148 Route De La Reine, 148 AU 152, 92100 Boulogne Billancourt, France
Nokia Solutions and Networks US LLC, 638 N Fifth Ave, Phoenix, AZ 85003
NEC Corporation, 7-1, Shiba 5-chome, Minato-ku, Tokyo 108-8001, Japan
NEC Networks & System Integration Corporation, Iidabashi First Tower, 2-6-1 Koraku, Bunkyo-ku, Tokyo, 112-8560, Japan
NEC Corporation of America, 3929 W. John Carpenter Freeway, Irving, TX 75063-2909

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW, Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination

and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: January 19, 2018.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2018-01379 Filed 1-25-18; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[USITC SE-18-004]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: January 30, 2018 at 11:00 a.m.

PLACE: Room 100, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205-2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.
2. Minutes.
3. Ratification List.
4. Vote in Inv. No. 731-TA-709 (Fourth Review)(Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe from Germany). The Commission is currently scheduled to complete and file its determination and views of the Commission by February 13, 2018.
5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: January 23, 2018.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2018-01625 Filed 1-24-18; 4:15 pm]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1097]

Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 21, 2017, under section 337 of the Tariff Act of 1930, as amended, on behalf of BiTMICRO, LLC of Reston, Virginia. An amended complaint was filed on January 9, 2018. A supplement to the amended complaint was filed on January 18, 2018. The amended complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain solid state storage drives, stacked electronics components, and products containing same by reason of infringement of U.S. Patent No. 7,826,243 ("the '243 Patent"); U.S. Patent No. 6,529,416 ("the '416 Patent"); U.S. Patent No. 9,135,190 ("the '190 Patent"); and U.S. Patent No. 8,093,103 ("the '103 Patent"). The amended complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The amended complaint, except for any confidential information contained therein, is 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, Room 112, Washington, DC 20436, telephone (202) 205-2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

FOR FURTHER INFORMATION CONTACT:

Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337

of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2017).

Scope of Investigation: Having considered the amended complaint, the U.S. International Trade Commission, on January 19, 2018, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain solid state storage drives, stacked electronics components, and products containing same by reason of infringement of one or more of claims 1, 2, 11, and 12 of the '243 Patent; claims 1-20 of the '416 Patent; claims 1-101 of the '190 Patent; and claims 12 and 16 of the '103 Patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Notwithstanding any Commission Rules that would otherwise apply, the presiding Administrative Law Judge shall hold an early evidentiary hearing, find facts, and issue an early decision, as to whether the complainant has satisfied the economic prong of the domestic industry requirement. Any such decision shall be in the form of an initial determination (ID). Petitions for review of such an ID shall be due five calendar days after service of the ID; any replies shall be due three business days after service of a petition. The ID will become the Commission's final determination 30 days after the date of service of the ID unless the Commission determines to review the ID. Any such review will be conducted in accordance with Commission Rules 210.43, 210.44, and 210.45, 19 CFR 210.43, 210.44, and 210.45. The Commission expects the issuance of an early ID relating to the economic prong of the domestic industry requirement within 100 days of institution, except that the presiding ALJ may grant a limited extension of the ID for good cause shown. The issuance of an early ID finding that complainant does not satisfy the economic prong of the domestic industry requirement shall stay the investigation unless the Commission orders otherwise; any other decision shall not stay the investigation or delay the issuance of a final ID covering the other issues of the investigation;

(3) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties or other

interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1)

(4) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: BiTMICRO, LLC, 11921 Freedom Drive, Suite 550, Reston, VA 20190.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Samsung Electronics Co., Ltd., 129 Samsung-Ro, Yeongtong-Gu, Suwon, Gyeonggi-do, Republic of Korea
Samsung Semiconductor, Inc., 3655 North First Street, San Jose, CA 95134
Samsung Electronics America, Inc., 85 Challenger Road, Ridgefield Park, NJ 07660

SK Hynix Inc., 2091, Gyeongchung-daero, Bubal-eub Icheon-si, Gyeonggi-do, Republic of Korea

SK Hynix America Inc., 3101 North First Street, San Jose, CA 95134

Dell Inc., 1 Dell Way, Round Rock, TX 78664

Dell Technologies Inc., 1 Dell Way, Round Rock, TX 78664

Lenovo Group Ltd., No. 6 Chuang Ye Road, Shangdi Information Industry Base, Haidan District, Beijing, China 100085

Lenovo (United States) Inc., 1009 Think Place, Morrisville, NC 27560

HP Inc., 1501 Page Mill Road, Palo Alto, CA 94304

Hewlett Packard Enterprise Co., 3000 Hanover Street, Palo Alto, CA 94304

ASUSTeK Computer Inc., No. 15, Li-Te Road, Peitou, Taipei, Taiwan

ASUS Computer International, 800 Corporate Way, Fremont, CA 94539

Acer Inc., 8F, 88, Sec. 1, Xintai 5th Road Xizhi, New Taipei City 221, Taiwan

Acer America Corp., 333 West San Carlos Street, Suite 1500, San Jose, CA 95110

VAIO Corporation, 5432 Toyoshina, Azumino, Japan 399-8282

Transcosmos America Inc., 879 West 190th Street, Suite 1050, Gardena, CA 90248

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(5) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission,

shall designate the presiding Administrative Law Judge.

Responses to the amended complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: January 19, 2018.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2018-01378 Filed 1-25-18; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

[OMB Number 1121-0240]

Agency Information Collection Activities: Proposed eCollection eComments Requested; Reinstatement, With Change, of a Previously Approved Collection: 2018 Census of State and Local Law Enforcement Agencies (CSLLEA)

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, 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 Volume 82, Number 220, page 53527, on Thursday, November 16, 2017, allowing a 60-day comment period. Following publication of the 60-day notice, the Bureau of Justice Statistics received three requests for the survey instrument and one communication containing general comments on the importance of the collection.

DATES: Comments are encouraged and will be accepted for 30 days until February 26, 2018.

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 Shelley S. Hyland, Statistician, Law Enforcement Statistics Unit, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: Shelley.Hyland@usdoj.gov; phone: 202-616-1706).

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 Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Reinstatement, with change, of a previously approved collection for which approval has expired.

(2) *The Title of the Form/Collection:* 2018 Census of State and Local Law Enforcement Agencies (CSLLEA).

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is CJ-38. The applicable component within the Department of Justice that is sponsoring this collection is the Bureau of Justice Statistics, Office of Justice Programs.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Respondents will include all publicly-funded state, county, local and tribal law enforcement agencies in the United States that employ the equivalent of at least one full-time sworn officer with general arrest powers. Both general purpose agencies (*i.e.*, any public agency with sworn officers whose patrol and enforcement responsibilities are primarily delimited by the boundaries of a municipal, county, or state government) and special purpose agencies (*e.g.*, tribal, campus law enforcement, transportation, natural resources, etc.) meeting the above description will be asked to respond.

Abstract: BJS has conducted the CSLLEA regularly since 1986. The 2018 CSLLEA will be the seventh administration. Historically, the CSLLEA generates an enumeration of all publically funded state, county, local and tribal law enforcement agencies operating in the United States. The CSLLEA provides complete personnel counts and an overview of the functions performed for approximately 20,000 law enforcement agencies operating nationally.

The 2018 CSLLEA collection involves two phases. In the first phase, BJS will cognitively test the revised instrument with 48 agencies based on agency type (*i.e.*, local and county police, sheriff's office, or special purpose) and size (*i.e.*, 100 or more full-time equivalent sworn officers or less than 100 full-time equivalent sworn officers). A maximum of 8 agencies of each type and size will participate in testing. BJS has reduced the number of items from the 2014 administration but has included additional items on limited sworn officers. Additionally, BJS will continue to refine the universe frame by verifying agency in-service status, contact information and de-duplicating agencies.

Pending positive results from the first phase, in the second phase, BJS will conduct the main data collection. The 2018 CSLLEA is designed to collect general information on state, county, local and tribal law enforcement agencies. The survey asks about the level of government that operates the agency; total operating budget; full-time and part-time personnel counts for fully sworn officers, limited sworn officers

and non-sworn employees; gender and primary job responsibility of full-time sworn officers; and the functions the agency performs on a regular or primary basis. Upon completion, the 2018 CSLLEA will serve as the sampling frame for future law enforcement surveys administered by BJS.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* For the cognitive testing, BJS is planning 48 agencies with an estimated total respondent burden of 90 minutes. For the full data collection, BJS estimates a maximum of 20,000 state, county, local and tribal law enforcement agencies with a respondent burden of about 45 minutes per agency, including the follow-up time.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated total respondent burden for the cognitive testing is 72 hours. The maximum respondent burden for the full data collection is approximately 15,000 burden hours. Therefore, total burden for both phases is approximately 15,072 burden hours.

If additional information is required 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, 3E.405A, Washington, DC 20530.

Dated: January 23, 2018.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2018-01410 Filed 1-25-18; 8:45 am]

BILLING CODE 4410-18-P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; YouthBuild (YB) Reporting System

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of Labor (DOL), Employment and Training Administration is soliciting comments concerning a proposed revision for the authority to conduct the information collection request (ICR) titled, "YouthBuild Reporting System." 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 March 27, 2018.

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 Jenn Smith by telephone at (202) 693-3597 (this is not a toll-free number), TTY at 1-877-889-5627, or by email at smith.jenn@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, Division of Youth Services, 200 Constitution Avenue NW, Room N4508, Washington, DC 20210; by email: smith.jenn@dol.gov; or by Fax: 202-693-3113.

FOR FURTHER INFORMATION CONTACT: Jenn Smith by telephone at (202) 693-3597 (this is not a toll-free number) or by email at smith.jenn@dol.gov.

SUPPLEMENTARY INFORMATION: The DOL, as part of continuing efforts to reduce paperwork and respondent burden, 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 OMB for final approval. This program helps to ensure 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 can be properly assessed.

The Department of Labor, Employment and Training Administration (ETA) proposes revising the reporting and recordkeeping requirements of the YouthBuild (YB) program. This reporting structure features standardized data collection for program participants through quarterly Management Information System (MIS) performance reports and Work Site Description and Housing Census report formats. All data collection and reporting is done by YouthBuild grantees.

The quarterly performance report (ETA-9136) includes aggregate and participant-level information on demographic characteristics, types of services received, placements, outcomes, and follow-up status. Specifically, these reports collect data on individuals who receive education, occupational skill training, leadership development services, and other

services essential to preparing at-risk youth for in-demand occupations through YouthBuild programs. There are no changes proposed for ETA-9136 in this information collection request package. The Work Site Description and Housing Census (ETA-9143) requests information on the proposed work sites for low-income or homeless individual or families on which YouthBuild participants will be trained and participate in construction skills activities. This form also requests annual information on the number of houses or apartments that were built or renovated each year and allows ETA to demonstrate on an annual basis the increase in affordable housing units supported by YouthBuild.

The accuracy, reliability, and comparability of program reports submitted by grantees using Federal funds are fundamental elements of good public administration and are necessary tools for maintaining and demonstrating system integrity. The use of a standard set of data elements, definitions, and specifications at all levels of the workforce system helps improve the quality of performance information that is received by ETA.

The Workforce Innovation and Opportunity Act (29 U.S.C. 3101) 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 the 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 1205-0464.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

The 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: REVISION.

Title of Collection: YouthBuild (YB) Reporting System.

Form: ETA-9136, ETA-9138, ETA-9143 Part A, ETA-9143 Part B, ETA-9143 Part C.

OMB Control Number: OMB 1205-0464.

Affected Public: Grantees.

Estimated Number of Respondents: 440.

Frequency: As necessary but at a minimum, quarterly.

Total Estimated Annual Responses: 8,330.

Estimated Average Time per

Response: 1.5 hours.

Estimated Total Annual Burden

Hours: 24,565 hours.

Total Estimated Annual Other Cost Burden: \$162,487.85.

Authority: 44 U.S.C. 3506(c)(2)(A).

Rosemary Lahasky,

Deputy Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2018-01333 Filed 1-25-18; 8:45 am]

BILLING CODE 4510-FT-P

OFFICE OF MANAGEMENT AND BUDGET

Notice; 2017 Statutory Pay-As-You-Go Act Annual Report

AGENCY: Office of Management and Budget (OMB).

ACTION: Notice.

SUMMARY: This report is being published as required by the Statutory Pay-As-You-Go (PAYGO) Act of 2010. The Act

requires that OMB issue an annual report and a sequestration order, if necessary.

FOR FURTHER INFORMATION CONTACT: Erin O'Brien. 202-395-3106.

SUPPLEMENTARY INFORMATION: This report can be found at <https://www.whitehouse.gov/omb/paygo/>.

Authority: 2 U.S.C. 934.

Kelly Kinneen,

Assistant Director for Budget.

This Report is being published pursuant to section 5 of the Statutory Pay-As-You-Go (PAYGO) Act of 2010, Public Law 111-139, 124 Stat. 8, 2 U.S.C. 934, which requires that OMB issue an annual PAYGO report, including a sequestration order if necessary, no later than 14 working days after the end of a congressional session.

This Report describes the budgetary effects of all PAYGO legislation enacted during the first session of the 115th Congress and presents the 5-year and 10-year PAYGO scorecards maintained by OMB. Because neither the 5-year nor 10-year scorecard shows a debit for the budget year, which for purposes of this Report is fiscal year 2018,¹ a sequestration order under subsection 5(b) of the PAYGO Act, 2 U.S.C. § 934(b) is not necessary.

During the first session of the 115th Congress, two laws were enacted with emergency requirements under section 4(g) of the PAYGO Act, 2 U.S.C. 933(g) that had PAYGO effects. Three laws had estimated budgetary effects on direct spending and revenues that were excluded from the calculations of the PAYGO scorecards due to provisions excluding all or part of the law from section 4(d) of the PAYGO Act, 2 U.S.C. 933(d).

I. PAYGO Legislation With Budgetary Effects

PAYGO legislation is authorizing legislation that affects direct spending or revenues, and appropriations legislation that affects direct spending in the years after the budget year or affects revenues in any year.² For a more complete description of the Statutory

¹ References to years on the PAYGO scorecards are to fiscal years.

² Provisions in appropriations acts that affect direct spending in the years after the budget year (also known as "outyears") or affect revenues in any year are considered to be budgetary effects for the purposes of the PAYGO scorecards except if the provisions produce outlay changes that net to zero over the current year, budget year, and the four subsequent years. As specified in section 3 of the PAYGO Act, off-budget effects are not counted as budgetary effects. Off-budget effects refer to effects on the Social Security trust funds (Old-Age and Survivors Insurance and Disability Insurance) and the Postal Service.

PAYGO Act, see Chapter 8, “Budget Concepts,” of the *Analytical Perspectives* volume of the 2018 President’s Budget, found on the website of the U.S. Government Printing Office (<https://www.gpo.gov/fdsys/pkg/BUDGET-2018-PER/pdf/BUDGET-2018-PER.pdf>).

The 5-year and 10-year PAYGO scorecards for each congressional session begin with the balances of costs or savings carried over from previous sessions and then tally the costs or savings of PAYGO laws enacted in the most recent session. The 5-year PAYGO scorecard for the first session of the 115th Congress began with balances of savings of \$3,579 million in 2018, \$3,604 million in 2019, and \$2,978 million in 2020, and with costs of \$478 million in 2021. The completed 5-year scorecard for the session shows that PAYGO legislation enacted during the session was estimated to have PAYGO budgetary effects that increased the deficit by an average of \$1,089 million each year from 2018 through 2022.³ These new costs on the scorecard decreased the balances of savings in each year on the 5-year scorecard from 2018 through 2020, and increased the balances of costs in 2021. The 5-year PAYGO window extended only through 2021 in the second session of the 114th Congress, so there were no 5-year scorecard balances in 2022 to carry over and the 5-year scorecard total is the average \$1,089 million cost from this session.

The 10-year PAYGO scorecard for the first session of the 115th Congress began with balances of savings of \$14,468 million in each year from 2018 to 2020, \$8,097 million in 2021, \$7,387 million in 2022, \$6,252 million in 2023, \$6,259 million in 2024, and \$4,738 million in 2025, and with costs of \$980 million in 2026. The completed 10-year scorecard for the session shows that PAYGO legislation for the session increased the deficit by an average of \$653 million each year from 2018 through 2027. These new costs decreased the balances of savings in each year on the 10-year

scorecard from 2018 through 2025, and increased the balances of costs in 2026. The 10-year PAYGO window extended only through 2026 in the second session of the 114th Congress, so there were no 10-year scorecard balances in 2027 to carry over and the 10-year scorecard total is the average \$653 million costs from this session.

In the first session of the 115th Congress, 28 laws were enacted that were determined to constitute PAYGO legislation. Of the 28 enacted PAYGO laws, 9 laws were estimated to have PAYGO budgetary effects (costs or savings) in excess of \$500,000 over one or both of the 5-year or 10-year PAYGO windows. These were:

- Consolidated Appropriations Act, 2017, Public Law 115–31;
- Countering America’s Adversaries Through Sanctions Act, Public Law 115–44;
- An Act to authorize appropriations and to appropriate amounts for the Veterans Choice Program of the Department of Veterans Affairs, to improve hiring authorities of the Department, to authorize major medical facility leases, and for other purposes, Public Law 115–46;
- Harry W. Colmery Veterans Educational Assistance Act of 2017, Public Law 115–48;
- Department of Veterans Affairs Expiring Authorities Act of 2017, Public Law 115–62;
- Disaster Tax Relief and Airport and Airway Extension Act of 2017, Public Law 115–63;
- Additional Supplemental Appropriations for Disaster Relief Requirements Act, 2017, Public Law 115–72;
- National Defense Authorization Act for Fiscal Year 2018, Public Law 115–91; and
- Western Oregon Tribal Fairness Act, Public Law 115–103.

In addition to the laws identified above, 19 laws enacted in this session were estimated to have negligible budgetary effects on the PAYGO scorecards—costs or savings of less than \$500,000 over both the 5-year and 10-year PAYGO windows.

II. Budgetary Effects Excluded From the Scorecard Balances

A. Legislation Designated as Emergency Requirements

As shown on the scorecards, two laws were enacted in the first session of the 115th Congress with an emergency

designation under the Statutory PAYGO Act, and that had PAYGO effects:

- Emergency Aid to American Survivors of Hurricanes Irma and Jose Overseas Act, Public Law 115–57; and
- Disaster Tax Relief and Airport and Airway Extension Act of 2017, Public Law 115–63.

The effects of the provisions in these laws that are designated as emergency requirements appear on the scorecard, but are subtracted before computing the scorecard totals.

Two additional laws included an emergency designation under the Statutory PAYGO Act, but OMB estimated that the designated portions of the laws did not have any PAYGO effects:

- Hurricanes Harvey, Irma, and Maria Education Relief Act of 2017, Public Law 115–64; and
- Additional Supplemental Appropriations for Disaster Relief Requirements Act, 2017, Public Law 115–72.

B. Statutory Provisions Excluding Legislation From the Scorecards

Three laws enacted in the first session of the 115th Congress had estimated budgetary effects on direct spending and revenues that were excluded from the calculations for the PAYGO scorecards due to provisions in law excluding all or part of the law from section 4(d) of the Statutory Pay-As-You-Go Act of 2010. One law, An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018, Public Law 115–97 (also referred to as H.R. 1, the Tax Cuts and Jobs Act), was excluded entirely from the scorecards by Section 5002 of Public Law 115–96.

In addition, budgetary effects in two laws were excluded by provisions excluding certain portions of those laws from the scorecards:

- Making further continuing appropriations for fiscal year 2017, and for other purposes, Public Law 115–30; and
- An Act to amend the Homeland Security Act of 2002 to require the Secretary of Homeland Security to issue Department of Homeland Security-wide guidance and develop training programs as part of the Department of Homeland Security Blue Campaign, and for other purposes, Public Law 115–96.

III. PAYGO Scorecards

³ As provided in section 4(d) of the PAYGO Act, 2 U.S.C. 933(d), budgetary effects on the PAYGO scorecards are based on congressional estimates for bills including a reference to a congressional estimate in the Congressional Record, and for which such a reference is indeed present in the Record. Absent such a congressional cost estimate, OMB is required to use its own estimate for the scorecard. None of the bills enacted during this session had such a congressional estimate and therefore OMB was required to provide an estimate for all PAYGO laws enacted during the session.

STATUTORY PAY-AS-YOU-GO SCORECARDS

[In millions of dollars, negative amounts portray decreases in deficits]

	2018	2019	2020	2021	2022					
First Session of the 115th Congress	1,089	1,089	1,089	1,089	1,089					
Balances from Previous Sessions	–3,579	–3,604	–2,978	478	0					
Five-year PAYGO Scorecard	–2,490	–2,515	–1,889	1,567	1,089					
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
First Session of the 115th Congress	653	653	653	653	653	653	653	653	653	653
Balances from Previous Sessions	–14,468	–14,468	–14,468	–8,097	–7,387	–6,252	–6,259	–4,738	980	0
Ten-year PAYGO Scorecard	–13,815	–13,815	–13,815	–7,444	–6,734	–5,999	–5,606	–4,085	1,633	653

IV. Sequestration Order

As shown on the scorecards, the budgetary effects of PAYGO legislation enacted in the first session of the 115th Congress, combined with the balances left on each scorecard, resulted in net savings on both the 5-year and the 10-year scorecard in the budget year, which is 2018 for the purposes of this Report. Because the costs for the budget year, as shown on the scorecards, do not exceed savings for the budget year, there is no “debit” on either scorecard under section 3 of the PAYGO Act, 2 U.S.C. 932, and there is no need for a sequestration order.⁴

The savings shown on the scorecards for 2018 will be removed from the scorecards that are used to record the budgetary effects of PAYGO legislation enacted in the second session of the 115th Congress. The totals shown in 2019 through 2027 will remain on the scorecards and will be used in determining whether a sequestration order will be necessary in the future. On the 5-year scorecard for the second session of the 115th Congress, 2019 and 2020 will show balances of savings. The years 2021 and 2022 will show balances of costs. On the 10-year scorecard, each year from 2019 to 2025 will show

balances of savings. The years 2026 and 2027 will show balances of costs.

[FR Doc. 2018–01319 Filed 1–25–18; 8:45 am]

BILLING CODE 3110–01–P

NATIONAL SCIENCE FOUNDATION

Astronomy and Astrophysics Advisory Committee; 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: Astronomy and Astrophysics Advisory Committee (#13883)

DATE AND TIME: February 27, 2018; 12:00 p.m.–4:00 p.m.

PLACE: National Science Foundation, 2415 Eisenhower Avenue, Room C2010, Alexandria, VA 22314.

TYPE OF MEETING: Open.

Attendance information for the meeting will be forthcoming on the website: <http://www.nsf.gov/mps/ast/aac.jsp>.

CONTACT PERSON: Dr. Christopher Davis, Program Director, Division of Astronomical Sciences, Suite W 9136, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: 703–292–4910.

PURPOSE OF MEETING: To provide advice and recommendations to the National Science Foundation (NSF), the National Aeronautics and Space Administration (NASA) and the U.S. Department of Energy (DOE) on issues within the field of astronomy and astrophysics that are

of mutual interest and concern to the agencies.

AGENDA: To provide updates on Agency activities and to discuss the Committee’s draft annual report due 15 March 2018.

Dated: January 23, 2018.

Crystal Robinson,
Committee Management Officer.

[FR Doc. 2018–01411 Filed 1–25–18; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0001]

Sunshine Act Meeting Notice

DATE: Weeks of January 29, February 5, 12, 19, 26, March 5, 2018.

PLACE: Commissioners’ Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of January 29, 2018

There are no meetings scheduled for the week of January 29, 2018.

Week of February 5, 2018—Tentative

Thursday, February 8, 2018

9:00 a.m. Discussion of Potential Changes to the 10 CFR 2.206 Enforcement Petition Process (Public Meeting), (Contact: Doug Broadus: 301–415–8124)

This meeting will be webcast live at the Web address—<http://www.nrc.gov/>.

⁴ Joint Committee reductions for 2018 were calculated and ordered in a separate report and are not affected by this determination. See, https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/sequestration_reports/FY_2018_Sequestration_Update_8-18-17.pdf

Week of February 12, 2018—Tentative

There are no meetings scheduled for the week of February 12, 2018.

Week of February 19, 2018—Tentative

There are no meetings scheduled for the week of February 19, 2018.

Week of February 26, 2018—Tentative

There are no meetings scheduled for the week of February 26, 2018.

Week of March 5, 2018—Tentative

Thursday, March 8, 2018

10:00 a.m. Meeting with the Advisory Committee on the Medical Uses of Isotopes (Public Meeting), (Contact: Sophie Holiday: 301-415-7865)

This meeting will be webcast live at the Web address—<http://www.nrc.gov/>.

* * * * *

The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301-415-0681 or via email at Denise.McGovern@nrc.gov.

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The NRC Commission Meeting Schedule can be found on the internet at: <http://www.nrc.gov/public-involve/public-meetings/schedule.html>.

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g., braille, large print), please notify Kimberly Meyer-Chambers, NRC Disability Program Manager, at 301-287-0739, by videophone at 240-428-3217, or by email at Kimberly.Meyer-Chambers@nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301-415-1969), or email Patricia.Jimenez@nrc.gov.

Dated: January 24, 2018.

Denise L. McGovern,
Policy Coordinator, Office of the Secretary.
[FR Doc. 2018-01663 Filed 1-24-18; 4:15 pm]

BILLING CODE 7590-01-P

POSTAL SERVICE**Privacy Act of 1974; System of Records**

AGENCY: Postal Service™.

ACTION: Notice of revisions to existing systems of records.

SUMMARY: The United States Postal Service® (Postal Service) is proposing to revise the Customer Privacy Act Systems of Records (SOR). These changes are being made to permit disclosure to the National Labor Relations Board (NLRB) in response to its request for investigative purposes, to the extent that the requested information is relevant and necessary.

DATES: These revisions will become effective without further notice on February 26, 2018, unless comments received on or before that date result in a contrary determination.

ADDRESSES: Comments may be mailed or delivered to the Privacy and Records Management Office, United States Postal Service, 475 L'Enfant Plaza SW, Room 1P830, Washington, DC 20260-1101. Copies of all written comments will be available at this address for public inspection and photocopying between 8 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Janine Castorina, Chief Privacy and Records Management Officer, Privacy and Records Management Office, 202-268-3069 or privacy@usps.gov.

SUPPLEMENTARY INFORMATION: This notice is in accordance with the Privacy Act requirement that agencies publish their systems of records in the **Federal Register** when there is a revision, change, or addition, or when the agency establishes a new system of records. The Postal Service™ has determined that three Customer Privacy Act Systems of Records should be revised to modify routine uses of records maintained in the system, including categories of users and the purposes of such uses.

I. Background

The Postal Service will provide the NLRB with necessary information so that it can effectively carry out its statutory duty to investigate and police alleged violations of the National Labor Relations Act.

II. Rationale for Changes to USPS Privacy Act Systems of Records

The following USPS Privacy Act System of Records are being revised to permit disclosure of records to the NLRB in response to its request for investigative purposes, to the extent that

the requested information is relevant and necessary:

a. USPS 100.000 System Name: General Personnel Records.

b. USPS 100.900 System Name: Employee Inquiry, Complaint, and Investigative Records.

c. USPS 200.000 System Name: Labor Relations Records.

III. Description of Changes to Systems of Records

Pursuant to 5 U.S.C. 552a(e)(11), interested persons are invited to submit written data, views, or arguments on this proposal. A report of the proposed revisions has been sent to Congress and to the Office of Management and Budget for their evaluations. The Postal Service does not expect these amended systems of records to have any adverse effect on individual privacy rights. The affected systems are as follows:

USPS 100.000**SYSTEM NAME:**

General Personnel Records.

* * * * *

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

[CHANGE TO READ]

* * * * *

c. Records may be disclosed to the National Labor Relations Board (NLRB) in response to its request for investigative purposes, to the extent that the requested information is relevant and necessary.

USPS 100.900**SYSTEM NAME:**

Employee Inquiry, Complaint, and Investigative Records.

* * * * *

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

[CHANGE TO READ]

* * * * *

Standard routine uses 1. through 9. apply. In addition:

a. Records may be disclosed to the National Labor Relations Board (NLRB) in response to its request for investigative purposes, to the extent that the requested information is relevant and necessary.

USPS 200.000**SYSTEM NAME:**

Labor Relations Records.

* * * * *

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

[CHANGE TO READ]

* * * * *

Standard routine uses 1. through 9. apply. In addition:

a. Records may be disclosed to the National Labor Relations Board (NLRB) in response to its request for investigative purposes, to the extent that the requested information is relevant and necessary.

Ruth B. Stevenson,

Attorney, Federal Compliance.

[FR Doc. 2018-01466 Filed 1-25-18; 8:45 am]

BILLING CODE 7710-12-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.

1. *Title and purpose of information collection:* Railroad Service and Compensation Reports/System Access Application; OMB 3220-0008.

Under Section 9 of the Railroad Retirement Act (RRA) and Section 6 of the Railroad Unemployment Insurance Act (RUIA), the Railroad Retirement Board (RRB) maintains for each railroad employee, a record of compensation paid to that employee by all railroad employers for whom the employee worked after 1936. This record, which is used by the RRB to determine eligibility for, and amount of, benefits due under the laws it administers, is conclusive as to the amount of compensation paid to an employee during such period(s) covered by the report(s) of the compensation by the employee's railroad employer(s), except in cases when an employee files a protest pertaining to his or her reported compensation within the statute of limitations cited in Section 9 of the RRA and Section 6 of the RUIA.

To enable the RRB to establish and maintain the record of compensation, employers are required to file with the RRB, reports of their employees' compensation, in such manner and form and at such times as the RRB prescribes. Railroad employers' reports and responsibilities are prescribed in 20 CFR 209. The RRB currently utilizes Form BA-3, *Annual Report of Creditable Compensation*, and Form BA-4, *Report of Creditable Compensation Adjustments*, to secure the required information from railroad employers. Form BA-3 provides the RRB with information regarding annual creditable service and compensation for each

individual who worked for a railroad employer covered by the RRA and RUIA in a given year. Form BA-4 provides for the adjustment of any previously submitted reports and also the opportunity to provide any service and compensation that had been previously omitted. Requirements specific to Forms BA-3 and BA-4 are prescribed in 20 CFR 209.8 and 209.9.

Employers currently have the option of submitting BA-3 and BA-4 reports electronically by CD-ROM, secure Email, File Transfer Protocol (FTP), or online via the RRB's Employer Reporting System (ERS).

The information collection also includes RRB Form BA-12, Application for Employer Reporting internet Access, and Form G-440, Report Specifications Sheet. Form BA-12 is completed by railroad employers to obtain system access to ERS. Once access is obtained, authorized employees may submit reporting forms online to the RRB. The form determines what degree of access (view/only, data entry/modification or approval/submission) is appropriate for that employee. It is also used to terminate an employee's access to ERS. Form G-440, Report Specifications Sheet, serves as a certification document for Forms BA-3 and BA-4 as well as other RRB employer reporting forms (Form BA-6a, BA-6 Address Report (OMB 3220-0005), Form BA-9, Report of Separation Allowance or Severance Pay (OMB 3220-0173) and Form BA-11, Report of Gross Earnings (OMB 3220-0132)). It records the type of medium the report was submitted on, and serves as a summary recapitulation sheet for reports filed on paper. The RRB proposes minor non-burden impacting changes to Form BA-12 and G-440.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Reporting	Responses	Time (minutes) ¹	Burden (hours)
BA-3:			
Electronic Media ²	96	46.25 (2,775 min)	4,440
BA-3 (Internet)	617	46.25 (2,775 min)	28,536
Total BA-3	713	32,976
BA-4:			
Paper	40	1.25 (75 min)	50
Electronic Media ²	345	1.00 (60 min)	345
BA-4 (Internet)	3,912	.33 (20 min)	1,304
Total BA-4	4,297	1,699
BA-12:			
Initial Access	295	.33 (20 min)	98
Access Termination	38	.166 (10 min)	7
Total BA-12	333	105
G-440 (certification):			
Form BA-3 (zero employees)	19	.25 (15 min)	5
Form BA-11 (zero employees)	60	.25 (15 min)	15

ESTIMATE OF ANNUAL RESPONDENT BURDEN—Continued

Reporting	Responses	Time (minutes) ¹	Burden (hours)
Paper forms (without recap)	7	.25 (15 min)	1
Electronic transactions	94	.50 (30 min)	47
BA-3 and BA-4 (with recap)	125	1.25 (75 min)	156
Total G-440	305	224
Grand Total	5,648	35,074

2. Title and purpose of information collection: Application for Benefits Due But Unpaid at Death; OMB 3220-0055.

Under Section 2(g) of the Railroad Unemployment Insurance Act, benefits that accrued but were not paid because of the death of the employee shall be paid to the same individual(s) to whom

benefits are payable under Section 6(a)(1) of the Railroad Retirement Act. The provisions relating to the payment of such benefits are prescribed in 20 CFR 325.5 and 20 CFR 335.5.

The RRB provides Form UI-63, Application for Benefits Due But Unpaid at Death, to those applying for

the accrued sickness or unemployment benefits unpaid at the death of the employee and for obtaining the information needed to identify the proper payee. One response is requested of each respondent. Completion is required to obtain a benefit. The RRB proposes no changes to Form UI-63.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
UI-63	15	7	2

3. Title and purpose of information collection: Medicare; OMB 3220-0082.

Under Section 7(d) of the Railroad Retirement Act (RRA), the Railroad Retirement Board (RRB) administers the Medicare program for persons covered by the railroad retirement system. The RRB uses Form AA-6, Employee Application for Medicare; Form AA-7, Spouse/Divorced Spouse Application for Medicare; and Form AA-8, Widow/Widower Application for Medicare; to obtain the information needed to

determine whether individuals who have not yet filed for benefits under the RRA are qualified for Medicare payments provided under Title XVIII of the Social Security Act.

Further, in order to determine if a qualified railroad retirement beneficiary who is claiming supplementary medical insurance coverage under Medicare is entitled to a Special Enrollment Period (SEP) and/or premium surcharge relief because of coverage under an Employer Group Health Plan (EGHP), the RRB

needs to obtain information regarding the claimant's EGHP coverage, if any. The RRB uses Form RL-311-F, Evidence of Coverage Under an Employer Group Health Plan, to obtain the basic information needed to establish EGHP coverage for a qualified railroad retirement beneficiary.

Completion of the forms is required to obtain a benefit. One response is requested of each respondent. The RRB proposes no changes to the forms in the collection.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
AA-6	180	8	24
AA-7	50	8	7
AA-8	10	8	1
RL-311-F	2,000	10	333
Total	2,240	365

4. Evidence for Application of Overall Minimum: OMB 3220-0083.

Under Section 3(f)(3) of the Railroad Retirement Act (RRA), the total monthly benefits payable to a railroad employee and his/her family are guaranteed to be no less than the amount which would be payable if the employee's railroad service had been covered by the Social Security Act. This is referred to as the Social Security Overall Minimum

Guarantee, which is prescribed in 20 CFR 229. To administer this provision, the Railroad Retirement Board (RRB) requires information about a retired employee's spouse and child(ren) who would not be eligible for benefits under the RRA but would be eligible for benefits under the Social Security Act if the employee's railroad service had been covered by that Act. The RRB

obtains the required information by the use of Forms G-319, Statement Regarding Family and Earnings for Special Guaranty Computation, and G-320, Student Questionnaire for Special Guaranty Computation. One response is required of each respondent. Completion is required to obtain or retain benefits. The RRB proposes no changes to Forms G-319 and G-320.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
G-319 (completed by the employee):			
With assistance	5	26	2
Without assistance	230	55	211
G-319 (completed by spouse):			
With assistance	5	30	2
Without assistance	10	60	10
G-320:			
(Age 18 at Special Guaranty Begin Date or Special Guaranty Age 18 Attainments)	30	15	7
G-320:			
(Student Monitoring done in Sept., March and at end of school year)	10	15	2
Total	290	234

5. Title and purpose of information collection: Request to Non-Railroad Employer for Information About Annuitant's Work and Earnings; OMB 3220-0107.

Under Section 2 of the Railroad Retirement Act (RRA), a railroad employee's retirement annuity or an annuity paid to the spouse of a railroad employee is subject to work deductions in the Tier II component of the annuity and any employee supplemental annuity for any month in which the annuitant works for a Last Pre-

Retirement Non-Railroad Employer (LPE). The LPE is defined as the last person, company, or institution, other than a railroad employer, that employed an employee or spouse annuitant. In addition, the employee, spouse, or divorced spouse Tier I annuity benefit is subject to work deductions under Section 2(f)(1) of the RRA for earnings from any non-railroad employer that are over the annual exempt amount. The regulations pertaining to non-payment of annuities by reason of work and LPE

are contained in 20 CFR 230.1 and 230.2.

The RRB utilizes Form RL-231-F, Request to Non-Railroad Employer for Information About Annuitant's Work and Earnings, to obtain the information needed to determine if a work deduction should be applied because an annuitant worked in non-railroad employment after the annuity beginning date. One response is requested of each respondent. Completion is voluntary. The RRB proposes no changes to Form RL-231-F.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
RL-231-F	300	30	150

6. Title and purpose of information collection: Gross Earnings Report; OMB 3220-0132. In order to carry out the financial interchange provisions of section 7(c)(2) of the Railroad Retirement Act (RRA), the RRB obtains annually from railroad employers the gross earnings for their employees on a one-percent basis, i.e., 1% of each employer's railroad employees. The gross earnings sample is based on the earnings of employees whose social security numbers end with the digits "30." The gross earnings are used to compute payroll taxes under the financial interchange.

The gross earnings information is essential in determining the tax amounts involved in the financial

interchange with the Social Security Administration and Centers for Medicare & Medicaid Services. Besides being necessary for current financial interchange calculations, the gross earnings file tabulations are also an integral part of the data needed to estimate future tax income and corresponding financial interchange amounts. These estimates are made for internal use and to satisfy requests from other government agencies and interested groups. In addition, cash flow projections of the social security equivalent benefit account, railroad retirement account and cost estimates made for proposed amendments to laws administered by the RRB are dependent

on input developed from the information collection.

The RRB utilizes Form BA-11 to obtain gross earnings information from railroad employers. Employers have the option of preparing and submitting BA-11 reports online via the RRB's Employer Reporting System or on paper (or in like format) on magnetic tape cartridges, by File Transfer Protocol (FTP), or secure Email. The online BA-11 includes the option to file a "negative report" (no employees, or no employees with the digits "30"). Completion is mandatory. One response is requested of each respondent. The RRB proposes no changes to Form BA-11.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
BA-11 File Transfer Protocol	7	300 (5 hours)	35
BA-11 CD-ROM	5	30	2
BA-11 secure Email	5	30	2
BA-11 (Internet)—Positive	137	30	68

ESTIMATE OF ANNUAL RESPONDENT BURDEN—Continued

Form No.	Annual responses	Time (minutes)	Burden (hours)
BA-11 (Internet)—Negative	329	15	82
Total	483	189

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Dana Hickman at (312) 751-4981 or Dana.Hickman@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 D. Foster,
Clearance Officer.

[FR Doc. 2018-01347 Filed 1-25-18; 8:45 am]

BILLING CODE 7905-01-P

RAILROAD RETIREMENT BOARD**Agency Forms Submitted for OMB Review, Request for Comments**

Summary: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Railroad Retirement Board (RRB) is forwarding an Information Collection Request (ICR) to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB). Our ICR describes the information we seek to collect from the public. Review and approval by OIRA ensures that we impose appropriate paperwork burdens.

The RRB invites comments on the proposed collection of information to determine (1) the practical utility of the collection; (2) the accuracy of the estimated burden of the collection; (3) ways to enhance the quality, utility, and clarity of the information that is the

subject of collection; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology. Comments to the RRB or OIRA must contain the OMB control number of the ICR. For proper consideration of your comments, it is best if the RRB and OIRA receive them within 30 days of the publication date.

Title and purpose of information collection: Student Beneficiary Monitoring; OMB 3220-0123. Under provisions of the Railroad Retirement Act (RRA), there are two types of benefit payments that are based on the status of a child being in full-time elementary or secondary school attendance at age 18-19: (1) A survivor child's annuity benefit under Section 2(d)(1)(iii) and (2) an increase in the employee retirement annuity under the Special Guaranty computation as prescribed in section 3(f)(2) and 20 CFR 229.

The survivor student annuity is usually paid by direct deposit to a financial institution either into the student's checking or savings account or into a joint bank account with a parent. The requirements for eligibility as a student are prescribed in 20 CFR 216.74, and include students in independent study and home schooling.

To help determine if a child is entitled to student benefits, the RRB requires evidence of full-time school attendance. This evidence is acquired through the RRB's student monitoring program, which utilizes the following forms. Form G-315, Student Questionnaire, obtains certification of a student's full-time school attendance as well as information on the student's marital status, social security benefits,

and employment, which are needed to determine entitlement or continued entitlement to benefits under the RRA. Form G-315A, Statement of School Official, is used to obtain, from a school, verification of a student's full-time attendance when the student fails to return a monitoring Form G-315. Form G-315A.1, School Official's Notice of Cessation of Full-Time School Attendance, is used by a school to notify the RRB that a student has ceased full-time school attendance.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (82 FR 55426 on November 21, 2017) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Student Beneficiary Monitoring.

OMB Control Number: 3220-0123.

Form(s) submitted: G-315, G-315a, G-315a.1.

Type of request: Extension without change of a currently approved collection.

Affected public: Individuals or Households.

Abstract: Under the Railroad Retirement Act (RRA), a student benefit is not payable if the student ceases full-time school attendance, marries, works in the railroad industry, has excessive earnings or attains the upper age limit under the RRA. The report obtains information to be used to determine if benefits should cease or be reduced.

Changes proposed: The RRB proposes no changes to the forms in this collection.

The burden estimate for the ICR is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
G-315	860	15	215
G-315a	20	3	1
G-315a.1	20	2	1
Total	900	217

Additional Information or Comments: Copies of the forms and supporting documents can be obtained from Dana

Hickman at (312) 751-4981 or Dana.Hickman@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 Brian.Foster@rrb.gov and to the OMB Desk Officer for the RRB,

Fax: 202-395-6974, Email address:
OIRA_Submission@omb.eop.gov.

Brian D. Foster,
Clearance Officer.

[FR Doc. 2018-01383 Filed 1-25-18; 8:45 am]

BILLING CODE 7905-01-P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Performance Review Board Membership

AGENCY: Office of Science and Technology Policy.

ACTION: Notice.

SUMMARY: The Office of Science and Technology Policy publishes the names of the members selected to serve on its SES Performance Review Board (PRB).

DATES: Membership is applicable on January 22, 2018.

FOR FURTHER INFORMATION CONTACT: Ms. Stacy L. Murphy, Operations Manager, Office of Science and Technology Policy, 1650 Pennsylvania Ave. NW, Washington, DC 20504. Telephone 202-456-6123.

SUPPLEMENTARY INFORMATION: Section 4314(c) of Title 5, U.S.C. requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more PRBs. The purpose of this PRB is to review and make recommendations concerning proposed performance appraisals, ratings, bonuses, pay adjustments, and other appropriate personnel actions for incumbents of the SES positions. The Board shall consist of at least three members and more than half of the members shall consist of career appointees. The names and titles of the PRB members are as follows:

Martha M. Gagné, Deputy Associate Director, Management and Administration, Office of National Drug Council Policy;

Jon E. Rice, Associate Director, Office of Policy, Research, and Budget, Office of National Drug Council Policy;

Barbara A. Menard, Chief, Health, Education, Veterans and Social Programs, Office of Management and Budget;

Fred L. Ames, Assistant United States Trade Representative for Administration, United States Trade Representative.

Applicability Date: Membership is applicable on the date of this notice.

Ted Wackler,
Deputy Chief of Staff and Assistant Director.

[FR Doc. 2018-01331 Filed 1-25-18; 8:45 am]

BILLING CODE 3270-F8-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82543; File No. SR-OCC-2018-003]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify OCC's Rules Regarding the Exercise Procedures for Certain Options on Futures

January 19, 2018.

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 January 11, 2018, The Options Clearing Corporation ("OCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by OCC. OCC filed the proposed rule change pursuant to Section 19(b)(3)(A)³ of the Act and Rule 19b-4(f)(4)(ii)⁴ thereunder so that the proposal was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

This proposed rule change by OCC concerns modifications to OCC's Rules regarding the exercise procedures for certain options on futures in order to conform to changes proposed by Nasdaq Futures, Inc. ("NFX"), a futures market for which OCC clears such contracts. The proposed changes to OCC's Rules can be found in Exhibit 5 to the filing. All terms with initial capitalization that are not otherwise defined herein have the same meaning as set forth in the By-Laws and Rules.⁵

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC 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. OCC 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*

(1) Purpose

The purpose of this proposed rule change is to amend OCC's Rules to permit a futures market that lists certain options on futures to instruct OCC to: (1) Eliminate a Clearing Member's ability to provide contrary instructions with respect to such futures options, and (2) permit automatic exercise of futures options that are call options and that settle at exactly the strike price for the option (*i.e.*, an "at-the-money" futures option). These amendments to OCC's Rules would accommodate certain corresponding amendments to the rules of NFX, for which OCC clears relevant futures option contracts, and would not apply to any options on security futures to the extent OCC clears such products in the future.⁶

Contrary Instructions

NFX has proposed to eliminate the ability of the holders of certain futures options contracts to provide "contrary instructions" or "contrary exercises" to the futures markets with respect to such contracts.⁷ *NFX has advised OCC that the New York Mercantile Exchange, Inc. ("NYMEX") has already made comparable changes to its rules for certain comparable options traded on NYMEX based on market feedback.⁸ NFX would like to replicate these changes for the comparable options contracts traded on NFX, none of which are options on security futures.*

A contrary instruction allows an option holder to exercise an "out-of-the-money" option to receive the underlying futures contract or to abandon an "in-the-money" option. Existing OCC Rule 1305 governs the exercise procedures for American and European-styled options on futures cleared by OCC that settle into the underlying futures contract. Subparagraph (c) of Rule 1305 provides

⁶ Options on security futures currently do not trade on the exchange for which OCC clears security futures. The proposed rule change would not apply to any securities, but rather futures products (*i.e.*, options on futures that are not security futures) that are subject to the exclusive jurisdiction of the Commodity Futures Trading Commission ("CFTC"). See *infra* note 16.

⁷ See SR-NFX-2017-56, filed December 15, 2017 with the CFTC.

⁸ See NYMEX Submission No. 17-272 filed July 21, 2017 with the CFTC. The filing also amended the rules of the Commodity Exchange, Inc. ("COMEX") to make comparable changes for certain options traded on COMEX.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4(f)(4)(ii).

⁵ OCC's By-Laws and Rules can be found on OCC's public website: <http://optionsclearing.com/about/publications/bylaws.jsp>.

for the automatic exercise of such options that are in-the-money at expiration by “such threshold amount as [OCC] may from time to time establish with respect to particular classes of options,” unless the Clearing Member instructs OCC not to exercise such in-the-money options. The provision also incorporates by reference certain operational aspects of the exercise-at-expiration procedures for listed options found in OCC Rule 805. Neither Rule 1305 nor Rule 805 provide a futures market with the ability to limit contrary instructions. Consequently, OCC proposes to add a new paragraph (d) to Rule 1305 that would provide futures markets with this ability in order to accommodate NFX’s proposal to prohibit the use of contrary instructions. The proposed ability would not apply, however, to options on security futures cleared by OCC to the extent OCC clears such products in the future.

At-the-Money Options

Existing Rules 1305 and 805 are silent on what happens to options that expire at-the-money. By specifying what happens to options that expire in-the-money (*i.e.*, automatic exercise), OCC’s Rules indicate that options expiring at-the-money would be treated as if they were out-of-the-money and not automatically exercised, and therefore the holders would not automatically buy (or sell) futures contracts or equity securities at the strike price. NFX has proposed to amend its own rules regarding the treatment of certain at-the-money options. In order to accommodate these proposed changes at NFX, OCC proposes to add a new paragraph (e) to Rule 1305, which would permit a futures market to instruct OCC that futures options that are call options and settle at-the-money should be treated as if they settled in-the-money and futures options that are put options and settle at-the-money should be treated as if they settled out-of-the-money. However, the proposed ability would not apply to options on security futures that are cleared by OCC to the extent OCC clears such products in the future. Therefore, in the case of a call option the holder of the option would automatically buy the underlying futures contract at the option strike price, and in the case of a put option the holder would not automatically sell the underlying futures contract at the option strike price.

Timing of Implementation

OCC proposes that the proposed amendments to Rule 1305 would apply to any futures option for which a futures market has instructed OCC to apply the

exercise procedures specified in Rules 1305(d) and/or (e).

(2) Statutory Basis

Section 17A(b)(3)(F) of the Act,⁹ requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities and derivatives transactions, to foster cooperation and coordination with persons engaged in clearance and settlement, and, in general, to protect investors and the public interest. OCC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act¹⁰ and the rules and regulations thereunder, because it would grant the futures markets for which OCC clears futures options contracts the ability to coordinate OCC’s exercise procedures with the futures market’s treatment of at-the-money options and to prohibit the use of contrary instructions, thereby promoting the prompt and accurate clearance and settlement of securities and derivatives transactions, fostering cooperation and coordination with persons engaged in clearance and settlement, and, in general, protecting investors and the public interest.

Rule 17Ad–22(e)(21)¹¹ requires that a covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to, in part, be efficient and effective in meeting the requirements of its participants and the markets it serves. OCC believes that granting futures markets, like NFX, this flexibility would encourage efficiency and coordination across the market as a whole and reduce potential sources of operational risk for market participants. A lack of conformity in futures option contract terms across different futures markets could reduce efficiency and pose operational risks to market participants and would require them to undertake additional monitoring. OCC therefore believes that the proposed rule change is reasonably designed to comply with the requirements of Rule 17Ad–22(e)(21).¹²

The proposed rule change is not inconsistent with the existing rules of OCC, including any other rules proposed to be amended.

(B) Clearing Agency’s Statement on Burden on Competition

Section 17A(b)(3)(I) of the Act¹³ requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the Act. OCC does not believe that the proposed rule change would impact or impose any burden on competition. This proposed rule change would not inhibit access to OCC’s services or disadvantage or favor any particular user in relationship to another, and it will be applied uniformly to all Clearing Members. The proposed rule change is intended to accommodate NFX’s proposed rule change, which is designed to bring the terms of the futures options contracts listed by NFX into conformity with those listed by other futures markets. Accommodating such a change would help promote a level playing field among market participants trading futures options by ensuring that such contracts could have identical terms. For the foregoing reasons, OCC believes the proposed rule change is in the public interest, would be consistent with the requirements of the Act applicable to clearing agencies, and would not impact or impose a burden on competition.

(C) Clearing Agency’s Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments on the proposed rule change were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A) of the Act,¹⁴ and Rule 19b–4(f)(4)(ii) thereunder,¹⁵ the proposed rule change is filed for immediate effectiveness because it effects a change in an existing service of OCC that (i) primarily affects the clearing operations of OCC with respect to products that are not securities, *i.e.*, options on futures that are not security futures,¹⁶ and (ii) does

¹³ 15 U.S.C. 78q–1(b)(3)(I).

¹⁴ 15 U.S.C. 78s(b)(3)(A).

¹⁵ 17 CFR 240.19b–4(f)(4)(ii).

¹⁶ Section 3(a)(10) of the Act defines a “security” as “any note, stock, treasury stock, security future, security-based swap, bond, debenture, certificate of interest or participation in any profit-sharing agreement or in any oil, gas, or other mineral royalty or lease, any collateral-trust certificate, preorganization certificate or subscription, transferable share, investment contract, voting-trust

Continued

⁹ 15 U.S.C. 78q–1(b)(3)(F).

¹⁰ *Id.*

¹¹ 17 CFR 240.17Ad–22(e)(21).

¹² *Id.*

not significantly affect any securities clearing operations of OCC or any rights or obligations of OCC with respect to securities clearing or persons using such securities clearing services.

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.¹⁷

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-OCC-2018-003 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-OCC-2018-003. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use

certificate, certificate of deposit for a security, any put, call, straddle, option, or privilege on any security, certificate of deposit, or group or index of securities (including any interest therein or based on the value thereof), or any put, call, straddle, option, or privilege entered into on a national securities exchange relating to foreign currency, or, in general, any instrument commonly known as a 'security'; or any certificate of interest or participation in, temporary or interim certificate for, receipt for, or warrant or right to subscribe to or purchase, any of the foregoing; but shall not include currency or any note, draft, bill of exchange, or banker's acceptance which has a maturity at the time of issuance of not exceeding nine months, exclusive of days of grace, or any renewal thereof the maturity of which is likewise limited." 15 U.S.C. 77b(a)(1). Section 3(a)(55) of the Exchange Act defines "security future" as "a contract of sale for future delivery of a single security or of a narrow-based security index, including any interest therein or based on the value thereof, except an exempted security." 15 U.S.C. 78c(a)(55). An option on a futures contract that is not a security future does not meet the definition of "security" and therefore is a product that is subject to the exclusive jurisdiction of the CFTC.

¹⁷ Notwithstanding its immediate effectiveness, implementation of this rule change will be delayed until this change is deemed certified under CFTC Rule 40.6.

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 OCC and on OCC's website at <https://www.theocc.com/about/publications/bylaws.jsp>.

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-OCC-2018-003 and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-01358 Filed 1-25-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82537; File No. SR-MRX-2018-01]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees To Introduce a New Pricing Model

January 19, 2018.

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 January 4, 2018, Nasdaq MRX, LLC ("MRX" or

"Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Schedule of Fees to introduce a new pricing model on MRX that is designed to reward members that bring order flow to the Exchange and thereby increase liquidity and trading opportunities for all members.

The text of the proposed rule change is available on the Exchange's website at <http://nasdaqmrxcchwallstreet.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

The purpose of the proposed rule change is to amend the Schedule of Fees to introduce a new pricing model on MRX that is designed to reward members that bring order flow to the Exchange and thereby increase liquidity and trading opportunities for all members. The Exchange believes that the proposed pricing model will encourage additional order flow to be sent to the Exchange, and contribute to a more active and quality market in MRX-listed options to the benefit of all market participants that trade on the Exchange.

I. Member Volume Program

Currently, the Exchange operates using a pricing schedule that rewards members that execute a higher average

¹⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

daily volume (“ADV”) of order flow on the Exchange by providing tiered rebates and fee discounts to market participants. Specifically, under the Member Volume Program (“MVP”), members can qualify for higher tiers based on Total Affiliated³ and/or Appointed⁴ Priority Customer⁵ ADV as follows: 0 to 19,999 contracts (Tier 1), 20,000 to 39,999 contracts (Tier 2), 40,000 to 59,999 contracts (Tier 3), 60,000 to 79,999 contracts (Tier 4), and 80,000 or more contracts (Tier 5).⁶

Based on the tier achieved, the Exchange provides tiered rebates to Priority Customer orders and tiered fee discounts to Market Maker⁷ orders. In particular, in both Penny Symbols and Non-Penny Symbols, Priority Customer orders are provided a rebate that is \$0.05 per contract (Tier 1), \$0.10 per contract (Tier 2), \$0.15 per contract (Tier 3), \$0.21 per contract (Tier 4), and \$0.24 per contract (Tier 5); and Market Maker orders are charged a fee that is

\$0.25 per contract (Tier 1), \$0.22 per contract (Tier 2), \$0.18 per contract (Tier 3), \$0.15 per contract (Tier 4), and \$0.10 per contract (Tier 5).⁸ Regardless of the tier achieved, Non-Nasdaq MRX Market Makers,⁹ Firm Proprietary,¹⁰ Broker-Dealer,¹¹ and Professional Customer¹² orders pay a flat fee that is \$0.47 per contract in Penny Symbols and \$0.90 per contract in Non-Penny Symbols.

The Exchange now proposes to eliminate the MVP structure¹³ and introduce a new pricing model that the Exchange believes will encourage members to bring more order flow to the Exchange. Specifically, the Exchange proposes to adopt a maker/taker fee model where all market participants are charged a fee (or are eligible for free executions) with potentially discounted fees based on ADV, whether the market participant is adding or removing liquidity, and whether both sides of the transaction belong to a member and its affiliated or appointed members.

With the proposed changes to the pricing model, the Exchange proposes to replace the current MVP tiers with a simple two tier structure based on Total Affiliated and/or Appointed Member ADV. Specifically, members would be able to qualify for higher tiers based on Total Affiliated and/or Appointed Member ADV as follows: 0 to 49,999 contracts (Tier 1), and 50,000 or more contracts (Tier 2). In order to attract order flow from all market participants, the Total Affiliated Member ADV category includes all volume executed on the Exchange in all symbols and order types, rather than only Priority Customer volume.¹⁴ The Exchange will

also continue to permit members to designate Nasdaq MRX Appointed Market Makers and Nasdaq MRX Appointed Order Flow Providers, and will aggregate order flow based on that designation in determining the member's tier. The Exchange already has language in its Schedule of Fees about designating Nasdaq MRX Appointed Market Makers and Nasdaq MRX Appointed Order Flow Providers and this language will remain a part of the Schedule of Fees.¹⁵

With respect to pricing, Market Maker orders would be charged a maker fee that is \$0.20 per contract for Tier 1 and \$0.00 per contract for Tier 2 in both Penny and Non-Penny Symbols, and a taker fee that is \$0.50 per contract for Penny Symbols and \$0.90 per contract for Non-Penny Symbols, regardless of the tier achieved.¹⁶ In addition, as an incentive for bringing order flow to the Exchange, Market Maker orders that take liquidity would also be eligible for ADV-based fee discounts in both Penny and Non-Penny Symbols when trading with Priority Customer orders entered by an affiliated or appointed member. The discounted fee would be \$0.05 per contract if the member has a Total Affiliated and/or Appointed Priority Customer ADV of 5,000 contracts or more, or \$0.00 per contract if the member has a Total Affiliated and/or Appointed Priority Customer ADV of 50,000 contracts or more. Regardless of the member's tier, Non-Nasdaq MRX Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders would pay a fee in Penny Symbols that is \$0.47 per contract for maker transactions and \$0.50 per contract for taker transactions, and both a maker and taker fee of \$0.90 per contract in Non-Penny Symbols. Priority Customer orders would not be charged a fee for regular executions in either Penny or Non-Penny Symbols.

II. Marketing Fees

Currently, Market Makers are charged a marketing fee of \$0.25 per contract in Penny Symbols and \$0.70 per contract in Non-Penny Symbols for each regular

³ The Total Affiliated Priority Customer ADV category includes all Priority Customer volume executed on the Exchange in all symbols and order types, including volume executed in the PIM, Facilitation, and QCC mechanisms. All eligible volume from affiliated Members will be aggregated in determining applicable tiers, provided there is at least 75% common ownership between the Members as reflected on the Member's Form BD, Schedule A.

⁴ A Nasdaq MRX Appointed Market Maker is eligible to receive and aggregate volume credit from both their affiliated Members and their Nasdaq MRX Appointed Order Flow Provider. A Nasdaq MRX Appointed Order Flow Provider will not receive volume credit from its Nasdaq MRX Appointed Market Maker or the Nasdaq MRX Appointed Market Maker's affiliates in determining its applicable tiers. Designating a Nasdaq MRX Appointed Market Maker/Appointed Order Flow Provider: An Nasdaq MRX Market Maker appoints an Electronic Access Member as its Appointed Order Flow Provider and an Electronic Access Member appoints an Nasdaq MRX Market Maker as its Appointed Market Maker, for the purposes of the Fee Schedule, by each sending an email to bizdev@ise.com. These corresponding emails will be viewed as acceptance of the appointment. The Exchange will recognize one such designation for each party. A party may make a designation not more than once every 6 months, which designation shall remain in effect until the Exchange receives an email from either party indicating that the appointment has been terminated.

⁵ A “Priority Customer” is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq MRX Rule 100(a)(37A).

⁶ The highest tier threshold attained applies retroactively in a given month to all eligible traded contracts and applies to all eligible market participants. Any day that the market is not open for the entire trading day or the Exchange instructs Members in writing to route their orders to other markets may be excluded from the ADV calculation; provided that the Exchange will only remove the day for members that would have a lower ADV with the day included.

⁷ The term Market Makers refers to “Competitive Market Makers” and “Primary Market Makers” collectively.

⁸ This fee also applies to Nasdaq MRX Market Maker orders sent to the Exchange by Electronic Access Members. Market Makers will receive a \$0.05 per contract discount when trading against a non-Priority Customer.

⁹ A “Non-Nasdaq MRX Market Maker” is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange.

¹⁰ A “Firm Proprietary” order is an order submitted by a member for its own proprietary account.

¹¹ A “Broker-Dealer” order is an order submitted by a member for a broker-dealer account that is not its own proprietary account.

¹² A “Professional Customer” is a person or entity that is not a broker/dealer and is not a Priority Customer.

¹³ Although the Exchange proposes to adopt a new structure it will keep the footnotes in the Qualifying Tier Threshold section as these will still apply to the calculation of ADV under the proposed structure.

¹⁴ The Exchange proposes to add a definition of Total Affiliated Member ADV to the Schedule of Fees to describe how this is calculated. The other footnotes to the Qualifying Tier Threshold language will remain as discussed above, and will be in addition to this proposed footnote.

¹⁵ Currently, the footnotes describing the process for designating a Nasdaq MRX Appointed Market Maker or Appointed Order Flow Provider indicate that members should email bizdev@ise.com. The Exchange proposes to change this to the appropriate Nasdaq email address, which is sales@nasdaq.com. The language describing the aggregation of eligible volume also contains an outdated reference to the Exchange's previous name, which the Exchange proposes to update to reflect its current name—i.e., Nasdaq MRX.

¹⁶ The fees charged to Market Makers will apply to Nasdaq MRX Market Maker orders sent to the Exchange by Electronic Access Members.

Priority Customer contract executed.¹⁷ This marketing fee is waived for Flash Order Responses. In connection with the fee changes described in Section I above, the Exchange also proposes to waive marketing fees for Market Maker orders that take liquidity from the order book. The Exchange believes that this change will ensure that Market Makers can benefit from the proposed fee incentives described above for taking liquidity, without the benefits provided thereunder being eroded by charging a marketing fee, which may or may not go into the marketing fee pool administered by the executing Market Maker. Furthermore, in connection with the changes to Crossing Order fees described in Section IV below, the Exchange proposes to waive marketing fees for Crossing Orders and Responses to Crossing Orders, which will ensure that the total fee paid by Market Makers that trade with this order flow will remain at a level the Exchange believes is appropriate.

III. Flash Orders

With the introduction of a maker/taker fee structure, the Exchange also proposes to introduce language clarifying how Flash Orders will be charged. A "Flash Order" is an order that is exposed at the National Best Bid or Offer by the Exchange to all members for execution, as provided under Supplementary Material .02 to Nasdaq MRX Rule 1901. Because a Flash Order being exposed to the market is entered prior to Responses to that order, the Exchange proposes to charge the applicable maker fee to all Flash Orders, which is similar to how pricing would be determined had the order rested on the order book. Similarly, because Responses that trade with a Flash Order are benefiting from the execution of a prior order, the Exchange proposes to charge the applicable taker fee for all Responses that trade against a Flash Order.

IV. Crossing Orders

Currently, the Exchange charges a fee for Crossing Orders (except PIM orders of 500 or fewer contracts)¹⁸ in Penny

and Non-Penny Symbols that is \$0.20 per contract for Market Maker,¹⁹ Non-Nasdaq MRX Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders, and \$0.00 per contract for Priority Customer Orders.²⁰ The Exchange also charges a fee in all symbols for PIM orders of 500 or fewer contracts that is \$0.05 per contract for Market Maker, Non-Nasdaq MRX Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders. Priority Customers receive a rebate for PIM orders of 500 or fewer contracts that is tiered based on the MVP tiers described above. Specifically, Priority Customer orders receive a rebate of \$0.11 per contract for Tiers 1–2 and \$0.13 per contract for Tiers 3–5. Priority Customer orders on the contra-side of a PIM auction for 500 or fewer contracts pay no fee and receive no rebate. The Exchange now proposes to eliminate the special fees described above for PIM orders of 500 contracts or fewer and apply the fee for Crossing Orders described above to all Crossing Orders, including PIM orders of 500 contracts or fewer.

In addition, the Exchange charges a fee for Responses to Crossing Orders that is \$0.50 per contract for Non-Nasdaq MRX Market Maker, Firm Proprietary, Broker-Dealer, Professional Customer, and Priority Customer orders in Penny Symbols, and \$0.95 per contract for the above market participant types in Non-Penny Symbols. Market Makers are charged a fee for Responses to Crossing Orders in Penny and Non-Penny Symbols that is \$0.25 per contract, subject to a discount whereby Market Makers that achieve Tier 2 or higher under the MVP are charged the discounted fee charged to regular executions for the tier reached—*i.e.*, from \$0.22 per contract for Tier 2 to \$0.10 per contract for Tier 5, as discussed in more detail in the MVP section above. The Exchange now proposes to charge Market Makers the same fee for Responses to Crossing Orders as is currently charged to other market participants. As such, Market Maker orders will be charged a fee for Responses to Crossing Orders that is \$0.50 per contract in Penny Symbols and \$0.95 per contract in Non-Penny Symbols, similar to the other market participants described above. Market Makers would not be eligible for any fee discounts based on the MVP tiers that are being discontinued.

¹⁹ Market Maker fees discussed in this section also apply to Market Maker orders sent to the Exchange by Electronic Access Members.

²⁰ Except as otherwise noted herein, the fees described in this paragraph apply to the originating and contra orders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,²¹ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,²² in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange is adopting a new pricing model for MRX and believes that the proposed changes will be attractive to market participants, and will encourage additional liquidity and trading opportunities on the Exchange to the benefit of all members.

I. Member Volume Program

The Exchange believes that the proposed fee change is reasonable, equitable, and not unfairly discriminatory as it is designed to increase liquidity and opportunities for all members to trade on the Exchange. The proposed fee structure being adopted represents a substantial change in the fee model for MRX that the Exchange believes will be attractive to market participants, and will assist the Exchange in competing in today's competitive environment. Generally, the proposed fee change would eliminate the current MVP structure and adopt a new maker/taker fee structure where market participants other than Priority Customers are charged a fee based on whether the market participant adds or removes liquidity. Priority Customer orders, meanwhile, would be eligible for free executions, and Market Makers would be eligible to qualify for substantially lower or no fees based on their contribution to the market. Qualifying tier thresholds for members would be based on Total Affiliated and/or Appointed Member ADV in two tiers that are designed to encourage members to bring order flow to the Exchange to qualify for higher tiers. For the reasons described in the following paragraphs, the Exchange believes that the proposed fee structure will be beneficial to market participants and will encourage an active and liquid market on MRX.

With respect to the proposed qualifying tier thresholds, the Exchange believes that the proposed ADV requirements are reasonable and equitable because they are set at levels that the Exchange believes will encourage market participants, and, in particular, Market Makers to execute

²¹ 15 U.S.C. 78f(b).

²² 15 U.S.C. 78f(b)(4) and (5).

¹⁷ The marketing fee will be rebated proportionately to the members that paid the fee such that on a monthly basis the marketing fee fund balance administered by a Primary Market Maker for a Group of options established under Rule 802(b) does not exceed \$100,000 and the marketing fee fund balance administered by a preferred Competitive Market Maker for such a Group does not exceed \$100,000. A preferred Competitive Market Maker that elects not to administer a fund will not be charged the marketing fee. The Exchange assesses an administrative fee of .45% on the total amount of the funds collected each month.

¹⁸ PIM orders of more than 500 contracts will pay the Fee for Crossing Orders.

more volume on the Exchange. As proposed, the qualifying tier thresholds would also reference Total Affiliated and/or Appointed Member ADV instead of Total Affiliated and/or Appointed Priority Customer ADV, which the Exchange believes will benefit firms that bring a wider range of order flow to the Exchange. The Exchange is also proposing to introduce new fee incentives (described in the paragraphs below) that specifically target Priority Customer order flow, thereby retaining the ability to attract those orders to the Exchange. The Exchange believes that the proposed changes will be attractive to market participants that trade on MRX. Furthermore, the Exchange believes that the qualifying tier thresholds are equitable and not unfairly discriminatory as all market participants can qualify for a higher tier by executing the required volume of contracts, either through the member, its affiliates, or an appointed member, as is the case today.

Under the proposed pricing structure, Priority Customer orders would be eligible for free executions. Although the Exchange will no longer provide rebates to Priority Customer orders, the Exchange believes that increased Market Maker participation would increase the opportunities for these orders to trade and therefore encourage members to bring this order flow to the Exchange. In addition, by receiving free executions Priority Customer orders would continue to be provided the most favorable rates on the Exchange. Only one other market participant type (*i.e.*, Market Makers) would be eligible to trade for free and only in specified circumstances. The Exchange believes that it is appropriate and not unfairly discriminatory to provide free executions to Priority Customer orders as the Exchange is seeking to attract this order flow. The Exchange believes that attracting more volume from Priority Customers will benefit all market participants that trade on MRX. In addition, the Exchange believes that it is equitable and not unfairly discriminatory to charge a lower fee for Priority Customer orders as a Priority Customer is by definition not a broker or dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). This limitation does not apply to market participants whose behavior is substantially similar to that of market professionals, and who will generally submit a higher number of orders than Priority Customers.

Market Makers would also benefit from a strong mix of incentives that are

designed to create an active and liquid market for MRX-listed options. First, Market Makers would pay a base fee that is equal to or lower than that charged to all market participants other than Priority Customers, with the potential to further lower those fees by qualifying for additional pricing incentives. The Exchange believes that charging lower fees to Market Maker orders is reasonable and equitable as doing so increases Market Maker activity and thereby creates additional opportunities for other market participants to trade. Furthermore, the Exchange believes that it is equitable and not unfairly discriminatory to charge lower fees to Market Makers because Market Makers have different requirements and obligations to the Exchange than other market participants do not (such as quoting requirements). For this reason, the Exchange also believes that the other incentives described below, which may further decrease execution costs for Market Makers, are also equitable and not unfairly discriminatory. These incentives are designed to increase Market Maker participation and reward Market Makers for the unique role that they play in ensuring a robust market.

Second, Market Makers would be rewarded for providing liquidity with a lower base rate for adding liquidity as opposed to taking liquidity, and the possibility for free executions if the Market Maker achieves a higher tier based on Total Affiliated and/or Appointed Member ADV. The Exchange believes that it is reasonable and equitable to charge a lower base rate for Market Maker orders that add liquidity because Market Makers provide an important function to the market when they provide liquidity to other market participants through their displayed quotes. The Exchange believes that incentivizing Market Makers to provide liquidity through lower maker fees will create additional displayed liquidity and opportunities for market participants to trade. Furthermore, providing an additional discount when the Market Maker meets the qualifying tier threshold for a higher ADV tier will encourage the member to transact additional business on the Exchange, and thereby create a more active market. The Exchange also believes that tying execution fees to whether the Market Maker is adding or removing liquidity, and based on ADV, is equitable and not unfairly discriminatory as all Market Makers will be treated uniformly based on these factors.

Third, although Market Makers would pay the same base rate for removing liquidity as other market participants,

Market Makers would be eligible for a discounted taker fee when trading with Priority Customer orders entered by an affiliated or appointed member. Market Makers would qualify for this discounted taker fee if the member has reached a threshold level of Total Affiliated and/or Appointed Priority Customer ADV, and would be eligible for free executions if the member executes a higher volume of contracts. The Exchange believes that it is reasonable and equitable to charge a lower fee to Market Makers when trading against Priority Customer orders that originate from affiliated or appointed members as this incentive is designed to encourage firms to bring additional Priority Customer order flow to the Exchange. For the same reason, the proposed ADV requirements are also based on ADV in Priority Customer contracts executed by affiliated or appointed members.

This discounted fee structure is similar to one in place on the Exchange's affiliate, the Nasdaq Options Market ("NOM"), where participants that meet specified volume requirements can qualify for discounted fees if the participant is: (i) Both the buyer and the seller or (ii) the participant removes liquidity from another participant under common ownership.²³ Similar to NOM, the Exchange believes that this structure will encourage additional order flow both from Market Makers and their affiliated and/or appointed members. This will benefit those members through reduced fees, and will also benefit other market participants that will have an opportunity to trade with the order flow that these firms bring to the market. When a Priority Customer order is entered on the Exchange, a Market Maker that wishes to interact with that order flow does not typically know whether that order originated from one of its affiliated or appointed members. The Exchange therefore believes that Market Makers would continue to aggressively pursue order flow in order to receive the benefit of the fee discount. Discounting fees in this manner will reward firms that bring more order flow to the Exchange. This is the case both because sending additional order flow would increase the chances of a firm qualifying for a reduced fee (*i.e.*, because it increases the chances that a contra-side order is entered by an affiliated or appointed member), and because a higher ADV is required to

²³ See NOM Rules, Chapter XV Options Pricing, Sec. 2 Nasdaq Options Market—Fees and Rebates, (1) Fees for Execution of Contracts on The Nasdaq Options Market.

qualify for free executions under the proposed pricing structure.

The Exchange also believes that the proposed fee discount described above is equitable and not unfairly discriminatory. As mentioned before, Market Makers have special obligations to the market that other market participants do not. The Exchange therefore believes that it is appropriate to reward those members with potentially lower fees. Furthermore, providing an incentive specifically to Market Makers whose affiliated and/or appointed members bring Priority Customer order flow to the Exchange encourages firms to bring more of this order flow to the Exchange. All Market Makers can benefit from this incentive either by interacting with order flow sent to the Exchange by its affiliates or by designating a Nasdaq MRX Appointed Order Flow Provider, who would be treated similar to an affiliate. Moreover, rewarding members that bring a more substantial investment of order flow is beneficial to all market participants, who are free to interact with such order flow.

Finally, Non-Nasdaq MRX Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders would be subject to maker/taker fees at rates that are similar to those currently charged on the Exchange. In Penny Symbols, these market participants would pay a maker fee that is the same as the fee charged today, and a taker fee that is modestly higher. For the reasons discussed above with respect to Market Maker orders, the Exchange believes that it is appropriate to charge higher fees for executions that remove liquidity than those that provide liquidity to other market participants—*i.e.*, because this encourages more displayed liquidity and opportunities for market participants to trade on the Exchange. In Non-Penny Symbols, these market participants will be charged the same fee as today, regardless of whether the order is executed as maker or taker. Although these market participants would continue to be charged fees that are higher than the fees charged to Priority Customer and Market Maker orders, the Exchange believes that this is equitable and not unfairly discriminatory for the reasons discussed in the paragraphs above on Priority Customer and Market Maker fees. Furthermore, although these market participants would be charged a modestly increased fee in the one instance described above, the Exchange believes that the effect of this fee increase is justified by the potential for the new fee structure to encourage additional liquidity and opportunities

for trading due to the incentives being provided to Market Maker and Priority Customer orders.

II. Marketing Fees

The Exchange believes that it is reasonable and equitable to eliminate the marketing fees charged to Market Maker orders that take liquidity from the order book as charging a marketing fee in these instances would frustrate the Exchange's incentives for firms that bring Priority Customer orders to the Exchange and receive a fee discount (including potentially free executions) when trading with that order flow. Furthermore, the marketing fee is designed to assist Market Makers in establishing marketing fee arrangements with Electronic Access Members in exchange for those members routing some or all of their order flow to such Market Makers. This purpose is not advanced when the Priority Customer order on the other side of the transaction is providing liquidity and is not routed to access displayed liquidity being provided by a Market Maker quoting on the Exchange. Furthermore, the Exchange has proposed changes to its Crossing Order fees that would result in Market Makers paying a higher Response fee that is the same as the fee charged to other market participants. The Exchange believes that it is reasonable and equitable to eliminate the marketing fee charged for Crossing Orders and Responses to Crossing Orders as this change will keep total execution costs down when Market Makers trade with Crossing Order flow. The Exchange also believes that both of the proposed changes to the marketing fee described above are not unfairly discriminatory as no Market Makers would be charged a marketing fee when removing liquidity or when executing Crossing Orders or Responses to Crossing Orders.

III. Flash Orders

The Exchange believes that the proposed pricing for Flash Orders is reasonable and equitable as the proposed changes clarify how the Exchange will charge members for Flash Orders with the introduction of maker/taker pricing. Without this change members would not be aware of how Flash Orders are charged because Flash Orders do not rest on the book and therefore could be treated as either maker or taker for purposes of pricing. The Exchange is proposing to charge the applicable maker fee for Flash Orders, and the applicable taker rebate for Responses that trade against a Flash Order. The Exchange believes that it is reasonable and equitable to charge the

applicable maker fee to a Flash Order as the order being exposed is entered first, and maker pricing would therefore apply the same as it would had that order rested on the order book. Similarly, the Exchange believes that it is reasonable and equitable to charge the applicable taker fee to Responses as these Responses are benefiting from the execution of a prior order. Furthermore, the Exchange believes the proposed Flash Order language is not unfairly discriminatory because Flash Orders entered by all market participants will be treated as maker and all Responses that trade against a Flash Order will be treated as taker.

IV. Crossing Order Fees

The Exchange believes that it is reasonable, equitable, and not unfairly discriminatory to eliminate the special incentive for PIM orders of 500 or fewer contracts as the proposed fees charged would now be consistent for all Crossing Orders. The Exchange currently has in place a fee structure that was implemented to encourage PIM orders for 500 or fewer contracts by charging lower fees to the originating and contra-side of those orders. The Exchange no longer believes that this incentive is necessary and is therefore removing it. With this change, members will be charged the same fees for all Crossing Orders, regardless of whether the order is executed in the PIM or another crossing mechanism, and regardless of the size of the order. The Exchange also believes that it is reasonable and equitable to increase the fees charged to Market Maker Responses to Crossing Orders as with this change Market Makers would be charged the same fees as other market participants.

The Exchange also believes that the Crossing Order changes are equitable and not unfairly discriminatory as the proposed fees would be more standardized across the various Crossing Order mechanisms, and across market participant types, with the exception that Priority Customer orders would continue to not be charged a fee for Crossing Orders.²⁴ As explained earlier in this proposed rule change, a Priority Customer is by definition not a broker or dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). This limitation does not apply to participants whose behavior is substantially similar to that of market

²⁴ Priority Customer orders would continue to pay a fee for Responses to Crossing Orders that is the same as the fee charged to other market participants.

professionals who will generally submit a higher number of orders than Priority Customers. The Exchange therefore believes that it is equitable and not unfairly discriminatory to provide more favorable pricing to Priority Customer orders in the one instance described above.

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 fee change is an overhaul of the Exchange's pricing model that is designed to incentivize members to bring additional order flow to the Exchange, and create a more active and quality market in MRX-listed options. The Exchange therefore believes that the proposed rule change is a product of the competitive environment in the options industry. The Exchange operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,²⁵ and Rule 19b-4(f)(2)²⁶ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in

furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-MRX-2018-01 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 Number SR-MRX-2018-01. 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 Number SR-MRX-2018-01 and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁷

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-01353 Filed 1-25-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82561; File No. SR-CboeBZX-2017-021]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Withdrawal of a Proposed Rule Change To List and Trade Shares of the First Trust Bitcoin Strategy ETF and the First Trust Inverse Bitcoin Strategy ETF, Each a Series of the First Trust Exchange-Traded Fund VII, Under Rule 14.11(i), Managed Fund Shares

January 22, 2018.

On December 19, 2017, Cboe BZX Exchange, Inc. ("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 list and trade shares of the First Trust Bitcoin Strategy ETF and the First Trust Inverse Bitcoin Strategy ETF, each a series of the First Trust Exchange-Traded Fund VII, under Rule 14.11(i), Managed Fund Shares. The proposed rule change was published for comment in the **Federal Register** on January 8, 2018.³ The Commission received three comment letters on the proposed rule change.⁴

On January 19, 2018, the Exchange withdrew the proposed rule change (SR-CboeBZX-2017-021).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-01416 Filed 1-25-18; 8:45 am]

BILLING CODE 8011-01-P

²⁷ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 82429 (Jan. 2, 2018), 83 FR 929 (Jan. 8, 2018).

⁴ See Letters from Anita Desai (Jan. 4, 2018); Carl Summersett (Jan. 4, 2018); and Stephen Knell (Jan. 9, 2018). All comments on the proposed rule change are available on the Commission's website at: <https://www.sec.gov/comments/sr-cboebzx-2017-021/cboebzx2017021.htm>.

⁵ 17 CFR 200.30-3(a)(12).

²⁵ 15 U.S.C. 78s(b)(3)(A)(ii).

²⁶ 17 CFR 240.19b-4(f)(2).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82541; File No. SR-NASDAQ-2018-004]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Exchange Rule 7047

January 19, 2018.

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 January 9, 2018, The Nasdaq Stock Market LLC (“Nasdaq” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 7047 to reflect substantial enhancements to Nasdaq Basic since the current distribution fees were set in 2009. Specifically, the Exchange proposes to modify distribution fees, currently set at \$1,500 for both internal and external distribution, into separate fees of \$2,000 per month for external (or external and internal) distribution and \$1,500 per month for internal-only distribution. The proposal is described in further detail below.

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

The Exchange proposes to adjust the fee schedule for Nasdaq Basic to reflect substantial enhancements to the product since the current distribution fees were set in 2009.³ Specifically, the Exchange proposes to amend the distribution fees for Nasdaq Basic at Rule 7047, currently set at \$1,500 for both internal and external distribution, into separate fees of \$2,000 per month for external (or external and internal) distribution and \$1,500 per month for internal-only distribution.⁴

Nasdaq Basic

Nasdaq Basic is a real-time market data product that offers Best Bid and Offer and Last Sale information for all U.S. exchange-listed securities based on liquidity within the Nasdaq Market Center and trades reported to the FINRA/Nasdaq Trade Reporting Facility (“TRF”). It is a subset of the “core” quotation and last sale data provided by securities information processors (“SIPs”) under the CTA Plan and the Nasdaq UTP Plan. Nasdaq Basic is separated into three components, which may be purchased individually or in combination: (i) Nasdaq Basic for Nasdaq, which contains the best bid and offer on the Nasdaq Market Center and last sale transaction reports for Nasdaq and the FINRA/Nasdaq TRF for Nasdaq-listed stocks; (ii) Nasdaq Basic for NYSE, which covers NYSE-listed stocks, and (iii) Nasdaq Basic for NYSE American (formerly NYSE MKT), which provides data on stocks listed on NYSE American and other listing venues whose quotes and trade reports are disseminated on Tape B. The specific data elements available through Nasdaq Basic are: (i) Nasdaq Basic Quotes (“QBBO”), the best bid and offer and associated size available in the Nasdaq Market Center, as well as last sale transaction reports; (ii) Nasdaq opening

and closing prices, as well as IPO and trading halt crosses; and (iii) general exchange information, including systems status reports, trading halt information, and a stock directory.

Each Distributor of Nasdaq Basic, or Derived Data therefrom, currently pays \$1,500 per month for either internal or external distribution or both,⁵ in addition to user fees set forth under Rule 7047(b).

Proposed Change

Nasdaq Basic is one of a number of market information services offered by the Exchange. Such services are inextricably connected to trade execution: Market information services require trade orders to provide useful information, and investors utilize market information to make trading decisions. Over the eight years that have elapsed since the current distribution fees were set in 2009,⁶ the Exchange has invested in an array of upgrades to both its trade execution and market information services, which have increased the value of these services overall, and Nasdaq Basic in particular.⁷

The Exchange proposes to adjust its fee schedule for Nasdaq Basic to reflect the value of the many improvements to the product, which include:

- *Enhanced Services.* In 2014, the Exchange enhanced the Nasdaq Basic data feed by: (i) Converting to binary codes to make more efficient use of bandwidth and to provide greater timestamp granularity; (ii) adding a symbol directory message to identify a security and its key characteristics; (iii) adding a new IPO message for Nasdaq-listed securities for quotation release time and IPO price; and (iv) adding the Market Wide Circuit Breaker (“MWCB”) Decline Level message to inform recipients of the setting for MWCB breach points for the trading day, and an MWCB Status Level Message to inform data recipients when an MWCB has breached an established level.⁸

- *Nanosecond Granularity.* In 2016 [sic], Nasdaq introduced a new version of Nasdaq Last Sale which allowed for timestamp granularity to the nanosecond.⁹

⁵ See Rule 7047(c)(1).

⁶ See Securities Exchange Act Release No. 59712 (April 6, 2009), 74 FR 17273 (April 14, 2009) (SR-NASDAQ-2009-028).

⁷ Many of these upgrades are common to several Nasdaq-affiliated exchanges, as improvements to the products and services of one exchange are reproduced in other exchanges.

⁸ See <http://www.nasdaqtrader.com/TraderNews.aspx?id=dtm2013-45> and <http://www.nasdaqtrader.com/TraderNews.aspx?id=dtm2013-33>.

⁹ See <http://www.nasdaqtrader.com/TraderNews.aspx?id=dtm2016-03>.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 59244 (January 13, 2009), 74 FR 4065 (January 22, 2009) (SR-NASDAQ-2008-102). The initial proposal included separate distribution fees for securities listed with other exchanges, which were removed in Securities Exchange Act Release No. 59712 (April 6, 2009), 74 FR 17273 (April 14, 2009) (SR-NASDAQ-2009-028). SR-NASDAQ-2009-028 also added a credit for user fees, which was removed in Securities Exchange Act Release No. 78578 (August 15, 2016), 81 FR 55513 (August 19, 2016) (SR-NASDAQ-2016-109).

⁴ Distribution fees for Nasdaq Last Sale (“NLS”) set forth at Rule 7039(c) shall remain unchanged.

- *Exchange Traded Managed Funds* (“ETMFs”). In 2015, the Exchange modified the data feed for Nasdaq Basic to accommodate an ETMF, a type of investment vehicle that combines the features of an open-end mutual fund and an Exchange Traded Fund (“ETF”) to support an actively managed-investment strategy.¹⁰ ETMF trading differs from other types of equity trading in that it uses a trading protocol called “Net Asset Value-Based Trading,” in which all bids, offers, and execution prices are expressed as a premium or discount to the ETMF’s next-determined Net Asset Value (“NAV”). This distinct pricing format requires an entirely new set of data fields in which to distribute information related to prices and trades, and the Exchange modified Nasdaq Basic to accommodate that format.¹¹

- *Qualified Contingent Trade Modifier*. In 2015, Nasdaq introduced a new field to Nasdaq Basic to identify a Qualified Contingent Trades [sic] (“QCT”),¹² a transaction consisting of two or more component orders executed as agent or principal where the execution of one component is contingent upon the execution of all other components at or near the same time, and the price is determined by the relationship between the component orders and not the current market price for the security.¹³ The additional field identifies whether a particular transaction is part of a QCT.

- *Adjusted Closing Price*. In 2013, Nasdaq introduced the adjusted closing price as a field to reflect a security’s previous day official closing price, adjusted for corporate actions. For Nasdaq-listed securities, the Nasdaq Official Closing Price is used,¹⁴ and the consolidated close from the security’s listing exchange is used for non-Nasdaq securities.¹⁵

- *New System Event Messages*. In 2013, Nasdaq began disseminating event messages to indicate the start and end of system hours.¹⁶

- *Geographic Diversity*. In 2015, all of the Nasdaq Exchanges moved their Disaster Recover [sic] (“DR”) center from Ashburn, Virginia, to Chicago, Illinois. As a result, customers can both receive market data and send orders through the Chicago facility, potentially reducing overall networking costs. Adding such geographic diversity helps protect the market in the event of a catastrophic event impacting the entire East Coast.¹⁷

- *Chicago “B” Feeds*. In 2017, all of the Nasdaq exchanges added a multicast IP address for proprietary equity and options data feeds in Chicago, allowing firms the choice of having additional redundancy to ensure data continuity.¹⁸

While these changes were being implemented, distributor fees for Nasdaq Basic were falling in real terms as a result of inflation. Indeed, the proposed fee increase is partially offset by inflation,¹⁹ and represents only an approximately 3.7 percent annual increase between 2009 and 2017. The Exchange believes that the remaining percentage increase over inflation is more than justified by the substantial upgrades described above.

As a result of these upgrades, the Exchange proposes to separate the internal and external distribution fees for Nasdaq Basic, increasing external (and combined internal and external) distribution fees from \$1,500 to \$2,000 per month, and leaving internal distribution fees unchanged. Given these specific enhancements to Nasdaq Basic, and to the Exchange’s system generally, and given the fact that the Exchange has not increased the distributor fees since 2009, the Exchange believes that the proposed fee increase is appropriate.

Nasdaq Basic is optional in that the Exchange is not required to offer it and broker-dealers are not required to purchase it. Firms can discontinue use at any time and for any reason, including an assessment of the fees charged.

The proposed change does not change the cost of any other Exchange product.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,²⁰ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5)

of the Act,²¹ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and self-regulatory organization (“SRO”) revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”²²

Likewise, in *NetCoalition v. Securities and Exchange Commission*²³ (“NetCoalition”) the D.C. Circuit upheld the Commission’s use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.²⁴ As the court emphasized, the Commission “intended in Regulation NMS that ‘market forces, rather than regulatory requirements’ play a role in determining the market data . . . to be made available to investors and at what cost.”²⁵

Further, “[n]o one disputes that competition for order flow is ‘fierce.’ . . . As the SEC explained, ‘[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution’; [and] ‘no exchange can afford to take its market share percentages for granted’ because ‘no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers’”²⁶

The Exchange proposes to separate the internal and external distribution fees for Nasdaq Basic, increasing external (and combined internal and

¹⁰ See Securities Exchange Act Release No. 73562 (November 7, 2014), 79 FR 68309 (November 14, 2014) (SR–NASDAQ–2014–020) (approving the listing and trading of Exchange-Traded Managed Fund Shares).

¹¹ See <http://www.nasdaqtrader.com/TraderNews.aspx?id=dtm2015-7>.

¹² See <http://www.nasdaqtrader.com/TraderNews.aspx?id=dtm2015-24>.

¹³ See Securities Exchange Act Release No. 54389 (August 31, 2006), 71 FR 52829 (September 7, 2006).

¹⁴ Nasdaq’s closing cross process produces a tradable closing price that represents either the closing cross or the best available price at the time of the transaction.

¹⁵ See <http://www.nasdaqtrader.com/TraderNews.aspx?id=dtm2013-25>.

¹⁶ See <http://www.nasdaqtrader.com/TraderNews.aspx?id=dtm2013-20>.

¹⁷ See <http://www.nasdaqtrader.com/TraderNews.aspx?id=dtm2015-17>.

¹⁸ See <http://www.nasdaqtrader.com/TraderNews.aspx?id=dtm2017-02>.

¹⁹ The Consumer Price Index indicates that prices increased approximately 17 percent between January 2009 and November 2017. See <https://data.bls.gov/cgi-bin/cpicalc.pl>.

²⁰ 15 U.S.C. 78f(b).

²¹ 15 U.S.C. 78f(b)(4) and (5).

²² See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (“Regulation NMS Adopting Release”).

²³ See *NetCoalition v. SEC*, 615 F.3d 525 (D.C. Cir. 2010).

²⁴ See *NetCoalition*, at 534–535.

²⁵ *Id.* at 537.

²⁶ *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

external) distribution fees from \$1,500 to \$2,000 per month, and leaving internal distribution fees unchanged. The Exchange believes that the proposed fee increase is reasonable. While the Exchange has not increased such fees since 2009, the Exchange has added a number of enhancements since that time to Nasdaq Basic and the Exchange systems that support it. These enhancements, which are described in greater detail above, increase the value of Nasdaq Basic. The proposed fee increase is therefore reflective of, and closely aligned to, these enhancements and the corresponding increased value of the data feed.

The proposed changes are equitable allocations of reasonable dues, fees and other charges because the Exchange makes all services and products subject to these fees available on a non-discriminatory basis to similarly-situated recipients, and the proposed fee increase here will apply equally to all members that are external (or combined internal and external) Distributors. As noted above, the Exchange has made a number of product and system enhancements to Nasdaq Basic, and, while internal Distributors have also received the benefit of these enhancements, the Exchange is not increasing the fee for internal Distributors at this time. This distinction is not unreasonable because a higher fee for external, as opposed to internal, distribution is based on the observation that external distributors typically charge fees for external distribution, while internal distributors usually do not. As such, external distributors have the opportunity to derive greater value from such distribution, and that greater value is reflected in higher external distribution fees. The differential between external and internal distribution fees is well-recognized in the financial services industry as a reasonable distinction, and has been repeatedly accepted by the Commission as an equitable allocation of reasonable dues, fees and other charges.²⁷ The Act does not prohibit all distinctions among customers, but rather discrimination that is unfair. As the Commission has recognized, “[i]f competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain

unreasonable or unfair behavior.”²⁸ Accordingly, “the existence of significant competition provides a substantial basis for finding that the terms of an exchange’s fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory.”²⁹

In adopting Regulation NMS, the Commission granted SROs and broker-dealers (“BDs”) increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Commission concluded that Regulation NMS—by deregulating the market in proprietary data—would itself further the Act’s goals of facilitating efficiency and competition:

[E]fficiency is promoted when broker-dealers who do not need the data beyond the prices, sizes, market center identifications of the NBBO and consolidated last sale information are not required to receive (and pay for) such data. The Commission also believes that efficiency is promoted when broker-dealers may choose to receive (and pay for) additional market data based on their own internal analysis of the need for such data.³⁰

The Commission was speaking to the question of whether BDs should be subject to a regulatory requirement to purchase data, such as depth-of-book data, that is *in excess of* the data provided through the consolidated tape feeds, and the Commission concluded that the choice should be left to them. Accordingly, Regulation NMS removed unnecessary regulatory restrictions on the ability of exchanges to sell their own data, thereby advancing the goals of the Act and the principles reflected in its legislative history. If the free market should determine whether proprietary data is sold to BDs at all, it follows that the price at which such data is sold should be set by the market as well. Accordingly, “the existence of significant competition provides a substantial basis for finding that the terms of an exchange’s fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory.”³¹

²⁸ See Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770 (December 9, 2008) (SR-NYSEArca-2006-21).

²⁹ *Id.*

³⁰ See Securities Exchange Act Release No. 51808 (June 29, 2005), 70 FR 37496 (June 29, 2005) (“Regulation NMS Adopting Release”).

³¹ See Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770 (December 9, 2008) (SR-NYSEArca-2006-21).

The proposed fees, like all market data fees, are constrained by the Exchange’s need to compete for order flow, as discussed below, and are subject to competition from other exchanges and among broker-dealers for customers. If Nasdaq is incorrect in its assessment of price, it may lose market share as a result.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Nasdaq Basic is a type of “non-core” data that provides a subset of the core quotation and last sale data provided by securities information processors under the CTA Plan and the Nasdaq UTP Plan. In 2016, an Administrative Law Judge in an application for review by the Securities Industry and Financial Markets Association of actions taken by Self-Regulatory Organizations examined whether another non-core product, Depth-of-Book data, is constrained by competitive forces.³² After a four-day hearing and presentation of substantial evidence, the administrative law judge stated that “competition plays a significant role in restraining exchange pricing of depth-of-book products”³³ because “depth-of-book products from different exchanges function as substitutes for each other.”³⁴ and, as such, “the threat of substitution from depth-of-book customers constrains

³² See *Securities Industry and Financial Markets Association*, Initial Decision Release No. 1015, 2016 SEC LEXIS 2278 (A.L.J. June 1, 2016).

³³ *Id.* at 92.

³⁴ *Id.*

²⁷ See, e.g., Rules 7019 (Market Data Distributor Fees); 7022(c) (Short Interest Report); 7023(c) (Enterprise License Fees for Depth-of-Book Data); and 7052(c) (Distributor Fees for Nasdaq Daily Short Volume and Monthly Short Sale Transaction Files).

their depth-of-book prices.”³⁵ As a result, “[s]hifts in order flow and threats of shifting order flow provide a significant competitive force in the pricing of . . . depth-of-book data.”³⁶ The judge concluded that “[u]nder the standards articulated by the Commission and D.C. Circuit, the Exchanges have shown that they are subject to significant competitive forces in setting fees for depth-of-book data: the availability of alternatives to the Exchanges’ depth-of-book products, and the Exchanges’ need to attract order flow from market participants constrains prices.”³⁷ As such, Nasdaq’s depth-of-book fees are “constrained by significant competitive forces.”³⁸

As an example of the impact of market forces on the price of proprietary data, the Exchange just last year lowered the Nasdaq Basic Enterprise License fee for the distribution of certain information by broker-dealers from \$350,000 to \$100,000.³⁹

Market forces constrain the price of Nasdaq Basic, just as they do other market data fees, in the competition among exchanges and other entities to attract order flow and in the competition among Distributors for customers. Order flow is the “life blood” of the exchanges. Broker-dealers currently have numerous alternative venues for their order flow, including SRO markets, as well as internalizing BDs and various forms of alternative trading systems (“ATs”), including dark pools and electronic communication networks (“ECNs”). Each SRO market competes to produce transaction reports via trade executions, and two FINRA-regulated TRFs compete to attract internalized transaction reports. The existence of fierce competition for order flow implies a high degree of price sensitivity on the part of BDs, which may readily reduce costs by directing orders toward the lowest-cost trading venues.

Transaction execution and proprietary data products are complementary in that market data is both an input and a byproduct of the execution service. In fact, market data and trade execution are a paradigmatic example of joint products with joint costs. The decision whether and on which platform to post

an order will depend on the attributes of the platform where the order can be posted, including the execution fees, data quality and price, and distribution of its data products. Without trade executions, exchange data products cannot exist. Moreover, data products are valuable to many end users only insofar as they provide information that end users expect will assist them or their customers in making trading decisions.

The costs of producing market data include not only the costs of the data distribution infrastructure, but also the costs of designing, maintaining, and operating the exchange’s transaction execution platform and the cost of regulating the exchange to ensure its fair operation and maintain investor confidence. The total return that a trading platform earns reflects the revenues it receives from both trading execution and data products and the joint costs it incurs to provide both.

Moreover, the operation of the exchange is characterized by high fixed costs and low marginal costs. This cost structure is common in content and content distribution industries such as software, where developing new software typically requires a large initial investment (and continuing large investments to upgrade the software), but once the software is developed, the incremental cost of providing that software to an additional user is typically small, or even zero (e.g., if the software can be downloaded over the internet after being purchased).⁴⁰

In Nasdaq’s case, it is costly to build and maintain a trading platform, but the incremental cost of trading each additional share on an existing platform, or distributing an additional instance of data, is very low. Market information and executions are each produced jointly (in the sense that the activities of trading and placing orders are the source of the information that is distributed) and are each subject to significant scale economies. In such cases, marginal cost pricing is not feasible because if all sales were priced at the margin, Nasdaq would be unable to defray its platform costs of providing the joint products.

An exchange’s BD customers view the costs of transaction executions and of data as a unified cost of doing business with the exchange. A BD will disfavor a particular exchange if the expected revenues from executing trades on the exchange do not exceed net transaction

execution costs and the cost of data that the BD chooses to buy to support its trading decisions (or those of its customers). The choice of data products is, in turn, a product of the value of the products in making profitable trading decisions. If the cost of the product exceeds its expected value, the BD will choose not to buy it. Moreover, as a BD chooses to direct fewer orders to a particular exchange, the value of the product to that BD decreases, for two reasons. First, the product will contain less information, because executions of the BD’s trading activity will not be reflected in it. Second, and perhaps more important, the product will be less valuable to that BD because it does not provide information about the venue to which it is directing its orders. Data from the competing venue to which the BD is directing more orders will become correspondingly more valuable.

Competition among trading platforms can be expected to constrain the aggregate return each platform earns from the sale of its joint products, but different platforms may choose from a range of possible, and equally reasonable, pricing strategies as the means of recovering total costs. Nasdaq pays rebates to attract orders, charges relatively low prices for market information and charges relatively high prices for accessing posted liquidity. Other platforms may choose a strategy of paying lower liquidity rebates to attract orders, setting relatively low prices for accessing posted liquidity, and setting relatively high prices for market information. Still others may provide most data free of charge and rely exclusively on transaction fees to recover their costs. Finally, some platforms may incentivize use by providing opportunities for equity ownership, which may allow them to charge lower direct fees for executions and data.

In this environment, there is no economic basis for regulating maximum prices for one of the joint products in an industry in which suppliers face competitive constraints with regard to the joint offering. Such regulation is unnecessary because an “excessive” price for one of the joint products will ultimately have to be reflected in lower prices for other products sold by the firm, or otherwise the firm will experience a loss in the volume of its sales that will be adverse to its overall profitability. In other words, an increase in the price of data will ultimately have to be accompanied by a decrease in the

³⁵ *Id.* at 93.

³⁶ *Id.* at 104.

³⁷ *Id.* at 86.

³⁸ *Id.* at 120.

³⁹ See Securities Exchange Act Release No. 79456 (December 2, 2016) 81 FR 88716 (December 8, 2016) (SR-NASDAQ-2016-162) (proposing a fee decrease for an enterprise license for the distribution of Nasdaq Basic to Non-Professional and Professional Subscribers with whom the broker-dealer has a brokerage relationship).

⁴⁰ See William J. Baumol and Daniel G. Swanson, “The New Economy and Ubiquitous Competitive Price Discrimination: Identifying Defensible Criteria of Market Power,” *Antitrust Law Journal*, Vol. 70, No. 3 (2003).

cost of executions, or the volume of both data and executions will fall.⁴¹

The proposed changes will separate the internal and external distribution fees for Nasdaq Basic, increasing external distribution fees from \$1,500 to \$2,000 per month, and leaving internal distribution fees unchanged. The proposed price changes will not impose any burden on competition because external distributors typically charge fees for external distribution, and thereby usually derive greater value from such distribution than internal distributors, which typically do not charge fees, and that greater value supports higher external distribution fees. This distinction between external and internal distribution fees is common in the financial services industry, and has been applied to other products without any anti-competitive effect. As explained, these fees will become one aspect of the total cost of interacting with the Exchange, and if these total costs prove to be excessive, the Exchange will lose revenue as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.⁴²

⁴¹ Moreover, the level of competition and contestability in the market is evident in the numerous alternative venues that compete for order flow, including SRO markets, internalizing BDs and various forms of ATSS, including dark pools and ECNs. Each SRO market competes to produce transaction reports via trade executions, and two FINRA-regulated TRFs compete to attract internalized transaction reports. It is common for BDs to further and exploit this competition by sending their order flow and transaction reports to multiple markets, rather than providing them all to a single market. Competitive markets for order flow, executions, and transaction reports provide pricing discipline for the inputs of proprietary data products. The large number of SROs, TRFs, BDs, and ATSS that currently produce proprietary data or are currently capable of producing it provides further pricing discipline for proprietary data products. Each SRO, TRF, ATS, and BD is currently permitted to produce proprietary data products, and many currently do or have announced plans to do so, including Nasdaq, NYSE, NYSE American, NYSE Arca, IEX, and Chicago Board Options Exchange ("CBOE").

⁴² 15 U.S.C. 78s(b)(3)(A)(ii).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NASDAQ-2018-004 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to File Number SR-NASDAQ-2018-004. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<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-2018-004 and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴³

Eduardo A. Aleman,
Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82566; File No. SR-NYSE-2018-04]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Listing Standard for Warrants in Section 703.12 of the Exchange's Listed Company Manual

January 22, 2018.

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 January 11, 2018, New York Stock Exchange LLC ("NYSE" 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.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its listing standard for warrants as set forth in Section 703.12 of the Exchange's Listed Company Manual (the "Manual") to create an exception to the prohibition on reducing the exercise price of listed warrants so as to permit exercise price reductions that are widely publicized and that continue in effect for at least 20 business days³ (or such longer period as may be required under the tender offer rules of the Securities and Exchange

⁴³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ The term "business day" is used as defined in Rule 14d-1(g)(3) under the Act (17 CFR 240.14d-1(g)(3)).

Commission (“SEC” or “Commission”) and otherwise comply with any other applicable tender offer regulatory provisions under the federal securities laws, including Section 13(e)⁴ of the Act and Rule 13e-4⁵ under the Act. The proposed rule change is available on the Exchange’s website at www.nyse.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 self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The NYSE proposes to amend its listing standard for warrants as set forth in Section 703.12 of the Manual to create an exception to the prohibition on reducing the exercise price of listed warrants so as to permit exercise price reductions that are widely publicized and that continue in effect for at least 20 business days (or such longer period as may be required under the SEC’s tender offer rules) and otherwise comply with any other applicable tender offer regulatory provisions under the federal securities laws, including Section 13(e)⁶ of the Act and Rule 13e-4⁷ under the Act.⁸

The Exchange’s initial listing standards for warrants are set forth in Section 703.12(A) of the Manual. Section 703.12(A) of the Manual provides that the terms of listed warrants must not give the company the right to reduce the established price (*i.e.*, the exercise price) for periods of time, or from time to time, during the life of the warrants. The Exchange has

interpreted this prohibition broadly as prohibiting the taking of any other action which has the same economic effect as a reduction in the exercise price of the warrant.⁹

The warrant listing standards of other exchanges either contain no limitation on the repricing of listed warrants¹⁰ or permit companies to reduce the price of their listed warrants subject to certain conditions.¹¹ Specifically, the warrant listing standard of the Nasdaq Global Market (“Nasdaq”) set forth in Nasdaq Marketplace Rule 5410 does not in any way restrict companies from reducing the exercise price of listed warrants. Separately, NYSE American permits reductions, but only if the reductions meet specific criteria. Specifically, Section 105(a) of the NYSE American Company Guide provides that NYSE American will not list warrants containing provisions which give the company the right, at its discretion, to reduce the exercise price of the warrants for periods of time, or from time to time, during the life of the warrants unless the company establishes a minimum period of ten business days within which such price reduction will be in effect. Section 105(a) specifies that this policy does not preclude the listing of warrants for which regularly scheduled and specified changes in the exercise price have been previously established.¹²

The Exchange proposes to amend Section 703.12(A) to provide an exception to its prohibition on the reduction in the exercise price of listed warrants subject to similar conditions to those set forth in the warrant listing standard of NYSE American, except that any reduction in the exercise price of a listed series of warrants would be required to be in effect for a minimum period of 20 business days rather than the 10 day period required by the NYSE American rule. In addition, the

⁹ For example, the Exchange would view an exchange of common stock for outstanding warrants as a transaction prohibited by the rule if the economic benefit to the warrant holder of participating in the exchange was effectively the same as the benefit to the holder of exercising the warrants at a reduced exercise price. Similarly, an increase in the number of shares for which a warrant is exercisable without a related increase in the warrant exercise price is economically equivalent to a reduction in the exercise price.

¹⁰ See Nasdaq Marketplace Rule 5410.

¹¹ See NYSE American Company Guide Section 105(a).

¹² While the applicable Nasdaq and NYSE American rules do not address the requirements of the SEC’s tender offer rules with respect to temporary reductions in the exercise price of warrants, companies listed on Nasdaq and NYSE American that reduce the exercise price of listed warrants are required to comply with the twenty business day minimum offering period required under the tender offer rules. The applicable SEC tender offer rules are described in detail below.

Exchange proposes to require any company that reduces the exercise price of a listed series of warrants to promptly give public notice of the reduction in exercise price in a manner consistent with the Exchange’s immediate release policy set forth in Section 202.06 of the Manual.¹³ The Exchange also proposes to add to Section 703.12(A) a statement that these policies will not preclude the listing of warrant issues for which regularly scheduled and specified changes in the exercise price have been previously established at the time of issuance of the warrants.

Notwithstanding the foregoing, the Exchange will not list any warrants under Section 703.12 whose exercise price is subject to possible modification for reasons other than scheduled and specified changes established at the time of issuance.

A reduction in the exercise price of publicly-traded warrants for a limited time period is deemed to be a tender offer by the SEC staff and is therefore subject to the requirements of the SEC’s tender offer rules as set forth in Regulation 14E under the Exchange Act.¹⁴ SEC Rule 14e-1(a)¹⁵ requires that any tender offer subject to Regulation 14E be held open for at least 20 business days. SEC Rule 14e-1(b)¹⁶ provides for certain circumstances in which a tender offer period must be extended beyond that initial 20 business day period. Rule 14e-1(c)¹⁷ under the Act requires securityholders to be paid promptly after tendering their securities into a tender offer. In addition, all tender offers for listed warrants will be subject to Section 13(e) of the Act, Rule 13e-4 under the Act, Section 14(e) of the Act, and Regulation 14E under the Act.

The Exchange’s proposal that any repricing of listed warrants be held open for at least 20 business days, or such longer period as may be required by the SEC’s tender offer rules, would be consistent with the SEC’s tender offer rules. The Exchange also believes that the proposed 20 business day minimum notice requirement would ensure that warrant holders have a reasonable

¹³ The Exchange proposes to include text in the proposed amended rule: (i) Specifying that it will apply these requirements to the taking of any other action which has the same economic effect as a reduction in the exercise price of a listed warrant and (ii) requiring that any issuer of listed warrants including a provision providing for repricings must undertake to comply with any applicable tender offer regulatory provisions under the federal securities laws, including a minimum period of 20 business days within which such price reduction will be in effect (or such longer period as may be required under the SEC’s tender offer rules).

¹⁴ 17 CFR 240.14e-1 *et seq.*

¹⁵ 17 CFR 240.14e-1(a).

¹⁶ 17 CFR 240.14e-1(b).

¹⁷ 17 CFR 240.14e-1(c).

⁴ 15 U.S.C. 78m(e).

⁵ 17 CFR 240.13e-4.

⁶ 15 U.S.C. 78m(e).

⁷ 17 CFR 240.13e-4.

⁸ In order to be listed on the Exchange under Section 703.12, warrants must be issued to purchase a common equity security that is already listed or that will be listed concurrent with the warrants.

amount of time to consider the advisability of exercising their warrants during the period in which the reduced exercise price is in effect and that warrant holders will therefore not be under unreasonable pressure to make a hasty, ill-informed investment decision. The Exchange also proposes to require that any listed company that reduces the exercise price of listed warrants announce that fact in a manner consistent with the Exchange's policies with respect to the dissemination of material news as set forth in Section 202.06 of the Manual. The Exchange believes that this requirement would give all warrant holders appropriate notice and the ability to avail themselves of the lower exercise price if they so desire.

The Exchange's warrant listing standard has been in place for many years and the Exchange has not been able to ascertain the basis for inclusion in that listing standard of the provision which it proposes to amend in this filing. However, the Exchange notes that the American Stock Exchange ("Amex") had a similar requirement in its own warrant listing standard until it adopted the rule currently in effect at NYSE American in 1986. In the SEC's notice of that Amex filing,¹⁸ the SEC noted that the Amex had stated in its filing that:

The primary impetus for adopting this prohibition arose from a perception that management's unfettered ability to temporarily reduce the exercise price would add a further element of speculation to an instrument already viewed as having inherent speculative qualities. Today, however, with the growth of new securities and commodities products, warrants are no longer viewed as being the speculative instruments they once were.

The Exchange notes that there may be valid reasons for a reduction in the exercise price of listed warrants, that such reductions are not uncommon among companies listed on other listing exchanges, and that it has found no evidence that these exercise price reductions have generally been controversial. The Exchange believes that the board of a listed company is best positioned to determine whether a reduction in the exercise price of the company's outstanding warrants is in the best interests of shareholders and therefore believes that a general prohibition on such reductions is unnecessarily restrictive as it completely deprives a listed company board of the discretion to make such a

determination. The Exchange believes it is appropriate to provide companies with the flexibility to make these determinations and that the state law fiduciary duties of officers and directors of listed companies would provide significant protection to shareholders against the possibility of inappropriate exercises of discretion by company boards and management in relation to reductions in warrant exercise prices. Given (i) the significant protections afforded to shareholders by the fiduciary duties of the boards and management of listed companies, (ii) the protections provided to warrant holders by the inclusion of a notice requirement and a minimum period, and (iii) the fact that the proposed amendment is consistent with the tender offer rules, the Exchange believes that the proposed amendment is consistent with the protection of investors and the public interest.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b)¹⁹ of the Act, in general, and furthers the objectives of Section 6(b)(5) of the Act,²⁰ in particular in that it is designed to promote just and equitable principles of trade, to 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 Exchange believes that the proposed amendment is consistent with the investor protection objectives of Section 6(b)(5) because: (i) There may be valid business reasons for a listed company to reduce the exercise price of its listed warrants and the company's board is best positioned to make this determination in light of its fiduciary duties, so a general prohibition is not in the best interests of shareholders; (ii) the proposed requirement that the price reduction must stay in effect for 20 business days or such longer period as required by the SEC's tender offer rules would give the warrant holders a reasonable amount of time to consider the advisability of exercising their warrants during the period in which the reduced exercise price was in effect and warrant holders would therefore not be under unreasonable pressure to make a hasty, ill-informed investment decision; and (iii) the proposed requirement that

any listed company which reduces the exercise price of listed warrants must announce that fact in a manner consistent with the Exchange's material news dissemination policies would give all warrant holders appropriate notice and the ability to avail themselves of the lower exercise price if they so desired.

The requirement that any warrant repricing under the proposed amendment must be held open for at least 20 business days (or such longer period as is required under the SEC's tender offer rules) and that the company must undertake to comply with applicable tender offer regulatory provisions [sic] would ensure that any warrant repricing under the proposed amendment would be in compliance with Section 13(e) of the Act, Rule 13e-4 under the Act, Section 14(e) of the Act, and Regulation 14E under the Act.

The addition to the rule of language stating that the Exchange will apply its requirements with respect to warrant repricings to the taking of any other action which has the same economic effect as a reduction in the exercise price of a listed warrant is consistent with the Act as it simply codifies a longstanding interpretation of the rule by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The purpose of the proposed rule change is to permit listed companies to adjust the exercise price of listed warrants in a manner that is consistent with the SEC's tender offer rules and permitted by the rules of the other listing markets. As such, the Exchange believes the proposed rule change does not impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act²¹ and Rule 19b-4(f)(6) thereunder.²² Because the proposed rule change does not: (i)

¹⁸ See Securities Exchange Act Release No. 22581 (October 29, 1985); 50 FR 46376 (November 7, 1985) (SR-Amex-85-35). The filing was approved in Securities Exchange Act Release No. 22777 (January 8, 1986); 51 FR 2613 (January 17, 1986).

¹⁹ 15 U.S.C. 78f(b).

²⁰ 15 U.S.C. 78f(b)(5).

²¹ 15 U.S.C. 78s(b)(3)(A)(iii).

²² 17 CFR 240.19b-4(f)(6).

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) thereunder.²³

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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-NYSE-2018-04 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-2018-04. 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-NYSE-2018-04, and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁴

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-01420 Filed 1-25-18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82546; File No. SR-CboeBZX-2018-002]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Harmonize the Definition of Non-Professional User in Its Fee Schedule With That of Its Affiliates

January 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on January 17, 2018, Cboe BZX Exchange, Inc. (the "Exchange" or "BZX") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f)(6)(iii) thereunder,⁴ which renders it effective upon filing with the Commission. The Commission is publishing this notice to

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the Market Data section of its fee schedule to harmonize the definition of "Non-Professional User" with that of its affiliates, Cboe Exchange, Inc. ("Cboe") and Cboe C2 Exchange, Inc. ("C2").

The text of the proposed rule change is available at the Exchange's website at www.markets.cboe.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 parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Market Data section of its fee schedule to harmonize the definition of "Non-Professional User" with that of its affiliates, Cboe and C2. In late 2016, the Exchange and its affiliates Cboe EDGA Exchange, Inc. ("EDGA"), Cboe BYX Exchange, Inc. ("BYX"), and Cboe EDGX Exchange, Inc. ("EDGX") received approval to effect a merger (the "Merger") of the Exchange's parent company, Bats Global Markets, Inc., the parent of EDGA, EDGX, BYX, and BZX with CBOE Holding, Inc. (now known as Cboe Global Markets, Inc.) the parent company of Cboe and C2.⁵ In order to provide consistent rules and terminology amongst the Exchange, Cboe, and C2, the Exchange proposes to amend the definition of "Non-Professional User" to harmonize it with that of its affiliates, Cboe and C2. The

²³ 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.

²⁴ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4(f)(6)(iii).

⁵ See Securities Exchange Act Release No. 79585 (December 16, 2016), 82 FR 6961 (December 22, 2016) (SR-BatsEDGX-2016-60; SR-BatsEDGA-2016-24; SR-BatsBYX-2017-29; and SR-BatsBYX-2016-68).

BZX Option's fee schedule currently defines "Non-Professional User" as:

a natural person who is not: (i) registered or qualified in any capacity with the Commission, the Commodity Futures Trading Commission, any state securities agency, any securities exchange or association, or any commodities or futures contract market or association; (ii) engaged as an "investment adviser" as that term is defined in Section 202(a)(11) of the Investment Advisers Act of 1940 (whether or not registered or qualified under that Act); or (iii) employed by a bank or other organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt.

As amended, "Non-Professional User" would be defined as:

a natural person or qualifying trust that uses Data only for personal purposes and not for any commercial purpose and, for a natural person who works in the United States, is not: (i) registered or qualified in any capacity with the Securities and Exchange Commission, the Commodity Futures Trading Commission, any state securities agency, any securities exchange or association, or any commodities or futures contract market or association; (ii) engaged as an "investment adviser" as that term is defined in Section 202(a)(11) of the Investment Advisers Act of 1940 (whether or not registered or qualified under that Act); or (iii) employed by a bank or other organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt; or, for a natural person who works outside of the United States, does not perform the same functions as would disqualify such person as a Non-Professional User if he or she worked in the United States.

The revised definition is substantially identical to the definition of "Non-Professional User" included within the Cboe and C2 fee schedules.⁶ The Exchange's current definition of "Non-Professional User" does differ from that contained in the Cboe and C2 fee schedules in following minor, non-substantive ways. First, the harmonized definition will make clear that a Non-Professional User may be a natural person or qualifying trust that uses Data only for personal purposes and not for any commercial purpose. To date, the Exchange is not aware of any entity that receives an Exchange market data

product would be deemed a qualifying trust and, therefore, has not had to determine whether such entity is a Professional or Non-Professional User under the prior definition. Second, the harmonized definition would specify that a natural person who works outside of the United States would not be deemed a Non-Professional User where that person does not perform the same functions as would disqualify such person as a Non-Professional User if he or she worked in the United States. The definition with regard to natural persons who work in the United States are substantively identical amongst the old and harmonized definition.

None of these differences impact the manner in which the Exchange would characterize a User and a Professional or Non-Professional. The harmonized definition would provide additional specificity while harmonizing the definition with that of its affiliates. Doing so would ensure consistent terms amongst the Exchange and its affiliates, thereby reducing the potential for confusion amongst market data subscribers regarding the type of User they may be considered by the Exchange.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,⁷ in general, and furthers the objectives of Section 6(b)(5) of the Act⁸ in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The harmonized definition of Non-Professional User is equitable, reasonable, and removes impediments to and perfect the mechanism of a free and open market and a national market system it would provide additional specificity while harmonizing the definition with that of its affiliates. Doing so would ensure consistent terms amongst the Exchange and its affiliates, thereby reducing the potential for confusion amongst market data subscribers regarding the type of User they may be considered by the Exchange.

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, as amended. The harmonized definition of Non-Professional User would have no impact on competition because it does not materially alter the definition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act⁹ and subparagraph (f)(6) of Rule 19b-4 thereunder.¹⁰ In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

In its filing, the Exchange requested that the Commission waive the 30-day operative delay in order to enable the Exchange to immediately ensure consistent use of terms amongst the Exchange and its affiliates, thereby reducing the potential for confusion amongst market data subscribers regarding the type of User they may be considered by the Exchange. The Commission believes that such waiver is consistent with the protection of investors and the public interest. Therefore, the Commission designates the proposed rule change to be operative upon filing. For purposes only of waiving the 30-day operative delay, the Commission has also considered the

⁶ See the Cboe fee schedule available at https://www.cboe.org/general-info/pdf/frames?content=/publish/mdxfees/cboe-cds-fees-schedule-for-cboe-datafeeds.pdf§ion=SEC_MDX_CSM&title=Cboe%20CDS%20Fees%20Schedule and the C2 fee schedule available at https://www.cboe.org/general-info/pdf/frames?content=/publish/mdxfees/c2-cds-fees-schedule.pdf§ion=SEC_MDX_CSM&title=C2%20CDS%20Fees%20Schedule.

⁷ 15 U.S.C. 78f.

⁸ 15 U.S.C. 78f(b)(5).

⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁰ 17 CFR 240.19b-4(f)(6).

proposed rule's impact on efficiency, competition, and capital formation.¹¹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-ChoeBZX-2018-002 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number ChoeBZX-2018-002. 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 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 ChoeBZX-2018-002 and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹²

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-01361 Filed 1-25-18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82563; File No. SR-NYSE-2018-03]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List

January 22, 2018.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (the "Act") ² and Rule 19b-4 thereunder, ³ notice is hereby given that, on January 8, 2018, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List for equity transactions in stocks with a per share stock price of \$1.00 or more to (1) revise the Non-Tier Adding Credit; (2) modify the market at-the-close ("MOC") and limit at-the-close ("LOC") tier and non-tier rates and add a new Floor broker MOC fee; (3) modify the fee for executions at the close (except MOC, LOC and Closing Offset ("CO") Orders), and Floor broker executions swept into the close,

excluding verbal interest above the first 750,000 average daily volume ("ADV") of aggregate executions at the close; (4) introduce a Tier 4 Adding Credit; (5) introduce tiered trading license fees; and (6) make certain non-substantive organizational and clarifying changes, including grouping fees for all executions at the close together. The Exchange proposes to implement these changes to its Price List effective January 8, 2018.⁴ The proposed rule change is available on the Exchange's website at www.nyse.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 self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Price List to (1) revise the Non-Tier Adding Credit; (2) modify the MOC and LOC tier and non-tier rates and add a Floor broker MOC fee; (3) modify the fee for executions at the close (except MOC, LOC and CO Orders), and Floor broker executions swept into the close, excluding verbal interest above the first 750,000 average daily volume ("ADV") of aggregate executions at the close; (4) introduce a Tier 4 Adding Credit; (5) introduce tiered trading license fees; and (6) make certain non-substantive organizational and clarifying changes, including grouping fees for all executions at the close together.

The proposed changes would only apply to fees and credits in transactions in securities priced \$1.00 or more.

The Exchange proposes to implement these changes to its Price List effective January 8, 2018.

¹² 17 CFR 200.30-3(a)(12).

¹⁵ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ The Exchange originally filed to amend the Price List on December 28, 2017 (SR-NYSE-2017-73). SR-NYSE-2017-73 was subsequently withdrawn and replaced by this filing.

¹¹ See 15 U.S.C. 78c(f).

Member Organization Non-Tier Adding Credit

Member organizations are currently eligible for the Non-Tier Adding Credit for all orders in securities priced \$1.00 or more, other than Midpoint Passive Liquidity ("MPL")⁵ and Non-Display Reserve orders, that add liquidity to the NYSE unless a higher credit applies. The applicable rate for the Non-Tier Adding Credit is \$0.0014 per share. The Exchange proposes to lower this credit to \$0.0012 per share. The credits applicable to MPL orders and Non-Display Reserve orders would be unchanged.

Executions at the Close

Overview

The Exchange proposes to group all fees relating to executions at the close together in a table under a new proposed heading titled "Executions at the Close Equity Per Share Charge—per transaction (both sides)." The current entries relating to charges for executions at the close, including verbal interest and MOC/LOC Tiers 1 and 2, would be moved and/or replaced with modified entries, as described more fully below. The Exchange also proposes modifications to the rates for non-tier MOC orders and a new fee for MOC order executed by Floor brokers. Finally, the Exchange proposes modifications for charges for executions at the close (except MOC, LOC and CO Orders), and Floor broker executions swept into the close, excluding verbal interest above the first 750,000 ADV of the aggregate of executions at the close by a member organization.⁶

MOC/LOC Tiers and Non-Tier MOC/LOC

MOC/LOC Tier 1

For MOC/LOC Tier 1, the Exchange currently charges \$0.0007 per share for all MOC and LOC orders from any member organization executing ADV of MOC and LOC activity on the NYSE in that month of at least 0.575% of consolidated average daily volume ("CADV") in NYSE-listed securities (*i.e.*, Tape A securities) during the billing month ("NYSE CADV").

⁵ An MPL Order is an undisplayed limit order that automatically executes at the mid-point of the best protected bid ("PBB") or best protected offer ("PBO"), as such terms are defined in Regulation NMS Rule 600(b)(57) (together, "PBBO"). See Rule 13. See also 17 CFR 242.600(b)(57).

⁶ The Exchange is not proposing to change the fees for verbal interest at the close and for CO Orders. The Exchange proposes non-substantive differences to describe these fees as the first and second entries on the table with the fees associated with executions at the close.

The Exchange proposes to move the MOC/LOC Tier 1 as the third [sic] entry on the table with the charges associated with executions at the close and modify it to provide that the MOC/LOC Tier 1 rates would be available for all MOC and LOC orders from any member organization in the prior three billing months executing (1) an ADV of MOC activity on the NYSE of at least 0.45% of NYSE CADV, (2) an ADV of total close activity (MOC/LOC and executions at the close) on the NYSE of at least 0.7% of NYSE CADV, and (3) whose MOC activity comprised at least 35% of the member organization's total close activity (MOC/LOC and other executions at the close).

For member organizations qualifying for the MOC/LOC Tier 1 requirements, the Exchange proposes to retain the \$0.0007 per share charge for LOC executions and to lower the per share charge for MOC executions to \$0.0004 per share.

MOC/LOC Tier 2

For MOC/LOC Tier 2, the Exchange currently charges \$0.0008 per share for all MOC and LOC orders from any member organization executing (i) an ADV of MOC and LOC activity on the Exchange in that month of at least 0.375% of NYSE CADV; or (ii) an ADV of MOC and LOC activity on the Exchange in that month of at least 0.300% of NYSE CADV plus an ADV of total close (MOC/LOC and executions at the close) activity on the Exchange in that month of at least 0.475% of NYSE CADV.

The Exchange proposes to move the MOC/LOC Tier 2 as the fourth [sic] entry on the table with the charges associated with executions at the close and modify it to provide that the MOC/LOC Tier 2 rates would be available for all MOC and LOC orders from any member organization in the prior three billing months executing (1) an ADV of MOC activity on the NYSE of at least 0.35% of NYSE CADV, (2) an ADV of total close activity (MOC/LOC and other executions at the close) on the NYSE of at least 0.525% of NYSE CADV, and (3) whose MOC activity comprised at least 35% of the member organization's total close activity (MOC/LOC and other executions at the close).

For member organizations qualifying for the MOC/LOC Tier 2 requirements, the Exchange proposes to retain the \$0.0008 per share charge for LOC executions and to lower the per share charge for MOC executions to \$0.0005 per share.

Non-Tier MOC/LOC

The Exchange proposes to move fees for Non-Tier MOC/LOC rates, which as proposed would include MOC Orders, LOC Orders, and MOC Orders entered by a Floor broker, as the fifth [sic] entry on the table with the charges associated with executions at the close.

For Non-Tier MOC/LOC, the Exchange currently charges member organizations \$0.0011 per share for MOC and LOC executions, unless a member organization meets specified thresholds set forth in the Price List for MOC and LOC activity. The Exchange proposes that the Non-Tier MOC/LOC rates would be available for any member organization not meeting the above requirements for MOC/LOC Tier 1 or MOC/LOC Tier 2.

For member organizations that qualify for Non-Tier MOC/LOC, the Exchange proposes to lower the fee for MOC executions to \$0.0010 per share. The charge for Non-Tier LOC executions would remain the same at \$0.0011.

Floor Broker MOC Orders

The Exchange propose [sic] a new fee for the execution of MOC orders sent to a Floor broker for representation on the Exchange of \$0.0005 per share unless a lower tiered fee applies. The proposed fee would appear in the table as part of the Non-Tier MOC/LOC entries.

Fees for d-Quotes and Other Executions at the Close

The Exchange proposes to move charges for d-Quotes and other executions at the close, which as proposed would include d-Quotes, Floor broker executions swept into the close, excluding verbal interest, and executions at the close but excluding MOC Orders, LOC Orders, and CO Orders, as the sixth [sic] entry on the table with the charges associated with executions at the close.

Currently, the Exchange charges \$0.0005 per share if a member organization executes an ADV on the NYSE during the billing month in excess of 750,000 shares in (1) executions at the close (except MOC and LOC executions), and/or (2) Floor broker executions swept into the close, excluding verbal interest. The fee is applicable to shares executed in excess of 750,000 ADV, while no charge is applicable to shares executed below 750,000 ADV.

The Exchange proposes to continue not to charge member organizations for the first 750,000 ADV of the aggregate of executions at the close for d-Quote, Floor broker executions swept into the close, excluding verbal interest, and

executions at the close, excluding MOC Orders, LOC Orders and CO Orders. For d-Quote, Floor broker executions swept into the close, excluding verbal interest, and executions at the close, excluding MOC Orders, LOC Orders and CO Orders after the first 750,000 ADV of the aggregate of executions at the close by a member organization, the Exchange proposes to change the rate to \$0.0007 per share.

Tier 4 Adding Credit

The Exchange proposes to establish a new adding credit tier titled the “Tier 4 Adding Credit” that would provide a credit of \$0.0015 per share for all orders, other than MPL and Non-Display Reserve orders, that add liquidity to the NYSE if:

- (i) The member organization has Adding ADV in MPL orders that is at least 4 million shares ADV, excluding any liquidity added by a DMM, and
- (ii) the member organization executes MOC and LOC orders of at least 0.10% of NYSE CADV.

Trading License Fees

Rule 300(b) provides, among other things, that the price per trading license will be published in the Exchange’s price list and that a tiered pricing structure based on the number of trading licenses held by a member organization may be utilized. The current trading license fee in place since 2016⁷ is \$50,000 per trading license and no charge for additional licenses held by a member organization. Regulated Only Members, as defined in Rule 2(b)(ii), are charged an annual administration fee of \$25,000.

The Exchange proposes to introduce tiered trading license fees and group all charges relating to trading license fees in a table under the “Trading License” heading.⁸

For all member organizations, including Floor brokers with more than ten trading licenses but excluding Regulated Only Members, the trading license fee would remain unchanged at \$50,000 for the first license held by the member organization unless one of the other rates is deemed applicable.

For member organizations with 3–9 trading licenses, the Exchange proposes a fee of \$35,000 for the first license held by a member organization that has Floor broker executions accounting for 40% or more of the member organization’s

combined adding and taking volumes during the billing month.

For Floor brokers with 1–2 trading licenses, the Exchange proposes a fee of \$25,000 for the first license held by a member organization that has Floor broker executions accounting for 40% or more of the member organization’s combined adding and taking volumes during the billing month.

As set forth in proposed footnote 15, there would continue to be no charge for additional licenses held by a member organization. In addition, the Exchange proposes not to charge for a trading license in place for 10 calendar days or less in a calendar month and eliminate the flat rate of \$100 per day for such license. Further, a trading license in place for 11 calendar days or more in a calendar month will be charged the applicable license fee for that month. Finally, for calculating the number of licenses described above, for the lower rates, the number of licenses will be based on those held by the member organization for 10 or more days in the billing month (including days the Exchange is not open for the entire trading day).⁹

For example, assume a member organization has 10 trading licenses in a given billing month with 9 licenses being held for 10 or more days that month and the tenth license being held for less than ten days. Further assume that the member organization also had Floor broker executions accounting for 40% or more of the member organization’s combined adding and taking volumes during that billing month. In such a case, the member organization would qualify for the lower license fee of \$35,000 in that billing month, prorated monthly.

If that same member organization in the following billing month held the same number of licenses, but with all 10 being held for 10 or more days, then the member organization would be billed the full rate of \$50,000 for that next billing month, prorated monthly, regardless of whether that member organization had Floor broker executions accounting for 40% or more of the member organization’s combined adding and taking volumes during that next billing month.

⁹ The Exchange also proposes non-substantive, clarifying changes to the current first sentence of footnote 15 to delete “indicated above” and add “indicated” before “annual,” “trading license” before “fee,” and “on a monthly basis” after “will be prorated.” Footnote 15 as amended would continue to apply to the first license held by a member organization in each category.

The annual administration fee for Regulated Only Members, as defined in Rule 2(b)(ii), would remain \$25,000.

* * * * *

The proposed changes are 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 change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹⁰ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,¹¹ in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed fee changes for certain executions at the close are reasonable. The Exchange’s closing auction is a recognized industry benchmark,¹² and member organizations receive a substantial benefit from the Exchange in obtaining high levels of executions at the Exchange’s closing price on a daily basis.

Member Organization Non-Tier Adding Credit

The Exchange believes that the change to the Member Organization Non-Tier Adding Credit for executions of orders in securities with a per share price of \$1.00 or more is reasonable, equitable and not unfairly discriminatory because it is intended to incentivize member organizations to submit additional amounts of liquidity to the Exchange to be eligible to receive the higher credits available from the Tier 1 Adding Credit, the Tier 2 Adding Credit, the Tier 3 Adding Credit and the proposed Tier 4 Adding Credit. The Exchange believes that the proposed lower credit for the Member Organization Non-Tier Adding Credit is equitable and not unfairly discriminatory because it would apply equally to all member organizations.

MOC/LOC Tiers and Non-Tier MOC/LOC

The Exchange believes that requiring an ADV of MOC activity on the NYSE of at least 0.45% of NYSE CADV, an

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4) & (5).

¹² For example, the pricing and valuation of certain indices, funds, and derivative products require primary market prints.

⁷ See Securities Exchange Act Release No. 78233 (July 6, 2016), 81 FR 45190 (July 12, 2016) (SR–NYSE–2016–47).

⁸ The Exchange also proposes to correct a typographical error in the heading and change “Licences” to “Licenses.”

ADV of Total Close activity on the NYSE of at least 0.7% of NYSE CADV, and MOC activity comprised at least 35% of the member organization's total close activity (MOC/LOC and other executions at the close) for the MOC/LOC Tier 1 fee, as well the requiring an ADV of MOC activity on the NYSE of at least 0.35% of NYSE CADV, an ADV of Total Close activity on the NYSE of at least 0.525% of NYSE CADV, and MOC activity comprised at least 35% of the member's total close activity (MOC/LOC and other executions at the close) for the MOC/LOC Tier 2 fee, is reasonable and not unfairly discriminatory because the proposed changes would encourage greater marketable and other liquidity at the closing auction.

The Exchange believes that charging a lower rate for MOC executions than LOC executions is reasonable and not unfairly discriminatory because MOC orders are always marketable and therefore have a higher likelihood of execution at the close. Charging a lower fee will encourage higher volumes of MOC orders at the close, which should result in a higher level of orders matched and greater liquidity for all Exchange auction participants.

The Exchange believes that introducing a requirement that at least 35% of the member organization's total close activity be comprised of MOC activity in order to qualify for MOC/LOC Tier 1 or 2 rates is reasonable and not unfairly discriminatory because MOC orders contribute meaningfully to the price and size discovery, which is the hallmark of the closing auction process. Charging a lower fee to member organizations utilizing MOC orders as a significant component of their closing auction participation will encourage higher volumes of MOC orders at the close, which should result in robust price discovery, a higher level of orders matched and greater liquidity for all Exchange auction participants.

The Exchange believes that lowering the MOC/LOC Non-Tier fee for MOC orders is reasonable as it is comparable to the above change in MOC rates for MOC/LOC Tier 1 and MOC/LOC Tier 2, and that MOC orders contribute meaningfully to the price and size discovery, which is the hallmark of the closing auction process. Charging a lower fee will encourage higher volumes of MOC orders at the close, which should result in a higher level of orders matched and greater liquidity for all Exchange auction participants.

Floor Broker MOC Orders

The Exchange believes that the proposed fee for executions of MOC orders sent to a Floor broker for

representation on the Exchange is reasonable because it would encourage additional displayed liquidity on the Exchange's closing auction. The Exchange believes the proposed change is equitable and not unfairly discriminatory because it would continue to encourage member organizations to send orders to the trading Floor for execution, thereby contributing to robust levels of liquidity on the trading Floor, which benefits all market participants. The Exchange further notes that the \$0.0005 fee for Floor broker MOC orders executed at the close is in line with the \$0.0007 fee for Floor broker executions swept into the close, excluding verbal interest.

Charges for d-Quotes and Other Executions at the Close

The Exchange believes it is appropriate to continue to not charge member organizations for the first 750,000 ADV of the aggregate of executions at the close for d-Quote, Floor broker executions swept into the close, excluding verbal interest, and executions at the close, excluding MOC Orders, LOC Orders, and CO Orders, as this will continue to provide less active member organizations a no-cost mechanism to participate in the closing auction. The proposed fee change for executions above 750,000 ADV is also reasonable, in that it is lower than applicable closing rates on the NASDAQ Stock Market, LLC ("NASDAQ"). For example, the default fee for Continuous Book executions in NASDAQ's "Closing Cross" is \$0.00085 per share, compared with the proposed \$0.0007 fee for d-Quote, Floor broker executions at the close, excluding verbal interest, and executions at the close, excluding MOC Orders, LOC Orders, and CO Orders.¹³

Tier 4 Adding Credit

The Exchange believes that the new Tier 4 Adding Credit of \$0.0015 per share for transactions in stocks with a per share stock price of \$1.00 or more when adding liquidity is reasonable because it would further contribute to incenting member organizations to provide additional liquidity to a public exchange, thereby promoting price discovery and transparency and enhancing order execution opportunities for member organizations. The Exchange believes that introducing a requirement for Adding ADV in MPL Orders that is at least 4 million shares ADV, excluding any liquidity added by a DMM is reasonable and not unfairly discriminatory because MPL orders provide opportunities for market

participants to interact with orders priced at the midpoint of the PBBO, thus providing price improving liquidity to market participants and increasing the quality of order execution on the Exchange's market, which benefits all market participants. These changes should encourage additional utilization of MPL Orders on the Exchange. The Exchange further believes that introducing a requirement for executions of MOC and LOC orders of at least 0.10% of NYSE CADV is reasonable and not unfairly discriminatory because it will encourage higher volumes of MOC and LOC orders at the close, which should result in a higher level of orders matched and greater liquidity for all Exchange auction participants.

The Exchange further believes that the proposed new Tier 4 Adding Credit of \$0.0015 is equitable and not unfairly discriminatory because all member organizations would benefit from such increased levels of liquidity. In addition, the new Tier 4 Adding Credit would provide a higher credit to member organizations that is reasonably related to the value to the Exchange's market quality associated with higher volumes of liquidity. The Exchange also believes that the proposed new Tier 4 Adding Credit is equitable and not unfairly discriminatory because it would provide several methods of qualifying for the credit, which would attract multiple sources of liquidity to the Exchange.

Trading License Fees

The Exchange believes that the proposal to maintain the current trading license fee, including the fee for Regulated Only Members, and lower the fee for member organizations with 9 or less trading licenses who have Floor broker executions accounting for 40% or more of the member organization's combined adding and taking volumes during the billing month as well as basing the requirement on licenses held 10 or more days in the billing month, is equitable and not unfairly discriminatory because all similarly situated member organizations would continue to be subject to the same trading license fee structure and because access to the Exchange's market would continue to be offered on fair and non-discriminatory terms. The Exchange also believes that the proposal is equitable and not unfairly discriminatory because all member organizations would continue to have the opportunity to enjoy the benefits of the fee relief with respect to additional trading licenses. The Exchange believes that allowing member organizations

¹³ See NASDAQ Rule 7018(d).

with 9 or less trading licenses that have the requisite Floor broker volumes to obtain a license at a lower cost will help preserve the diversity of the Exchange's membership and encourage smaller member organizations to send orders to the Exchange. The Exchange believes that the threshold it has selected will continue to incent order flow from multiple sources and help maintain the quality of the Exchange's executions, which benefits all market participants. The Exchange further believes that continuing to not charge for additional licenses above the first license held by a member organization, not charging for a trading license in place for 10 calendar days or less, and charging the applicable trading license fee for a trading license in place for 11 calendar days or more is reasonable because it will continue to encourage member organizations to hold additional trading licenses, which will increase the number of market participants on the Exchange trading Floor, thereby promoting liquidity, price discovery, and the opportunity for price improvement for the benefit of all market participants. The proposal is also equitable and not unfairly discriminatory because it would apply equally to all license holders over the same number of days.

Non-Substantive Changes

The Exchange believes that the proposed non-substantive changes to consolidate and streamline the presentation of charges for executions at the close and trading license fees into a table, correct a typographical error and clarify the first sentence of footnote 15 are reasonable because they are designed to provide greater specificity and clarity to the Price List, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in general, protecting investors and the public interest.

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 the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,¹⁴ the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the

Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting price discovery and transparency and enhancing order execution opportunities for member organizations. The Exchange believes that this could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. As a result of all of these considerations, the Exchange does not believe that the proposed changes will impair the ability of member organizations or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)¹⁵ of the Act and subparagraph (f)(2) of Rule 19b-4¹⁶ thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the

Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹⁷ 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-NYSE-2018-03 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-2018-03. 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.

¹⁵ 15 U.S.C. 78s(b)(3)(A).

¹⁶ 17 CFR 240.19b-4(f)(2).

¹⁷ 15 U.S.C. 78s(b)(2)(B).

¹⁴ 15 U.S.C. 78f(b)(8).

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–2018–03 and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018–01417 Filed 1–25–18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82544; File No. SR–NSCC–2017–019]

Self-Regulatory Organizations; National Securities Clearing Corporation; Order Approving Proposed Rule Change To Enhance the Process for Submitting and Accepting ETF Creations and Redemptions

January 19, 2018.

On November 28, 2017, National Securities Clearing Corporation (“NSCC”) filed with the Securities and Exchange Commission (“Commission”) proposed rule change SR–NSCC–2017–019, pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder. ² The proposed rule change was published for comment in the **Federal Register** on December 7, 2017. ³ The Commission did not receive any comment letters on the proposed rule change. For the reasons discussed below, the Commission approves the proposed rule change.

I. Description of the Proposed Rule Change

This proposed rule change would modify NSCC’s Rules & Procedures (“Rules”) ⁴ to add two new time frames during which exchange traded fund (“ETF”) agents may submit creation and redemption instructions, including as-of instructions, reversals, and corrections

(“ETF Instructions”) ⁵ to NSCC on behalf of ETF sponsors and ETF authorized participants. ⁶ The existing time frame during which ETF agents can submit ETF Instructions to NSCC extends from 2:00 p.m. to 8:00 p.m. (the “Primary Cycle”). ⁷ The two proposed time frames would extend from 12:30 a.m. to 2:00 p.m. (the “Intraday Cycle”) and from 9:00 p.m. to 11:30 p.m. (the “Supplemental Cycle”). ⁸

The two proposed cycles would enable ETF agents to submit ETF Instructions to NSCC later in the day, or earlier on the following day than currently possible, in order to make corrections to prior submissions. ⁹ The ability to make such new submission would help to avoid a situation where the NSCC member (“Member”) would need to post margin ¹⁰ to cover exposures from the prior erroneous submission. ¹¹ Specifically, the proposed Intraday Cycle would enable NSCC to receive, on an intraday basis, (1) ETF Instructions that are marked as-of a prior trade date, ¹² and (2) ETF Instructions for same-day settlement until the designated cut-off time of 11:30 a.m. ¹³ Meanwhile, the proposed

⁵ An as-of instruction is an instruction that is submitted with a trade date as of an earlier date. As-of reversal instructions and as-of corrections are types of as-of instructions. An as-of reversal instruction is an instruction that is submitted with a trade date as of an earlier date that reverses an instruction that was already processed by NSCC. Reversals and corrections are submitted on the same business day as the incorrect instruction, whereas as-of reversal instructions and as-of correction instructions are submitted on a business day after the date on which the incorrect instruction was submitted (but they would have the same trade date as the incorrect instruction). Notice, 82 FR at 57792.

⁶ ETF sponsors are issuers of ETFs. ETF authorized participants are (1) broker/dealers that have authorized participant agreements with ETF sponsors, and/or (2) broker/dealers that are NSCC members with an established ETF trading relationship with an ETF agent that is representing the ETF. See Rule 2, *supra* note 4.

⁷ All times referenced herein are Eastern Standard Time.

⁸ Notice, 82 FR at 57792–94.

⁹ *Id.* at 57793.

¹⁰ Rules, *supra* note 4. One way that NSCC mitigates its risk exposure to its Members is through a number of risk-based component charges (such as margin) that are calculated and assessed on Members daily. Each of the component charges collectively constitutes a Member’s daily required deposit (“Required Deposit”). The objective of the Required Deposit is to mitigate potential losses to NSCC associated with liquidation of the Member’s portfolio in the event that NSCC ceases to act for a Member (hereinafter referred to as a “Default”). The aggregate of all Members’ Required Deposits constitutes the Clearing Fund, which NSCC would be able to access should a defaulting Member’s own Required Deposit be insufficient to satisfy losses to NSCC caused by the liquidation of that Member’s portfolio.

¹¹ Notice, 82 FR at 57793.

¹² *Id.*

¹³ *Id.*

Supplemental Cycle would enable ETF agents to submit ETF Instructions later than the Primary Cycle cut-off of 8:00 p.m. ¹⁴

In connection with the two proposed cycles, NSCC also proposes to revise the standardized input files, which are submitted by ETF agents to NSCC, and the output files, which are sent by NSCC to ETF agents and ETF authorized participants, to include additional information, such as a reversal/correction indicator and transaction time. ¹⁵

NSCC also proposes an “automated threshold value reasonability check.” This check would hold any ETF Instructions in a “pending” status if such instructions exceed certain thresholds established by NSCC when compared to the most recent closing price. ¹⁶

Finally, NSCC proposes a technical correction to the Rules to clarify that next-day settling ETF Instructions are no longer processed differently than other ETF Instructions when submitted to NSCC. ¹⁷

A. Current ETF Submission Processes

According to NSCC, ETF sponsors have processes outside of NSCC that allow the sponsors to create or redeem ETF shares with ETF authorized participants intraday. The details of the creations or redemptions are then recorded by ETF agents. ¹⁸ The processes conducted outside of NSCC are not uniformly automated and may involve manual data entry that the ETF agent eventually submits to NSCC using the standardized ETF create-and-redeem input file. ¹⁹

Currently, the Primary Cycle is the only time in which ETF agents can submit the input file to NSCC. ²⁰ However, according to NSCC, a risk exists that the manually entered data may contain errors that could result in incorrectly valued transactions. ²¹ NSCC states that any errors in the manually entered data contained in the input file may result in NSCC recording ETF Instructions that may be materially different than the value upon which the ETF sponsor and ETF authorized participant agreed. ²² Nevertheless, NSCC uses that information when calculating both the ETF agent’s and the ETF authorized participant’s daily

¹⁴ *Id.* at 57792.

¹⁵ *Id.* at 57794.

¹⁶ *Id.* at 57795–96.

¹⁷ *Id.* at 57794–95.

¹⁸ *Id.* at 57791.

¹⁹ *Id.*

²⁰ *Id.* at 57792.

²¹ *Id.* at 57791–92.

²² *Id.* at 57792.

¹⁸ 17 CFR 200.30–3(a)(12).

¹⁵ U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 82193 (December 1, 2017), 82 FR 57791 (December 7, 2017) (SR–NSCC–2017–019) (“Notice”).

⁴ Available at <http://www.dtcc.com/en/legal/rules-and-procedures>.

Required Deposit.²³ If the input file contained incorrect information, then the applicable Member's Required Deposit may reflect the error.²⁴ ETF agents currently do not have an opportunity to submit correcting ETF Instructions to NSCC until the next Primary Cycle, which is after the deadline for Members to satisfy their Required Deposit.²⁵

B. Proposed New Cycles

NSCC proposes to add two new cycles during which ETF agents may submit ETF Instructions to NSCC: The Intraday Cycle and the Supplemental Cycle.²⁶ These proposed cycles would enable ETF agents to submit (1) creation and redemption instructions that would either reverse or correct creation and redemption instructions previously processed by NSCC that day (*i.e.*, reversals and corrections), or (2) as-of instructions (*e.g.*, as-of reversal instructions and as-of correction instructions) intended to correct as-of instructions processed by NSCC on an earlier day. In either case, ETF agents would have an opportunity to submit the applicable ETF Instruction prior to the 10:00 a.m. deadline for satisfying any Required Deposit.²⁷

NSCC would continue to maintain its current deadline of 8:00 p.m. for the submission of the input files during the Primary Cycle on trade date ("T").²⁸ Any late ETF Instructions that are submitted to NSCC between 8:00 p.m. and 9:00 p.m. would be held until 9:00 p.m. and then processed at 9:00 p.m. during the Supplemental Cycle.²⁹ The Supplemental Cycle would remove the need for manual extensions to the existing deadline of 8:00 p.m. for the Primary Cycle because ETF Instructions received by NSCC after 8:00 p.m. would be held and processed during the Supplemental Cycle, which would begin at 9:00 p.m.³⁰

The proposed Intraday Cycle would enable NSCC to receive, on an intraday basis, ETF Instructions that are marked as-of a prior trade date.³¹ Furthermore, ETF agents would be able to submit ETF Instructions (corrections or otherwise)

to NSCC for same-day settlement during the Intraday Cycle until the designated cut-off time of 11:30 a.m.³² However, ETF agents would not be able to submit ETF Instructions to NSCC for same-day settlement during the Primary Cycle because NSCC lacks the functionality to process such same-day transactions.³³ Upon implementation of the two proposed cycles, NSCC would be able to receive ETF Instructions in the standardized input file from 12:30 a.m. to 11:30 p.m. each business day.³⁴

According to NSCC, ETF agents currently submit ETF Instructions to NSCC using a standardized electronic input file.³⁵ NSCC states that adding the Intraday Cycle and Supplemental Cycle would require some coding changes to the existing standardized input file and the output files distributed by NSCC to ETF agents and ETF authorized participants.³⁶ Specifically, NSCC proposes to add additional information to the input file, such as the reversal/correction indicator and transaction time.³⁷ NSCC would also revise the format of the input file to accommodate the additional information.³⁸

As a result of these changes, ETF agents, ETF sponsors, and any third party service providers they may use would be required to make coding changes to their systems to submit the standardized input file during any of the cycles.³⁹ Although ETF agents would not be required to submit input files during all of the cycles, they would still be required to make coding changes to their systems because one standardized input file would be submitted to NSCC.⁴⁰ The additional information that would be included in the output files, such as the reversal/correction indicator and transaction time, would either be appended to the output files or would appear in fields in the output

files that are currently reserved and do not contain any information.⁴¹

ETF agents would be responsible for communicating these changes to their clients (*i.e.*, ETF sponsors) or any third party service providers that they utilize.⁴² NSCC would continue to distribute all existing output files during the Primary Cycle and would also distribute output files during the two proposed cycles.⁴³

C. Automated Threshold Value Reasonability Check

NSCC proposes an "automated threshold value reasonability check" that would hold in a "pending" status certain potentially mis-valued ETF Instructions (whether due to mistakes in manual entry or otherwise) that exceed certain thresholds established by NSCC.⁴⁴

The automated threshold value reasonability check would apply to all submissions of ETF Instructions.⁴⁵ NSCC would perform automated threshold value reasonability checks using the most recently available closing price from the primary listing marketplace compared to the per-share value for every individual ETF Instruction submitted.⁴⁶ NSCC would mark and assign a pended status to an ETF Instruction in which the per-share values exceed established thresholds compared to the most recently available closing price.⁴⁷ NSCC would automatically notify the ETF agent of a pended ETF Instruction via email and through the output files.⁴⁸ NSCC would also notify NSCC's internal operations of the pended ETF Instruction.⁴⁹ The ETF Instruction would remain in a pended status while awaiting confirmation for reinstatement (or rejection) by the submitting ETF agent.⁵⁰

A submitting ETF agent could authorize NSCC to process a pended ETF Instruction by affirmatively confirming the ETF Instruction.⁵¹ The ETF Instruction would then be processed as long as NSCC received the confirmation by the end of the Supplemental Cycle.⁵² If the submitting ETF agent does not respond by the specified time or responds that the ETF Instruction should be rejected, then

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.* at 57792–94.

²⁷ *Id.* at 57797.

²⁸ NSCC states that maintaining the current 8:00 p.m. deadline will help ensure that the existing end of day reconciliation processes conducted by ETF agents and ETF authorized participants continue to be conducted timely, and will also help prevent unnecessary delays to the end of day reconciliation processes. *Id.* at 57793.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² The cut-off time of 11:30 a.m. would align the deadline for same-day settling creation and redemption instructions with the 11:30 a.m. deadline for other same-day settling non-ETF activity. For example, same-day settling corporate bond trades and transactions in municipal securities are subject to the 11:30 a.m. deadline. NSCC believes aligning these deadlines would streamline the processing of same-day settling items for NSCC and its Members. *Id.*

³³ NSCC would reject ETF Instructions submitted for same-day settlement during the Primary Cycle instead of assigning such ETF Instructions a new settlement date. *Id.* Currently, ETF agents are able to settle same-day transactions outside of NSCC, and this proposal would preserve that ability. *Id.*

³⁴ *Id.*

³⁵ *Id.* at 57792–94.

³⁶ *Id.* at 57793–94.

³⁷ *Id.* at 57792–94.

³⁸ *Id.* at 57793–94.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.* at 57794.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.* at 57795–96.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

NSCC would reject the ETF Instruction.⁵³

NSCC proposes to establish the following threshold values initially:

- *For ETFs with a Current Market Price equal to or greater than \$3.00:* The ETF contract value (*i.e.*, the calculated effective price per share) is greater than or equal to a 98 percent variance from the market closing price from the trade date provided on the order; and
- *for ETFs with a Current Market Price less than \$3.00:* The ETF contract value (*i.e.*, the calculated effective price per share) is greater than or equal to a 98 percent variance from the market closing price from the trade date provided on the order.⁵⁴

NSCC believes that setting the initial threshold value at 98 percent would capture overvalued and undervalued ETF Instructions while not being an excessively narrow control.⁵⁵ NSCC would retain the flexibility and discretion to adjust the price range and the threshold values described above.⁵⁶ NSCC may consider market conditions and feedback from Members and internal NSCC stakeholders (*i.e.*, product management, risk management, and operations management) when considering threshold adjustments.⁵⁷

NSCC believes that threshold adjustments might be warranted under specific scenarios: (1) If requested by Members and/or internal NSCC stakeholders, or (2) in response to a future market event.⁵⁸ In the first scenario, NSCC could make threshold adjustments upon the request of Members and/or internal NSCC stakeholders to set thresholds closer to an ETF's closing market price than the initial setting.⁵⁹ Such threshold adjustments may prevent unnecessary reversals and margining on orders that contain errors because the threshold check would be triggered at smaller value differences.⁶⁰ Internal NSCC stakeholders would discuss the necessity of a threshold adjustment, with the final decision left to NSCC product management.⁶¹

In the second scenario, NSCC could make threshold adjustments in response to a future market event that results in a significant number of ETFs trading at market prices below the initial price range setting of \$3.00.⁶² NSCC would

notify Members of any adjustment via Important Notice.⁶³ NSCC expects that changes to either setting would be rare.⁶⁴

D. Technical Correction

NSCC proposes to make a technical correction to clarify how NSCC processes next-day settling instructions.⁶⁵ Since implementation of NSCC's accelerated trade guaranty,⁶⁶ NSCC no longer processes next-day settling instructions differently than other instructions when submitted to NSCC.⁶⁷ As such, next-day settling index receipts (with a Settlement Date of T+1) are no longer treated differently than regular-way instructions (*i.e.*, those with a Settlement Date of T+2).⁶⁸ The proposed correction would remove repetitive language regarding such instructions.⁶⁹

II. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act⁷⁰ directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and rules and regulations thereunder applicable to such organization. The Commission believes the proposal is consistent with Act, specifically Section 17A(b)(3)(F) of the Act and Rules 17Ad-22(e)(6) and (21) under the Act.⁷¹

Section 17A(b)(3)(F) of the Act requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions.⁷² As discussed above, under NSCC's current processes, ETF agents may submit ETF Instructions to NSCC only during the Primary Cycle. Therefore, in the event that an ETF Instruction was incorrectly entered, the ETF agent must wait until the Primary Cycle on the following day to submit a new ETF Instruction to correct the error. In the meantime, the erroneous instruction might affect the amount of

an ETF agent's and/or the ETF authorized participant's Required Deposit. This situation occurs because Required Deposits are updated daily at 7:05 a.m., with any outstanding deposits due to NSCC by 10:00 a.m., before the next Primary Cycle.

To help address this issue, NSCC proposes to add two new cycles (*i.e.*, the Intraday Cycle and Supplemental Cycle, as described above) during the day, thereby expanding the time frame within which ETF agents may submit ETF Instructions to NSCC. The proposed cycles would enable ETF agents to submit new ETF Instructions to correct previously submitted ETF Instructions that were incorrect before the next Required Deposits were due. As such, the proposal would provide ETF agents with an opportunity to address erroneous ETF Instructions before needing to satisfy their next Required Deposit. Accordingly, the proposed Intraday Cycle and Supplemental Cycle would help ensure that Members' Required Deposits more closely reflect the risk presented by their intended transactions. Therefore, the Commission finds the proposed addition of the Intraday and Supplemental Cycles would help promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.⁷³

The Intraday Cycle also would enable NSCC to receive same-day settling ETF Instructions (corrections or otherwise), which NSCC cannot do under its current processes. Consequently, the proposed change would allow such same-day settling ETF Instructions to receive the benefits of NSCC processing. These same-day settling instructions would also allow netting reversals and corrections with other primary and secondary market activity. Due to the increased opportunities described above for accurate same-day settling ETF Instructions, the Commission finds that NSCC's proposed change to add the Intraday Cycle would help promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.⁷⁴

The Commission also finds that NSCC's proposal to implement the automated threshold value reasonability check would promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.⁷⁵ As describe above, the automated threshold value reasonability check would hold

⁵³ *Id.*

⁵⁴ *Id.* at 57796.

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.* at 57794–95.

⁶⁶ See Securities Exchange Act Release No. 79598 (December 19, 2016), 81 FR 94462 (December 23, 2016) (SR–NSCC–2016–005). NSCC's accelerated trade guaranty, among other things, accelerated NSCC's trade guaranty from midnight of trade date plus one day ("T+1") to the point of trade comparison and validation for bilateral submissions or to the point of trade validation for locked-in submissions.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ Notice, 82 FR at 57794–95.

⁷⁰ 15 U.S.C. 78s(b)(2)(C).

⁷¹ 15 U.S.C. 78q–1(b)(3)(F); 17 CFR 240.17Ad–22(e)(6) and (21).

⁷² 15 U.S.C. 78q–1(b)(3)(F).

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

certain potentially erroneous ETF Instructions (whether due to mistakes in manual entry or otherwise) in a pending status until confirmed by the submitting ETF agent. Holding potentially erroneous ETF Instructions in a “pending” status would help minimize the potential impact of erroneous ETF Instructions on Members’ Required Deposits by preventing such ETF Instructions from being processed without confirmation from the submitting ETF agent. Thus, the automated threshold value reasonability check would help to ensure that Members are subject to Required Deposits that more closely reflect the Members’ intended trading activity and not erroneously entered information because Members would be required to confirm that the entered information is in fact correct. Therefore, the Commission finds that the proposed change to add the automated threshold value reasonability check would help promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.⁷⁶

Finally, the Commission finds that NSCC’s proposal to remove the repetitive language regarding next-day settling creates and redeems would promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.⁷⁷ Removing such repetitive language would help make the Rules more accurate and clear. Maintaining accurate and clear Rules would enable Members and other stakeholders to better understand their respective rights and obligations regarding NSCC’s clearance and settlement of securities transactions. Accordingly, the Commission finds that the proposed change to remove repetitive language from the Rules would promote the prompt and accurate clearance and settlement of securities transactions, consistent with the requirements of Section 17A(b)(3)(F) of the Act.⁷⁸

Rule 17Ad-22(e)(6)(i) under the Act requires NSCC to cover its credit exposures to its Members by establishing a risk-based margin system that, at a minimum considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market.⁷⁹ As described above, ETF agents submit ETF Instructions to NSCC using a standardized input file, which

involves manual data entry that poses an inherent risk of communicating potentially erroneous information. The proposed Intraday Cycle and Supplemental Cycle would enable ETF agents to submit new ETF Instructions to correct previously submitted ETF Instructions before Members need to satisfy their next Required Deposit. Similarly, the automated threshold value reasonability check would help minimize the potential impact of erroneous ETF Instructions on Members’ Required Deposits by preventing such ETF Instructions from being processed absent confirmation from the submitting ETF agent. Thus, the proposed cycles and automated threshold value reasonability check are ETF-specific proposals designed to better produce margin levels commensurate with the risk and particular attributes of ETFs. Accordingly, the Commission finds that the proposed cycles and automated threshold value reasonability check would enhance NSCC’s risk-based margin system in a manner that considers the risks and particular attributes specific to ETFs, consistent with Rule 17Ad-22(e)(6)(i).⁸⁰

Rule 17Ad-22(e)(21) under the Act requires NSCC to be efficient and effective in meeting the requirements of its Members and the markets it serves, and regularly review the efficiency and effectiveness of its (1) clearing and settlement arrangements, (2) operating structure, including risk management policies, procedures, and systems, and (3) use of technology and communication procedures.⁸¹ As stated above, the proposed cycles would enable ETF agents to submit new ETF Instructions to correct previously submitted ETF Instructions before Members need to satisfy their next Required Deposit. Similarly, the automated threshold value reasonability check would help minimize the potential impact of erroneous ETF Instructions on Members’ Required Deposits by preventing such ETF Instructions from being processed absent confirmation from the submitting ETF agent. The Intraday Cycle also would enable NSCC to receive same-day settling ETF Instructions (corrections or otherwise), and thereby allow such same-day settling ETF Instructions to receive the benefits of NSCC processing. The proposed cycles and automated threshold reasonability check constitute changes designed to improve the efficiency and effectiveness of NSCC’s ETF clearance and settlement

arrangements, NSCC’s related operating structure, and NSCC’s communications with ETF agents and authorized participants via the input and output reports. The proposal would enhance the efficiency and effectiveness of NSCC’s provision of ETF-related services by (1) enabling ETF agents to correct previously submitted errors before additional Required Deposits are required, (2) preventing potentially erroneous ETF Instructions from being processing until confirmed, and (3) enabling same-day settling ETF Instructions to receive the benefits of NSCC processing. Accordingly, the Commission finds that the proposal would enhance NSCC’s efficiency and effectiveness in meeting the requirements of its Members, as well as the efficiency and effectiveness of NSCC’s ETF-related clearing and settlement arrangements, operating structure, and communication procedures, consistent with Rule 17Ad-22(e)(21).⁸²

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act, in particular the requirements of Section 17A of the Act⁸³ and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that proposed rule change SR-NSCC-2017-019 be, and hereby is, *approved*.⁸⁴

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸⁵

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-01359 Filed 1-25-18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82538; File No. SR-CboeBZX-2018-005]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To List and Trade Shares of the Cboe Vest S&P 500® Premium Income ETF Under Rule 14.11(c)(5)

January 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the

⁸² *Id.*

⁸³ 15 U.S.C. 78q-1.

⁸⁴ In approving the proposed rule change, the Commission considered the proposals’ impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

⁸⁵ 17 CFR 200.30-3(a)(12).

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ 17 CFR 240.17Ad-22(e)(6)(i).

⁸⁰ *Id.*

⁸¹ 17 CFR 240.17Ad-22(e)(21).

“Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on January 10, 2018, Cboe BZX Exchange, Inc. (“Exchange” or “BZX”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to list and trade shares of the Cboe Vest S&P 500® Premium Income ETF (formerly known as the Cboe Vest S&P 500® Market-Neutral Option Income ETF), a series of ETF Series Solutions (the “Trust”), under Rule 14.11(c)(5) (“Index Fund Shares”).

The text of the proposed rule change is available at the Exchange’s website at www.markets.cboe.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 parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade shares (“Shares”) of Cboe Vest S&P 500® Premium Income ETF (the “Fund”) under Rule 14.11(c)(5), which governs the listing and trading of Index Fund Shares based on equity and fixed income securities indexes on the Exchange. The Fund will be an index-based exchange traded fund (“ETF”). The Fund will track the Cboe S&P 500® Volatility Risk Premia Index (the “Index”).³

The Shares will be offered by the Trust, which was established as a Delaware statutory trust on February 9, 2012. The Trust is registered with the Commission as an open-end investment company and has filed a registration statement on behalf of the Fund on Form N-1A (“Registration Statement”) with the Commission.⁴ The Fund’s adviser, Cboe Vest Financial, LLC (the “Adviser”), and index provider, Cboe Exchange, Inc. (“Cboe Options” or the “Index Provider”), are affiliates and have implemented and will maintain a “fire wall” with respect to their respective personnel regarding access to information concerning the composition and/or changes to the underlying index or portfolio, as applicable. The Adviser and the Index Provider are not registered as broker-dealers, but are affiliated with a broker-dealer. The Index Provider has implemented and will maintain a “fire wall” with respect to such broker-dealer and its personnel regarding access to information concerning the composition and/or changes to the Index. In addition, Index Provider personnel who make decisions regarding the Index composition or methodology are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Index, pursuant to Rule 14.11(c)(5)(A)(iii). The Adviser has also implemented and will maintain a “fire wall” with respect to such broker-dealer and its personnel regarding access to information concerning the composition and/or changes to the portfolio. In addition, Adviser personnel who make decisions regarding the Fund’s portfolio are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Fund’s portfolio. In the event that (a) the Adviser becomes registered as a broker-dealer or newly affiliated with another broker-dealer; or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer; it will implement a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access

2018-004 was subsequently withdrawn on January 10, 2018 and replaced by this filing.

⁴ See Registration Statement on Form N-1A for the Trust, dated September 28, 2017 (File Nos. 333-179562 and 811-22668). The descriptions of the Fund and the Shares contained herein are based, in part, on information in the Registration Statement. The Commission has not yet issued an order granting exemptive relief to the Trust under the Investment Company Act of 1940 (15 U.S.C. 80a-1) applicable to the activities of the Fund, but the Fund will not be listed on the Exchange until such an order is issued and any conditions contained therein are satisfied.

to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding such portfolio. The Exchange also notes that the Adviser is a BZX Affiliate as defined in Rule 14.3(e)(1)(A),⁵ but the Fund is not an Affiliate Security, as defined in Rule 14.11(e)(1)(B),⁶ and is therefore not subject to the additional requirements applicable to Affiliate Securities because such definition explicitly excludes Index Fund Shares. The Fund intends to qualify each year as a regulated investment company under Subchapter M of the Internal Revenue Code of 1986, as amended.

The Exchange is submitting this proposed rule change because the Index for the Fund does not meet the listing requirements of Rule 14.11(c)(5) applicable to an index that consists of both equity securities and Fixed Income Securities,⁷ which requires that the equity and fixed income component securities in an index or portfolio separately meet the criteria set forth in Rules 14.11(c)(3) and 14.11(c)(4), respectively. As further described below, the Index consists of options on an index that consists of “U.S. Component Stocks” as defined in Rule 14.11(c)(1)(D),⁸ and Fixed Income Securities. The Fixed Income Security component of the Index, which consists of only Treasury bills, meets the “generic” listing requirements of Rule 14.11(c)(4). However, because the Index consists partially of options based on an index of U.S. Component Stocks (the

⁵ As defined in Rule 14.3(e)(1)(A), the term “BZX Affiliate” means the Exchange and any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the Exchange, where “control” means that one entity possesses, directly or indirectly, voting control of the other entity either through ownership of capital stock or other equity securities or through majority representation on the board of directors or other management body of such entity.

⁶ As defined in Rule 14.3(e)(1)(B), the term “Affiliate Security” means any security issued by a BZX Affiliate or any Exchange-listed option on any such security, with the exception of Portfolio Depository Receipts as defined in Rule 14.11(b) and Index Fund Shares as defined in Rule 14.11(c).

⁷ As defined in Rule 14.11(c)(4), the term “Fixed Income Security” shall mean debt securities that are notes, bonds, debentures or evidence of indebtedness that include, but are not limited to, Treasury bills, government-sponsored entity securities (“GSE Securities”), municipal securities, trust preferred securities, supranational debt and debt of a foreign country or subdivision thereof.

⁸ As defined in Rule 14.11(c)(1)(D), the term “U.S. Component Stock” shall mean an equity security that is registered under Sections 12(b) or 12(g) of the Act, or an American Depositary receipt, the underlying equity security of which is registered under Sections 12(b) or 12(g) of the Act.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ This filing was originally submitted on January 10, 2018 as SR-CboeBZX-2018-004. SR-CboeBZX-

S&P 500 Index) and Rule 14.11(c)(3)(A)(i) applies only to U.S. Component Stocks (that is, the rule provides criteria for an index composed of equity securities and not for an index that includes options on an index of equity securities), it does not meet the criteria set forth in Rule 14.11(c)(3) and, thus, does not meet Rule 14.11(c)(5).

Cboe S&P 500® Volatility Risk Premia Index

The Index is a rules-based options index created by the Index Provider, an affiliate of the Adviser, and designed to capture the “volatility risk premium” in standardized options on the S&P 500 Index (“S&P 500 Index Options”) by writing one-month call and put S&P 500 Index Options (“Sold SPX Options”) and buying an identical number of one-month call and put S&P 500 Index Options (together, the “Bought SPX Options”) with a lesser market value (*i.e.*, buying call options with a higher strike price and put options with a lower strike price).⁹ The “volatility risk premium” in S&P 500 Index Options is based on the premise that the expected level of volatility of the S&P 500 Index priced into such options (the options’ “implied volatility”) is, on average, higher than the volatility actually experienced by the S&P 500 Index (the “realized volatility”). The Index will only include S&P 500 Index Options and Treasury bills.

On the last trading day of each month, the Index writes (sells) and buys call and put S&P 500 Index Options with an expiration date of the last trading day of the following month. The strike prices for the Sold SPX Options will be “out-of-the-money” (*i.e.*, the strike price of the sold put options will be less than the level of S&P 500 Index and the strike price of the sold call options will be more than the level of the S&P 500 Index). The strike prices for the Bought SPX Options will be higher and lower, respectively, than the strike price for the Sold SPX Options, which offsets some of the Index’s risk from the Sold SPX Options. The difference between the strike prices of the Sold SPX Options and the Bought SPX Options represents the net liability for the Index, and the Index maintains an allocation to one- and three-month Treasury bills at least equal to such net liability. The Index receives premiums from the sale of the

Sold SPX Options and pays premiums to buy the Bought SPX Options. The Index invests the net premium difference between the Sold SPX Options and the Bought SPX Options in one- and three-month Treasury bills. The Index holds each option until its expiration.

If the value of the S&P 500 Index rises above the strike price of the put S&P 500 Index Options (the “SPX Puts”) or falls below the strike price of the call S&P 500 Index Options (the “SPX Calls”) sold by the Index, the Sold SPX Options will not be exercised and will expire worthless, resulting in a gain to the Index equal to the premiums received from the Sold SPX Options. If the value of the S&P 500 Index falls below the strike price of the SPX Puts or rises above the strike price of the SPX Calls sold by the Index, the Sold SPX Options will finish “in-the-money” and the Index incurs a loss equal to the difference between the Sold SPX Options’ strike price and the value of the S&P 500 Index, less the value of the premiums received from the Sold SPX Options.

If the value of the S&P 500 Index rises above the strike price of the SPX Puts or falls below the strike price of the SPX Calls bought by the Index, the Bought SPX Options will not be exercised and will expire worthless, resulting in a loss to the Index equal to the premiums paid for the Bought SPX Options. If the value of the S&P 500 Index falls below the strike price of the SPX Puts or rises above the strike price of the SPX Calls sold by the Index, the Bought SPX Options will finish “in-the-money” and the Index receives a gain equal to the difference between the Bought SPX Options’ strike price and the value of the S&P 500 Index, less the value of the premiums paid for the Bought SPX Options.

The strike prices of the SPX Puts and SPX Calls are calculated such that the Index is equity-market-neutral, meaning that it seeks to earn a total return in most equity market conditions regardless of general market direction as measured by the move in value of the S&P 500 Index. The cash and net option premium proceeds will be invested in short-term Treasury bills which will be rolled at maturity. This makes the Index bond-market-neutral, meaning that as interest rates and the yield for Treasury bills go up or down, the short duration of the Treasury bills will result in minimal effect on the Index.

Fund Holdings

Under Normal Market Conditions,¹⁰ the Fund will invest all, or substantially all, of its assets in the S&P 500 Index Options that make up the Index, as well as the Treasury bills included in the Index. Under Normal Market Conditions, at least 80% of the Fund’s total assets (exclusive of any collateral held from securities lending) will be invested in the S&P 500 Index Options or Treasury bills that make up the Index. In addition to the S&P 500 Index Options and Treasury bills that make up the Index, the Fund may invest up to 20% of its total assets in U.S. exchange-listed options based on one or more ETFs that track the performance of the S&P 500 Index (“Comparable ETF Options”). The Fund will hold only S&P 500 Index Options, Comparable ETF Options, Treasury bills included in the Index, and other cash and cash equivalents.¹¹

Additional Discussion

The Exchange believes that sufficient protections are in place to protect against market manipulation of the Fund’s Shares and S&P 500 Index Options and Comparable ETF Options for the following reasons: (i) The diversity, liquidity, and market cap of the securities underlying the S&P 500 Index;¹² (ii) the liquidity of the S&P 500 Index Options;¹³ and (iii) surveillance

¹⁰ The term “Normal Market Conditions” includes, but is not limited to, the absence of trading halts in the applicable financial markets generally; operational issues causing dissemination of inaccurate market information or system failures; or force majeure type events such as natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.

¹¹ For purposes of this filing, cash equivalents are short-term instruments with maturities of less than three months, including: (i) U.S. Government securities, including bills, notes, and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. Government agencies or instrumentalities; (ii) certificates of deposit issued against funds deposited in a bank or savings and loan association; (iii) bankers acceptances, which are short-term credit instruments used to finance commercial transactions; (iv) repurchase agreements and reverse repurchase agreements; (v) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (vi) commercial paper, which are short-term unsecured promissory notes; and (vii) money market funds.

¹² The Exchange notes that the diversity, liquidity, and market cap of the components of the S&P 500 Index are such that the S&P 500 Index would meet the generic listing standards applicable to an index composed of U.S. Component Stocks in Rule 14.11(c)(3)(A)(i).

¹³ The market for S&P 500 Index Options traded on Cboe Options is among the most liquid markets in the world. In 2016, 1,023,623 options contracts on the S&P 500 Index were traded per day on Cboe

⁹ For purposes of this filing, when describing the Index, the terms “buy,” “sell,” “write,” “hold,” or any other term related to the acquisition, disposition, or issuance of an asset are intended to describe a theoretical transaction conducted by the Index that will be reflected in the Index constituents, rather than to imply that the Index is actually transacting.

by the Exchange, Cboe Options and the Financial Industry Regulatory Authority ("FINRA") designed to detect violations of the federal securities laws and self-regulatory organization ("SRO") rules.

Trading in the Shares and the underlying investments will be subject to the federal securities laws and Exchange, Cboe Options, FINRA, and, with respect to the Comparable ETF Options, other U.S. options exchanges' rules and surveillance programs.¹⁴

The Exchange has in place a surveillance program for transactions in ETFs to ensure the availability of information necessary to detect and deter potential manipulations and other trading abuses, thereby making the Shares less readily susceptible to manipulation. Further, the Exchange believes that because the assets in the Fund's portfolio, which are comprised primarily of S&P 500 Index Options, will be acquired in extremely liquid and highly regulated markets,¹⁵ the Shares are less readily susceptible to manipulation.

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Index Fund Shares. FINRA conducts certain cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

All statements and representations made in this filing regarding the index composition, the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of index,

reference asset, and intraday indicative values (as applicable), or the applicability of Exchange listing rules shall constitute continued listing requirements for listing the Shares on the Exchange. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund or Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. If the Fund or Shares are not in compliance with the applicable listing requirements, then, with respect to such Fund or Shares, the Exchange will commence delisting procedures under Exchange Rule 14.12.

The Exchange or FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and exchange-traded options contracts with other markets and other entities that are members of the ISG and may obtain trading information regarding trading in the Shares and exchange-traded options contracts from such markets and other entities. The Exchange is also able to access, as needed, trade information for certain fixed income instruments reported to FINRA's Trade Reporting and Compliance Engine ("TRACE"). In addition, the Exchange may obtain information regarding trading in the Shares and exchange-traded options contracts from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

As noted above, S&P 500 Index Options are among the most liquid options in the world and derive their value from the actively traded S&P 500 Index components. The contracts are cash-settled with no delivery of stocks or ETFs, and trade in competitive auction markets with price and quote transparency. The Exchange believes the highly regulated options markets and the broad base and scope of the S&P 500 Index make securities that derive their value from that index less susceptible to market manipulation in view of market capitalization and liquidity of the S&P 500 Index components, price and quote transparency, and arbitrage opportunities.

The Exchange believes that the liquidity of the markets for S&P 500 Index securities, S&P 500 Index Options, and other related derivatives is sufficiently great to deter fraudulent or

manipulative acts associated with the price of the Shares. The Exchange also believes that such liquidity are [sic] sufficient to support the creation and redemption mechanism. Coupled with the surveillance programs of the SROs described above, the Exchange does not believe that trading in the Fund's Shares would present manipulation concerns. The Fund's investments will be consistent with the Fund's investment objective and will not be used to enhance leverage (although certain derivatives and other investments may result in leverage).¹⁶ The Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*i.e.* 2x or -2x) of the Index. The Fund's use of derivative instruments will be collateralized.

The Exchange represents that, except as described above, the Fund will meet each of the initial and continued listing criteria in BZX Rule 14.11(c)(5) with the exception of meeting the requirements of Rule 14.11(c)(3)(A)(i), applicable to the listing of Index Fund Shares based upon an index of "U.S. Component Stocks," as required under Rule 14.11(c)(5). Further to this point, the three-month Treasury bills that compose the entirety of the fixed income portion of the Index will satisfy all requirements of Rule 14.11(c)(4). The Trust is required to comply with Rule 10A-3 under the Act for the initial and continued listing of the Shares of the Fund. A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange. In addition, the Exchange represents that the Shares of the Fund will comply with all other requirements applicable to Index Fund Shares, which includes requirements relating to the dissemination of key information such as the Net Asset Value, Index value, and the Intraday Indicative Value, rules governing the trading of equity securities, trading hours, trading halts, firewalls for the Index Provider and Adviser, surveillance, and the information circular, as set forth in Exchange rules applicable to Index Fund Shares and the orders approving such rules.

¹⁶ The Fund will include appropriate risk disclosure in its offering documents, including leveraging risk. Leveraging risk is the risk that certain transactions of a fund, including a fund's use of derivatives, may give rise to leverage, causing a fund to be more volatile than if it had not been leveraged. To mitigate leveraging risk, the Adviser will segregate or earmark liquid assets or otherwise cover the transactions that give rise to such risk. See 15 U.S.C. 80a-18; Investment Company Act Release No. 10666 (April 18, 1979), 44 FR 25128 (April 27, 1979); *Dreyfus Strategic Investing*, Commission No-Action Letter (June 22, 1987); *Merrill Lynch Asset Management, L.P.*, Commission No-Action Letter (July 2, 1996).

Options, which is more than \$200 billion in notional volume traded on a daily basis.

¹⁴ The Exchange notes that Cboe Options is a member of the Option Price Regulatory Surveillance Authority, which was established in 2006, to provide efficiencies in looking for insider trading and serves as a central organization to facilitate collaboration in insider trading and investigations for the U.S. options exchanges. For more information, see <http://www.cboe.com/aboutcboe/legal/departments/orsareg.aspx>.

¹⁵ All exchange-listed securities that the Fund may hold will trade on a market that is a member of the Intermarket Surveillance Group ("ISG") and the Fund will not hold any non-exchange-listed options, however, not all of the components of the portfolio for the Fund may trade on exchanges that are members of the ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. For a list of the current members of ISG, see www.isgportal.org.

Quotation and last sale information for S&P 500 Index Options will be available via the Options Price Reporting Authority. The intra-day, closing and settlement prices of exchange-traded options will be readily available from the options exchanges, automated quotation systems, published or other public sources, or online information services such as Bloomberg or Reuters. Price information on Treasury bills and other cash equivalents is available from major broker-dealer firms or market data vendors, as well as from automated quotation systems, published or other public sources, or online information services.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act¹⁷ in general and Section 6(b)(5) of the Act¹⁸ in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest in that the Shares of the Fund will meet each of the initial and continued listing criteria required by BZX Rule 14.11(c)(5), which includes the listing requirements for an index that is composed of both equity securities and fixed income securities, with the exception of the requirement that the equity portion of the Index meets the criteria set forth in Rule 14.11(c)(3). Specifically, the Index does not meet the requirements of Rule 14.11(c)(3) because the equity portion of the Index consists of options on U.S. Component Stocks and Rule 14.11(c)(3)(A)(i) applies only to U.S. Component Stocks (that is, the rule provides criteria for an index composed of equity securities and not for an index

that includes options on an index of equity securities), it does not meet the criteria set forth in Rule 14.11(c)(3) and, thus, does not meet Rule 14.11(c)(5).¹⁹ The Exchange believes that the concerns that Rule 14.11(c)(3)(A)(i) are intended to address are mitigated and that sufficient protections are in place to protect against market manipulation of the Fund's Shares and S&P 500 Index Options and Comparable ETF Options for the following reasons: (i) The diversity, liquidity, and market cap of the securities underlying the S&P 500 Index;²⁰ (ii) the liquidity of the S&P 500 Index Options;²¹ and (iii) surveillance by the Exchange, Cboe Options and FINRA designed to detect violations of the federal securities laws and self-regulatory organization ("SRO") rules.

The Exchange has in place a surveillance program for transactions in ETFs to ensure the availability of information necessary to detect and deter potential manipulations and other trading abuses, thereby making the Shares less readily susceptible to manipulation. Further, the Exchange believes that because the assets in the Fund's portfolio, which are comprised primarily of S&P 500 Index Options, will be acquired in extremely liquid and highly regulated markets, the Shares are less readily susceptible to manipulation.

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for

derivative products, including Index Fund Shares. All statements and representations made in this filing regarding the index composition, the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of index, reference asset, and intraday indicative values (as applicable), or the applicability of Exchange listing rules shall constitute continued listing requirements for listing the Shares on the Exchange. . [sic] The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund or Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. If the Fund or Shares are not in compliance with the applicable listing requirements, then, with respect to such Fund or Shares, the Exchange will commence delisting procedures under Exchange Rule 14.12. FINRA conducts certain cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures with respect to such Fund under Exchange Rule 14.12.

The Exchange or FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and exchange-traded options contracts with other markets and other entities that are members of the ISG and may obtain trading information regarding trading in the Shares and exchange-traded options contracts from such markets and other entities. The Exchange is also able to access, as needed, trade information for certain fixed income instruments reported to TRACE. In addition, the Exchange may obtain information regarding trading in the Shares and exchange-traded options contracts from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

As noted above, S&P 500 Index Options are among the most liquid options in the world and derive their value from the actively traded S&P 500 Index components. The contracts are cash-settled with no delivery of stocks or ETFs, and trade in competitive

¹⁹ Rule 14.11(c)(3)(A)(i)(e) provides that all securities in the applicable index or portfolio shall be U.S. Component Stocks listed on a national securities exchange and shall be NMS Stocks as defined in Rule 600 under Regulation NMS of the Act. Each component stock of the S&P 500 Index is a U.S. Component Stock that is listed on a national securities exchange and is an NMS Stock. Options are excluded from the definition of NMS Stock. The Fund and the Index meet all of the requirements of the listing standards for Index Fund Shares in Rule 14.11(c)(3), except the requirements in Rule 14.11(c)(3)(A)(i)(a)–(e), as the Index consists of options on the S&P 500 Index. The S&P 500 Index consists of U.S. Component Stocks and satisfies the requirements of Rule 14.11(c)(3)(A)(i)(a)–(e).

²⁰ The Exchange notes that the diversity, liquidity, and market cap of the components of the S&P 500 Index are such that the S&P 500 Index would meet the generic listing standards applicable to an index composed of U.S. Component Stocks in Rule 14.11(c)(3)(A)(i).

²¹ The market for S&P 500 Index Options traded on Cboe Options is among the most liquid markets in the world. In 2016, 1,023,623 options contracts on the S&P 500 Index were traded per day on Cboe Options, which is more than \$200 billion in notional volume traded on a daily basis.

¹⁷ 15 U.S.C. 78f.

¹⁸ 15 U.S.C. 78f(b)(5).

auction markets with price and quote transparency. The Exchange believes the highly regulated options markets and the broad base and scope of the S&P 500 Index make securities that derive their value from that index less susceptible to market manipulation in view of market capitalization and liquidity of the S&P 500 Index components, price and quote transparency, and arbitrage opportunities.

The Exchange believes that the liquidity of the markets for S&P 500 Index securities, S&P 500 Index Options, and other related derivatives is sufficiently great to deter fraudulent or manipulative acts associated with the price of the Shares. The Exchange also believes that such efficiency and liquidity are sufficient to support the creation and redemption mechanism. Coupled with the extensive surveillance programs of the SROs described above, the Exchange does not believe that trading in the Fund's Shares would present manipulation concerns.

The Exchange represents that, except as it relates to the options portion of the Index and the index dissemination requirements described above, the Fund will meet and be subject to all other requirements of Rule 14.11(c)(5) related to generic listing standards of the Index and other applicable requirements for such a series of Index Fund Shares under Rule 14.11(c) on an initial and continued listing basis, including those requirements regarding the dissemination of key information such as the Net Asset Value, and the Intraday Indicative Value, rules governing the trading of equity securities, trading hours, trading halts, surveillance, and the information circular, as set forth in Exchange rules applicable to Index Fund Shares and the orders approving such rules. The Trust is required to comply with Rule 10A-3 under the Act for the initial and continued listing of the Shares of the Fund. Moreover, all of the options contracts held by the Fund will trade on markets that are a member of ISG or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change will

facilitate the listing and trading of an additional type of Index Fund Shares that will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

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 up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove the proposed rule change, or
- (B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CboeBZX-2018-005 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-CboeBZX-2018-005. 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-CboeBZX-2018-005 and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-01354 Filed 1-25-18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82565; File No. SR-NYSE-2017-42]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change To Amend the NYSE Listed Company Manual To Modify Its Requirements With Respect to Physical Delivery of Proxy Materials to the Exchange

January 22, 2018.

On November 22, 2017, New York Stock Exchange LLC ("NYSE" or the "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 the NYSE Listed Company Manual (the "Manual") to modify its requirements with respect to the physical delivery of proxy materials to the Exchange. The proposed rule change was published for comment in the

²² 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Federal Register on December 12, 2017.³ The Commission received no comments on the proposed rule change.

Section 19(b)(2) of the Act⁴ provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this filing is January 26, 2018.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the Exchange's proposal. Accordingly, pursuant to Section 19(b)(2) of the Act,⁵ the Commission designates March 12, 2018, as the date by which the Commission shall either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File No. SR-NYSE-2017-42).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-01419 Filed 1-25-18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82547; File No. SR-BOX-2018-02]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Clarify the Manner in Which the Exchange Assesses Its Options Regulatory Fee

January 19, 2018.

Pursuant to Section 19(b)(1) under the Securities Exchange Act of 1934 (the "Act")¹ and Rule 19b-4 thereunder,²

notice is hereby given that on January 12, 2018, BOX Options Exchange LLC (the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act,³ and Rule 19b-4(f)(2) thereunder,⁴ which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission ("Commission") a proposed rule change to amend the Fee Schedule to clarify the manner in which the Exchange assesses its Options Regulatory Fee ("ORF"). The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at <http://boxexchange.com>.

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

The Exchange proposes to amend the BOX Fee Schedule (the "Fee Schedule") to clarify the manner in which the Exchange assesses its Options Regulatory Fee ("ORF"). Currently, the Exchange charges an ORF in the amount of \$0.0038 per contract side. The proposed rule change does not change the amount of the ORF, but instead modifies the rule text to clarify how the ORF is assessed and collected. The

proposed rule change also aligns the ORF rule text of the Exchange to rule text recently adopted by Miami International Securities Exchange ("MIAX").⁵

The per-contract ORF will continue to be assessed by BOX Options to each BOX Options Participant for all options transactions, cleared or ultimately cleared by the BOX Options Participant that 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 BOX from either (1) a Participant that was the ultimate clearing firm for the transaction or (2) a non-Participant that was the ultimate clearing firm where a Participant 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 Participant 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 Participant or non-Participant 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 Participant or non-Participant 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 Participant (even if a Participant is "given-up" or "CMTAed" and then such Participant subsequently "gives-up" or "CMTAs" the transaction to another non-Participant via a CMTA

³ See Securities Exchange Act Release No. 82225 (December 6, 2017), 82 FR 58473.

⁴ 15 U.S.C. 78s(b)(2).

⁵ 15 U.S.C. 78s(b)(2).

⁶ 17 CFR 200.30-3(a)(31).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴ 17 CFR 240.19b-4(f)(2).

⁵ See Securities Exchange Act Release No. 81063 (June 30, 2017, 82 FR 31668 (July 7, 2017) (SR-MIAX-2017-31).

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.

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 Participant 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.

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 Participant's activities supports applying the ORF to transactions cleared but not executed by a Participant. The Exchange's regulatory responsibilities are the same regardless of whether a Participant 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 Participants' 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 Participant 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 BOX 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 Participants 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 Participants 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-Participants) 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 Participants' 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 Participant 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")⁶ system in order to surveil a Participant'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"),⁷ 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.⁸

The Exchange believes that charging the ORF across markets will avoid having Participants 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 Participant would send their orders to the least cost, least regulated exchange. Other exchanges do impose a similar fee on their member's activity.⁹

The Exchange notes that there is established precedent for an SRO

⁶ COATS effectively enhances intermarket options surveillance by enabling the options exchanges to reconstruct the market promptly to effectively surveil certain rules.

⁷ 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.

⁸ See Section 6(h)(3)(I) of the Act.

⁹ Similar regulatory fees have been instituted by MIAx (See Securities Exchange Act Release No. 68711 (January 23, 2013), 78FR 6115 (January 29, 2013) (SR-MIAx-2013-01); MIAx PEARL (See Securities Exchange Act Release No. 808075 (June 7, 2017), 82FR 27096 (SR-PEARL-2017-26); Nasdaq PHLX (See Securities Exchange Act Release No. 61133 (December 9, 2009), 74FR 66715 (December 16, 2009) (SR-PHLX-2009-100)); Nasdaq ISE (See Securities Exchange Act Release No. 61154 (December 11, 2009), 74FR 67278 (December 18, 2009) (SR-ISE-2009-105)); and Nasdaq GEMX (See Securities Exchange Act Release No. 70200 (August 14, 2013) 78FR 51242 (August 20, 2013) (SR-Topaz-2013-01)).

charging a fee across markets, namely, FINRA's Trading Activity Fee¹⁰ and MIAX, CBOE, Nasdaq PHLX, Nasdaq ISE, and Nasdaq GEMX 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 Participant'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 would apply only to a Participant'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 also proposes to remove a sentence from the ORF section which states that Market Makers and Order Flow Providers will not be assessed the Fee until the firm has become a fully certified BOX Market Maker or Order Flow Provider, that has met and has satisfied certain minimum technological requirements necessary to be capable of commencing participation on BOX. The Exchange believes this sentence is no longer appropriate and adds confusion as to when the ORF applies.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act¹¹ in general, and furthers the objectives of Section 6(b)(4) of the Act¹² 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 Act¹³ 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 the proposed clarifications in the Fee Schedule to the ORF furthers the objectives of Section 6(b)(4) of the Act and are equitable and reasonable since they expressly describe the Exchange's existing practices regarding the manner in which the Exchange assesses its ORF.

The Exchange believes the ORF is equitable and not unfairly discriminatory because it is objectively allocated to Participants in that it is charged to all Participants on all their transactions that clear as customer at the OCC. Moreover, the Exchange believes the ORF ensures fairness by assessing fees to those Participants 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.*, Participant proprietary transactions) of its regulatory program.

The ORF is designed to recover a material portion of the costs of supervising and regulating Participants' customer options business including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities. The Exchange will monitor, on at least a semi-annual basis 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 current amount of the fee is reasonable.

The Exchange believes that limiting changes to the ORF to twice a year on specific dates with advance notice is reasonable because it will give participants certainty on the timing of changes, if any, and better enable them to properly account for ORF charges among their customers. The Exchange believes that the proposed change is equitable and not unfairly discriminatory because it will apply in the same manner to all Participants 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-Participants when such non-Participants ultimately clear the transaction (that is, when the non-Participant is the "ultimate clearing firm" for a transaction in which a Participant 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 Participant 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-Participants. Once, however, the ORF is assessed to a Participant for a particular transaction, the ORF may be collected from the Participant or a non-Participant, 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 Participant. If there was a change to the clearing account of the original transaction and a non-Participant becomes the ultimate clearing firm for that transaction, then the ORF will be collected from that non-Participant. The Exchange believes that this collection practice is 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.

Finally, the Exchange believes removing the sentence that states that the ORF will not be assessed until the firm has become a fully certified is reasonable, equitable and not unfairly discriminatory. The Exchange believes this sentence is no longer appropriate and adds confusion as to when the ORF applies. The removal of this sentence

¹⁰ See Securities Exchange Act Release No. 47946 (May 30, 2003), 68FR 34021 (June 6, 2003) (SR-NASD-2002-148).

¹¹ 15 U.S.C. 78f(b).

¹² 15 U.S.C. 78f(b)(4).

¹³ 15 U.S.C. 78f(b)(5).

will have no effect on the assessment of fees for current BOX Participants as they are all fully certified to transact business on the Exchange. Future BOX Participants will be assessed the ORF once their application has been approved; as BOX's regulatory responsibility begins as soon as a firm becomes a Participant and not when the Participant is technologically certified.

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 ORF is not intended to have any impact on competition. Rather, it is designed to enable the Exchange to recover a material portion of the Exchange's cost related to its regulatory activities. 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 BOX in establishing fees for services provided to its Participants and others using its facilities will not have an impact on competition. In the highly competitive environment for equity options trading, BOX 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 limiting 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 Participants 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

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act¹⁴ and Rule 19b-4(f)(2) thereunder,¹⁵ because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings 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-BOX-2018-02 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-BOX-2018-02. 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-BOX-2018-02, and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

Eduardo A. Aleman,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82548; File No. SR-CBOE-2018-005]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Schedule Concerning Firm Incentive Programs

January 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on January 12, 2017, Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

¹⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

¹⁴ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁵ 17 CFR 240.19b-4(f)(2).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule. Particularly, the Exchange proposes to amend Footnote 11 of its Fees Schedule, which governs the Clearing Trading Permit Holder Fee Cap, Proprietary Products Sliding Scale, Proprietary VIX Sliding Scale, and Supplemental VIX Total Firm Discount (collectively, "Firm Incentive Programs") which applies to (i) Clearing Trading Permit Holder proprietary orders ("F" origin code), and (ii) orders of Non-Trading Permit Holder Affiliates ("Non-TPH Affiliates") of a Clearing Trading Permit Holder ("Clearing TPH") orders ("L" origin code). Footnote 11 currently defines a "Non-Trading Permit Holder Affiliate" for this purpose as a 100% wholly-owned affiliate or subsidiary of a Clearing TPH that is registered as a United States or foreign broker-dealer and that is not a Cboe Options Trading Permit Holder ("TPH"). It also provides that only proprietary orders of the Non-TPH Affiliate effected for purposes of hedging the proprietary over-the-counter trading of the Clearing TPH or its affiliates will be included in calculating the Firm Incentive Programs. Additionally, Footnote 11 provides that the Exchange will aggregate the fees and trading activity of separate Clearing TPHs for the purposes of the Firm Incentive Programs if there is at least 75% common ownership between the Clearing TPHs as reflected on each Clearing TPH's Form BD, Schedule A. Footnote 11 further states that each Clearing TPH is responsible for notifying the TPH Department of all of its affiliations so that fees and contracts of the Clearing TPH and its affiliates may be aggregated and each Clearing TPH is required to inform the Exchange immediately of any event that causes an

entity to cease to be an affiliate. A Clearing TPH is also required to certify the affiliate status of any Non-TPH Affiliate whose trading activity it seeks to aggregate.

The Exchange first proposes to modify which "L" orders may be included in calculating the Firm Incentive Programs. Particularly, the Exchange proposes to eliminate the requirement that to be included in calculating the Firm Incentive Programs, "L" orders must be proprietary orders of a Non-TPH Affiliate effected for purposes of hedging the proprietary over-the-counter trading of the Clearing TPH or its affiliates. In its place, the Exchange proposes to provide that all proprietary orders of a Non-TPH Affiliate may be included in the above-mentioned calculations. The Exchange wishes to encourage Non-TPH Affiliates to send all of their proprietary orders to the Exchange, not just transactions that are effected for purposes of hedging over-the-counter trading.

Next, the Exchange proposes to clarify that in order to provide "L" origin code rates to "L" origin code orders, the orders need to clear through an Exchange-registered OCC number. The Exchange notes that if an order marked with an "L" origin code uses a non-Exchange registered OCC clearing number, the orders would not be aggregated with any "F" orders, as the clearing number is not known to the Exchange's billing system. In order to avoid confusion, the Exchange proposes to make clear that only proprietary orders of a Non-TPH Affiliate that clears through a Cboe Options-registered OCC clearing number(s) will be included in calculating the Firm Incentive Programs. Similarly, the Exchange wishes to further clarify Footnote 16 and add a reference to "L" origin codes to Footnote 16. Footnote 16 currently provides that Broker-Dealer transaction fees (*i.e.*, fees assessed for orders with a "B" origin code) will apply to certain orders with an "F" origin code if those orders are from OCC members that are not Cboe Options TPHs. As noted above, if an order uses a non-Exchange registered OCC clearing number, the clearing number is not known to the Exchange's billing system. This is true regardless of if the order came from an OCC member that is or is not a Cboe Options TPH. As such, the Exchange proposes to also clarify that "F" and "L" orders will be billed as "B" orders if the orders are from OCC numbers that are not from Cboe Options TPHs or are not registered with the Exchange.

The Exchange next proposes to eliminate the requirement that each Clearing TPH certify the affiliate status

of any Non-TPH Affiliate who's trading activity it seeks to aggregate. The Exchange believes that it is incumbent on any TPH marking an order with any origin code to ensure that it is marking the order appropriately and meeting any stated criteria. Orders should only be marked with an "L" origin code if it meets the definition provided for in Footnote 11, which, as noted above, requires that the order be from a 100% wholly-owned affiliate or subsidiary of a Clearing TPH that is registered as a United States or foreign broker-dealer and that is not a Cboe Options TPH. Accordingly, the Exchange does not believe it's necessary for further certification and therefore does not believe this language is necessary to maintain in the Fees Schedule.

Lastly, the Exchange proposes to (i) relocate to a new Footnote and (2) modify, the language currently in Footnote 11 requiring each Clearing TPH to notify the TPH Department of all of its affiliations and of any event that causes an entity to cease to be an affiliate. Particularly, the Exchange notes that the definition of an "affiliate" as used in Footnote 11 (*i.e.*, 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A) is also referenced numerous times throughout the Fees Schedule. Particularly, there are a number of other occasions for which the Exchange may aggregate activity between affiliates.³ As such, the Exchange believes it would be more appropriate to relocate the notice requirement to its own footnote (proposed Footnote 39) and expand the scope of the notice requirement to apply to all TPHs (not just Clearing TPHs). Accordingly, the Fees Schedule will now provide that each TPH is responsible for notifying the Exchange of all its affiliates and is required to inform the Exchange immediately of any event that causes an entity to cease to be an affiliate, in a form and manner to be determined by the Exchange. As noted above, an "affiliate" is defined as having at least 75% common ownership between two entities as reflected on each entity's Form BD, Schedule A.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations

³ See *e.g.*, Cboe Exchange, Inc. Fees Schedule, Footnote 10, which provides the Exchange will aggregate the trading activity of separate Liquidity Provider firms for purposes of the Liquidity Provider Sliding Scale if there is at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A.

thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁴ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁵ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act,⁶ which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

The Exchange believes allowing a Clearing TPH to aggregate its trading activity for purposes of the Firm Incentive Programs with its Non-TPH Affiliate(s) for all proprietary orders of the Non-TPH Affiliate(s) and not just those effected for purposes of hedging the proprietary over-the-counter trading of the Clearing TPH or its affiliates is equitable, reasonable and not unfairly discriminatory. Particularly, the Exchange notes that “L” orders will continue to get the benefit of “L” order rates (now just a wider universe of orders). The Exchange believes it’s equitable and not unfairly discriminatory to expand the scope of allowable “L” orders, as it still requires Non-TPH Affiliate(s) to be registered as a United States or foreign broker-dealer and for there to be complete identity of common ownership between the Clearing TPH and Non-TPH Affiliate. The Exchange does not believe it’s necessary to continue to require the Non-TPH Affiliate’s orders be effected for purposes of hedging. The elimination of this requirement would encourage the sending of all Non-TPH Affiliate’s proprietary orders, which thereby brings greater trading activity, volume and liquidity, benefitting all market participants.

The Exchange next believes that clarifying Footnote 11 to state that only proprietary orders of a Non-TPH Affiliate (“L” origin code) that clear through a Cboe Options-registered OCC

clearing number(s) will be processed as an “L” order, maintains transparency in the Fees Schedule and reduces potential confusion. For the same reasons, the Exchange is further clarifying Footnote 16 to provide that both “F” and “L” orders will be processed as Broker-Dealer (origin code “B”) orders if they are from an OCC number that does not belong to a Cboe Options TPH or is not registered with the Exchange. As noted above, orders marked with either an “F” or “L” origin code that clear through a non-Exchange registered OCC clearing number are not processed as such, as the clearing number is not known to the Exchange’s billing system. The Exchange believes that explicitly clarifying this requirement in both Footnote 11 and Footnote 16 will reduce potential confusion. The alleviation of confusion removes impediments to and perfects the mechanism of a free and open market and a national market system, and, in general, protects investors and the public interest.

The Exchange next believes it’s reasonable to eliminate the requirement that each Clearing TPH certify the affiliate status of any Non-TPH Affiliate who’s trading activity it seeks to aggregate because the Exchange believes marking an order with an “L” origin code should serve as certification that the order meets the requirements described above. Therefore, the Exchange does not believe this current language is necessary to maintain in the Fees Schedule. Eliminating unnecessary language reduces potential confusion, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in general, protecting investors and the public interest.

Lastly, the Exchange believes its proposal to (i) relocate the language requiring each Clearing TPH to notify the TPH Department of all of its affiliations and of any event that causes an entity to cease to be an affiliate from Footnote 11 to a new Footnote and (ii) modify the language to expand the scope of the language such that the notice requirement applies to the entire Fees Schedule, and all TPHs generally, promotes transparency in the Fees Schedule and reduces confusion. As noted above, the definition of an affiliate (*i.e.*, 75% common ownership between the firms as reflected on each firm’s Form BD, Schedule A) is referenced numerous times throughout the Fees Schedule and there are a number of other occasions for which the Exchange aggregates activity between such affiliates. As such, the Exchange believes it would be more appropriate for the language requiring notice of

affiliations and termination of such relationships to be applicable to all TPHs and therefore be relocated to its own footnote which would apply to the entire Fees Schedule. Additionally, clarifying that such information shall be communicated to the Exchange in a form and manner to be determined by the Exchange allows the Exchange to provide a uniform and orderly manner in which to receive the information.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burdens on competition that are not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because to the extent Non-TPH Affiliates receive beneficial pricing, the Exchange notes that Non-TPH Affiliate(s) are required to have complete identity of common ownership between itself and its affiliated Clearing TPH, and Clearing TPHs have clearing obligations that other market participants do not have. Moreover, the proposed changes are intended to encourage market participants to bring increased volume to the Exchange (which benefits all market participants). Additionally, the clarifying rule changes are not intended to address any competitive issues but rather to provide more clarity and transparency regarding Non-TPH Affiliates and affiliates. The Exchange does not believe that the proposed change will cause any unnecessary burden on intermarket competition because the proposed change only affects trading on Cboe Options. To the extent that the proposed changes make Cboe Options a more attractive marketplace for market participants at other exchanges, such market participants are welcome to become Cboe Options market participants.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)

⁴ 15 U.S.C. 78f(b).

⁵ 15 U.S.C. 78f(b)(5).

⁶ 15 U.S.C. 78f(b)(4).

of the Act⁷ and paragraph (f) of Rule 19b-4⁸ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CBOE-2018-005 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-CBOE-2018-005. 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-CBOE-2018-005 and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-01363 Filed 1-25-18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82560; File No. SR-CboeBZX-2017-013]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Withdrawal of a Proposed Rule Change To List and Trade Shares of the REX Bitcoin Strategy ETF and the REX Short Bitcoin Strategy ETF, Each a Series of the Exchange Listed Funds Trust, Under Rule 14.11(i), Managed Fund Shares

January 22, 2018.

On December 15, 2017, Cboe BZX Exchange, Inc. ("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 list and trade shares of the REX Bitcoin Strategy ETF and the REX Short Bitcoin Strategy ETF, each a series of the Exchange Listed Funds Trust, under Rule 14.11(i), Managed Fund Shares. The proposed rule change was published for comment in the **Federal Register** on January 4, 2018.³ The Commission received one comment letter on the proposed rule change.⁴

On January 19, 2018, the Exchange withdrew the proposed rule change (SR-CboeBZX-2017-013).

⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 82417 (Dec. 28, 2017), 83 FR 570 (Jan. 4, 2018).

⁴ See Letter from Stephen Knell (Jan. 9, 2018). The comment on the proposed rule change is available on the Commission's website at: www.sec.gov/comments/sr-cboebzx-2017-013/cboebzx2017013.htm.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-01415 Filed 1-25-18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82552; File No. SR-CboeBZX-2017-006]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change to List and Trade Shares of a Series of the Cboe Vest S&P 500 Enhanced Growth Strategy ETF Under the ETF Series Solutions Trust, Under Rule 14.11(c)(3), Index Fund Shares

January 19, 2018.

On November 21, 2017, Cboe BZX Exchange, Inc. ("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 list and trade shares of a series of the Cboe Vest S&P 500® Enhanced Growth Strategy ETF under the ETF Series Solutions Trust under Exchange Rule 14.11(c)(3), Index Fund Shares. The proposed rule change was published for comment in the **Federal Register** on December 11, 2017.³ The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act⁴ provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is January 25, 2018. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period

⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 82216 (December 5, 2017), 82 FR 58235.

⁴ 15 U.S.C. 78s(b)(2).

⁷ 15 U.S.C. 78s(b)(3)(A).

⁸ 17 CFR 240.19b-4(f).

within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,⁵ designates March 11, 2018, as the date by which the Commission shall either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File Number SR–CboeBZX–2017–006).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018–01366 Filed 1–25–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82559; File No. SR–CboeBZX–2017–011]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change To List and Trade the Common Shares of Beneficial Interest of the PowerShares Income Builder Portfolio, a Series of PowerShares Exchange-Traded Fund Trust II

January 22, 2018.

On December 1, 2017, Cboe BZX Exchange, Inc. (“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 list and trade under Exchange Rule 14.11(c)(3) the common shares of beneficial interest of the PowerShares Income Builder Portfolio, a series of PowerShares Exchange-Traded Fund Trust II. The proposed rule change was published for comment in the **Federal Register** on December 20, 2017.³ The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act⁴ provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its

reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is February 3, 2018. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,⁵ designates March 20, 2018 as the date by which the Commission shall either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File Number SR–CboeBZX–2017–011).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018–01414 Filed 1–25–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82558; File No. SR–CboeBZX–2017–005]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change To List and Trade Shares of a Series of the Cboe Vest S&P 500 Buffer Protect Strategy ETF Under the ETF Series Solutions Trust, Under Rule 14.11(c)(3), Index Fund Shares

January 22, 2018.

On November 21, 2017, Cboe BZX Exchange, Inc. (“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 list and trade shares of a series of the Cboe Vest S&P 500® Buffer Protect Strategy ETF under the ETF Series Solutions Trust, under Exchange Rule 14.11(c)(3). The proposed rule change was published for comment in

the **Federal Register** on December 11, 2017.³ The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act⁴ provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is January 25, 2018. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,⁵ designates March 11, 2018 as the date by which the Commission shall either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File Number SR–CboeBZX–2017–005).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018–01413 Filed 1–25–18; 8:45 am]

BILLING CODE 8011–01–P

⁵ *Id.*

⁶ 17 CFR 200.30–3(a)(31).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 82328 (December 14, 2017), 82 FR 60443.

⁴ 15 U.S.C. 78s(b)(2).

⁵ *Id.*

⁶ 17 CFR 200.30–3(a)(31).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 82217 (December 5, 2017), 82 FR 58243.

⁴ 15 U.S.C. 78s(b)(2).

⁵ *Id.*

⁶ 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82542; File No. SR-ICC-2018-001]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change, Security-Based Swap Submission, or Advance Notice Relating to the ICC Rules, ICC Risk Management Model Description Document, ICC Risk Management Framework, ICC Stress Testing Framework, and ICC Liquidity Risk Management Framework

January 19, 2018.

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 January 16, 2018, ICE Clear Credit LLC (“ICC”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change described in Items I, II, and III below, which Items have been prepared primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change.

I. Clearing Agency’s Statement of the Terms of Substance of the Proposed Rule Change, Security-Based Swap Submission, or Advance Notice

The purpose of the proposed rule change is to make revisions to the ICC Clearing Rules (the “Rules”) to support clearing of a new transaction type. ICC also proposes related loss given default enhancements to the ICC Risk Management Model Description Document, the ICC Risk Management Framework, the ICC Stress Testing Framework, and the ICC Liquidity Risk Management Framework.

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change, Security-Based Swap Submission, or Advance Notice

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change, security-based swap submission, or advance notice and discussed any comments it received on the proposed rule change, security-based swap submission, or advance notice. 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, Security-Based Swap Submission, or Advance Notice

(a) Purpose

ICC proposes revisions to its Rules, Risk Management Model Description Document, Risk Management Framework, Stress Testing Framework, and Liquidity Risk Management Framework. ICC believes such revisions will facilitate the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions for which it is responsible. The proposed revisions are described in detail as follows.

Proposed Amendments to the ICC Rules

The purpose of the proposed changes to the ICC Rules is to support clearing of a new transaction type, Standard European Senior Non-Preferred Financial Corporate, which was recently published by the International Swaps and Derivatives Association, Inc. (“ISDA”). ICC proposes amending its Rules to provide for the clearance of contracts referencing this new transaction type. ICC believes the addition of these contracts will benefit the market for credit default swaps by providing market participants the benefits of clearing, including reduction in counterparty risk and safeguarding of margin assets pursuant to clearing house rules.

Specifically, ICC proposes amending Rule 26H-102 (Definitions), ‘List of Eligible Standard European Financial Corporate (“STEF”) Reference Entities’ to include Standard European Senior Non-Preferred Financial Corporate in the list of Eligible STEFC Reference Entities to be cleared by ICC. ICC also proposes amending Rule 26H-102 (Definitions), ‘STEF Contract Reference Obligations’ to note that in the case of a STEFC Reference Entity where the transaction type is Standard European Senior Non-Preferred Financial Corporate, the STEFC Contracts Reference Obligation shall be determined in accordance with the Additional Provisions for Senior Non-Preferred Reference Obligations, as published by ISDA. ICC also proposes conforming changes to Rule 26H-303 (STEF Contract Adjustments) and Rule 26H-315 (Terms of the Cleared STEFC Contract), to incorporate reference to the new transaction type.

Proposed Loss Given Default Enhancements

ICC’s risk management methodology incorporates considerations of idiosyncratic credit events and the

associated potential losses. These credit event losses are termed Loss-Given-Default (“LGD”). In order to support clearing of the new transaction type, ICC proposes certain LGD enhancements to its risk model. A description of these changes is set forth below.

ICC first proposes Risk Factor (“RF”) level LGD enhancements. These proposed RF level enhancements are designed to better capture the LGD risk associated with the issuance of new debt structures by European banks, and provide a consistent recovery rate scenario approach to different sub-factors.

Under ICC’s risk model, every Single Name (“SN”) reference entity is deemed a RF. Each combination of definition, doc-clause, tier, and currency for a given SN RF determines a SN Risk Sub-Factor (“RSF”). Currently, ICC measures losses associated with credit events (“LGD”) by means of a stress-based approach, which utilizes three recovery rate (“RR”) scenarios: Minimum RR, expected RR, and maximum RR. Outright and index-derived RSF exposures are combined at each RR scenario.

The results of these RR scenarios are used as an input into the Profit/Loss-Given-Default (“P/LGD”) calculations at both the RSF and RF levels. For each RSF, P/LGD is calculated as the worst credit event outcome, and for each RF, P/LGD is calculated as the sum of the worst credit outcomes per RSF. These final P/LGD results are used as part of the determination of risk requirements.

ICC proposes enhancements to the RF level LGD calculation. Specifically, ICC proposes a change to the calculation by incorporating a more consistent approach in the calculation of the P/LGD by using the same RR scenarios applied to the different RSFs which part of the considered RF.

For each RF, ICC will continue to calculate an “extreme outcome” as the sum of the worst RSF P/LGDs across all scenarios. ICC will also, for each RF, calculate an “expected outcome” as the worst sum of all the RSF P/LGDs across all of the same scenarios. Under the proposed approach, ICC will then combine the results of the “extreme outcome” calculation and the “expected outcome” calculation to compute the total LGD for each RF.

ICC also proposes to expand its LGD analysis to Risk Factor Groups (“RFG”). Under the proposed changes, a collection of related RFs will form a RFG. These related RFs will be defined as a RFG based on either (1) having a common majority parental sovereign ownership (e.g. quasi-sovereigns and sovereigns), or (2) being a majority

¹ 15 U.S.C. 78s(b)(1)

² 17 CFR 240.19b-4

owned subsidiary of a common parent entity according to the Bloomberg Related Securities Analysis. A RFG can consist of only one RF. This change will better capture the risk exposure dynamics of related RFs, and will allow ICC the ability to provide limited LGD benefits across RFs with opposite exposures, as well as allow for the ability to capture accumulation of directional exposure for related RFs.

Under the proposed approach, the total quantity LGD will be calculated on a RFG level, and account for the exposure due to credit events associated with the reference entities within a given RFG. If a RFG contains only one RF, the LGD will continue to be computed as the risk exposure due to a credit event for a given underlying reference entity. Under the proposed approach, ICC will sum the P/LGDs for each RF in a given RFG, with limited offsets in the event RFs exhibit positive PLGD. Using the results of the above calculation, ICC will obtain the RFG level LGD. The proposed approach also includes a calculation which allows for the RFG level LGD to be attributed to each RF within the considered RFG.

ICC proposes changes to the 'Loss Given Default Risk Analysis' section of the Risk Management Model Description Document to reflect the described RF and RFG LGD calculation changes. ICC also proposes conforming changes to other sections of the Risk Management Description Document to incorporate these methodology changes and reflect the RFG analysis.

ICC proposes a revision to the 'Uncollateralized Loss Given Default' calculation in order to incorporate the RFG level LGD attribution calculation mentioned above.

ICC proposes changes to the 'Idiosyncratic Jump-to-Default Requirements' section of the Risk Management Model Description document. Currently, the portfolio JTD approach collateralizes the worst uncollateralized LGD ("ULGD") exposure among all RFs. Under the proposed approach, the portfolio JTD approach will collateralize, through the portfolio JTD IM requirement that accounts for the RFG-specific LGD collateralization, the worst ULGD exposure among all RFGs. The ULGD exposure for a given RFG will be calculated as a sum of the associated RF ULGDs.

ICC also proposes minor edits to the 'Portfolio Level Wrong-Way Risk and Contagion Risk Analysis' section to update language and calculation descriptions to accommodate the introduction of the RFG to the

'Idiosyncratic Jump-to-Default Requirements' section.

ICC proposes changes to the 'Guaranty Fund Methodology' section. ICC's risk management approach establishes GF to provide for the mutualization of losses under extreme credit market scenarios. Specifically, the ICC GF is designed to provide adequate funds to cover losses associated with the default of the two CP affiliate groups that would potentially cause the largest aggregate credit exposure to ICC under extreme but plausible market conditions. ICC's current GF methodology includes, among other assumptions and adverse market conditions, the assumption that up to three credit events, different from the ones associated with CPs, occur during the established risk horizon. ICC proposes expanding this analysis to the RFG level. Under this proposed approach, it will be assumed that credit events associated with up to three RFGs, different from the ones associated with the CPs and the RFs that are in the RFGs as the CPs, occur during the established risk horizon. As such, the uncollateralized losses, used in the Guaranty Fund analysis, reflect the proposed expansion to the RFG level.

ICC also proposes clarifications to the calculation for the Specific Wrong Way Risk component of the Guaranty Fund. Currently, for a given CP, the Specific Wrong Way Risk component is based on self-referencing positions arising from one or more RFs; ICC proposes clarifying this analysis to be based on the RFG level.

ICC proposes conforming changes to its Risk Management Framework, Liquidity Risk Management Framework, and Stress Testing Framework, to reflect the LGD enhancements described above. For the Risk Management Framework, ICC proposes revisions to the 'Jump-to-Default Requirements' section to note that the worst LGD associated with a RFG is selected to establish the portfolio idiosyncratic JTD requirements. ICC also proposes revisions to the 'Guaranty Fund' section to reflect the RFG LGD enhancements related to ICC's Guaranty Fund calculation.

With regards to the Stress Testing Framework, ICC proposes changes to its stress testing methodology to be based on the reference entity group level (also referred to as the RFG level). Currently, ICC utilizes scenarios based on hypothetically constructed (forward looking) extreme but plausible market scenarios augmented with adverse credit events affecting up to two additional reference entities per CP affiliate group; ICC proposes expanding its adverse credit event analysis to include up to two additional reference

entity groups. ICC also proposes that the selected RFG for stress testing purposes must contain one or more reference entities displaying 500 bps or greater 1-Y end-of-day spread level in order to be subjected to credit events. ICC also proposes changes to its reverse stress testing, general wrong way risk, and contagion stress testing analyses, to be at the RFG level. ICC proposes removing RF level references under its Recovery Rate Sensitivity analysis to be consistent with the proposed changes related to RFG.

Finally, with regards to the ICC Liquidity Risk Management Framework, ICC proposes changes to its liquidity stress testing methodology to be based on the reference entity group level (also referred to as the RFG level). Currently (consistent with the stress testing methodology), ICC utilizes scenarios based on hypothetically constructed (forward looking) extreme but plausible market scenarios augmented with adverse credit events affecting up to two additional reference entities per CP affiliate group; ICC proposes expanding its adverse credit event analysis to include up to two additional reference entity groups. Similar to the Stress Testing Framework, ICC also proposes that the selected RFG for liquidity stress testing purposes must contain one or more reference entities displaying 500 bps or greater 1-Y end-of-day spread level in order to be subjected to credit events. Finally, ICC is adding additional language to the liquidity framework detailing the rationale behind the selection of the 500 bps threshold, to be consistent with Stress Testing Framework.

(b) Statutory Basis

Section 17A(b)(3)(F) of the Act³ 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 and to comply with the provisions of the Act and the rules and regulations thereunder. ICC believes that the proposed rule changes are 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),⁴ because ICC believes that the proposed rule changes will promote the prompt and accurate clearance and settlement of securities

³ 15 U.S.C. 78q-1(b)(3)(F).

⁴ Id.

transactions, derivatives agreements, contracts, and transactions.

In regards to the proposed amendments to the ICC Rules, contracts referencing the Standard European Senior Non-Preferred Financial Corporate transaction type are similar to the STEFC contracts currently cleared by ICC, and will be cleared pursuant to ICC's existing clearing arrangements and related financial safeguards, protections and risk management procedures. Clearing of these contracts will allow market participants an increased ability to manage risk and ensure the safeguarding of margin assets pursuant to clearing house rules. ICC believes that acceptance of these contracts, on the terms and conditions set out in the Rules, is consistent with the prompt and accurate clearance of and settlement of securities transactions and derivative agreements, contracts and transactions cleared by ICC, the safeguarding of securities and funds in the custody or control of ICC, and the protection of investors and the public interest, within the meaning of Section 17A(b)(3)(F) of the Act.⁵

Clearing of contracts referencing the Standard European Senior Non-Preferred Financial Corporate transaction type will also satisfy the requirements of Rule 17Ad-22.⁶ In particular, in terms of financial resources, ICC will apply its existing initial margin methodology to the contracts. ICC believes that this model will provide sufficient initial margin requirements to cover its credit exposure to its clearing members from clearing such contracts, consistent with the requirements of Rule 17Ad-22(b)(2).⁷ In addition, ICC believes its Guaranty Fund, under its existing methodology, will, together with the required initial margin, provide sufficient financial resources to support the clearing of the contracts consistent with the requirements of Rule 17Ad-22(b)(3).⁸ ICC also believes that its existing operational and managerial resources will be sufficient for clearing of the contracts, consistent with the requirements of Rule 17Ad-22(d)(4),⁹ as the new contracts are substantially the same from an operational perspective as existing contracts. Similarly, ICC will use its existing settlement procedures and account structures for the new contracts, consistent with the requirements of Rule 17Ad-22(d)(5),

(12) and (15)¹⁰ as to the finality and accuracy of its daily settlement process and avoidance of the risk to ICC of settlement failures. ICC determined to accept the contracts for clearing in accordance with its governance process, which included review of the contracts and related risk management considerations by the ICC Risk Committee and approval by its Board. These governance arrangements are consistent with the requirements of Rule 17Ad-22(d)(8).¹¹ Finally, ICC will apply its existing default management policies and procedures for the contracts. ICC believes that these procedures allow for it to take timely action to contain losses and liquidity pressures and to continue meeting its obligations in the event of clearing member insolvencies or defaults in respect of the additional single names, in accordance with Rule 17Ad-22(d)(11).¹²

With regards to the LGD enhancements, the proposed risk model revisions enhance ICC's risk methodology and are expected to impose more conservative requirements, which would enhance the financial resources available to ICC and thereby facilitate its ability to promptly and accurately clear and settle its cleared CDS contracts. In addition, the proposed revisions are consistent with the relevant requirements of Rule 17Ad-22.¹³ In particular, the LGD related amendments will enhance the financial resources available to the clearing house, and continue to ensure that ICC maintains sufficient financial resources to withstand a default by the Clearing Participant ("CP") family to which it has the largest exposure in extreme but plausible market conditions, and are therefore reasonably designed to meet the margin and financial resource requirements of Rule 17Ad-22(b)(2-3).¹⁴

(B) Clearing Agency's Statement on Burden on Competition

ICC does not believe the proposed rule changes would have any impact, or impose any burden, on competition. Contracts referencing the Standard European Senior Non-Preferred Financial Corporate transaction type will be available to all ICC participants for clearing. The clearing of these contracts by ICC does not preclude the offering of the contracts for clearing by other market participants. Additionally, the LGD enhancements apply uniformly

across all CPs. Therefore, ICC does not believe the proposed rule changes impose 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, Security-Based Swap Submission, or Advance Notice 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, Security-Based Swap Submission, or Advance Notice 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-2018-001 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-ICC-2018-001. 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

⁵ 15 U.S.C. 78q-1(b)(3)(F).

⁶ 17 CFR 240.17Ad-22.

⁷ 17 CFR 240.17Ad-22(b)(2).

⁸ 17 CFR 240.17Ad-22(b)(3).

⁹ 17 CFR 240.17Ad-22(d)(4).

¹⁰ 17 CFR 240.17Ad-22(d)(5), (12) and (15).

¹¹ 17 CFR 240.17Ad-22(d)(8).

¹² 17 CFR 240.17Ad-22(d)(11).

¹³ 17 CFR 240.17Ad-22.

¹⁴ 17 CFR 240.17Ad-22(b)(2-3).

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 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-2018-001 and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-01357 Filed 1-25-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting; Cancellation

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 83 FR 3239, January 23, 2018

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Wednesday, January 24, 2018 at 11:00 a.m.

CHANGES IN THE MEETING: The Closed Meeting scheduled for Wednesday, January 24, 2018 at 11:00 a.m., has been cancelled.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact Brent J. Fields of the Office of the Secretary at (202) 551-5400.

Dated: January 23, 2018.

Brent J. Fields,
Secretary.

[FR Doc. 2018-01550 Filed 1-24-18; 11:15 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82553; File No. SR-CBOE-2018-007]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Schedule

January 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on January 19, 2018, Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make a number of changes to its Fees Schedule.³

Liquidity Provider Sliding Scale

Under the Liquidity Provider Sliding Scale ("LP Sliding Scale"), a Liquidity Provider's (Cboe Options Market-Makers, DPMs and LMMs) standard per-contract transaction fees for all products except Underlying Symbol List A⁴ are reduced based upon the Liquidity Provider ("LP") reaching certain contract volume thresholds in a month.⁵ The Exchange proposes to adjust the volume thresholds. Specifically, the Exchange proposes to adjust Tiers 2 through 5. Tier 1 remains unchanged and there are no changes to any of the LP Sliding Scale rates. The proposed changes are as follows:

Tier	Percentage thresholds of National Market-Maker Contract Volume excluding underlying Symbol List A		Rate
	Current	Proposed	
1	0.00%–0.05%	No change	\$0.23
2	Above 0.05%–0.70%	Above 0.05%–0.80%	0.17
3	Above 0.70%–1.40%	Above 0.80%–1.50%	0.10
4	Above 1.40%–2.00%	Above 1.50%–2.25%	0.05
5	Above 2.00%	Above 2.25%	0.03

¹⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ The Exchange initially filed the proposed fee changes on January 2, 2018 (SR-CBOE-2018-001).

On business date January 19, 2018, the Exchange withdrew that filing and submitted this filing.

⁴ As of January 19, 2018, Underlying Symbol List A includes Underlying Symbol List A consists of OEX, XEO, RUT, RLG, RLV, RUI, AWDE, FTEM,

FXTM, UKXM, SPX (includes SPXw), VIX, VOLATILITY INDEXES and binary options.

⁵ See Cboe Options Fees Schedule, Liquidity Provider Sliding Scale.

The purpose of this change is to adjust for the Exchange's market share gains, which the Exchange has an interest in maintaining, while continuing to offer an incremental incentive for LPs to strive for the highest tier level.

LP Sliding Scale Adjustment Table

The Exchange proposes to amend the LP Sliding Scale Adjustment Table which provides that Taker fees be applied to "Taker" volume and a Maker rebate be applied to "Maker" volume in addition to the transaction fees assessed under the LP Sliding Scale. The amount of the Taker fee (or Maker rebate) is

determined by the LP's percentage of volume from the previous month that was Maker ("Make Rate").⁶ The Exchange proposes to adjust the Performance Tiers (determined by the Make Rate), fees and rebates. Specifically the Exchange proposes to amend the volume thresholds for the make rate as follows:

Tier	Make rate (% based on prior month)	
	Current	Proposed
1	0%–50%	No change.
2	Above 50%–75%	Above 50%–60%.
3	Above 75%–85%	Above 60%–75%.
4	Above 85%–90%	Above 75%–90%.
5	Above 90%	No change.

The Exchange also proposes to amend the Maker rebates and Taker fees as follows:

Tier	Maker rebate			Taker fee			
	Penny classes		Non-Penny Classes	Penny classes		Non-Penny classes	
	Current	Proposed		Current	Proposed	Current	Proposed
1	(\$0.00)	No change	No change	\$0.04	\$0.05	\$0.08	\$0.10.
2	(0.00)	No change	No change	0.03	\$0.04	0.06	\$0.07.
3	(0.00)	(0.01)	No change	0.02	\$0.03	0.04	\$0.05.
4	(0.00)	(0.02)	No change	0.01	\$0.00	0.02	\$0.04.
5	(0.01)	(0.03)	No change	0.00	No change	0.00	No change.

The Exchange notes that Taker fees for Penny classes will continue to be subject to a cap of 0.50 per contract, which includes the LP Sliding Scale transaction fee, Adjustment Table fee and Marketing Fee.⁷ The Exchange notes that the proposed changes to the Adjustment Table are designed to encourage LPs to provide and post liquidity to the Exchange and continue to encourage market participation and price improvement.

Hybrid Agency Liaison ("HAL") Step-Up Rebate

The Exchange currently rebates a Market-Maker \$0.05 per contract against

transaction fees generated from a transaction on the HAL system in a penny pilot class, provided that at least 70% of the Market-Maker's quotes in that class (excluding quotes in LEAPS series) in the prior calendar month were on one side of the NBBO. The Exchange no longer desires to provide this incentive and therefore proposes to eliminate the HAL Step-Up Rebate from the Fees Schedule.

Volume Incentive Program

Under the Volume Incentive Program ("VIP"), the Exchange credits each Trading Permit Holder ("TPH") the per contract amount set forth in the VIP

table for Public Customer orders ("C" origin code) transmitted by that TPH (with certain exceptions) which is executed electronically on the Exchange, provided the TPH meets certain volume thresholds in a month.⁸ The Exchange proposes to make a few amendments to VIP. First, the Exchange proposes to amend the volume thresholds for Tiers 2, 3 and 4 and also add a Tier 5.⁹ The changes are as follows:

⁶ See Cboe Options Fees Schedule, Liquidity Provider Sliding Scale Adjustment Table.

⁷ For example, if an LP is assessed the Marketing Fee on a given transaction (0.25 per contract) for which it was a Taker in a Penny class, and that LP falls in Tier 1 of the LP Sliding Scale (\$0.23 per

contract) and Performance Tier 1 of the Adjustment Table (\$0.05 per contract), the LP would be assessed \$0.50 per contract for the transaction, instead of \$0.53 per contract.

⁸ See Cboe Options Fees Schedule, Volume Incentive Program.

⁹ The Exchange notes that the Tier 5 rates for Simple and Complex Non-AIM will be the same as the rates for Tier 4 for Simple and Complex Non-AIM.

Tier	Percentage thresholds of National Customer Volume in all underlying symbols excluding underlying Symbol List A, DJX, MXEA, MXEF, MNX, NDX, XSP and XSPAM	
	Current	Proposed
1	0.00%–0.75%	No change.
2	Above 0.75% to 1.80%	Above 0.75% to 2.00%.
3	Above 1.80% to 3.00%	Above 2.00% to 3.00%.
4	Above 3.00%	Above 3.00% to 4.00%.
5	N/A	Above 4.00%.

The Exchange also proposes to reduce the per contract credits for AIM orders. The proposed changes are as follows:

	Per contract credit for AIM orders			
	Simple			Complex
	Tier	Current	Proposed	Current
1	\$0.00	No change	\$0.00	No change.
2	0.09	No change	0.20	0.19.
3	0.11	0.10	0.23	0.22.
4	0.14	0.13	0.24	0.23.
5	N/A	0.14	N/A	0.24.

The purpose of these changes is to adjust for current volume trends while maintaining an incremental incentive for TPH's to strive for the highest tier level. The Exchange does not believe it's necessary to maintain the existing credits for AIM volume, but still seeks to maintain an incremental incentive for TPHs to strive for the highest tier level.

Lastly, the Exchange proposes to provide that a TPH will only receive the Complex credit rates for both its Complex AIM and Non-AIM volume if at least 40% of that TPH's qualifying VIP volume (in both AIM and Non-AIM) in the previous month was comprised of Simple volume. If the TPH's previous month's volume does not meet the 40% Simple volume threshold, then the TPH's Customer (C) Complex volume will receive credits at the Simple rate only (*i.e.*, all volume, both Simple and Complex, will receive credits at the applicable Simple rate). The proposed 40% requirement will apply beginning in February 2018 (*i.e.*, the proposed threshold will not affect January's credits. Rather, February 2018 volume will be based on whether a TPH's volume in January 2018 was comprised of at least 40% Simple volume). Notwithstanding the higher credits offered for Complex volume, the Exchange believes the proposed change will encourage TPHs to continue to send both Simple and Complex volume to the Exchange.

Market-Maker Affiliate Volume Plan

The Exchange proposes to amend its Market-Maker Affiliate Volume Plan ("AVP"). By way of background, under AVP, if a TPH Affiliate¹⁰ or Appointed OFP¹¹ of a Market-Maker qualifies under VIP, that Market-Maker will also qualify for a discount on that Market-Maker's LP Sliding Scale transaction fees and Trading Permit fees. As noted above, the Exchange proposes to add an additional tier to VIP. As such, the Exchange also proposes to add an additional tier to AVP (Tier 5). Particularly, Market-Makers will receive a discount on transaction fees and Trading Permit fees of 35% if their Affiliate or Appointed OFP reach Tier 5 of VIP. The Exchange also proposes to reduce the discount for reaching Tier 3 from 20% to 15%.

Electronic Transaction Fees for Clearing Trading Permit Holder Proprietary

The Exchange proposes to increase the transaction fees for electronic executions for Clearing Trading Permit Holder Proprietary (origin codes "F" and "L") orders in equity, ETF, ETN and

¹⁰ For purposes of AVP, "Affiliate" is defined as having at least 75% common ownership between the two entities as reflected on each entity's Form BD, Schedule A.

¹¹ See Cboe Options Fees Schedule Footnote 23. Particularly, a Market-Maker may designate an Order Flow Provider ("OFP") as its "Appointed OFP" and an OFP may designate a Market-Maker to be its "Appointed Market-Maker" for purposes of qualifying for credits under AVP.

index options (excluding Underlying Symbol List A) classes from \$0.38 per contract to \$0.43 per contract in Penny Classes and \$0.65 per contract to \$0.70 per contract in Non-Penny classes.¹² The Exchange notes that this increase is in line with the amounts assessed by others exchanges for similar transactions.¹³

Complex Surcharge

Currently, the Exchange assesses a Complex Surcharge of \$0.10 per contract per side for non-customer complex order executions that take liquidity from the Complex Order Book ("COB") and auction responses in the Complex Order Auction ("COA") and the Automated Improvement Mechanism ("AIM") in all classes except Underlying Symbol List A.¹⁴ The Exchange proposes to increase the amount of the Complex Surcharge from \$0.10 per contract to \$0.12 per contract.

¹² The Exchange notes that it inadvertently did not update the Clearing Trading Permit Holder Proprietary transaction fee rates for electronic executions for in the Clearing Trading Permit Holder Fee Cap table in the Fees Schedule. Currently, the rate is listed as \$0.35 per contract. The Exchange notes it is now updating the fee to the proposed amounts of \$0.43 for Penny Classes and \$0.70 for Non-Penny Classes.

¹³ See *e.g.*, Nasdaq PHLX LLC Pricing Schedule, Section II, Multiply Listed Options Fees. See also NYSE American Options Fees Schedule, Section I.A, Options Transaction Fees and Credits.

¹⁴ See Cboe Options Fees Schedule, Complex Surcharge and Footnote 35 for more details regarding the Complex Surcharge.

The Exchange notes that it will continue to cap noncustomer complex auction responses in COA and AIM in Penny classes at \$0.50 per contract, which includes the applicable transaction fee, Complex Surcharge and Marketing Fee (if applicable).¹⁵

AIM Contra

The Exchange proposes to increase the AIM Contra Execution Fee for Broker-Dealer, Firm, Joint Back-Office, Non-TPH Market-Maker and Professional/Voluntary Professional orders from \$0.05 to \$0.07. The Exchange notes that the proposed amount of the fee is in line with the amount assessed for similar transactions at another exchange.¹⁶

ORS and CORS

The Exchange proposes to amend its Order Routing Subsidy (ORS) and Complex Order Routing Subsidy (CORS) Programs (collectively “Programs”). By way of background, the ORS and CORS

Programs allow the Exchange to enter into subsidy arrangements with any TPH (each, a “Participating TPH”) or Non-TPH broker-dealer (each a “Participating Non-TPH”) that meet certain criteria and provide certain order routing functionalities to other TPHs, Non-TPHs and/or use such functionalities themselves.¹⁷ Participants in the ORS Program receive a payment for every executed contract for simple orders routed to the Exchange through their system and participants in the CORS Program receive a payment for every executed contract for complex orders routed to the Exchange through their system. Additionally, participants whose total aggregate non-customer ORS and CORS volume is greater than 0.40% of the total national volume (excluding volume in options classes included in Underlying Symbol List A, DJX, MXEA, MXEF, XSP or XSPAM) receive an additional payment of \$0.07 per contract for all executed contracts exceeding that threshold during a

calendar month. The Exchange proposes to reduce the threshold required to receive the additional \$0.07 per contract from 0.40% to 0.25%.

Liquidity Provider Sliding Scale for SPX and SPXW

The Exchange proposes to amend its sliding scale for LP transaction fees in SPX and SPXW (“SPX LP Sliding Scale”). Currently, LPs’ transaction fees in SPX and SPXW are determined by their average monthly contracts in SPX and SPXW. The SPX LP Sliding Scale currently provides for three tiers. The Exchange proposes to add two additional tiers, adjust the volume thresholds, and amend the transaction fees for each tier. The SPX LP Sliding Scale will continue to provide progressively lower rates if increased volume thresholds in SPX (including SPXW) options are attained during a month. The changes to the SPX LP Sliding Scale are as follows:

Tier	Volume thresholds		Rate	
	Current	Proposed	Current	Proposed
1	0.00%–1.50%	0.00%–1.00%	\$0.25	\$0.28
2	Above 1.01%–10.00%	Above 1.00%–4.00%	0.23	0.26
3	Above 10.00%	Above 4.00%–9.00%	0.21	0.24
4	N/A	Above 9.00%–15.00%	N/A	0.22
5	N/A	Above 15.00%	N/A	0.20

The proposed changes to the SPX LP Sliding Scale continue to provide incremental incentives for LPs to reach the highest tier level and encourage trading of SPX options.

Proprietary Products Sliding Scale

The Proprietary Products Sliding Scale (“Proprietary Sliding Scale”) table provides that Clearing Trading Permit Holder Proprietary transaction fees for Clearing Trading Permit Holders and for Non-Clearing Trading Permit Holder Affiliates (“Non-TPH Affiliates”) (collectively, “Clearing TPHs”) in Underlying Symbol List A are reduced provided a Clearing TPH reaches certain average daily volume (“ADV”) thresholds in all underlying symbols excluding Underlying Symbol List A on the Exchange in a month. The Exchange proposes to increase the rates set forth in Tiers B2 and A1. Specifically, the Exchange proposes to increase the rate

in Tier B2 to \$0.18 from \$0.12 and in Tier A1 to \$0.04 from \$0.02. The purpose of increasing the transaction Fee Per Contract rates (and thereby reducing the amount of the discount Clearing TPHs may receive on proprietary products) is to moderate the discount levels for these products in view of their growth and performance. Particularly, the Exchange does not believe it’s necessary to maintain the existing discounted rates for these tiers, but still seeks to maintain an incremental incentive for Clearing TPHs to strive for the highest tier level.

VIX Sliding Scale

The Exchange proposes to amend its Clearing Trading Permit Holder Proprietary VIX Sliding Scale (the “VIX Sliding Scale”). The VIX Sliding Scale allows VIX volatility index options (“VIX options”) transaction fees for Clearing TPH (including its Non-TPH

Affiliates) proprietary orders to be reduced provided a Clearing TPH reaches certain proprietary VIX options volume thresholds during a month. The Exchange wishes to reduce the VIX fees in Tier 2 of the VIX Sliding Scale from \$0.17 per contract to \$0.15 per contract.

Supplemental VIX Discount

The Exchange proposes to amend its Supplemental VIX Total Firm Volume Discount (“Supplemental VIX Discount”). The Supplemental VIX Discount allows VIX options transaction fees for Clearing TPHs (including its Non-TPH Affiliates) proprietary orders to be discounted provided a Clearing TPH reaches certain VIX firm volume percentage thresholds during a calendar month. The Exchange wishes to lower the volume thresholds in Tiers 1 and 2 as follows in order to reduce VIX transaction fees and encourage greater VIX trading activity:

¹⁵ For example, a Market-Maker COA response in a Penny class that is subject to the Marketing Fee (\$0.25 per contract), the Liquidity Provider Sliding Scale Tier 1 rate (\$0.23 per contract) and Complex Surcharge (\$0.12 per contract), would only be

charged \$0.50 per contract, instead of \$0.60 per contract.

¹⁶ See PHLX Pricing Schedule, Section IV, PIXL Pricing.

¹⁷ See Cboe Options Fees Schedule, “Order Router Subsidy Program” and “Complex Order Router Subsidy Program” tables for more details on the ORS and CORS Programs.

Tier	VIX Firm volume percentage	
	Current	Proposed
1	0.00%–10.99%	0.00%–7.00%.
2	11.00%–12.99%	7.01%–11.00%.
3	13.00%–14.99%	11.01%–15.00%.
4	Above 14.99%	Above 15.00%.

SPX Index License Surcharge

The Exchange proposes to increase the Index License Surcharge Fee for SPX (including SPXW) (the “SPX Surcharge”) from \$0.14 per contract to \$0.16 per contract. The Exchange licenses from S&P Dow Jones Indices (“SPDJI”) (the “SPDJI License”) the right to offer an index option product based on the S&P 500 index (that product being SPX and other SPX-based

index option products). In order to offset the costs of the SPDJI License, the Exchange assesses the SPX Surcharge. The Exchange therefore proposes to increase the SPX Surcharge from \$0.14 per contract to \$0.16 per contract in order to offset more of the costs associated with the SPX license.

Floor Broker Trading Permit Fees

The Exchange proposes to amend its Floor Broker Trading Permit Sliding

Scale Program (“FB TP Sliding Scale”). The FB TP Sliding Scale allows Floor Brokers to pay reduced rates for their Trading Permits if they commit in advance to a specific tier that includes a minimum number of eligible Floor Broker Trading Permits for each calendar year. The Exchange proposes to amend the Permit thresholds as follows:

Tiers	Number of permits		Amount per month per permit
	Current	Proposed	
1	1	No change	\$9,000
1	2–7	2–5	5,000
2	8 or more	6 or more	3,000

The purpose of this change is to reduce access costs and thereby encourage greater Floor Broker access.

Floor Brokerage Fees Discount

The Exchange proposes to adopt a new discount for floor brokerage fees. Currently, floor brokerage fees for OEX, XEO, RUT, RLG, RLV, RUI, AWDE, FTEM, FXTM, UKXM and SPX Index Options are \$0.04 per contract (crossed orders \$0.02) and VIX and volatility

index options are \$0.03 per contract (crossed orders \$0.015). The Exchange wishes to implement a new floor brokerage fees discount for Floor Brokers (“FB Discount”). The FB Discount will be based on a Floor Broker’s total monthly Floor Broker volume and will allow Floor Brokers to reduce their floor brokerage fees provided certain volume thresholds are attained during a month. The Exchange

notes that only volume that is assessed transaction fees will be considered qualifying volume to meet the volume thresholds (*i.e.*, OEX, XEO, RUT, SPX, SPXw, VIX and volatility index options). The Exchange notes that currently transaction fees for RLG, RLV, RUI, AWDE, FTEM, FXTM, UKXM are waived and as such will not count towards the volume thresholds. The FBD will be as follows:

Tiers	Total monthly floor broker contracts traded in qualifying classes	% Discount on all floor brokerage fees ¹⁸
1	0–250,000	0
2	250,001–1,500,000	3
3	1,500,001–5,000,000	4
4	5,000,001–7,500,000	5
5	Above 7,500,000	6

Cboe Command Connectivity Charges

Next, the Exchange proposes to increase Cboe Command Connectivity Fees. First, the Exchange proposes to increase the monthly fee for a 1 gigabit per second (“Gbps”) Network Access Port from \$750 per port to \$1,500 per

port.¹⁹ The Exchange also proposes to increase the monthly fee for a 10 Gbps Network Access Port from \$4,000 per port to \$5,000 per port. The Exchange has expended significant resources setting up, providing and maintaining this connectivity and the Exchange desires to offset such costs. The Exchange notes that such costs are also increasing due to network infrastructure upgrades. This fee amount is still within

the range of, and in some cases less than, similar fees assessed by other exchanges.²⁰

Linkage

The Exchange proposes to increase the Linkage fee (in addition to the applicable away fees) for Customer orders from \$0.10 to \$0.15. The Fees Schedule currently provides that, in

¹⁸ Once a volume threshold is attained during the month, the corresponding discount percentage will apply to all qualifying contracts. For example, if a Floor Broker has 2,000,000 contracts in qualifying volume in a given month, all 2,000,000 contracts will receive a discount of 4%.

¹⁹ The Exchange also proposes to update the example in the Notes section to reflect the increased fee for the 1 Gbps Network Access Ports.

²⁰ See *e.g.*, Cboe BZX Exchange, Inc., Options Exchange Fees Schedule, Options Physical Connection Fees, which lists connectivity fees of \$2,000 per month for 1 Gbps and \$6,000 per month for 10 Gbps.

addition to the customary Cboe Options execution charges, for each customer order that is routed, in whole or in part, to one or more exchanges in connection with the Options Order Protection and Locked/Crossed Market Plan referenced in Rule 6.80, the Exchange shall pass through the actual transaction fee assessed by the exchange(s) to which the order was routed. The Exchange proposes to assess an additional \$0.05 per contract for customer orders routed away in addition to the applicable pass through fees. The proposed increase

will help offset costs incurred by the Exchange associated with routing customer orders through linkage. Indeed, the Exchange notes that it is, and will still be, subsidizing the costs associated with routing customer orders through linkage. The Exchange notes that the proposed amount of the fee is also in line with the amount assessed at other exchanges.²¹

Frequent Trader

The Exchange next proposes to amend its Frequent Trader Program. By way of background, the Frequent Trader

Program offers transaction fee rebates to registered Customers, Professional Customers and Voluntary Professionals (origin codes "C" and "W") (collectively, "Customers") that meet certain volume thresholds in VIX, RUT, and SPX (including SPXW) options provided the Customer registers for the program. The Exchange proposes to amend the Frequent Trader Program to increase the volume thresholds and increase the rebates for RUT options. Specifically, the proposed changes will be as follows:

Tier	RUT			
	Monthly contracts trade		Fee rebate	
	Current	Proposed	Current (%)	Proposed (%)
1	5,000–9,999	10,000–24,999	3	10
2	10,000–12,999	25,000–49,999	6	15
3	13,000 and above	50,000 and above	9	25

The Exchange believes the proposed changes incentivizes the sending of RUT Customer orders to the Exchange while maintaining an incremental incentive for Customers to strive for the highest tier level.

VIX License Index Surcharge

The Exchange proposes to extend the current waiver of the VIX Index License Surcharge of \$0.10 per contract for Clearing Trading Permit Holder Proprietary ("Firm") (origin codes "F" or "L") VIX orders that have a premium of \$0.10 or lower and have series with an expiration of seven (7) calendar days or less. The Exchange adopted the current waiver to reduce transaction costs on expiring, low-priced VIX options, which the Exchange believed would encourage Firms to seek to close and/or roll over such positions close to expiration at low premium levels, including facilitating customers to do so, in order to free up capital and encourage additional trading. The Exchange had proposed to waive the surcharge through December 31, 2017, at which time the Exchange had stated that it would evaluate whether the waiver has in fact prompted Firms to close and roll over these positions close to expiration as intended. The Exchange believes the proposed change has in fact continued to encourage Firms to do so and as such, proposes to extend the waiver of the surcharge through June 30, 2018, at which time the Exchange will again reevaluate whether the waiver has

continued to prompt Firms to close and roll over positions close to expiration at low premium levels. Accordingly, the Exchange proposes to delete the reference to the current waiver period of December 31, 2017 from the Fees Schedule and replace it with June 30, 2018.

Extended Trading Hour Fees

In order to promote and encourage trading during the Extended Trading Hours ("ETH") session, the Exchange currently waives ETH Trading Permit and Bandwidth Packet fees for one (1) of each initial Trading Permits and one (1) of each initial Bandwidth Packet, per affiliated TPH. The Exchange notes that waiver is set to expire December 31, 2017. The Exchange also waives fees through June 30, 2018 for a CMI and FIX login ID if the CMI and/or FIX login ID is related to a waived ETH Trading Permit and/or waived Bandwidth packet. In order to continue to promote trading during ETH, the Exchange wishes to extend these waivers through June 30, 2018.

RLG, RLV, RUI, AWDE, FTEM, FXTM and UKXM Transaction Fees

In order to promote and encourage trading of seven new FTSE Russell Index products (i.e., Russell 1000 Growth Index ("RLG"), Russell 1000 Value Index ("RLV"), Russell 1000 Index ("RUI"), FTSE Developed Europe Index ("AWDE"), FTSE Emerging Markets Index ("FTEM"), China 50

Index ("FXTM") and FTSE 100 Index ("UKXM")), the Exchange waives all transaction fees (including the Floor Brokerage Fee, Index License Surcharge and CFLEX Surcharge Fee) for each of these products. This waiver however, expired December 31, 2017. In order to continue to promote trading of these options classes, the Exchange proposes to extend the fee waiver through June 30, 2018.

FLEX Asian and Cliquet Flex Trader Incentive Program

By way of background, a FLEX Trader is entitled to a pro-rata share of the monthly compensation pool based on the customer order fees collected from customer orders traded against that FLEX Trader's orders with origin codes other than "C" in FLEX Broad-Based Index Options with Asian or Cliquet style settlement ("Exotics") each month ("Incentive Program"). The Fees Schedule provides that the Incentive Program is set to expire either by December 31, 2017 or until total average daily volume in Exotics exceeds 15,000 contracts for three consecutive months, whichever comes first. The Exchange notes that total average daily volume in Exotics has not yet exceeded 15,000 contracts for three consecutive months. In order to continue to incentivize FLEX Traders to provide liquidity in FLEX Asian and Cliquet options, the Exchange proposes to extend the program to June 30, 2018 or until total average daily volume in Exotics exceeds 15,000

²¹ See e.g., PHLX Pricing Schedule, Section V., Customer Routing Fees.

contracts for three consecutive months, whichever comes first.

AWDE, FTEM, FXTM, UKXM, RVX DPM Payment

The Exchange currently offers a compensation plan to the Designated Primary Market-Maker(s) ("DPM(s)") appointed in AWDE, FTEM, FXTM, UKXM or RVX to offset the initial DPM costs. Specifically, the Fees Schedule provides that DPM(s) appointed for an entire month in AWDE, FTEM, FXTM or UKXM classes will receive a payment of \$7,500 per class per month, and the DPM appointed in RVX will receive a payment of \$8,500 per month, through December 31, 2017. The Exchange notes that it plans on delisting AWDE, FTEM, FXTM and RVX shortly and therefore no longer wishes to extend these DPM payments. The Exchange also notes however, that it does not intend on delisting UKXM at this time and wishes to extend the payment to help offset ongoing costs associated with being the DPM in UKXM. The Exchange proposes to reduce the payment to \$5,000 per month through December 31, 2018.

OHS Order Cancellation Fee

The Exchange notes that the OHS (Order Handling Service) Order Cancellation Fee used to be assessed to an executing Clearing Trading Permit Holder (single OHS firm) for each cancelled public customer (origin code "C") OHS order in excess of the number of public customer orders that the executing Clearing Trading Permit Holder executed in a month for itself or for a correspondent firm. However, this fee has been set at \$0.00 for some time now. The Exchange does not intend on assessing this fee in the near future and as such, desires to remove the fee from the Fees Schedule to avoid any confusion.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.²² Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)²³ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling,

processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act,²⁴ which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

The Exchange believes adjusting the LP Sliding Scale volume thresholds is reasonable because it adjusts for the current volume trends and the Exchange's market share gains. The Exchange also notes that the rates set forth in the LP Sliding Scale are not changing. Rather, the rebalance of tiers still allows the Exchange to maintain an incremental incentive for LP's to strive for the highest tier level, which provides increasingly lower fees. The Exchange believes it is equitable and not unfairly discriminatory because the proposed changes to the qualifying volume thresholds apply to all LPs uniformly. The Exchange also believes the proposed change is equitable and not unfairly discriminatory for the reasons discussed below in the Burden of Competition section relating to the favorable treatment of LPs.

The Exchange believes that the proposed amendments to the LP Sliding Scale Adjustment Table thresholds are reasonable because the amount of LP transaction fees including the proposed changes to Taker adjustments per contract are similar and in line with the amount assessed for similar transactions at other exchanges and because the adjustments are still subject to a \$0.50 per contract cap.²⁵ The proposed changes to the Maker rebates provide LPs additional opportunities to qualify for a rebate they would not otherwise receive. Additionally the proposed rule change is designed to encourage LPs to provide and post liquidity to the Exchange. The Exchange believes that the proposed changes are equitable and not unfairly discriminatory because they apply to all LPs. The Exchange also notes that it believes it's equitable and not unfairly discriminatory to assess additional Taker fees to transactions removing liquidity from the market ("Takers") and not Maker volume because the Exchange wants to continue

to encourage market participation and price improvement.

The Exchange believes it's reasonable to eliminate the HAL Step-Up Rebate because it is not required to provide such a rebate. Additionally, the Exchange notes that it originally adopted the HAL Step-Up rebate to incent Market-Makers to execute orders at Cboe Options versus routing orders away via Linkage (as the Exchange had been subsidizing most of the costs associated with linkage for competitive reasons). However, the Exchange no longer subsidizes most of the linkage costs, as routing practices have changed over the years. Therefore, the Exchange no longer wishes to offer the rebate. The Exchange believes it's equitable and not unfairly discriminatory because it applies uniformly to all TPHs.

The Exchange believes adjusting VIP volume thresholds is reasonable because it adjusts for current volume trends and given the Exchange's market share gains. The Exchange notes that the rebalance of tiers still allows the Exchange to maintain an incremental incentive for TPHs to strive for the highest tier level, which provides increasingly higher credits. This change is also equitable and not unfairly discriminatory because it will be applied to all TPHs uniformly. The Exchange believes adding an additional Tier is reasonable because it provides a rebate for AIM executions, the amount of which is the same as previously offered, albeit at a different threshold. The Exchange believes it's reasonable to reduce the credits available for Simple and Complex AIM executions because VIP still provides an opportunity for TPHs to receive credits for Simple and Complex AIM orders for reaching certain qualifying volume thresholds that they would not otherwise receive (now just a smaller credit). The Exchange also believes it's reasonable, equitable and not unfairly discriminatory to establish lower credits for AIM executions than non-AIM executions under VIP because AIM transactions are already assessed lower transaction fees than non-AIM.²⁶ The Exchange believes the proposal to provide that a TPH will only receive the Complex credit rates for both its Complex AIM and Non-AIM volume if at least 40% of that TPH's qualifying VIP volume (in both AIM and Non-AIM) in the previous month was comprised of Simple volume is reasonable because TPHs still receive credits they would not otherwise receive. The Exchange

²⁴ 15 U.S.C. 78f(b)(4).

²⁵ See e.g., NYSE Arca Options Fees and Charge, Transaction Fee for Electronic Executions—Per Contract.

²⁶ See Cboe Options Fees Schedule, Equity, ETF, ETN and Index Options (excluding Underlying Symbol List A) rate tables.

²² 15 U.S.C. 78f(b).

²³ 15 U.S.C. 78f(b)(5).

believes the proposed rule changes incentivize the sending of both Simple and Complex orders to the Exchange. The greater liquidity and trading opportunities of both Simple and Complex orders should benefit not just customers (whose orders are the only ones that qualify for the VIP) but all market participants. The Exchange believes the proposed change is equitable and not unfairly discriminatory because it applies to all TPHs that meet the qualifying volume thresholds.

The Exchange believes that adding an additional tier to AVP is reasonable because it provides LPs an additional opportunity to receive increased discounts on their transaction fees and Trading Permit fees. Additionally, the Exchange notes that the proposed tier is made in conjunction with the proposal to add a tier to VIP. Moreover, enhancing the incentives under AVP further incentivizes a Market-Maker Affiliate to achieve the highest tier on VIP so that the Market-Maker can achieve those higher credits, which thereby can result in greater customer liquidity. The resulting increased volume benefits all market participants (including Market-Makers or their affiliates who do not achieve the higher tiers on the VIP; indeed, this increased volume may allow them to reach these tiers). The Exchange believes reducing the discount in Tier 2 of AVP from 20% to 15% is reasonable because it still provides an opportunity for LPs to receive a discount they would not otherwise receive (now just a smaller discount). The Exchange believes the proposed changes are equitable and not unfairly discriminatory because they apply uniformly to all Market-Makers whose Affiliates or Appointed Affiliates meet the VIP tiers. The Exchange also notes that any Market-Maker may enter into a relationship with an Appointed Affiliate and thus have the opportunity to avail itself of AVP discounts. Lastly, the Exchange believes the proposed change is equitable and not unfairly discriminatory for the reasons discussed below in the Burden of Competition section relating to the favorable treatment of LPs.

Increasing the fee for electronic executions for Clearing Trading Permit Holder Proprietary orders in Penny and Non-Penny equity, ETF, ETN and index options (excluding Underlying Symbol List A) classes is reasonable because the proposed fee amounts are in line with the amounts assessed by another exchange for similar transactions.²⁷ The

Exchange believes that this proposed change is also equitable and not unfairly discriminatory because the proposed changes will apply equally to all Clearing Trading Permit Holders.

The Exchange believes that the proposed increase of the Complex Surcharge from \$0.10 per contract per side to \$0.12 per contract per side is reasonable because it helps offset high credits given to complex orders under VIP. The Exchange also notes that notwithstanding the increase, noncustomer COA and AIM auction responses in Penny classes continue to be capped at \$0.50 per contract. The Exchange believes the proposed change is equitable and not unfairly discriminatory because it applies uniformly to all noncustomer orders.

The Exchange believes increasing the AIM Contra fee is reasonable because the proposed amount of the fee is in line with the amount assessed for similar transactions at another exchange.²⁸ Additionally, as noted above AIM transactions are already assessed lower transaction fees than non-AIM.²⁹ The Exchange believes the proposed change is equitable and not unfairly discriminatory because it applies equally to applicable TPH transactions.

The Exchange believes the proposed amendments to the ORS and CORS Programs are reasonable because the proposed changes make it easier for Participants to receive additional payments to subsidize the costs associated with providing certain order routing functionalities. Additionally, the Exchange believes the subsidy helps attract order flow to the Exchange, which brings greater liquidity and trading opportunity, which benefits all market participants. The Exchange also believes the proposed change is equitable and not unfairly discriminatory because it applies equally to all participating TPHs and Non-TPH broker dealers.

The Exchange believes adding two additional tiers, adjusting the volume thresholds, and amending the transaction fees for each tier of the SPX LP Sliding Scale is reasonable because the sliding scale continues to provide incremental incentives for LPs to reach the highest tier level and encourage trading of SPX options. Additionally, the Exchange believes increasing SPX transaction fees for LPs is reasonable

because the Exchange has expended considerable resources developing and maintaining SPX. The Exchange believes that this proposed change is equitable and not unfairly discriminatory because it applies uniformly to all LPs. The Exchange also believes that this proposed change is equitable and not unfairly discriminatory because although LPs still pay lower SPX transaction fees than certain other market participants, LPs are valuable market participants that provide liquidity in the marketplace and incur costs that other market participants do not incur.

The Exchange believes increasing the SPX Surcharge is reasonable because it helps offset the costs of the SPDJI License. The Exchange notes in particular, that the proposed surcharge still does not offset the full cost of the SPDJI License. This increase is equitable and not unfairly discriminatory because all non-Customer market participants will be assessed the same increased SPX Surcharge. Not applying the SPX Surcharge to customer orders is equitable and not unfairly discriminatory because this is designed to attract customer SPX orders, which increases liquidity and provides greater trading opportunities to all market participants.

The Exchange believes increasing the rates in Tiers B2 and A1 of the Proprietary Sliding Scale (and thereby reducing the overall discount) is reasonable because it still provides Clearing TPHs (including their Non-TPH Affiliates) an opportunity to receive notable discounted rates on classes in Underlying Symbol List A for reaching certain qualifying volume thresholds that they would not otherwise receive (now just a smaller discount). Additionally, the Exchange notes that lower fees for executing more contracts is equitable and not unfairly discriminatory because it provides market participants with an incentive to execute more contracts on the Exchange. This brings greater liquidity and trading opportunity, which benefits all market participants. The Exchange believes that the proposed change is not unfairly discriminatory because it will apply to all Clearing TPHs that meet the qualifying volume thresholds. The Exchange also believes offering lower fees under the Proprietary Sliding Scale to Clearing TPHs and not other market participants is equitable and not unfairly discriminatory because Clearing TPHs must take on certain obligations and responsibilities, such as clearing and membership with the Options Clearing Corporation, as well as significant regulatory burdens and

Options Fees Schedule, Section I.A, Options Transaction Fees and Credits, Rates for Standard Options Transactions.

²⁸ See PHLX Pricing Schedule, Section IV, PIXL Pricing.

²⁹ See Cboe Options Fees Schedule, Equity, ETF, ETN and Index Options (excluding Underlying Symbol List A) rate tables.

²⁷ See e.g., PHLX Pricing Schedule, Section II, Multiply Listed Options Fees and NYSE Amex

financial obligations, that other market participants are not required to undertake.

The Exchange believes decreasing the rate in Tier 2 of the VIX Sliding Scale (and thereby increasing the overall discount) is reasonable because it provides Clearing TPHs (including their Non-TPH Affiliates) an opportunity to receive an additional discounted rates in VIX for reaching the qualifying volume threshold in VIX. The Exchange notes that lowering the VIX fee is equitable and not unfairly discriminatory because it provides Clearing TPHs with an incentive to execute more VIX contracts on the Exchange. The Exchange believes that the proposed change is not unfairly discriminatory because it will apply to all Clearing TPHs that meet the qualifying volume threshold. The Exchange also believes offering lower fees under the VIX Sliding Scale to Clearing TPHs and not other market participants is equitable and not unfairly discriminatory because Clearing TPHs must take on certain obligations and responsibilities, such as clearing and membership with the Options Clearing Corporation, as well as significant regulatory burdens and financial obligations, that other market participants are not required to undertake.

The Exchange believes adjusting the qualifying thresholds under the Supplemental VIX Discount allows Clearing TPHs the opportunity to obtain a discount on its VIX transaction fees at a quicker rate. The proposed rule change is designed to encourage increased Clearing TPH proprietary VIX options volume, which provides increased VIX options volume and greater trading opportunities for all market participants. Similarly, applying higher discount rates for Clearing TPHs who hit the higher percentage of total VIX options contract proprietary volume of all Clearing TPHs on the VIX Discount is equitable and not unfairly discriminatory because this is designed to encourage increased TPH proprietary VIX options volume, which provides increased VIX options volume and greater trading opportunities for all Clearing TPHs, including those who are not able to reach the higher volume percentages. The Exchange believes the proposed change is equitable and not unfairly discriminatory because it applies uniformly to all Clearing TPHs. Additionally, as discussed above (and below in the Burden of Competition section), Clearing TPHs have clearing obligations that other market participants do not have.

The Exchange believes the proposal to amend the Trading Permit thresholds under the FB TP Sliding Scale are reasonable because it reduces Floor Broker access costs. Lower access costs may encourage greater Floor Broker access, which thereby brings greater trading activity, volume and liquidity, benefitting all market participants. The Exchange believes the proposed change is equitable and not unfairly discriminatory because it applies to all Floor Brokers.

Similarly, the Exchange believes the FB Discount is reasonable because it provides Floor Brokers the opportunity to receive discounts on floor brokerage fees that they otherwise would not receive. Discounted floor brokerage rates may encourage the execution of more orders in the classes that are currently assessed floor brokerage fees, which should increase volume, which would benefit all market participants (including Floor Brokers who do not hit the volume thresholds). The Exchange believes the proposed changes are equitable and not unfairly discriminatory because they apply to qualifying Floor Brokers equally. The Exchange believes it's reasonable, equitable and not unfairly discriminatory to provide that only volume that is assessed transaction fees will be considered qualifying volume to meet the volume thresholds because the Exchange is not collecting any floor brokerage fees on that volume. Providing that the discounts apply only to OEX, XEO, RUT, SPX, SPXw, VIX and volatility index options is equitable and not unfairly discriminatory because those products currently are assessed floor brokerage fees.³⁰

The proposed change to increase the 1 Gbps and 10 Gbps Network Access Port fees is reasonable because the fees are within the same range as those assessed on other exchanges,³¹ and because such increase will assist in recouping ongoing expenditures made by the Exchange. Additionally, as noted above, such expenditures are increasing due to network infrastructure upgrades. This proposed change is equitable and not unfairly discriminatory because the proposed change will apply to all TPHs.

The Exchange's proposal to increase the Linkage fee from \$0.10 per contract to \$0.15 per contract (in addition to applicable transaction fees) for customer

orders is reasonable because the increase will help offset the costs associated with routing orders through Linkage. Additionally, the proposed amount is reasonable as it is in line with amounts charged by other Exchanges for similar transactions.³² The Exchange believes it's equitable and not unfairly discriminatory because the proposed change will apply to all customer orders that are linked away.

The Exchange believes it's reasonable to increase the Frequent Trader rebates for RUT because it provides Customers an opportunity to receive increased rebates for reaching certain qualifying volume thresholds that they would not otherwise receive. The proposed rule change is designed to encourage greater Customer RUT options trading, which, along with bringing greater RUT options trading opportunities to all market participants, would bring in more fees to the Exchange, and such fees can be used to recoup the Exchange's costs and expenditures from maintaining RUT options. The Exchange believes it's also reasonable to increase the qualifying volume thresholds for RUT as it still allows the Exchange to maintain an incremental incentive for Customers to strive for the highest tier level and because the Exchange has increased the rebates for each of the tiers. The Exchange believes it's equitable and not unfairly discriminatory to establish higher rebates under the Frequent Trader Program for RUT as compared to SPX and VIX options because the Exchange would like to encourage more RUT trading. The Exchange believes that the proposed change is not unfairly discriminatory because it will apply to all Frequent Trader Customers and because any Customer may avail itself of the Frequent Trader Program provided it registers with the Exchange and its executing TPH participates. The Exchange believes it's reasonable to continue to waive the VIX Index License Surcharge for Clearing Trading Permit Holder Proprietary VIX orders that have a premium of \$0.10 or lower and have series with an expiration of 7 calendar days or less because, the fee is being waived in its entirety and the Exchange wants to continue encouraging Firms to roll and close over positions close to expiration at low premium levels. The Exchange notes that without the waiver, firms are less likely to engage in these transactions, as opposed to other VIX transactions, due to the associated transaction costs. The Exchange believes it's equitable and not unfairly discriminatory to limit the waiver to

³⁰ As previously noted, transaction fees for RLG, RLV, RUI, AWDE, FTEM, FXTM, UKXM are currently waived.

³¹ See e.g., Cboe BZX Exchange, Inc., Options Exchange Fees Schedule, Options Physical Connection Fees, which lists connectivity fees of \$2,000 per month for 1 Gbps and \$6,000 per month for 10 Gbps.

³² See e.g., PHLX Pricing Schedule, Section V., Customer Routing Fees.

Clearing Trading Permit Holder Proprietary orders because they contribute capital to facilitate the execution of VIX customer orders with a premium of \$0.10 or lower and series with an expiration of 7 calendar days or less. Additionally, encouraging firms to roll and close over these positions would free up capital that the firm can then use to benefit others. Finally, the Exchange believes it's reasonable, equitable and not unfairly discriminatory to provide that the surcharge will be waived through June 30, 2018, as it gives the Exchange additional time to evaluate if the waiver is continuing to have the desired effect of encouraging these transactions.

The Exchange believes extending the waiver of ETH Trading Permit and Bandwidth Packet fees for one of each type of Trading Permit and Bandwidth Packet, per affiliated TPH through June 30, 2018 is reasonable, equitable and not unfairly discriminatory, because those respective fees are being waived in their entirety, which promotes and encourages trading during the ETH session and applies to all ETH TPHs. The Exchange believes it's also reasonable, equitable and not unfairly discriminatory to waive fees for Login IDs related to waived Trading Permits and/or Bandwidth Packets in order to promote and encourage ongoing participation in ETH and also applies to all ETH TPHs.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory to extend the waiver of all transaction fees for RLG, RLV, RUI, AWDE, FTEM, FXTM and UKXM transactions, including the Floor Brokerage fee, the License Index Surcharge and CFLEX Surcharge Fee, because the respective fees are being waived in their entirety, which promotes and encourages trading of these products which are still relatively new and applies to all TPHs.

The Exchange believes extending the FLEX Asian and Cliquet Flex Trading Incentive Program is reasonable, equitable and not unfairly discriminatory because the Exchange believes the amount of the current incentives provided to FLEX Traders should encourage the Flex Traders to trade FLEX Asian and Cliquet options, which should result in a more robust price discovery process that will result in better execution prices for customers. In addition, the proposed change applies equally to all FLEX Traders.

The Exchange believes that it is reasonable, equitable and not unfairly discriminatory to extend the compensation plan to the DPM appointed in UKXM to continue to

offset its ongoing DPM costs and continue to incentivize the DPM to continue to serve as a DPM in this products. The Exchange believes it's reasonable to reduce the payment to \$5,000 because the DPM is still receiving a payment it would not otherwise receive. The Exchange believes it's reasonable, equitable and not unfairly discriminatory to eliminate (i.e., not extend) the DPM payments for AWDE, FTEM, FXTM, UKXM, and RVX because the Exchange either does not trade or plans to delist these classes shortly.

Finally, the Exchange believes eliminating the OHS Cancellation Fee from the Fees Schedule will eliminate unnecessary language and alleviate confusion as the fee is currently set to \$0.00. The alleviation of confusion removes impediments to and perfects the mechanism of a free and open market and a national market system, and, in general, protects investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition that are not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because, while different fees and rebates are assessed to different market participants in some circumstances, these different market participants have different obligations and different circumstances. For example, Clearing TPHs have clearing obligations that other market participants do not have. Market-Makers have quoting obligations that other market participants do not have. There is also a history in the options markets of providing preferential treatment to customers, as they often do not have as sophisticated trading operations and systems as other market participants, which often makes other market participants prefer to trade with customers. Further, the Exchange fees and rebates, both current and those proposed to be changed, are intended to encourage market participants to bring increased volume to the Exchange (which benefits all market participants), while still covering Exchange costs (including those associated with the upgrading and maintenance of Exchange systems).

The Exchange does not believe that the proposed rule changes will impose any burden on intermarket competition

that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed changes are intended to promote competition and better improve the Exchange's competitive position and make Cboe Options a more attractive marketplace in order to encourage market participants to bring increased volume to the Exchange (while still covering costs as necessary). Further, the proposed changes only affect trading on the Exchange. To the extent that the proposed changes make Cboe Options a more attractive marketplace for market participants at other exchanges, such market participants are welcome to become Cboe Options market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act³³ and paragraph (f) of Rule 19b-4³⁴ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CBOE-2018-007 on the subject line.

³³ 15 U.S.C. 78s(b)(3)(A).

³⁴ 17 CFR 240.19b-4(f).

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-CBOE-2018-007. 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-CBOE-2018-007, and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁵

Eduardo A. Aleman,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-82545; File No. SR-BX-2018-001]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Add a New Rule 4765 and Commentary Thereto To Codify Participant Risk Settings and To Authorize the Exchange To Share those Risk Settings With the Clearing Member That Clears Transactions on Behalf of the Participant

January 19, 2018.

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 January 11, 2018, Nasdaq BX, Inc. ("BX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to add a new Rule 4765 and commentary thereto to codify Participant risk settings in the Exchange's trading system and to authorize the Exchange to share such risk settings with the clearing member that clears transactions on behalf of the Participant.

The text of the proposed rule change is set forth below. Proposed new language is italicized; deleted text is in brackets.

* * * * *

Rules of Nasdaq BX

Equity Rules

* * * * *

Rule 4765. Exchange Sharing of Participant Risk Settings

The Exchange may share any Participant risk settings in the trading system specified in the commentary below with the clearing member that clears transactions on behalf of the Participant. For purposes of this Rule, the term "Participant" has the meaning set forth in Rule 4701(c).

Commentary

The Exchange offers certain risk settings applicable to a Participant's activities on the Exchange. The risk settings currently offered by the Exchange are:

(a) Share Size Control—When enabled by a Participant, this optional control will allow a Participant to limit the number of shares that the Participant may associate with an order placed on the Exchange;

(b) ISO Control—When enabled by a Participant, this optional control will prevent a Participant from entering an ISO order onto the Exchange;

(c) Cancel-on-Disconnect Control—When enabled by a Participant, this optional control will allow a Participant, when it experiences a disruption in its connection to the Exchange, to immediately cancel all pending Exchange orders except for Good-Till-Canceled orders (RASH & FIX only);

(d) The BX Kill Switch—This control is described in Rule 4764;

(e) Limit Order Protection—This control is described in Rule 4757(d);

(f) Price Collar Check—This control will automatically restrict a routed order from executing at a price that differs from the NBBO (at the time of order entry) by more than five percent or \$0.25, whichever difference is greater. The system will proceed to route an order unless and until it crosses the greater of these two price collars, and if it does so, then the system will block further routings of the order that fall outside of the collars. For example, if the NBBO is \$99 x \$100 at the time of entry of a buy order, then the system will route the order at prices at or below \$105, but will stop doing so if the offer price rises above \$105 (five percent of the NBO);

(g) Maximum Order Volume Check—This control will automatically reject an order for routing away that exceeds a maximum volume of shares. As applied to equity orders, the default maximum order volume is set at 25,000 shares, but the Participant may request that the Exchange set a higher default based on historic volume;

(h) Cumulative Order Volume Check—This control will automatically block an attempt by a Participant using a particular MPID to route orders away to buy or sell equity securities that, cumulatively, exceed 9.5 million shares during a five second time period; and

(i) Duplication Control—This control will automatically reject an order that a Participant submits to the Exchange to the extent that it is duplicative of another order that the Participant submitted to the Exchange during the prior five seconds.

* * * * *

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³⁵ 17 CFR 200.30-3(a)(12).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt proposed commentary to Rule 4765, which codifies a comprehensive list of Participant risk settings in the Exchange's trading system. The Exchange also proposes to adopt new Rule 4765 to authorize the Exchange to share these risk settings with the clearing member that clears transactions on behalf of the Participant. For purposes of Rule 4765, the term "Participant" has the meaning set forth in Rule 4701(c).³

Participants are required to be members of the Exchange. Rule 4618 states that "all transactions through the facilities of the Nasdaq BX Equities Market shall be cleared and settled through a registered clearing agency using a continuous net settlement system." It further provides that this requirement may be satisfied by "direct participation, use of direct clearing services, by entry into a correspondent clearing arrangement with another member that clears trades through such a clearing agency. . . ." Further, pursuant to Rule 4627, every clearing member acting on a Participant's behalf that constitutes a side of a system trade is responsible for honoring such trades of that Participant.

All Participants that are not clearing members require a clearing member's consent to clear transactions on their behalf in order to conduct business on the Exchange. Each Participant that transacts through a clearing member on the Exchange must have an arrangement between the Participant and the clearing member. The Exchange is provided

notice of which clearing members have relationships with which Participants. The clearing member that guarantees the Participant's transactions on the Exchange has a financial interest in understanding the risk tolerance of the Participant. The proposal would provide the Exchange with authority to directly provide clearing members with information that may otherwise be available to such clearing members by virtue of their relationship with the respective Participants.⁴

The proposed commentary to Rule 4765 would codify a list of risk settings that are currently offered by the Exchange and would be covered by proposed Rule 4765. This list is comprehensive with respect to the risk settings that the Exchange presently offers. Certain of these risk settings are mandatory for Participants, meaning that the Exchange either imposes specific risk tolerances that are uniform for all Participants or it sets default risk tolerances, but it affords flexibility to Participants to select their own risk tolerance levels. In certain instances, the Exchange does not require Participants to utilize risk settings, but instead makes them available for use at the option of Participants. The risk settings set forth in the proposed commentary to Rule 4765 comprise the following:

- **Share Size Control**—When enabled by a Participant, this optional control will allow a Participant to limit the number of shares that the Participant may associate with an order placed on the Exchange;
- **ISO Control**—When enabled by a Participant, this optional control will prevent a Participant from entering an ISO order onto the Exchange;
- **Cancel-on-Disconnect Control**—When enabled by a Participant, this optional control will allow a Participant, when it experiences a disruption in its connection to the Exchange, to immediately cancel all pending Exchange orders except for Good-Till-Canceled orders (RASH & FIX only);
- **The BX Kill Switch**—This control is described in Rule 4764;
- **Limit Order Protection**—This control is described in Rule 4757(d);
- **Price Collar Check**—This control will automatically restrict a routed order from executing at a price that differs from the NBBO (at the time of order entry) by more than five percent or \$0.25, whichever difference is greater.

The system will proceed to route an order unless and until it crosses the greater of these two price collars, and if it does so, then the system will block further routings of the order that fall outside of the collars. For example, if the NBBO is \$99 x \$100 at the time of entry of a buy order, then the system will route the order at prices at or below \$105, but will stop doing so if the offer price rises above \$105 (five percent of the NBO);

- **Maximum Order Volume Check**—This control will automatically reject an order for routing away that exceeds a maximum volume of shares. As applied to equity orders, the default maximum order volume is set at 25,000 shares, but the Participant may request that the Exchange set a higher default based on historic volume;

- **Cumulative Order Volume Check**—This control will automatically block an attempt by a Participant using a particular MPID to route orders away to buy or sell equity securities that, cumulatively, exceed 9.5 million shares during a five second time period; and

- **Duplication Control**—This control will automatically reject an order that a Participant submits to the Exchange to the extent that it is duplicative of another order that the Participant submitted to the Exchange during the prior five seconds.

As set forth above, the proposal to authorize the Exchange to share any of the Participant's risk settings with the clearing member that clears transactions on behalf of the Participant would be limited to the risk settings specified in the proposed commentary to Rule 4765. The Exchange notes that use by a Participant of the risk settings offered by the Exchange is optional for share size, ISO, kill switch, and cancel-on disconnect controls, and is required in other instances.⁵ By using the optional risk settings, following this proposed Rule change a Participant therefore also opts-in to the Exchange sharing its risk settings with its clearing member. The Exchange notes that any Participant that does not wish to share its mandatory risk settings with its clearing member could avoid sharing such settings by becoming a clearing member.

To the extent that a clearing member might reasonably require a Participant to provide access to its risk settings as a prerequisite to continuing to clear trades on the Participant's behalf, the Exchange's proposal to share those risk settings directly reduces the

³ Rule 4701(c) defines a "Participant" as an entity that fulfills the obligations contained in Rule 4611 regarding participation in the System, and includes Equities ECNs, Equities Market Makers, and Order Entry Firms.

⁴ The Exchange notes that its proposal would cover Sponsored Participants, as set forth in Rule 4615, meaning that the proposal would authorize the Exchange to share the risk settings of Sponsored Participants with clearing members that clear trades on their behalf.

⁵ As noted above, for the Maximum Order Volume Check, the Exchange sets a default order volume but Participants have flexibility to adjust this level.

administrative burden on Participants and ensures that clearing members are receiving information that is up-to-date and conforms to the settings active in the Exchange's trading system. Further, the Exchange believes that the proposal will help such clearing members to better monitor and manage the potential risks that they assume when clearing for Participants of the Exchange.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁶ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁷ 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 transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The proposed rule change will allow the Exchange to directly provide a Participant's risk settings to the clearing member that clears trades on behalf of the Participant. A clearing member guarantees transactions executed on BX for members with whom it has entered into a clearing arrangement, and therefore bears the risk associated with those transactions. The Exchange therefore believes that it is appropriate for the clearing member to have knowledge of what risk settings the Participant may utilize within the Exchange's trading system. The proposal will permit clearing members who have a financial interest in the risk settings of Participants with whom the Participants have entered into clearing arrangements to better monitor and manage the potential risks assumed by clearing members, thereby providing clearing members with greater control and flexibility over setting their own risk tolerance and exposure and aiding clearing members in complying with the Act. To the extent a clearing member might reasonably require a Participant to provide access to its risk settings as a prerequisite to continuing to clear trades on the Participant's behalf, the Exchange's proposal to share those risk settings directly reduces the administrative burden on Participants and ensures that clearing members are receiving information that is up-to-date and conforms to the settings active in the Exchange's trading system.

Moreover, the proposal will foster cooperation and coordination with persons engaged in facilitating transactions in securities and more generally, will protect investors and the public interest, by reducing administrative burdens on both clearing members and other Participants and by allowing clearing members to better monitor their risk exposure.

The Exchange further believes that codifying the risk settings described above in proposed commentary to Rule 4765 is consistent with the Act. These settings assist Participants in managing and controlling the risks associated with their access to and activity on the Exchange, both for the benefit of Participants and investors. The Exchange's risk settings, moreover, are consistent with risk settings employed by other exchanges, such as Cboe BYX. Although the Exchange presently offers these risk settings, codifying them will provide additional transparency to Participants regarding the risk settings offered by the Exchange. It will also foster cooperation and coordination with persons engaged in facilitating transactions in securities and more generally, will protect investors and the public interest, by providing additional transparency regarding risk settings offered by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The proposed rule change is not designed to address any competitive issues and does not pose an undue burden on non-clearing members because, unlike clearing members, non-clearing members do not guarantee the execution of a Participant's transactions on the Exchange. Moreover, the proposal to share risk settings with clearing members will not burden competition among clearing members because it will apply to all clearing members equally and regardless of size. The Exchange notes that this proposal will not affect competition among Participants because the proposal provides for sharing of all of Participants' risk settings set forth in the commentary to Rule 4765. Any Participant that does not wish to share its risk settings with its clearing member could avoid sharing such settings by becoming a clearing member. Lastly, the proposal to codify the Exchange's risk settings will not burden competition among Participants because the risk settings are already available to or

required of Participants and will continue to be available or required of all Participants going forward.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act⁸ and Rule 19b-4(f)(6) thereunder.⁹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BX-2018-001 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

⁶ 15 U.S.C. 78s(b)(3)(A).

⁹ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(5).

Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2018–001. 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 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–BX–2018–001 and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁰

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018–01360 Filed 1–25–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82540; File No. SR–CBOE–2018–004]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Establish Fees for Customized Functionality and/or Connectivity on the Silexx Trading Platform

January 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on January 8, 2018, Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish fees for customized functionality and/or connectivity on the Silexx trading platform (“Silexx” or the “platform”). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to adopt fees for customized functionality and/or connectivity on Silexx.³ Silexx is a front-end, broker-neutral, multi-asset class order entry and management trading platform owned by Cboe Silexx, LLC (“Cboe Silexx” a wholly owned subsidiary of Cboe Options' parent company, Cboe Global Markets, Inc.).

Silexx is an order entry and management trading platform for listed stocks and options that support [sic] both simple and complex orders.⁴ The platform is a software application that is installed locally on a user's desktop. The platform provides users with the capability to send option orders to U.S. options exchanges and stock orders to U.S. stock exchanges (and other trading centers), and allows users to input parameters to control the size, timing and other variables of their trades. Silexx includes access to real-time options and stock market data, as well as access to certain historical data. The platform provides users with the ability to maintain an electronic audit trail and provide detailed trade reporting. In addition, Silexx offers other functionality such as access to crossing orders tickets, equity order reports and market data feeds (for specific fees).

The Exchange is now proposing an addition to the Silexx fee schedule related to customized development of new functionality and/or connectivity. Pursuant to a Silexx user's request, Cboe Silexx will develop specifications and a statement of work relating to customized functionality and/or connectivity. The statement of work will show the time and materials costs associated with building Silexx to support the user's request. This addition to the Silexx fee schedule will allow Cboe Silexx to support users with user-specific functionality and connectivity. The same reasonable hourly and materials rates will apply to all users based on then-current rates in line with industry standards, which costs (and any reasonable, standard mark-up) will be passed through to users. As such, the Exchange believes the addition

³ The Exchange initially filed the proposed fee changes on January 2, 2018 (SR–CBOE–2018–002). On January 8, 2018, the Exchange withdrew that filing and submitted this filing.

⁴ The platform also permits users to submit orders for commodity futures, commodity options and other non-security products to be sent to designated contract markets, futures commission merchants, introducing brokers or other applicable destinations of the users' choice.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

¹⁰ 17 CFR 200.30–3(a)(12).

represents an equitable allocation of reasonable fees.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the “Act”) and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁵ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁶ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act,⁷ which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

Specifically, the Exchange believes the proposed change provides for the equitable allocation of reasonable fees because the same hourly and materials rates will apply to all users. The hourly and material rates will be based on then-current rates in line with industry standards, which costs (and any reasonable, standard mark-up) will be passed through to users. Any user may elect to customize their Silexx platform. Customization is completely optional and subject to an agreement on a statement of work between the user and Cboe Silexx.

B. Self-Regulatory Organization’s Statement on Burden on Competition

Cboe Options does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Each version of Silexx and any additional customized functionality and/or connectivity will be available to all market participants. Users have discretion to determine whether to customize their version of the platform. Any market participants will continue to have the flexibility to

use any order entry and management technology they choose. The Exchange will not distinguish orders coming from a customized Silexx platform versus any other order management platform.

The proposed fees related to customized functionality and/or connectivity will not impose any burden on competition because the same rates will apply to all Silexx users. Those rates will be based on then-current rates in line with industry standards, which costs (and any reasonable, standard mark-up) will be passed through to Silexx users.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act⁸ and paragraph (f) of Rule 19b-4⁹ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CBOE-2018-004 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-CBOE-2018-004. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (<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-CBOE-2018-004 and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁰

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-01355 Filed 1-25-18; 8:45 am]

BILLING CODE 8011-01-P

⁵ 15 U.S.C. 78f(b).

⁶ 15 U.S.C. 78f(b)(5).

⁷ 15 U.S.C. 78f(b)(4).

⁸ 15 U.S.C. 78s(b)(3)(A).

⁹ 17 CFR 240.19b-4(f).

¹⁰ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82550; File No. SR–Phlx–2018–03]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Add a New Rule 3215 and Commentary Thereto To Codify PSX Participant Risk Settings in PSX and To Authorize the Exchange To Share Those Settings With the Clearing Member That Clears Transactions on Behalf of the PSX Participant

January 19, 2018.

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 January 16, 2018, Nasdaq PHLX LLC (“Phlx” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The 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 add a new Rule 3215 and commentary thereto to codify PSX Participant risk settings in PSX and to authorize the Exchange to share those settings with the clearing member that clears transactions on behalf of the PSX Participant.

The text of the proposed rule change is set forth below. Proposed new language is italicized; deleted text is in brackets.

* * * * *

Nasdaq PHLX Rules

Rules of the Exchange

* * * * *

Nasdaq PSX

* * * * *

[Rule 3215. Reserved.]

Rule 3215. Exchange Sharing of PSX Participant Risk Settings

The Exchange may share any PSX Participant risk settings in the trading system specified in the commentary below with the clearing member that clears transactions on behalf of the PSX Participant. For purposes of this Rule,

the term “PSX Participant” has the meaning set forth in Rule 3301(c).

Commentary

The Exchange offers certain risk settings applicable to a PSX Participant’s activities on the Exchange. The risk settings currently offered by the Exchange are:

(a) *Share Size Control*—When enabled by a PSX Participant, this optional control will allow a PSX Participant to limit the number of shares that the PSX Participant may associate with an order placed on the Exchange;

(b) *ISO Control*—When enabled by a PSX Participant, this optional control will prevent a PSX Participant from entering an ISO order onto the Exchange;

(c) *Cancel-on-Disconnect Control*—When enabled by a PSX Participant, this optional control will allow a PSX Participant, when it experiences a disruption in its connection to the Exchange, to immediately cancel all pending Exchange orders except for Good-Till-Canceled orders (RASH & FIX only);

(d) *The Phlx Kill Switch*—This control is described in Rule 3316;

(e) *Limit Order Protection*—This control is described in Rule 3307(f);

(f) *Price Collar Check*—This control will automatically restrict a routed order from executing at a price that differs from the NBBO (at the time of order entry) by more than five percent or \$0.25, whichever difference is greater. The system will proceed to route an order unless and until it crosses the greater of these two price collars, and if it does so, then the system will block further routings of the order that fall outside of the collars. For example, if the NBBO is \$99 × \$100 at the time of entry of a buy order, then the system will route the order at prices at or below \$105, but will stop doing so if the offer price rises above \$105 (five percent of the NBO);

(g) *Maximum Order Volume Check*—This control will automatically reject an order for routing away that exceeds a maximum volume of shares. As applied to equity orders, the default maximum order volume is set at 25,000 shares, but the PSX Participant may request that the Exchange set a higher default based on historic volume;

(h) *Cumulative Order Volume Check*—This control will automatically block an attempt by a PSX Participant using a particular MPID to route orders away to buy or sell equity securities that, cumulatively, exceed 9.5 million shares during a five second time period; and

(i) *Duplication Control*—This control will automatically reject an order that a

PSX Participant submits to the Exchange to the extent that it is duplicative of another order that the PSX Participant submitted to the Exchange during the prior five seconds.

* * * * *

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt the proposed commentary to Rule 3215, which codifies a comprehensive list of PSX Participant risk settings in the Exchange’s trading system. The Exchange also proposes to adopt new Rule 3215 to authorize the Exchange to share these risk settings with the clearing member that clears transactions on behalf of the PSX Participant. For purposes of Rule 3215, the term “PSX Participant” has the meaning set forth in Rule 3301(c).³

PSX Participants are required to be members of the Exchange. Rule 3218 states that “all transactions through the facilities of PSX shall be cleared and settled through a registered clearing agency using a continuous net settlement system.” It further provides that this requirement may be satisfied by “direct participation, use of direct clearing services, by entry into a correspondent clearing arrangement with another member organization that clears trades through such a clearing agency. . . .” Further, pursuant to Rule 3227, every clearing member acting on a PSX Participant’s behalf that constitutes a side of a system trade is responsible for honoring such trades of that PSX Participant.

All PSX Participants that are not clearing members require a clearing

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ Rule 3301(c) defines a “PSX Participant” as an entity that fulfills the obligations contained in Rule 3211 regarding participation in the System, and includes Equities ECNs, PSX Market Makers, and Order Entry Firms.

member's consent to clear transactions on their behalf in order to conduct business on the Exchange. Each PSX Participant that transacts through a clearing member on the Exchange must have an arrangement between the PSX Participant and the clearing member. The Exchange is provided notice of which clearing members have relationships with which PSX Participants. The clearing member that guarantees the PSX Participant's transactions on the Exchange has a financial interest in understanding the risk tolerance of the PSX Participant. The proposal would provide the Exchange with authority to directly provide clearing members with information that may otherwise be available to such clearing members by virtue of their relationship with the respective PSX Participants.

The proposed commentary to Rule 3215 would codify a list of risk settings that are currently offered by the Exchange and would be covered by proposed Rule 3215. This list is comprehensive with respect to the risk settings that the Exchange presently offers. Certain of these risk settings are mandatory for PSX Participants, meaning that the Exchange either imposes specific risk tolerances that are uniform for all PSX Participants or it sets default risk tolerances, but it affords flexibility to PSX Participants to select their own risk tolerance levels. In certain instances, the Exchange does not require PSX Participants to utilize risk settings, but instead makes them available for use at the option of PSX Participants. The risk settings set forth in the proposed commentary to Rule 3215 comprise the following:

- *Share Size Control*—When enabled by a PSX Participant, this optional control will allow a PSX Participant to limit the number of shares that the PSX Participant may associate with an order placed on the Exchange;

- *ISO Control*—When enabled by a PSX Participant, this optional control will prevent a PSX Participant from entering an ISO order onto the Exchange;

- *Cancel-on-Disconnect Control*—When enabled by a PSX Participant, this optional control will allow a PSX Participant, when it experiences a disruption in its connection to the Exchange, to immediately cancel all pending Exchange orders except for Good-Till-Canceled orders (RASH & FIX only);

- *The Phlx Kill Switch*—This control is described in Rule 3316;

- *Limit Order Protection*—This control is described in Rule 3307(f);

- *Price Collar Check*—This control will automatically restrict a routed order from executing at a price that differs from the NBBO (at the time of order entry) by more than five percent or \$0.25, whichever difference is greater. The system will proceed to route an order unless and until it crosses the greater of these two price collars, and if it does so, then the system will block further routings of the order that fall outside of the collars. For example, if the NBBO is \$99 x \$100 at the time of entry of a buy order, then the system will route the order at prices at or below \$105, but will stop doing so if the offer price rises above \$105 (five percent of the NBO).

- *Maximum Order Volume Check*—This control will automatically reject an order for routing away that exceeds a maximum volume of shares. As applied to equity orders, the default maximum order volume is set at 25,000 shares, but the PSX Participant may request that the Exchange set a higher default based on historic volume.

- *Cumulative Order Volume Check*—This control will automatically block an attempt by a PSX Participant using a particular MPID to route orders away to buy or sell equity securities that, cumulatively, exceed 9.5 million shares during a five second time period; and

- *Duplication Control*—This control will automatically reject an order that a PSX Participant submits to the Exchange to the extent that it is duplicative of another order that the PSX Participant submitted to the Exchange during the prior five seconds.

As set forth above, the proposal to authorize the Exchange to share any of the PSX Participant's risk settings with the clearing member that clears transactions on behalf of the PSX Participant would be limited to the risk settings specified in the proposed commentary. The Exchange notes that use by a PSX Participant of the risk settings offered by the Exchange is optional for share size, ISO, kill switch, and cancel-on disconnect controls, and is required in other instances.⁴ By using the optional risk settings, following this proposed Rule change a PSX Participant therefore also opts-in to the Exchange sharing its risk settings with its clearing member. The Exchange notes that any PSX Participant that does not wish to share its mandatory risk settings with its clearing member could avoid sharing

⁴ As noted above, for the Maximum Order Volume Check, the Exchange sets a default order volume but PSX Participants have flexibility to adjust this level.

such settings by becoming a clearing member.

To the extent that a clearing member might reasonably require a PSX Participant to provide access to its risk settings as a prerequisite to continuing to clear trades on the PSX Participant's behalf, the Exchange's proposal to share those risk settings directly reduces the administrative burden on PSX Participants and ensures that clearing members are receiving information that is up-to-date and conforms to the settings active in the Exchange's trading system. Further, the Exchange believes that the proposal will help such clearing members to better monitor and manage the potential risks that they assume when clearing for PSX Participants of the Exchange.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁵ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁶ 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 transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The proposed rule change will allow the Exchange to directly provide a PSX Participant's risk settings to the clearing member that clears trades on behalf of the PSX Participant. A clearing member guarantees transactions executed on PSX for members with whom it has entered into a clearing arrangement, and therefore bears the risk associated with those transactions. The Exchange believes that it is appropriate for the clearing member to have knowledge of what risk settings the PSX Participant may utilize within the Exchange's trading system. The proposal will permit clearing members who have a financial interest in the risk settings of PSX Participants with whom the PSX Participants have entered into clearing arrangements to better monitor and manage the potential risks assumed by clearing members, thereby providing clearing members with greater control and flexibility over setting their own risk tolerance and exposure and aiding clearing members in complying with the Act. To the extent a clearing member might reasonably require a PSX

⁵ 15 U.S.C. 78f(b).

⁶ 15 U.S.C. 78f(b)(5).

Participant to provide access to its risk settings as a prerequisite to continuing to clear trades on the PSX Participant's behalf, the Exchange's proposal to share those risk settings directly reduces the administrative burden on PSX Participants and ensures that clearing members are receiving information that is up-to-date and conforms to the settings active in the Exchange's trading system. Moreover, the proposal will foster cooperation and coordination with persons engaged in facilitating transactions in securities and more generally, will protect investors and the public interest, by reducing administrative burden on both clearing members and other PSX Participants and by allowing clearing members to better monitor their risk exposure.

The Exchange further believes that codifying the risk settings described above in the proposed commentary is consistent with the Act. These settings assist PSX Participants in managing and controlling the risks associated with their access to and activity on the Exchange, both for the benefit of PSX Participants and investors. The Exchange's risk settings, moreover, are consistent with risk settings employed by other exchanges, such as Cboe BYX. Although the Exchange presently offers these risk settings, codifying them will provide additional transparency to PSX Participants regarding the risk settings offered by the Exchange. It will also foster cooperation and coordination with persons engaged in facilitating transactions in securities and more generally, will protect investors and the public interest, by providing additional transparency regarding risk settings offered by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The proposed rule change is not designed to address any competitive issues and does not pose an undue burden on non-clearing members because, unlike clearing members, non-clearing members do not guarantee the execution of a Participant's transactions on the Exchange. Moreover, the proposal to share risk settings with clearing members will not burden competition among clearing members because it will apply to all clearing members equally and regardless of size. The Exchange notes that this proposal will not affect competition among PSX Participants because the proposal provides for sharing of all of PSX

Participants' risk settings set forth in the commentary to Rule 3215. Any PSX Participant that does not wish to share its risk settings with its clearing member could avoid sharing such settings by becoming a clearing member. Lastly, the proposal to codify the Exchange's risk settings will not burden competition among PSX Participants because the risk settings are already available to or required of PSX Participants and will continue to be available or required of all PSX Participants going forward.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act⁷ and Rule 19b-4(f)(6) thereunder.⁸

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

⁷ 15 U.S.C. 78s(b)(3)(A).

⁸ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-Phlx-2018-03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-Phlx-2018-03. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-Phlx-2018-03 and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-01365 Filed 1-25-18; 8:45 am]

BILLING CODE 8011-01-P

⁹ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82564; File No. SR–NASDAQ–2017–123]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of the Causeway International Value NextShares™ and the Causeway Global Value NextShares™ Under Nasdaq Rule 5745

January 22, 2018.

I. Introduction

On November 28, 2017, The Nasdaq Stock Market LLC (“Nasdaq” 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 list and trade common shares (“Shares”) of the Causeway International Value NextShares™ (“International Value NextShares”) and the Causeway Global Value NextShares™ (“Global Value NextShares”) (each, a “Fund,” and collectively, the “Funds”) under Nasdaq Rule 5745. The proposed rule change was published for comment in the **Federal Register** on December 15, 2017.³ On January 4, 2018, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the original filing.⁴ The Commission received no comments on the proposed rule change. This order grants approval of the proposed rule change, as modified by Amendment No. 1.

II. Exchange’s Description of the Proposed Rule Change, as Modified by Amendment No. 1

The Exchange proposes to list and trade the Shares of the Funds under Nasdaq Rule 5745, which governs the listing and trading of Exchange-Traded

Managed Fund Shares, as defined in Nasdaq Rule 5745(c)(1). Each Fund is a series of the Causeway ETMF Trust (“Trust”). The Exchange represents that the Trust is registered with the Commission as an open-end investment company and that it has filed a registration statement on Form N–1A (“Registration Statement”) with the Commission with respect to the Funds.⁵

Causeway Capital Management LLC (“Adviser”) will be the adviser to the Funds. SEI Investments Distribution Co. (“SIDCO”) will be the principal underwriter and distributor of each Fund’s Shares; SEI Investments Global Funds Services, Inc. will act as the administrator and accounting agent to each Fund; The Bank of New York Mellon will act as transfer agent and custodian to the Funds; and ICE Data Indices, LLC will calculate intraday indicative values (“IIVs”) for each Fund.

The Exchange has made the following representations and statements in describing the Funds.⁶ According to the Exchange, each Fund will be actively managed and will pursue the principal investment strategies described below.⁷

A. Principal Investment Strategies

International Value NextShares

The investment objective of the International Value NextShares is to seek long-term growth of capital and income. Under normal market conditions, the International Value NextShares will invest primarily in equity securities of companies in

developed countries outside the U.S. Normally, the International Value NextShares will invest at least 80% of its total assets in equity securities of companies in a number of foreign countries and normally will invest the majority of its total assets in equity securities of companies that pay dividends or repurchase their shares. The International Value NextShares may invest in equity securities of companies in emerging (less developed) markets. The International Value NextShares considers a country to be an emerging market if the country is included in the MSCI Emerging Markets Index. The International Value NextShares may invest in equity securities of companies of any market capitalization, and will not be required to invest a minimum amount and will not be limited to investing a maximum amount in any particular country.

Global Value NextShares

The investment objective of the Global Value NextShares is to seek long-term growth of capital and income. Under normal market conditions, the Global Value NextShares will invest primarily in equity securities of companies in developed and emerging or frontier countries outside the U.S. and of companies in the U.S. Normally, the Global Value NextShares will invest the majority of its total assets in equity securities of companies that pay dividends or repurchase their shares. Under normal circumstances, the Global Value NextShares will invest at least 40% of its total assets in a number of countries outside the U.S. The Global Value NextShares may invest in equity securities of companies in emerging (less developed) markets. The Global Value NextShares considers a country to be an emerging market if the country is included in the MSCI Emerging Markets Index. The Global Value NextShares may also invest in equity securities of companies in frontier markets. The Global Value NextShares considers a country to be a frontier market if the country is classified by MSCI, based on a country’s economic development, size, liquidity and market accessibility, as a frontier market. The Global Value NextShares may invest in equity securities of companies of any market capitalization, and will not be required to invest a minimum amount and will not be limited to investing a maximum amount in any particular country.

B. Portfolio Disclosure and Composition File

Consistent with the disclosure requirements that apply to traditional open-end investment companies, a

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 82290 (December 11, 2017), 82 FR 59687.

⁴ In Amendment No. 1, the Exchange: (a) Clarified the investments of the Funds; (b) stated that it will obtain a representation from the issuer of the Shares that the Funds’ net asset value (“NAV”) will be made available to all market participants at the same time; and (c) made other technical, non-substantive changes in the proposed rule change. Amendment No. 1 is available at: <https://www.sec.gov/comments/sr-nasdaq-2017-123/nasdaq2017123-2872828-161765.pdf>. Because Amendment No. 1 does not materially alter the substance of the proposed rule change or raise unique or novel regulatory issues, Amendment No. 1 is not subject to notice and comment.

⁵ See initial Registration Statement on Form N–1A for Causeway ETMF Trust dated September 20, 2017 (File Nos. 333–220536 and 811–23294). According to the Exchange, the Commission has issued an order granting the Trust and certain affiliates exemptive relief under the Investment Company Act of 1940 (“1940 Act”). See Investment Company Act Release No. 32485 (February 22, 2017) (File No. 812–14729). In compliance with Nasdaq Rule 5745(b)(5), which applies to Shares based on an international or global portfolio, the Trust’s application for exemptive relief under the 1940 Act states that the Trust will comply with the federal securities laws in accepting securities for deposits and satisfying redemptions with securities, including that the securities accepted for deposits and the securities used to satisfy redemption requests are sold in transactions that would be exempt from registration under the Securities Act of 1933, as amended.

⁶ The Commission notes that additional information regarding the Trust, the Funds, and the Shares, including investment strategies, risks, creation and redemption procedures, calculation of NAV, fees, distributions, and taxes, among other things, can be found in Amendment No. 1 and the Registration Statement, as applicable. See *supra* notes 4 and 5, respectively.

⁷ According to the Exchange, additional information regarding the Funds will be available on a free public website for the Funds (www.causewayfunds.com, which may contain links for certain information to www.nextshares.com) and in the Registration Statement for the Funds.

complete list of current portfolio positions for each Fund will be made available at least once each calendar quarter, with a reporting lag of not more than 60 days. A Fund may provide more frequent disclosures of portfolio positions at its discretion.

As defined in Nasdaq Rule 5745(c)(3), the Composition File is the specified portfolio of securities and/or cash that a Fund will accept as a deposit in issuing a creation unit of Shares, and the specified portfolio of securities and/or cash that a Fund will deliver in a redemption of a creation unit of Shares. The Composition File will be disseminated through the National Securities Clearing Corporation once each business day before the open of trading in Shares on such day and also will be made available to the public each day on a free public website.⁸ Because each Fund seeks to preserve the confidentiality of its current portfolio trading program, a Fund's Composition File generally will not be a pro rata reflection of the Fund's investment positions. Each security included in the Composition File will be a current holding of the relevant Fund, but the Composition File generally will not include all of the securities in that Fund's portfolio or match the weightings of the included securities in the portfolio. Securities that the Adviser is in the process of acquiring for a Fund generally will not be represented in the Fund's Composition File until the purchase has been completed. Similarly, securities that are held in a Fund's portfolio but are in the process of being sold may not be removed from its Composition File until the sale is substantially completed. To the extent that a Fund creates or redeems Shares in kind, it will use cash amounts to supplement the in-kind transactions to the extent necessary to ensure that creation units are purchased and redeemed at NAV. The Composition File also may consist entirely of cash, in which case it will not include any of the securities in a Fund's portfolio.

C. IIV

An estimated value of an individual Share, defined in Nasdaq Rule 5745(c)(2) as the IIV, will be calculated and disseminated at intervals of not more than 15 minutes throughout the Regular Market Session⁹ when Shares

trade on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the IIV for each Fund will be calculated on an intraday basis and provided to Nasdaq for dissemination via the Nasdaq Global Index Service. The IIV for each Fund will be based on current information regarding the value of the securities and other assets held by a Fund.¹⁰ The purpose of the IIV for each Fund is to enable investors to estimate the next-determined NAV so they can determine the number of Shares to buy or sell if they want to transact in an approximate dollar amount.¹¹

D. NAV-Based Trading

Because Shares will be listed and traded on the Exchange, Shares will be available for purchase and sale on an intraday basis. Shares will be purchased and sold in the secondary market at prices directly linked to a Fund's next-determined NAV using a trading protocol called "NAV-Based Trading." All bids, offers, and execution prices of Shares will be expressed as a premium/discount (which may be zero) to a Fund's next-determined NAV (*e.g.*, NAV – \$0.01, NAV + \$0.01).¹² A Fund's NAV will be determined daily (on each day the New York Stock Exchange is open for trading), as of 4:00 p.m. E.T. Trade executions will be binding at the time orders are matched on Nasdaq's facilities, with the transaction prices contingent upon the determination of NAV. The Exchange represents that all

Session from 4:00 p.m. or 4:15 p.m. to 8:00 p.m. E.T.).

¹⁰ The IIVs for each Fund disseminated throughout each trading day would be based on the same portfolio as used to calculate that day's NAV. A Fund will reflect purchases and sales of portfolio positions in its NAV the next business day after trades are executed.

¹¹ In NAV-Based Trading (as referenced herein), prices of executed trades are not determined until the reference NAV is calculated, so buyers and sellers of Shares during the trading day will not know the final value of their purchases and sales until the end of the trading day. The Exchange represents that the Registration Statement, the Funds' free public website, and any advertising or marketing materials will include prominent disclosure of this fact. The Exchange states that although the IIV for a Fund may provide useful estimates of the value of intraday trades, it cannot be used to calculate with precision the dollar value of the Shares to be bought or sold.

¹² According to the Exchange, the premium or discount to NAV at which Share prices are quoted and transactions are executed will vary depending on market factors, including the balance of supply and demand for Shares among investors, transaction fees, and other costs in connection with creating and redeeming creation units of Shares, the cost and availability of borrowing Shares, competition among market makers, the Share inventory positions and inventory strategies of market makers, the profitability requirements and business objectives of market makers, and the volume of Share trading.

Shares listed on the Exchange will have a unique identifier associated with their ticker symbols, which will indicate that the Shares are traded using NAV-Based Trading.

According to the Exchange, member firms will utilize certain existing order types and interfaces to transmit Share bids and offers to Nasdaq, which will process Share trades like trades in shares of other listed securities.¹³ In the systems used to transmit and process transactions in Shares, a Fund's next-determined NAV will be represented by a proxy price (*e.g.*, 100.00) and a premium/discount of a stated amount to the next-determined NAV will be represented by the same increment/decrement from the proxy price used to denote NAV (*e.g.*, NAV – \$0.01 would be represented as 99.99; NAV + \$0.01 as 100.01).

To avoid potential investor confusion, the Exchange represents that it will work with member firms and providers of market data services to seek to ensure that representations of intraday bids, offers, and execution prices of Shares that are made available to the investing public follow the "NAV – \$0.01/NAV + \$0.01" (or similar) display format. Nasdaq makes available to member firms and market data services certain proprietary data feeds that are designed to supplement the market information disseminated through the consolidated tape ("Consolidated Tape"). Specifically, the Exchange will use the Nasdaq Basic and Nasdaq Last Sale data feeds to disseminate intraday price and quote data for Shares in real time in the "NAV – \$0.01/NAV + \$0.01" (or similar) display format. Member firms may use the Nasdaq Basic and Nasdaq Last Sale data feeds to source intraday Share prices for presentation to the investing public in the "NAV – \$0.01/NAV + \$0.01" (or similar) display format.

Alternatively, member firms may source intraday Share prices in proxy price format from the Consolidated Tape and other Nasdaq data feeds (*e.g.*, Nasdaq TotalView and Nasdaq Level 2) and use a simple algorithm to convert prices into the "NAV – \$0.01/NAV + \$0.01" (or similar) display format. Prior to the commencement of trading in a Fund, the Exchange will inform its members in an Information Circular of the identities of the specific Nasdaq data

⁸ The Exchange represents that the free public website containing the Composition File will be www.nextshares.com.

⁹ See Nasdaq Rule 4120(b)(4) (describing the three trading sessions on the Exchange: (1) Pre-Market Session from 4:00 a.m. to 9:30 a.m. Eastern Time ("E.T."); (2) Regular Market Session from 9:30 a.m. to 4:00 p.m. or 4:15 p.m. E.T.; and (3) Post-Market

¹³ According to the Exchange, all orders to buy or sell Shares that are not executed on the day the order is submitted will be automatically cancelled as of the close of trading on that day. Prior to the commencement of trading in a Fund, the Exchange will inform its members in an Information Circular of the effect of this characteristic on existing order types.

feeds from which intraday Share prices in proxy price format may be obtained.

III. Discussion and Commission Findings

After careful review, the Commission finds that the Exchange's proposal to list and trade the Shares is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.¹⁴ 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,¹⁵ 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 foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Shares will conform to the initial and continued listing criteria applicable to Exchange-Traded Managed Fund Shares set forth in Nasdaq Rule 5745. A minimum of 50,000 Shares for each Fund and no less than two creation units of each Fund will be outstanding at the commencement of trading on the Exchange.

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Every order to trade Shares of a Fund is subject to the proxy price protection threshold of plus/minus \$1.00, which determines the lower and upper thresholds for the life of the order and provides that the order will be cancelled at any point if it exceeds \$101.00 or falls below \$99.00.¹⁶ With certain exceptions, each order also must contain the applicable order attributes, including routing instructions and time-in-force information, as described in Nasdaq Rule 4703.¹⁷

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by both Nasdaq and the Financial Industry Regulatory Authority, Inc. ("FINRA") on behalf of the Exchange, which are designed to detect violations of Exchange rules and

applicable federal securities laws.¹⁸ The Exchange represents that these surveillance procedures are adequate to properly monitor trading of Shares on the Exchange and to deter and detect violations of Exchange rules and applicable federal securities laws. FINRA, on behalf of the Exchange, will communicate as needed with, and may obtain information from, other markets and other entities that are members of the Intermarket Surveillance Group ("ISG") regarding trading in the Shares, and in exchange-traded securities and instruments held by a Fund (to the extent those exchange-traded securities and instruments are known through the publication of the Composition File and periodic public disclosures of a Fund's portfolio holdings). In addition, the Exchange may obtain information regarding trading in the Shares, and in exchange-traded securities and instruments held by a Fund (to the extent those exchange-traded securities and instruments are known through the publication of the Composition File and periodic public disclosures of a Fund's portfolio holdings), from markets and other entities that are members of ISG, or with which the Exchange has in place a comprehensive surveillance sharing agreement.

Prior to the commencement of trading in a Fund, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares of each Fund. Specifically, the Information Circular will discuss the following: (a) The procedures for purchases and redemptions of Shares in creation units (and that Shares are not individually redeemable); (b) Nasdaq Rule 2111A, which imposes suitability obligations on Nasdaq members with respect to recommending transactions in the Shares to customers; (c) how information regarding the IIV and Composition File is disseminated; (d) the requirement that members deliver a prospectus to investors purchasing Shares prior to or concurrently with the confirmation of a transaction; and (e) information regarding NAV-Based Trading protocols.

The Information Circular also will identify the specific Nasdaq data feeds from which intraday Share prices in proxy price format may be obtained. As noted above, all orders to buy or sell Shares that are not executed on the day the order is submitted will be automatically cancelled as of the close

of trading on that day, and the Information Circular will discuss the effect of this characteristic on existing order types. In addition, Nasdaq intends to provide its members with a detailed explanation of NAV-Based Trading through a Trader Alert issued prior to the commencement of trading in Shares on the Exchange.

The Exchange represents that the Adviser is not a registered broker-dealer and is not affiliated with a broker-dealer, and that personnel who make decisions on a Fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the portfolio.¹⁹ In the event that (a) the Adviser registers as a broker-dealer or becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser to a Fund is a registered broker-dealer or is affiliated with a broker-dealer, such adviser or sub-adviser will implement and will maintain a fire wall with respect to its relevant personnel and/or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition of, and/or changes to, a Fund's portfolio and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the portfolio. The Reporting Authority²⁰ will implement and maintain, or will ensure that the Composition File will be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding a Fund's portfolio positions and changes in the positions. In addition, the Exchange represents that it has a general policy prohibiting the distribution of material non-public information by its employees.

The Commission finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Act,²¹ which sets forth Congress's finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities. Information regarding NAV-Based Trading prices, best bids and offers for Shares, and volume of Shares traded will be continuously available on a real-time

¹⁴ 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).

¹⁵ 15 U.S.C. 78f(b)(5).

¹⁶ See Nasdaq Rule 5745(g).

¹⁷ See Nasdaq Rule 5745(b)(6).

¹⁸ The Exchange states that FINRA provides surveillance of trading on the Exchange pursuant to a regulatory services agreement and that the Exchange is responsible for FINRA's performance under this regulatory services agreement.

¹⁹ The Exchange also represents that an investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940.

²⁰ See Nasdaq Rule 5745(c)(4).

²¹ 15 U.S.C. 78k-1(a)(1)(C)(iii).

basis throughout each trading day on brokers' computer screens and other electronic services. All bids and offers for Shares and all Share trade executions will be reported intraday in real time by the Exchange to the Consolidated Tape²² and separately disseminated to member firms and market data services through Exchange data feeds.

The Commission notes that once a Fund's daily NAV has been calculated and disseminated, Nasdaq will price each Share trade entered into during the day at the relevant Fund's NAV plus/minus the trade's executed premium/discount. Using the final trade price, each executed Share trade will then be disseminated to member firms and market data services via a File Transfer Protocol ("FTP") file²³ that will be created for exchange-traded managed funds and will be confirmed to the member firms participating in the trade to supplement the previously provided information with final pricing.

The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily (on each day the New York Stock Exchange is open for trading) and that the NAV will be made available to all market participants at the same time and provided to Nasdaq via the Mutual Fund Quotation Service ("MFQS") by the fund accounting agent. As soon as the NAV is entered into MFQS, Nasdaq will disseminate the NAV to market participants and market data vendors via the Mutual Fund Dissemination Service so that all firms will receive the NAV per Share at the same time.

The Exchange further represents that it may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. The Exchange will halt trading in the Shares under the conditions specified in Nasdaq Rules 4120 and 5745(d)(2)(D). Additionally, Nasdaq may cease trading the Shares if other unusual conditions or circumstances exist that, in the opinion of Nasdaq, make further

dealings on Nasdaq detrimental to the maintenance of a fair and orderly market. To manage the risk of a non-regulatory Share trading halt, Nasdaq has in place back-up processes and procedures to ensure orderly trading.

Prior to the commencement of market trading in the Shares, each Fund will be required to establish and maintain a free public website through which its current prospectus may be downloaded.²⁴ The free public website will include directly or through a link additional information concerning the Funds updated on a daily basis, including the prior business day's NAV, and the following trading information for that business day expressed as premiums/discounts to NAV: (a) Intraday high, low, average, and closing prices of Shares in Exchange trading; (b) the midpoint of the highest bid and lowest offer prices as of the close of Exchange trading, expressed as a premium/discount to NAV ("Closing Bid/Ask Midpoint"); and (c) the spread between highest bid and lowest offer prices as of the close of Exchange trading ("Closing Bid/Ask Spread").²⁵ The free public website will also contain charts showing the frequency distribution and range of values of trading prices, Closing Bid/Ask Midpoints, and Closing Bid/Ask Spreads over time.

The Exchange represents that all statements and representations made in the filing regarding (a) the description of the portfolios or reference assets, (b) limitations on portfolio holdings or reference assets, (c) dissemination and availability of the reference asset or intraday indicative values, or (d) the applicability of Exchange listing rules shall constitute continued listing requirements for listing the Shares on the Exchange. The issuer has represented to the Exchange that it will advise the Exchange of any failure by either Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements.²⁶ If a

Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under the Nasdaq 5800 Series.

This approval order is based on all of the Exchange's representations, including those set forth above and in Amendment No. 1.²⁷ In particular, the Commission notes that, although the Shares will be available for purchase and sale on an intraday basis, the Shares will be purchased and sold at prices directly linked to the relevant Fund's next-determined NAV. Further, the Commission notes that the Funds and the Shares must comply with the requirements of Nasdaq Rule 5745 and the conditions set forth in this proposed rule change to be listed and traded on the Exchange on an initial and continuing basis.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5)²⁸ and Section 11A(a)(1)(C)(iii)²⁹ of the Act, and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,³⁰ that the proposed rule change (SR-NASDAQ-2017-123), as modified by Amendment No. 1, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³¹

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-01418 Filed 1-25-18; 8:45 am]

BILLING CODE 8011-01-P

²² Due to systems limitations, the Consolidated Tape will report intraday execution prices and quotes for Shares using a proxy price format. Nasdaq has represented that it will separately report real-time execution prices and quotes to member firms and providers of market data services in the "NAV-\$0.01/NAV+\$0.01" (or similar) display format, and will otherwise seek to ensure that representations of intraday bids, offers, and execution prices for Shares that are made available to the investing public follow the same display format.

²³ According to Nasdaq, FTP is a standard network protocol used to transfer computer files on the internet. Nasdaq will arrange for the daily dissemination of an FTP file with executed Share trades to member firms and market data services.

²⁴ The Exchange represents that the free public website containing this information will be www.causewayfunds.com.

²⁵ The Exchange represents that the free public website containing a Fund's NAV will be www.causewayfunds.com and all other information listed will be made available on www.nextshares.com, which can be accessed directly and via a link on www.causewayfunds.com.

²⁶ The Commission notes that certain proposals for the listing and trading of exchange-traded products include a representation that the exchange will "surveil" for compliance with the continued listing requirements. *See, e.g.*, Securities Exchange Act Release No. 77499 (April 1, 2016), 81 FR 20428,

20432 (April 7, 2016) (SR-BATS-2016-04). In the context of this representation, it is the Commission's view that "monitor" and "surveil" both mean ongoing oversight of a fund's compliance with the continued listing requirements. Therefore, the Commission does not view "monitor" as a more or less stringent obligation than "surveil" with respect to the continued listing requirements.

²⁷ *See supra* note 4.

²⁸ 15 U.S.C. 78f(b)(5).

²⁹ 15 U.S.C. 78k-1(a)(1)(C)(iii).

³⁰ 15 U.S.C. 78s(b)(2).

³¹ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82549; File No. SR–NYSEArca–2018–04]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To Adopt a New NYSE Arca Rule 8.900–E and To List and Trade Shares of the Royce Pennsylvania ETF; Royce Premier ETF; and Royce Total Return ETF Under Proposed NYSE Arca Equities Rule 8.900–E

January 19, 2018.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the “Act”)² and Rule 19b–4 thereunder,³ notice is hereby given that, on January 8, 2018, NYSE Arca, Inc. (the “Exchange” or “NYSE Arca”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt a new NYSE Arca Rule 8.900–E to permit it to list and trade Managed Portfolio Shares, which are shares of actively managed exchange-traded funds (“ETFs”) for which the portfolio is disclosed in accordance with standard mutual fund disclosure rules. In addition, the Exchange proposes to list and trade shares of the following under proposed NYSE Arca Rule 8.900–E: Royce Pennsylvania ETF; Royce Premier ETF; and Royce Total Return ETF. The proposed change is available on the Exchange’s website at www.nyse.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 self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at

the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to add new NYSE Arca Rule 8.900–E for the purpose of permitting the listing and trading, or trading pursuant to unlisted trading privileges (“UTP”), of Managed Portfolio Shares, which are securities issued by an actively managed open-end investment management company.⁴

In addition to the above-mentioned proposed rule changes, the Exchange proposes to list and trade shares (“Shares”) of the following under proposed NYSE Arca Rule 8.900–E: Royce Pennsylvania ETF; Royce Premier ETF; and Royce Total Return ETF (each, a “Fund” and, collectively, the “Funds”).

Proposed Listing Rules

Proposed Rule 8.900–E (a) provides that the Exchange will consider for trading, whether by listing or pursuant to UTP, Managed Portfolio Shares that meet the criteria of Rule 8.900–E.

Proposed Rule 8.900–E (b) provides that Rule 8.900–E is applicable only to Managed Portfolio Shares and that, except to the extent inconsistent with Rule 8.900–E, or unless the context otherwise requires, the rules and procedures of the Exchange’s Board of Directors shall be applicable to the trading on the Exchange of such securities. Proposed Rule 8.900–E (b) provides further that Managed Portfolio Shares are included within the definition of “security” or “securities” as such terms are used in the Rules of the Exchange.

Proposed Definitions

Proposed Rule 8.900–E(c)(1) defines the term “Managed Portfolio Share” as a security that (a) represents an interest in a registered investment company (“Investment Company”) organized as an open-end management investment company or similar entity, that invests in a portfolio of securities selected by the Investment Company’s investment

adviser consistent with the Investment Company’s investment objectives and policies; (b) is issued in a specified aggregate minimum number of shares equal to a Creation Unit, or multiples thereof, in return for a designated portfolio of securities (and/or an amount of cash) with a value equal to the next determined net asset value; and (c) when aggregated in the same specified aggregate number of shares equal to a Redemption Unit, or multiples thereof, may be redeemed at the request of an Authorized Participant (as defined in the Investment Company’s Form N–1A filed with the Commission), which AP Participant will be paid through a confidential account established for its benefit a portfolio of securities and/or cash with a value equal to the next determined net asset value (“NAV”).

Proposed Rule 8.900–E(c)(2) defines the term “Verified Intraday Indicative Value” (“VIIV”) as the estimated indicative value of a Managed Portfolio Share based on all of the holdings of a series of Managed Portfolio Shares as of the close of business on the prior business day and, for corporate actions, based on the applicable holdings as of the opening of business on the current business day, priced and disseminated in one second intervals during the Core Trading Session. The VIIV is monitored by an Investment Company’s pricing verification agent responsible for processing Consolidated Tape best bid and offer quotation information into more than one “Calculation Engines,” each of which then calculates a separate intraday indicative value for comparison by the pricing verification agent based on the mid-point of the highest bid and lowest offer for the portfolio constituents of a series of Managed Portfolio Shares. A single VIIV will be disseminated publicly during the Core Trading Session for each series of Managed Portfolio Shares; and the pricing verification agent will continuously compare the publicly-disseminated VIIV against one or more non-public alternative intra-day indicative values to which the pricing verification agent has access.⁵

Proposed Rule 8.900–E(c)(3) defines the term “Creation Unit” as a specified minimum number of Managed Portfolio Shares issued by an Investment Company at the request of an Authorized Participant in return for a designated portfolio of securities (and/or an amount of cash) specified each day consistent with the Investment

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

⁴ A Managed Portfolio Share is a security that represents an interest in an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (“1940 Act”) organized as an open-end investment management company or similar entity that invests in a portfolio of securities selected by its investment adviser consistent with its investment objectives and policies.

⁵ Each Calculation Engine is a computer that receives a file from a real-time quote feed, calculates a price for the securities in the portfolio, and aggregates the weights of the securities in the portfolio to produce an intra-day indicative value.

Company's investment objectives and policies.

Proposed Rule 8.900–E(c)(4) defines the term “Redemption Unit” as a specified minimum number of Managed Portfolio Shares that may be redeemed to an Investment Company at the request of an Authorized Participant in return for a portfolio of securities and/or cash.

Proposed Rule 8.900–E(c)(5) defines the term “Reporting Authority” in respect of a particular series of Managed Portfolio Shares as the Exchange, the exchange that lists a particular series of Managed Portfolio Shares (if the Exchange is trading such series pursuant to unlisted trading privileges), an institution, or a reporting service designated by the issuer of a series of Managed Portfolio Shares as the official source for calculating and reporting information relating to such series, including, the net asset value, or other information (with the exception of the VIIV) relating to the issuance, redemption or trading of Managed Portfolio Shares. A series of Managed Portfolio Shares may have more than one Reporting Authority, each having different functions.

Proposed Rule 8.900–E(c)(6) defines the term “normal market conditions” as including, but not limited to, the absence of trading halts in the applicable financial markets generally; operational issues (e.g., systems failure) causing dissemination of inaccurate market information; or force majeure type events such as natural or manmade disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

Proposed Rule 8.900–E (d) sets forth initial and continued listing criteria applicable to Managed Portfolio Shares. Proposed Rule 8.900–E(d)(1)(A) provides that, for each series of Managed Portfolio Shares, the Exchange will establish a minimum number of Managed Portfolio Shares required to be outstanding at the time of commencement of trading on the Exchange. In addition, proposed Rule 8.900–E(d)(1)(B) provides that the Exchange will obtain a representation from the issuer of each series of Managed Portfolio Shares that the NAV per share for the series will be calculated daily and that the NAV will be made available to all market participants at the same time.⁶ Proposed

Rule 8.900–E(d)(1)(C) provides that all Managed Portfolio Shares shall have a stated investment objective, which shall be adhered to under normal market conditions.

Proposed Rule 8.900–E(d)(2) provides that each series of Managed Portfolio Shares will be listed and traded subject to application of the following continued listing criteria:

- Proposed Rule 8.900–E(d)(2)(A) provides that the VIIV for Managed Portfolio Shares will be widely disseminated by the Reporting Authority and/or by one or more major market data vendors every second during the Exchange's Core Trading Session (as defined in NYSE Arca Rule 7.34–E) and will be disseminated to all market participants at the same time.
- Proposed Rule 8.900–E(d)(2)(B) provides that the Corporation will maintain surveillance procedures for securities listed under this rule and will consider the suspension of trading in, and will commence delisting proceedings under Rule 5.5–E(m) of, a series of Managed Portfolio Shares under any of the following circumstances:

(i) If, following the initial twelve-month period after commencement of trading on the Exchange of a series of Managed Portfolio Shares, there are fewer than 50 beneficial holders of the series of Managed Portfolio Shares;

(ii) if the value of the Verified Intraday Indicative Value is no longer calculated or available to all market participants at the same time;

(iii) if the Investment Company issuing the Managed Portfolio Shares has failed to file any filings required by the Securities and Exchange Commission or if the Exchange is aware that the Investment Company is not in compliance with the conditions of any exemptive order or no-action relief granted by the Securities and Exchange Commission to the Investment Company with respect to the series of Managed Portfolio Shares;

(iv) if any of the continued listing requirements set forth in Rule 8.900–E are not continuously maintained;

(v) if the Exchange submits a rule filing pursuant to Section 19(b) of the Securities Exchange Act of 1934 to permit the listing and trading of a series of Managed Portfolio Shares and any of the statements or representations regarding (a) the description of the portfolio, (b) limitations on portfolio holdings, or (c) the applicability of

Exchange listing rules specified in such rule filing are not continuously maintained; or

(vi) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.

Proposed Rule 8.900–E(d)(2)(C) provides that, upon notification to the Exchange by the Investment Company or its agent that (i) the intraday indicative values calculated by more than one Calculation Engines to be compared by the Investment Company's pricing verification agent differ by more than 25 basis points for 60 seconds in connection with pricing of the Verified Intraday Indicative Value, or (ii) that the Verified Intraday Indicative Value of a series of Managed Portfolio Shares is not being calculated or disseminated in one-second intervals, as required, the Exchange shall halt trading in the Managed Portfolio Shares as soon as practicable. Such halt in trading shall continue until the Investment Company or its agent notifies the Exchange that the intraday indicative values calculated by the Calculation Engines no longer differ by more than 25 basis points for 60 seconds or that the Verified Intraday Indicative Value is being calculated and disseminated as required. The Investment Company or its agent shall be responsible for monitoring that the Verified Intraday Indicative Value is being priced and disseminated as required and whether the intraday indicative values to be calculated by more than one Calculation Engines differ by more than 25 basis points for 60 seconds. In addition, if the Exchange becomes aware that the net asset value with respect to a series of Managed Portfolio Shares is not disseminated to all market participants at the same time, it will halt trading in such series until such time as the net asset value is available to all market participants.

Proposed Rule 8.900–E(d)(2)(D) provides that, upon termination of an Investment Company, the Exchange requires that Managed Portfolio Shares issued in connection with such entity be removed from Exchange listing.

Proposed Rule 8.900–E(d)(2)(E) provides that voting rights shall be as set forth in the applicable Investment Company prospectus.

Proposed Rule 8.900–E(e), which relates to limitation of Exchange liability, provides that Neither [sic] the Exchange, the Reporting Authority, nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions, or delays in calculating or disseminating any current portfolio value; the current value of the portfolio

⁶NYSE Arca Rule 7.18–E(d)(2) (“Halts of Derivative Securities Products Listed on the NYSE Arca Marketplace”) provides that, with respect to Derivative Securities Products listed on the NYSE Arca Marketplace for which a net asset value is disseminated, if the Exchange becomes aware that the net asset value is not being disseminated to all

market participants at the same time, it will halt trading in the affected Derivative Securities Product on the NYSE Arca Marketplace until such time as the net asset value is available to all market participants.

of securities required to be deposited to the open-end management investment company in connection with issuance of Managed Portfolio Shares; the Verified Intraday Indicative Value; the amount of any dividend equivalent payment or cash distribution to holders of Managed Portfolio Shares; net asset value; or other information relating to the purchase, redemption, or trading of Managed Portfolio Shares, resulting from any negligent act or omission by the Exchange, the Reporting Authority or any agent of the Exchange, or any act, condition, or cause beyond the reasonable control of the Exchange, its agent, or the Reporting Authority, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission, or delay in the reports of transactions in one or more underlying securities.

Proposed Commentary .01 to NYSE Arca Rule 8.900-E provides that The [sic] Exchange will file separate proposals under Section 19(b) of the Securities Exchange Act of 1934 before the listing and trading of Managed Portfolio Shares. All statements or representations contained in such rule filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings, or (c) the applicability of Exchange listing rules specified in such rule filing will constitute continued listing requirements. An issuer of such securities must notify the Exchange of any failure to comply with such continued listing requirements.

Proposed Commentary .02 to NYSE Arca Rule 8.900-E provides that transactions in Managed Portfolio Shares will occur only during the Core Trading Session as specified in NYSE Arca Rule 7.34-E(a)(2).

Proposed Commentary .03 to NYSE Arca Rule 8.900-E provides that the Exchange will implement written surveillance procedures for Managed Portfolio Shares.

Proposed Commentary .04 to NYSE Arca Rule 8.900-E provides that Authorized Participants (as defined in the Investment Company's Form N-1A filed with the Commission) creating or redeeming Managed Portfolio Shares will sign an agreement with an agent ("AP Representative") to establish a confidential account for the benefit of such Authorized Participant that will deliver or receive all consideration from the issuer in a creation or redemption. An AP Representative may not disclose the consideration delivered or received in a creation or redemption.

Proposed Commentary .05(a) to NYSE Arca Rule 8.900-E provides that, if the investment adviser to the Investment Company issuing Managed Portfolio Shares is registered as a broker-dealer or is affiliated with a broker-dealer such investment adviser will erect and maintain a "fire wall" between the investment adviser and personnel of the broker-dealer or broker-dealer affiliate, as applicable, with respect to access to information concerning the composition and/or changes to such Investment Company portfolio. Personnel who make decisions on the Investment Company's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable Investment Company portfolio.

Proposed Commentary .05(b) to NYSE Arca Rule 8.900-E provides that, if an AP Representative, the custodian or pricing verification agent for an Investment Company issuing Managed Portfolio Shares, or any other entity that has access to information concerning the composition and/or changes to such Investment Company's portfolio, is registered as a broker-dealer or affiliated with a broker-dealer, such AP Representative, custodian, pricing verification agent or other entity will erect and maintain a "fire wall" between such AP Representative, custodian, pricing verification agent, or other entity and personnel of the broker-dealer or broker-dealer affiliate, as applicable, with respect to access to information concerning the composition and/or changes to such Investment Company portfolio. Personnel who make decisions on the Investment Company's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable Investment Company portfolio.⁷

Key Features of Managed Portfolio Shares

While funds issuing Managed Portfolio Shares will be actively-managed and, to that extent, will be similar to Managed Fund Shares, Managed Portfolio Shares differ from Managed Fund Shares in the following important respects. First, in contrast to Managed Fund Shares, which are actively-managed funds listed and traded under NYSE Arca Rule 8.600-E⁸

and for which a "Disclosed Portfolio" is required to be disseminated at least once daily,⁹ the portfolio for an issue of Managed Portfolio Shares will be disclosed quarterly in accordance with normal disclosure requirements otherwise applicable to open-end investment companies registered under the 1940 Act.¹⁰ The composition of the portfolio of an issue of Managed Portfolio Shares would not be available at commencement of Exchange listing and trading. Second, in connection with the creation and redemption of shares in "Creation Unit" or "Redemption Unit" size (as described below), the delivery of any portfolio securities in kind will be effected through a "Confidential Account" (as described below) for the benefit of the redeeming AP (as described below in "Creation and Redemption of Shares") without disclosing the identity of such securities to the Authorized Participant ("AP").

For each series of Managed Portfolio Shares, an estimated value—the VIIV—that reflects an estimated intraday value of a fund's portfolio will be disseminated. With respect to the Funds, the VIIV will be based upon all of a Fund's holdings as of the close of

issues of Managed Fund Shares under Rule 8.600. See, e.g., Securities Exchange Act Release Nos. 57801 (May 8, 2008), 73 FR 27878 (May 14, 2008) (SR-NYSEArca-2008-31) (order approving Exchange listing and trading of twelve actively-managed funds of the WisdomTree Trust); 60460 (August 7, 2009), 74 FR 41468 (August 17, 2009) (SR-NYSEArca-2009-55) (order approving listing of Dent Tactical ETF); 63076 (October 12, 2010), 75 FR 63874 (October 18, 2010) (SR-NYSEArca-2010-79) (order approving Exchange listing and trading of Cambria Global Tactical ETF); 63802 (January 31, 2011), 76 FR 6503 (February 4, 2011) (SR-NYSEArca-2010-118) (order approving Exchange listing and trading of the SIM Dynamic Allocation Diversified Income ETF and SIM Dynamic Allocation Growth Income ETF). More recently, the Commission approved a proposed rule change to adopt generic listing standards for Managed Fund Shares. Securities Exchange Act Release No. 78397 (July 22, 2016), 81 FR 49320 (July 27, 2016) (SR-NYSEArca-2015-110) (amending NYSE Arca Equities Rule 8.600 to adopt generic listing standards for Managed Fund Shares).

⁹ NYSE Arca Rule 8.600-E(c)(2) defines the term "Disclosed Portfolio" as the identities and quantities of the securities and other assets held by the Investment Company that will form the basis for the Investment Company's calculation of net asset value at the end of the business day. NYSE Arca Rule 8.600-E(d)(2)(B)(i) requires that the Disclosed Portfolio will be disseminated at least once daily and will be made available to all market participants at the same time.

¹⁰ A mutual fund is required to file with the Commission its complete portfolio schedules for the second and fourth fiscal quarters on Form N-CSR under the 1940 Act, and is required to file its complete portfolio schedules for the first and third fiscal quarters on Form N-Q under the 1940 Act, within 60 days of the end of the quarter. Form N-Q requires funds to file the same schedules of investments that are required in annual and semi-annual reports to shareholders. These forms are available to the public on the Commission's website at www.sec.gov.

⁷ The Exchange will propose applicable NYSE Arca listing fees for Managed Portfolio Shares in the NYSE Arca Equities Schedule of Fees and Charges via a separate proposed rule change.

⁸ The Commission has previously approved listing and trading on the Exchange of a number of

the prior business day and, for corporate actions, based on the applicable holdings as of the opening of business on the current business day, and will be widely disseminated by one or more major market data vendors every second during the Exchange's Core Trading Session (normally, 9:30 a.m. to 4:00 p.m., Eastern Time ("E.T.")). The dissemination of the VIIV will allow investors to determine the estimated intra-day value of the underlying portfolio of a series of Managed Portfolio Shares and will provide a close estimate of that value throughout the trading day.

The Exchange, after consulting with various Lead Market Makers that trade exchange-traded funds ("ETFs") on the Exchange, believes that market makers will be able to make efficient and liquid markets priced near the VIIV as long as a VIIV is disseminated every second, and market makers employ market making techniques such as "statistical arbitrage," including correlation hedging, beta hedging, and dispersion trading, which is currently used throughout the financial services industry, to make efficient markets in exchange-traded products.¹¹ This ability should permit market makers to make efficient markets in an issue of Managed Portfolio Shares without precise knowledge of a Fund's underlying portfolio.¹²

On each "Business Day" (as defined below), before commencement of trading in Shares on the Exchange, the Funds will provide to an "AP

Representative" (as described below) of each AP the identities and quantities of portfolio securities that will form the basis for a Fund's calculation of NAV per Share at the end of the Business Day, as well as the names and quantities of the instruments comprising a "Creation Basket" or the "Redemption Instruments" and the estimated "Balancing Amount" (if any) (as described below), for that day. This information will permit APs to purchase "Creation Units" or redeem "Redemption Units" through an in-kind transaction with a Fund, as described below.

Using various trading methodologies such as statistical arbitrage, both APs and "Non-Authorized Participant Market Makers" will be able to hedge exposures by trading correlative portfolios, securities or other proxy instruments, thereby enabling an arbitrage functionality throughout the trading day. For example, if an AP believes that Shares of a Fund are trading at a price that is higher than the value of its underlying portfolio based on the VIIV, the AP may sell Shares short and purchase securities that the AP believes will track the movements of a Fund's Shares until the spread narrows and the AP executes offsetting orders or the AP enters an order with its AP Representative to create Fund Shares. Upon the completion of the Creation Unit, the AP will unwind its correlative hedge. A non-AP Market Maker would be able to perform the same function but would be required to employ an AP to create or redeem Shares on its behalf.

The AP Representative's execution of a Creation Unit in a Confidential Account,¹³ combined with the sale of Fund Shares, may create downward pressure on the price of Shares and/or upward pressure on the price of the portfolio securities, bringing the market price of Shares and the value of a Fund's portfolio securities closer together. Similarly, an AP could buy Shares and instruct the AP Representative to redeem Fund Shares and liquidate underlying portfolio securities in a Confidential Account.

The AP's purchase of a Fund's Shares in the secondary market, combined with the liquidation of the portfolio securities from its Confidential Account by an AP Representative, may also create upward pressure on the price of Shares and/or downward pressure on the price of portfolio securities, driving the market price of Shares and the value of a Fund's portfolio securities closer together. The "Adviser" (as defined below) represents that it understands that, other than the confidential nature of the account, this process is identical to how many APs currently arbitrage existing traditional ETFs.

APs can engage in arbitrage by creating or redeeming Shares if the AP believes the Shares are overvalued or undervalued. As discussed above, the trading of a Fund's Shares and the creation or redemption of portfolio securities may bring the prices of a Fund's Shares and its portfolio assets closer together through market pressure.

The Exchange understands that traders use statistical analysis to derive correlations between different sets of instruments to identify opportunities to buy or sell one set of instruments when it is mispriced relative to the others. For Managed Portfolio Shares, market makers may use the knowledge of a Fund's means of achieving its investment objective, as described in the applicable Fund registration statement, to construct a hedging proxy for a Fund to manage a market maker's quoting risk in connection with trading Fund Shares. Market makers can then conduct statistical arbitrage between their hedging proxy (for example, the Russell 1000 Index) and Shares of a Fund, buying and selling one against the other over the course of the trading day. They will evaluate how their proxy performed in comparison to the price of a Fund's Shares, and use that analysis as well as knowledge of risk metrics, such as volatility and turnover, to enhance their proxy calculation to make it a more efficient hedge.

Market makers have indicated to the Exchange that there will be sufficient data to run a statistical analysis which will lead to spreads being tightened substantially around the VIIV. This is similar to certain other existing exchange traded products (for example, ETFs that invest in foreign securities that do not trade during U. S. trading hours), in which spreads may be generally wider in the early days of trading and then narrow as market makers gain more confidence in their real-time hedges.

¹¹ Statistical arbitrage enables a trader to construct an accurate proxy for another instrument, allowing it to hedge the other instrument or buy or sell the instrument when it is cheap or expensive in relation to the proxy. Statistical analysis permits traders to discover correlations based purely on trading data without regard to other fundamental drivers. These correlations are a function of differentials, over time, between one instrument or group of instruments and one or more other instruments. Once the nature of these price deviations have been quantified, a universe of securities is searched in an effort to, in the case of a hedging strategy, minimize the differential. Once a suitable hedging proxy has been identified, a trader can minimize portfolio risk by executing the hedging basket. The trader then can monitor the performance of this hedge throughout the trade period making correction where warranted. In the case of correlation hedging, the analysis seeks to find a proxy that matches the pricing behavior of the Fund. In the case of beta hedging, the analysis seeks to determine the relationship between the price movement over time of the Fund and that of another stock.

¹² APs that enter into their own separate Confidential Accounts shall have enough information to ensure that they are able to comply with applicable regulatory requirements. For example, for purposes of net capital requirements, the maximum Securities Haircut applicable to the securities in a Creation Basket, as determined under Rule 15c3-1, will be disclosed daily on each Fund's website.

¹³ A Confidential Account is a restricted account owned by an AP and held at a broker-dealer who will act as an AP Representative (execution agent acting on agency basis) on their behalf. The restricted account will be established and governed via contract and used solely for creation and redemption activity, while protecting the confidentiality of the portfolio constituents. For reporting purposes, the books and records of the Confidential Account will be maintained by the AP Representative and provided to the appropriate regulatory agency as required. The Confidential Account will be liquidated daily, so that the account holds no positions at the end of day.

Description of the Funds and the Trust

The Shares of each Fund will be issued by Precidian ETF Trust II ("Trust"), a statutory trust organized under the laws of the State of Delaware and registered with the Commission as an open-end management investment company.¹⁴ The investment adviser to the Trust will be Precidian Funds LLC (the "Adviser"). Royce & Associates, LP ("Royce"), will be the Fund's investment sub-adviser ("Sub-Adviser"). Foreside Fund Services, LLC ("Distributor") will serve as the distributor of the Fund's Shares.

As noted above, if the investment adviser to the Investment Company issuing Managed Portfolio Shares is registered as a broker-dealer or is affiliated with a broker-dealer such investment adviser will erect and maintain a "fire wall" between the investment adviser and personnel of the broker-dealer or broker-dealer affiliate, as applicable, with respect to access to information concerning the composition and/or changes to such Investment Company portfolio. Personnel who make decisions on the Investment Company's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable Investment Company portfolio. Proposed Commentary .05(a) is similar to Commentary .03(a)(i) and (iii) to NYSE Arca Rule 5.2-E(j)(3); however, Commentary .05(a) in connection with the establishment of a "fire wall" between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds.¹⁵ The

Adviser is not registered as a broker-dealer or affiliated with a broker-dealer. The Sub-Adviser is not registered as a broker-dealer but is affiliated with a broker-dealer and has implemented and will maintain a fire wall with respect to such broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio.

In the event (a) the Adviser or Sub-Adviser becomes registered as a broker-dealer or becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer, or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to its relevant personnel or its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

The portfolio for each Fund primarily will consist of long and/or short positions in U.S. exchange-listed equity securities and shares issued by other U.S.-listed ETFs.¹⁶ All exchange-listed equity securities in which the Funds will invest will be listed and traded on U.S. national securities exchanges.

Description of the Funds

Royce Pennsylvania ETF

Under normal market conditions (as defined in proposed Rule 8.900-E(c)(5)), the Royce Pennsylvania ETF will invest

requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A-1 under the Advisers Act. In addition, Rule 206(4)-7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violations, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

¹⁶ For purposes of this filing, ETFs include Investment Company Units (as described in NYSE Arca Rule 5.2-E(j)(3)); Portfolio Depository Receipts (as described in NYSE Arca Rule 8.100-E); and Managed Fund Shares (as described in NYSE Arca Rule 8.600-E). The ETFs in which a Fund will invest all will be listed and traded on U.S. national securities exchanges. While the Funds may invest in inverse ETFs, the Funds will not invest in leveraged (e.g., 2X, -2X, 3X or -3X) ETFs.

at least 65% of its assets in US exchange-listed equity securities of small-cap companies with stock market capitalizations up to \$3 billion that the Sub-Adviser believes are trading below its estimate of their current worth. The Fund may invest in U.S. exchange-listed ETFs. The Fund may sell securities to, among other things, secure gains, limit losses, redeploy assets into what Royce deems to be more promising opportunities, and/or manage cash levels in the Fund's portfolio.

Royce Premier ETF

Under normal market conditions, the Royce Premier ETF will invest at least 80% of its net assets in a limited number (generally less than 100) of US exchange-listed equity securities of primarily small-cap companies with stock market capitalizations from \$1 billion to \$3 billion at the time of investment. The Fund may invest in U.S. exchange-listed ETFs. The Fund may sell securities to, among other things, secure gains, limit losses, redeploy assets into what Royce deems to be more promising opportunities, and/or manage cash levels in the Fund's portfolio.

Royce Total Return ETF

Under normal market conditions, the Royce Total Return ETF will invest at least 65% of its assets in dividend-paying U.S.-listed equity securities of small-cap companies with stock market capitalizations up to \$3 billion that it believes are trading below its estimate of their current worth. The Fund may invest in U.S. exchange-listed ETFs. The Fund may sell securities to, among other things, secure gains, limit losses, redeploy assets into what Royce deems to be more promising opportunities, and/or manage cash levels in the Fund's portfolio.

Other Investments

While each Fund, under normal market conditions, will invest primarily in U.S.-listed equity securities, as described above, each Fund may invest its remaining assets in other securities and financial instruments, as described below.

Each Fund may invest up to 5% of its total assets in U.S. exchange-listed warrants and rights and U.S. exchange-listed options.

Each Fund may invest a portion of its assets in cash or cash equivalents.¹⁷

¹⁷ For purposes of this filing, cash equivalents include short-term instruments (instruments with maturities of less than 3 months) of the following types: (i) U.S. Government securities, including bills, notes and bonds differing as to maturity and rates of interest, which are either issued or

¹⁴ The Trust will be registered under the 1940 Act. On April 5, 2017, the Trust filed a registration statement on Form N-1A under the Securities Act of 1933 (the "1933 Act") (15 U.S.C. 77a), and under the 1940 Act relating to the Funds (File Nos. 333-217142 and 811-23246) (the "Registration Statement"). The Trust filed a Fifth Amended and Restated Application for an Order under Section 6(c) of the 1940 Act for exemptions from various provisions of the 1940 Act and rules thereunder (File No. 812-14405), dated December 4, 2017 ("Exemptive Application"). The Shares will not be listed on the Exchange until an order ("Exemptive Order") under the 1940 Act has been issued by the Commission with respect to the Exemptive Application. Investments made by the Funds will comply with the conditions set forth in the Exemptive Order. The description of the operation of the Trust and the Funds herein is based, in part, on the Registration Statement and the Exemptive Application.

¹⁵ An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the "Advisers Act"). As a result, the Adviser and its related personnel will be subject to the provisions of Rule 204A-1 under the Advisers Act relating to codes of ethics. This Rule

In addition to investments in U.S.-listed ETFs, as referenced above, each Fund may invest in the securities of other investment companies to the extent allowed by law.

Investment Restrictions

The Shares of each Fund will conform to the initial and continued listing criteria under proposed Rule 8.900–E. The Funds will not invest in futures, forwards or swaps.

Each Fund's investments will be consistent with its investment objective and will not be used to enhance leverage. While a Fund may invest in inverse ETFs, a Fund will not invest in leveraged (*e.g.*, 2X, –2X, 3X or –3X) ETFs.

The equity securities (other than non-exchange-listed investment company securities) and options in which the Funds invest will be listed on a U.S. national securities exchange.

Creations and Redemptions of Shares

In connection with the creation and redemption of Creation Units and Redemption Units, the delivery or receipt of any portfolio securities in-kind will be required to be effected through a separate confidential brokerage account (*i.e.*, a Confidential Account) with an AP Representative,¹⁸ which will be a bank or broker-dealer such as broker-dealer affiliates of JP Morgan Chase, State Street Bank and Trust, or Bank of New York Mellon, for the benefit of an AP.¹⁹ An AP must be a Depository Trust Company (“DTC”) Participant that has executed a “Participant Agreement” with the Distributor with respect to the creation and redemption of Creation Units and formed a Confidential Account for its benefit in accordance with the terms of the Participant Agreement. For purposes of creations or redemptions, all

transactions will be effected through the respective Authorized Participant's Confidential Account, for the benefit of the AP without disclosing the identity of such securities to the AP. Each AP Representative will be given, before the commencement of trading each Business Day (defined below), the “Creation Basket” (as described below) for that day. This information will permit an AP that has established a Confidential Account with an AP Representative to instruct the AP Representative to buy and sell positions in the portfolio securities to permit creation and redemption of Creation Units and Redemption Units.

In the case of a creation, the Authorized Participant would enter into an irrevocable creation order with the Fund and then direct the AP Representative to purchase the necessary basket of portfolio securities. The AP Representative would then purchase the necessary securities in the Confidential Account. In purchasing the necessary securities, the AP Representative would be required, by the terms of the Confidential Account Agreement, to obfuscate the purchase by use of tactics such as breaking the purchase into multiple purchases and transacting in multiple marketplaces. Once the necessary basket of securities has been acquired, the purchased securities held in the Confidential Account would be contributed in-kind to the Fund.

Shares of each Fund will be issued in Creation Units of 5,000 or more Shares. The Funds will offer and sell Creation Units and Redemption Units on a continuous basis at the NAV per Share next determined after receipt of an order in proper form. The NAV per Share of each Fund will be determined as of the close of regular trading on the New York Stock Exchange (“NYSE”) on each day that the NYSE is open. A “Business Day” is defined as any day that the Exchange is open for business. The Funds will sell and redeem Creation Units and Redemption Units only on Business Days. The Adviser anticipates that the initial price of a Share will range from \$20 to \$60, and that the price of a minimum Creation Unit initially will range from \$100,000 to \$300,000.

In order to keep costs low and permit each Fund to be as fully invested as possible, Shares will be purchased and redeemed in Creation Units and Redemption Units and generally on an in-kind basis. Accordingly, except where the purchase or redemption will include cash under the circumstances described in the Registration Statement, purchasers will be required to purchase Creation Units by making an in-kind

deposit of specified instruments (“Deposit Instruments”), and AP will receive an in-kind transfer of specified instruments (“Redemption Instruments”) through the AP Representative in their Confidential Account.²⁰ On any given Business Day, the names and quantities of the instruments that constitute the Deposit Instruments and the names and quantities of the instruments that constitute the Redemption Instruments will be identical, and these instruments may be referred to, in the case of either a purchase or a redemption, as the “Creation Basket.”²¹

As noted above, each AP will be required to establish a Confidential Account with an AP Representative and transact with each Fund through that Confidential Account.²² Therefore, before the commencement of trading on each Business Day, the AP Representative of each AP will be provided, on a confidential basis and at the same time as other Authorized Participants, with a list of the names and quantities of the instruments comprising a Creation Basket, as well as the estimated Balancing Amount (if any), for that day. The published Creation Basket will apply until a new Creation Basket is announced on the following Business Day, and there will be no intra-day changes to the Creation Basket except to correct errors in the published Creation Basket. The instruments and cash that the purchaser is required to deliver in exchange for the

²⁰ The Funds must comply with the federal securities laws in accepting Deposit Instruments and satisfying redemptions with Redemption Instruments.

²¹ In determining whether a particular Fund will sell or redeem Creation Units entirely on a cash or in-kind basis, whether for a given day or a given order, the key consideration will be the benefit that would accrue to a Fund and its investors. The Adviser represents that the Funds do not currently anticipate the need to sell or redeem Creation Units or Redemption Units entirely on a cash basis. To the extent a Fund allows creations or redemptions to be conducted in cash, such transactions will be effected in the same manner for all APs.

²² The Adviser represents that transacting through a Confidential Account is similar to transacting through any broker-dealer account, except that the AP Representative will be bound to keep the names and weights of the portfolio securities confidential. Each service provider that has access to the identity and weightings of securities in a Fund's Creation Basket or portfolio securities, such as a Fund's Custodian or pricing verification agent, shall be restricted contractually from disclosing that information to any other person, or using that information for any purpose other than providing services to the Fund. To comply with certain recordkeeping requirements applicable to APs, the AP Representative will maintain and preserve, and make available to the Commission, certain required records related to the securities held in the Confidential Account.

guaranteed by the U.S. Treasury or by U.S. Government agencies or instrumentalities; (ii) certificates of deposit issued against funds deposited in a bank or savings and loan association; (iii) bankers' acceptances, which are short-term credit instruments used to finance commercial transactions; (iv) repurchase agreements and reverse repurchase agreements; (v) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (vi) commercial paper, which are short-term unsecured promissory notes; and (vii) money market funds. It will be the policy of the Trust to enter into repurchase agreements only with recognized securities dealers, banks and Fixed Income Clearing Corporation, a securities clearing agency registered with the Commission.

¹⁸ Each AP shall enter into its own separate Confidential Account with an AP Representative.

¹⁹ In the event that an AP Representative is a bank, the bank will be required to have an affiliated broker-dealer to accommodate the execution of hedging transactions on behalf of the holder of a Confidential Account.

Creation Units it is purchasing are referred to as the "Portfolio Deposit."

APs will enter into an agreement with an AP Representative to open a Confidential Account, for the benefit of the AP. The AP Representative will serve as an agent between a Fund and each AP and act as a broker-dealer on behalf of the AP. Each day, the Custodian (defined below) will transmit the Fund Constituent file to each AP Representative and, acting on execution instructions from AP, the AP Representative may purchase or sell the securities currently held in a Fund's portfolio for purposes of effecting in-kind creation and redemption activity during the day.²³

As with the AP, Non-Authorized Participant Market Makers will have the ability to facilitate efficient market making in the Shares. However, Non-Authorized Participant Market Makers will not have the ability to create or redeem shares directly with a Fund. Rather, if a Non-Authorized Participant Market Maker wishes to create Shares in a Fund, it will have to do so through an AP.

Placement of Purchase Orders

Each Fund will issue Shares through the Distributor on a continuous basis at NAV. The Exchange represents that the issuance of Shares will operate in a manner substantially similar to that of other ETFs.

Each Fund will issue Shares only at the NAV per Share next determined after an order in proper form is received.

Shares may be purchased from a Fund by an AP for its own account or for the benefit of a customer. The Distributor will furnish acknowledgements to those placing such orders that the orders have been accepted, but the Distributor may reject any order which is not submitted in proper form, as described in a Fund's prospectus or Statement of Additional Information ("SAI"). Purchases of Shares will be settled in-kind and/or cash for an amount equal to the applicable NAV per Share purchased plus applicable "Transaction Fees," as discussed below.

The NAV of each Fund is expected to be determined once each Business Day at a time determined by the Trust's Board of Directors ("Board"), currently anticipated to be as of the close of the regular trading session on the NYSE (ordinarily 4:00 p.m. E.T.) (the "Valuation Time"). Each Fund will establish a cut-off time ("Order Cut-Off Time") (*i.e.*, the scheduled closing time of the regular trading session on the NYSE, ordinarily 4:00 p.m. E.T.) for purchase orders in proper form. To initiate a purchase of Shares, an AP must submit to the Distributor an irrevocable order to purchase such Shares after the most recent prior Valuation Time.

All orders to purchase Creation Units must be received by the Distributor no later than the scheduled closing time of the regular trading session on the NYSE (ordinarily 4:00 p.m. E.T.) in each case on the date such order is placed ("Transmittal Date") in order for the purchaser to receive the NAV per Share determined on the Transmittal Date. In the case of custom orders made in connection with creations or redemptions in whole or in part in cash, the order must be received by the Distributor, no later than the order cut-off time.²⁴ The Distributor will maintain a record of Creation Unit purchases and will send out confirmations of such purchases.²⁵

Transaction Fees

The Trust may impose purchase or redemption transaction fees ("Transaction Fees") in connection with the purchase or redemption of Shares from the Funds. The exact amounts of any such Transaction Fees will be determined by the Adviser. The purpose of the Transaction Fees is to protect the continuing shareholders against possible dilutive transactional expenses, including operational processing and brokerage costs, associated with establishing and liquidating portfolio positions, including short positions, in connection with the purchase and redemption of Shares.

Purchases of Shares—Secondary Market

Only APs will be able to acquire Shares at NAV directly from a Fund through the Distributor. The required payment must be transferred in the

manner set forth in a Fund's SAI by the specified time on the second DTC settlement day following the day it is transmitted (the "Transmittal Date"). These investors and others will also be able to purchase Shares in secondary market transactions at prevailing market prices.

Redemption

Beneficial Owners may sell their Shares in the secondary market. Alternatively, investors that own enough Shares to constitute a Redemption Unit (currently, 25,000 Shares) or multiples thereof may redeem those Shares through the Distributor, which will act as the Trust's representative for redemption. The size of a Redemption Unit will be subject to change. Redemption orders for Redemption Units or multiples thereof must be placed by or through an AP.

Authorized Participant Redemption

The Shares may be redeemed to a Fund in Redemption Unit size or multiples thereof as described below. Redemption orders of Redemption Units must be placed by or through an AP ("AP Redemption Order"). Each Fund will establish an Order Cut-Off Time for redemption (ordinarily 4:00 p.m., E.T.) for orders of Redemption Units in proper form. Redemption Units of the Fund will be redeemable at their NAV per Share next determined after receipt of a request for redemption by the Trust in the manner specified below before the Order Cut-Off Time. To initiate an AP Redemption Order, an AP must submit to the Distributor an irrevocable order to redeem such Redemption Unit after the most recent prior Valuation Time but not later than the Order Cut-Off Time. The Order Cut-Off Time for a Fund will ordinarily be its Valuation Time, or may be prior to the Valuation Time if the Board determines that an earlier Order Cut-Off Time for redemption of Redemption Units is necessary and is in the best interests of Fund shareholders.

In the case of a redemption, the Authorized Participant would enter into an irrevocable redemption order, and then immediately instruct the AP Representative to sell the underlying basket of securities that it will receive in the redemption. As with the purchase of securities, the AP Representative would be required to obfuscate the sale of the portfolio securities it will receive as redemption proceeds using similar tactics. The positions in the underlying portfolio securities sold from the Confidential Account would be covered by the in-kind redemption proceeds

²³ Each Fund will identify one or more entities to enter into a contractual arrangement with the Fund to serve as an AP Representative. In selecting entities to serve as AP Representatives, a Fund will obtain representations from the entity related to the confidentiality of the Fund's Creation Basket portfolio securities, the effectiveness of information barriers, and the adequacy of insider trading policies and procedures. In addition, as a broker-dealer, Section 15(g) of the Act requires the AP Representative to establish, maintain, and enforce written policies and procedures reasonably designed to prevent the misuse of material, nonpublic information by the AP Representative or any person associated with the AP Representative.

²⁴ A "custom order" is any purchase or redemption of Shares made in whole or in part on a cash basis, as provided in the Registration Statement.

²⁵ An AP Representative will provide information related to creations and redemption of Creation Units and Redemption Units to the Financial Industry Regulatory Authority ("FINRA") upon request.

received by the Confidential Account from the Fund.

Consistent with the provisions of Section 22(e) of the 1940 Act and Rule 22e-2 thereunder, the right to redeem will not be suspended, nor payment upon redemption delayed, except for: (1) Any period during which the NYSE is closed other than customary weekend and holiday closings, (2) any period during which trading on the NYSE is restricted, (3) any period during which an emergency exists as a result of which disposal by a Fund of securities owned by it is not reasonably practicable or it is not reasonably practicable for a Fund to determine its NAV, and (4) for such other periods as the Commission may by order permit for the protection of shareholders.

Redemptions will occur primarily in-kind, although redemption payments may also be made partly or wholly in cash.²⁶ The Participant Agreement signed by each AP will require establishment of a Confidential Account to receive distributions of securities in-kind upon redemption.²⁷ Each AP will be required to open a Confidential Account with an AP Representative in order to facilitate orderly processing of redemptions. While a Fund will generally distribute securities in-kind, the Adviser may determine from time to time that it is not in a Fund's best interests to distribute securities in-kind, but rather to sell securities and/or distribute cash. For example, the Adviser may distribute cash to facilitate orderly portfolio management in connection with rebalancing or transitioning a portfolio in line with its investment objective, or if there is substantially more creation than redemption activity during the period immediately preceding a redemption request, or as necessary or appropriate in accordance with applicable laws and regulations. In this manner, a Fund can use in-kind redemptions to reduce the unrealized capital gains that may, at times, exist in a Fund by distributing low cost lots of each security that a Fund needs to dispose of to maintain its desired portfolio exposures. Shareholders of a Fund would benefit

from the in-kind redemptions through the reduction of the unrealized capital gains in a Fund that would otherwise have to be realized and, eventually, distributed to shareholders.

The redemption basket will consist of the same securities for all APs on any given day subject to the Adviser's ability to make minor adjustments to address odd lots, fractional shares, tradeable sizes or other situations.

After receipt of a Redemption Order, a Fund's custodian ("Custodian") will typically deliver securities to the Confidential Account on a pro rata basis (which securities are determined by the Adviser) with a value approximately equal to the value of the Shares²⁸ tendered for redemption at the Cut-Off time. The Custodian will make delivery of the securities by appropriate entries on its books and records transferring ownership of the securities to the AP's Confidential Account, subject to delivery of the Shares redeemed. The AP Representative of the Confidential Account will in turn liquidate the securities based on instructions from the AP.²⁹ The AP Representative will pay the liquidation proceeds net of expenses plus or minus any cash balancing amount to the AP through DTC.³⁰ The redemption securities that the Confidential Account receives are expected to mirror the portfolio holdings of a Fund pro rata. To the extent a Fund distributes portfolio securities through an in-kind distribution to more than one Confidential Account for the benefit of each account's AP, each Fund expects to distribute a pro rata portion of the portfolio securities selected for distribution to each redeeming AP.

If the AP would receive a security that it is restricted from receiving, for example if the AP is engaged in a distribution of the security, a Fund will deliver cash equal to the value of that

security. APs and Non-Authorized Participant Market Makers will provide the AP Representative with a list of restricted securities applicable to the AP or Non-Authorized Participant Market Maker on a daily basis, and a Fund will substitute cash for those securities in the applicable Confidential Account.

To address odd lots, fractional shares, tradeable sizes or other situations where dividing securities is not practical or possible, the Adviser may make minor adjustments to the pro rata portion of portfolio securities selected for distribution to each redeeming AP on such Business Day.

The Trust will accept a Redemption Order in proper form. A Redemption Order is subject to acceptance by the Trust and must be preceded or accompanied by an irrevocable commitment to deliver the requisite number of Shares. At the time of settlement, an AP will initiate a delivery of the Shares versus subsequent payment against the proceeds, if any, of the sale of portfolio securities distributed to the applicable Confidential Account plus or minus any cash balancing amounts, and less the expenses of liquidation.

Independent Pricing Calculations

According to the Exemptive Application, the Pricing Verification Agent, on behalf of each Fund, will utilize at least two separate calculation engines to calculate intra-day indicative values ("Calculation Engines"), based on the mid-point between the current national best bid and offer disseminated by the Consolidated Quotation System ("CQS") and Unlisted Trading Privileges ("UTP") Plan Securities Information Processor,³¹ to provide the real-time value on a per Share basis of each Fund's holdings every second during the Exchange's Core Trading Session.³² The Custodian will provide, on a daily basis, the identities and quantities of portfolio securities that

²⁸ If the NAV of the Shares redeemed differs from the value of the securities delivered to the applicable Confidential Account, the Fund will pay a cash balancing amount to compensate for the difference between the value of the securities delivered and the NAV.

²⁹ An AP will issue execution instructions to the AP Representative and be responsible for all associated profit or losses. Like a traditional ETF, the AP has the ability to sell the basket securities at any point during normal trading hours.

³⁰ Under applicable provisions of the Internal Revenue Code, the AP is expected to be deemed a "substantial owner" of the Confidential Account because it receives distributions from the Confidential Account. As a result, all income, gain or loss realized by the Confidential Account will be directly attributed to the AP. In a redemption, the AP will have a basis in the distributed securities equal to the fair market value at the time of the distribution and any gain or loss realized on the sale of those Shares will be taxable income to the AP.

³¹ According to the Exemptive Application, all Commission-registered exchanges and market centers send their trades and quotes to a central consolidator where the Consolidated Tape System (CTS) and CQS data streams are produced and distributed worldwide. See <https://www.ctaplant.com/index>. Although there is only one source of market quotations, each Calculation Engine will receive the data directly and calculate an indicative value separately and independently from each other Calculation Engine.

³² The Adviser represents that the dissemination of VIIV at one second intervals strikes a balance of providing all investors with useable information at a rate that can be processed by retail investors, does not provide so much information so as to allow market participants to accurately determine the constituents, and their weightings, of the portfolio, can be accurately calculated and disseminated, and still provides professional traders with per second data.

²⁶ It is anticipated that any portion of a Fund's NAV attributable to appreciated short positions will be paid in cash, as securities sold short are not susceptible to in-kind settlement. The value of other positions not susceptible to in-kind settlement may also be paid in cash.

²⁷ The terms of each Confidential Account will be set forth as an exhibit to the Participant Agreement, which will be signed by each Authorized Participant. The Authorized Participant will be free to choose an AP Representative for its Confidential Account from a list of banks and trust companies that have signed confidentiality agreements with the Fund.

will form the basis for the Fund's calculation of NAV at the end of the Business Day,³³ plus any cash in the portfolio, to the Pricing Verification Agent for purposes of pricing.

According to the Exemptive Application, it is anticipated that each Calculation Engine could be using some combination of different hardware, software and communications platforms to process the CQS data. Different hardware platforms' operating systems could be receiving and calculating the CQS data inputs differently, potentially resulting in one Calculation Engine processing the indicative value in a different time slice than another Calculation Engine's system, thus processing values in different sequences. The processing differences between different Calculation Engines will most likely be in the sub-second range. Consequently, the frequency of occurrence of out of sequence values among different Calculation Engines due to differences in operating system environments should be minimal. Other factors that could result in sequencing that is not uniform among the different Calculation Engines are message gapping, internal system software design, and how the CQS data is transmitted to the Calculation Engine. While the expectation is that the separately calculated intraday indicative values will generally match, having dual streams of redundant data that must be compared by the Pricing Verification Agent will provide an additional check that the resulting VIIV is accurate.

According to the Exemptive Application, each Fund's Board has a responsibility to oversee the process of calculating an accurate VIIV and to make an affirmative determination, at least annually, that the procedures used to calculate the VIIV and maintain its accuracy are, in its reasonable business judgment, appropriate. These procedures and their continued effectiveness will be subject to the ongoing oversight of the Fund's chief compliance officer. The specific methodology for calculating the VIIV will be disclosed on each Fund's website. While each Fund will oversee the calculation of the VIIV, a Fund will utilize multiple Calculation Engines, one of which may be supplied by the Pricing Verification Agent.

Net Asset Value

The NAV per Share of a Fund will be computed by dividing the value of the net assets of a Fund (*i.e.* the value of its total assets less total liabilities) by the total number of Shares of a Fund outstanding, rounded to the nearest cent. Expenses and fees, including, without limitation, the management, administration and distribution fees, will be accrued daily and taken into account for purposes of determining NAV. Interest and investment income on the Trust's assets accrue daily and will be included in the Fund's total assets. The NAV per Share for a Fund will be calculated by a Fund's administrator ("Administrator") and determined as of the close of the regular trading session on the NYSE (ordinarily 4:00 p.m., E.T.) on each day that the NYSE is open.

Shares of exchange-listed equity securities and exchange-listed options will be valued at market value, which will generally be determined using the last reported official closing or last trading price on the exchange or market on which the securities are primarily traded at the time of valuation. Repurchase agreements will be valued based on price quotations or other equivalent indications of value provided by a third-party pricing service. Money market funds and other non-exchange-traded investment company securities will be valued based on price quotations or other equivalent indications of value provided by a third-party pricing service. Other cash equivalents will generally be valued on the basis of separate pricing services or quotes obtained from brokers and dealers.

When last sale prices and market quotations are not readily available, are deemed unreliable or do not reflect material events occurring between the close of local markets and the time of valuation, investments will be valued using fair value pricing, as determined in good faith by the Adviser under procedures established by and under the general supervision and responsibility of the Trust's Board of Trustees. Investments that may be valued using fair value pricing include, but are not limited to: (1) Securities that are not actively traded; (2) securities of an issuer that becomes bankrupt or enters into a restructuring; and (3) securities whose trading has been halted or suspended.

The frequency with which each Fund's investments will be valued using fair value pricing will primarily be a function of the types of securities and other assets in which the respective Fund will invest pursuant to its

investment objective, strategies and limitations. If the Funds invest in open-end management investment companies registered under the 1940 Act (other than ETFs), they may rely on the NAVs of those companies to value the shares they hold of them.

Valuing the Funds' investments using fair value pricing involves the consideration of a number of subjective factors and thus the prices for those investments may differ from current market valuations. Accordingly, fair value pricing could result in a difference between the prices used to calculate NAV and the prices used to determine a Fund's VIIV, which could result in the market prices for Shares deviating from NAV. In cases where the fair value price of the security is materially different from the mid-point of the bid/ask spread provided to the Calculation Engines and the Adviser determined that the ongoing pricing information is not likely to be reliable, the fair value will be used for calculation of the VIIV, and a Fund's Custodian will be instructed to disclose the identity and weight of the fair valued securities, as well as the fair value price being used for the security.

Availability of Information

The Funds' website (www.precidianfunds.com), which will be publicly available prior to the listing and trading of Shares, will include a form of the prospectus for each Fund that may be downloaded. The Funds' website will include additional quantitative information updated on a daily basis, including, for each Fund, (1) daily trading volume, the prior Business Day's reported closing price, NAV and mid-point of the bid/ask spread at the time of calculation of such NAV (the "Bid/Ask Price"),³⁴ and a calculation of the premium and discount of the Bid/Ask Price against the NAV, and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. The website and information will be publicly available at no charge.

As noted above, a mutual fund is required to file with the Commission its complete portfolio schedules for the second and fourth fiscal quarters on Form N-CSR under the 1940 Act, and is required to file its complete portfolio schedules for the first and third fiscal

³³ Under accounting procedures followed by the Funds, trades made on the prior Business Day (T) will be booked and reflected in the NAV on the current Business Day (T+1). Thus, the VIIV calculated throughout the day will be based on the same portfolio as is used to calculate the NAV on that day.

³⁴ The Bid/Ask Price of a Fund will be determined using the mid-point of the highest bid and the lowest offer on the Exchange as of the time of calculation of a Fund's NAV. The records relating to Bid/Ask Prices will be retained by each Fund and its service providers.

quarters on Form N-Q under the 1940 Act, within 60 days of the end of the quarter. Form N-Q requires funds to file the same schedules of investments that are required in annual and semi-annual reports to shareholders. The Trust's SAI and each Fund's shareholder reports will be available free upon request from the Trust. These documents and forms may be viewed on-screen or downloaded from the Commission's website at www.sec.gov.

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last sale information for the Shares will be available via the Consolidated Tape Association ("CTA") high-speed line. In addition, the VIIV, as defined in NYSE Arca Rule 8.900-E (c)(3) and as described further below, will be widely disseminated by one or more major market data vendors every second during the Exchange's Core Trading Session.

Dissemination of the Verified Intraday Indicative Value

The VIIV, which is approximate value of each Fund's investments on a per Share basis, will be disseminated every second during the Exchange's Core Trading Session. The VIIV should not be viewed as a "real-time" update of NAV because the VIIV may not be calculated in the same manner as NAV, which is computed once per day.

The VIIV for each Fund will be disseminated by one or more major market data vendors in one-second intervals during the Core Trading Session. The VIIV is an intraday approximation of the Fund's value calculated every second during the Core Trading Session. Each Fund will adopt procedures governing the calculation of the VIIV. Pursuant to those procedures, the VIIV will include all accrued income and expenses of a Fund and will assure that any extraordinary expenses booked during the day that would be taken into account in calculating a Fund's NAV for that day are also taken into account in calculating the VIIV. For purposes of the VIIV, securities held by a Fund will be valued throughout the day based on the mid-point between the disseminated current national best bid and offer. If the Adviser determines that the mid-point of the bid/ask spread is inaccurate, a Fund will use fair value pricing. That fair value pricing will be

carried over to the next day's VIIV until the first trade in that stock is reported unless the Adviser deems a particular portfolio security to be illiquid and/or the available ongoing pricing information unlikely to be reliable. In such case, that fact will be disclosed as soon as practicable on each Fund's website, including the identity and weighting of that security in a Fund's portfolio, and the impact of that security on VIIV calculation, including the fair value price for that security being used for the calculation of that day's VIIV.

The Adviser represents that, by utilizing the mid-point pricing for purposes of VIIV calculation, stale prices are eliminated and more accurate representation of the real time value of the underlying securities is provided to the market. Specifically, quotations based on the mid-point of bid/ask spreads more accurately reflect current market sentiment by providing real time information on where market participants are willing to buy or sell securities at that point in time. Using quotations rather than last sale information addresses concerns regarding the staleness of pricing information of less actively traded securities. Because quotations are updated more frequently than last sale information especially for inactive securities, the VIIV will be based on more current and accurate information. The use of quotations will also dampen the impact of any momentary spikes in the price of a portfolio security.

Each Fund will utilize two separate pricing feeds to provide two separate sources of pricing information. Each Fund will also utilize a "Pricing Verification Agent" and establish a computer-based protocol that will permit the Pricing Verification Agent to continuously compare the multiple intraday indicative values from the Calculation Engines on a real time basis.³⁵ A single VIIV will be disseminated publicly for each Fund; however, the Pricing Verification Agent will continuously compare the public VIIV against a non-public alternative intra-day indicative value to which the Pricing Verification Agent has access. Upon notification to the Exchange by the issuer of a series of Managed Portfolio Shares or its agent that the public VIIV and non-public alternative intra-day indicative value differ by more than 25 basis points for 60 seconds, the Exchange will halt trading as soon as

³⁵ A Fund's Custodian will provide, on a daily basis, the identities and quantities of portfolio securities that will form the basis for a Fund's calculation of NAV at the end of the Business Day, plus any cash in the portfolio, to the Pricing Verification Agent for purposes of pricing.

practicable in a Fund until the discrepancy is resolved.³⁶ Each Fund's Board will review the procedures used to calculate the VIIV and maintain its accuracy as appropriate, but not less than annually. The specific methodology for calculating the VIIV will be disclosed on each Fund's website.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Funds. Trading in Shares of the Funds will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12-E have been reached.³⁷ Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Trading in the Shares will be subject to NYSE Arca Rule 8.900-E(d)(2)(C), which sets forth circumstances under which Shares of the Funds will be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace only during the Core Trading Session in accordance with NYSE Arca Rule 7.34-E (a)(2). As provided in NYSE Arca Rule 7.6-E, the minimum price variation ("MPV") for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is \$0.01, with the exception of securities that are priced less than \$1.00 for which the MPV for order entry is \$0.0001.

The Shares will conform to the initial and continued listing criteria under NYSE Arca Rule 8.900-E. The Exchange represents that, for initial and/or continued listing, each Fund will be in compliance with Rule 10A-3 under the Act,³⁸ as provided by NYSE Arca Rule 5.3-E. A minimum of 100,000 Shares of each Fund will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a

³⁶ For the period January 1, 2017, to October 31, 2017, the average bid/ask spread on actively managed equity ETFs (Managed Fund Shares) traded on NYSE Arca, as a percentage, was 38 basis points. For the same period, the spread on all exchange-traded products traded on NYSE Arca, as a percentage, was 54 basis points. A continuous deviation for sixty seconds could indicate an error in the feed or in a Calculation Engine. The Trust reserves the right to change these thresholds to the extent deemed appropriate and approved by a Fund's Board.

³⁷ See NYSE Arca Rule 7.12-E.

³⁸ See 17 CFR 240.10A-3.

representation from the issuer of the Shares of each Fund that the NAV per Share of each Fund will be calculated daily and will be made available to all market participants at the same time.

Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by the Exchange, as well as cross-market surveillances administered by FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.³⁹ The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares, common stocks, rights, warrants, ETFs and exchange-listed options with other markets and other entities that are members of the Intermarket Surveillance Group ("ISG"), and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading such securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in such securities from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.⁴⁰

The Funds' Adviser will make available daily to FINRA and the Exchange the portfolio holdings of each Fund in order to facilitate the performance of the surveillances referred to above.

In addition, the Exchange also has a general policy prohibiting the

distribution of material, non-public information by its employees.

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit ("ETP") Holders in an Information Bulletin ("Bulletin") of the special characteristics and risks associated with trading the Shares. Specifically, the Bulletin will discuss the following: (1) The procedures for purchases and redemptions of Shares; (2) NYSE Arca Rule 9.2-E(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) how information regarding the VIIV is disseminated; (4) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (5) trading information.

In addition, the Bulletin will reference that the Funds are subject to various fees and expenses described in the Registration Statement. The Bulletin will discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act. The Bulletin will also disclose that the NAV for the Shares will be calculated after 4:00 p.m., E.T. each trading day.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁴¹ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁴² in particular, in that it is 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 Exchange believes that proposed Rule 8.900-E is designed to prevent fraudulent and manipulative acts and practices in that the proposed rules relating to listing and trading of Managed Portfolio Shares provide specific initial and continued listing criteria required to be met by such securities. Proposed Rule 8.900-E(d) sets forth initial and continued listing criteria applicable to Managed Portfolio Shares. Proposed Rule 8.900-E (d)(1) provides that, for each series of Managed Portfolio Shares, the Exchange will establish a minimum number of

Managed Portfolio Shares required to be outstanding at the time of commencement of trading. In addition, the Exchange will obtain a representation from the issuer of each series of Managed Portfolio Shares that the NAV per share for the series will be calculated daily and that the NAV will be made available to all market participants at the same time. Proposed Rule 8.900-E (d)(2) provides that each series of Managed Portfolio Shares will be listed and traded subject to application of the specified continued listing criteria, as described above. Proposed Rule 8.900-E (d)(2)(A) provides that the VIIV for Managed Portfolio Shares will be widely disseminated by one or more major market data vendors every second during the Exchange's Core Trading Session. Proposed Rule 8.900-E (d)(2)(B) provides that the Exchange will maintain surveillance procedures for securities listed under Rule 8.900 and will consider the suspension of trading in, and will commence delisting proceedings under Rule 5.5-E (m) of a series of Managed Portfolio Shares under any of the circumstances set forth in proposed Rules 8.900-E (d)(2)(B)(i) through (vi), as described above, including if any of the continued listing requirements set forth in Rule 8.900-E are not continuously maintained (proposed Rule 8.900-E (d)(2)(B)(iv)), and if the Exchange submits a rule filing pursuant to Section 19(b) of the Act to permit the listing and trading of a series of Managed Portfolio Shares and any of the statements or representations regarding (a) the description of the portfolio, (b) limitations on portfolio holdings, or (c) the applicability of Exchange listing rules specified in such rule filing are not continuously maintained (proposed Rule 8.900-E (d)(2)(B)(v)). Proposed Rule 8.900-E (d)(2)(C) provides that, upon notification to the Corporation by the Investment Company or its agent that (i) the intraday indicative values calculated from more than one Calculation Engines to be compared by the Investment Company's pricing verification agent differ by more than 25 basis points for 60 seconds in connection with pricing of the VIIV, or (ii) that the VIIV of a series of Managed Portfolio Shares is not being calculated or disseminated in one-second intervals, as required, the Exchange shall halt trading in the Managed Portfolio Shares as soon as practicable. Such halt in trading shall continue until the Investment Company or its agent notifies the Exchange that the intraday indicative values no longer differ by more than 25 basis points for

³⁹ FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

⁴⁰ For a list of the current members of ISG, see www.isgportal.org.

⁴¹ 15 U.S.C. 78f(b).

⁴² 15 U.S.C. 78f(b)(5).

60 seconds or that the VIIV is being calculated and disseminated as required. Proposed Commentary .05(a) to NYSE Arca Rule 8.900–E provides that, if the investment adviser to the Investment Company issuing Managed Portfolio Shares is registered as a broker-dealer or is affiliated with a broker-dealer such investment adviser will erect and maintain a “fire wall” between the investment adviser and personnel of the broker-dealer or broker-dealer affiliate, as applicable, with respect to access to information concerning the composition and/or changes to such Investment Company portfolio. Proposed Commentary .05(b) provides that, if an AP Representative, the custodian or pricing verification agent for an Investment Company issuing Managed Portfolio Shares, or any other entity that has access to information concerning the composition and/or changes to such Investment Company’s portfolio, is registered as a broker-dealer or affiliated with a broker-dealer, such AP Representative, custodian, pricing verification agent or other entity will erect and maintain a “fire wall” between such AP Representative, custodian, pricing verification agent, or other entity and personnel of the broker-dealer or broker-dealer affiliate, as applicable, with respect to access to information concerning the composition and/or changes to such Investment Company portfolio. With respect to both Commentary .05(a) and .05(b), personnel who make decisions on the Investment Company’s portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable Investment Company portfolio.

With respect to the proposed listing and trading of Shares of the Funds, the Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Rule 8.900–E. Price information for the exchange-listed equity securities held by the Funds will be available through major market data vendors or securities exchanges listing and trading such securities. All exchange-listed equity securities held by the Funds will be listed on U.S. national securities exchanges. The listing and trading of such securities is subject to rules of the exchanges on which they are listed and traded, as approved by the Commission.

The Funds will primarily hold U.S.-listed equity securities and shares issued by other U.S.-listed ETFs. All exchange-listed equity securities in which the Funds will invest will be listed and traded on U.S. national securities exchanges. A Fund’s investments will be consistent with its respective investment objective and will not be used to enhance leverage. The Funds will not invest in non-U.S.-listed securities. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares and underlying stocks and ETFs with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading such securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares, underlying stocks and ETFs from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. An AP Representative will provide information related to creations and redemption of Creation Units and Redemption Instruments to FINRA upon request. The Funds’ Adviser will make available daily to FINRA and the Exchange the portfolio holdings of each Fund in order to facilitate the performance of the surveillances referred to above.

The Exchange, after consulting with various Lead Market Makers that trade ETFs on the Exchange, believes that market makers will be able to make efficient and liquid markets priced near the VIIV, market makers have knowledge of a fund’s means of achieving its investment objective even without daily disclosure of a fund’s underlying portfolio. The Exchange believes that market makers will employ risk-management techniques to make efficient markets in exchange traded products.⁴³ This ability should permit market makers to make efficient markets in shares without knowledge of a fund’s underlying portfolio.

The Exchange understands that traders use statistical analysis to derive correlations between different sets of instruments to identify opportunities to buy or sell one set of instruments when it is mispriced relative to the others. For Managed Portfolio Shares, market makers utilizing statistical arbitrage use the knowledge of a fund’s means of achieving its investment objective, as described in the applicable fund registration statement, to construct a

hedging proxy for a fund to manage a market maker’s quoting risk in connection with trading fund shares. Market makers will then conduct statistical arbitrage between their hedging proxy (for example, the Russell 1000 Index) and shares of a fund, buying and selling one against the other over the course of the trading day. Eventually, at the end of each day, they will evaluate how their proxy performed in comparison to the price of a fund’s shares, and use that analysis as well as knowledge of risk metrics, such as volatility and turnover, to enhance their proxy calculation to make it a more efficient hedge.

The Lead Market Makers also indicated that, as with some other new exchange-traded products, spreads would tend to narrow as market makers gain more confidence in the accuracy of their hedges and their ability to adjust these hedges in real-time relative to the published VIIV and gain an understanding of the applicable market risk metrics such as volatility and turnover, and as natural buyers and sellers enter the market. Other relevant factors cited by Lead Market Makers were that a fund’s investment objectives are clearly disclosed in the applicable prospectus, the existence of quarterly portfolio disclosure and the ability to create shares in creation unit size.

The real-time dissemination of a fund’s VIIV, together with the right of APs to create and redeem each day at the NAV, will be sufficient for market participants to value and trade shares in a manner that will not lead to significant deviations between the shares’ Bid/Ask Price and NAV.

The pricing efficiency with respect to trading a series of Managed Portfolio Shares will generally rest on the ability of market participants to arbitrage between the shares and a fund’s portfolio, in addition to the ability of market participants to assess a fund’s underlying value accurately enough throughout the trading day in order to hedge positions in shares effectively. Professional traders can buy shares that they perceive to be trading at a price less than that which will be available at a subsequent time, and sell shares they perceive to be trading at a price higher than that which will be available at a subsequent time. It is expected that, as part of their normal day-to-day trading activity, market makers assigned to shares by the Exchange, off-exchange market makers, firms that specialize in electronic trading, hedge funds and other professionals specializing in short-term, non-fundamental trading strategies will assume the risk of being “long” or “short” shares through such

⁴³ See note 11, *supra*.

trading and will hedge such risk wholly or partly by simultaneously taking positions in correlated assets⁴⁴ or by netting the exposure against other, offsetting trading positions—much as such firms do with existing ETFs and other equities. Disclosure of a fund's investment objective and principal investment strategies in its prospectus and SAI, along with the dissemination of the VIIV every second, should permit professional investors to engage easily in this type of hedging activity.⁴⁵

With respect to trading of Shares of the Funds, the ability of market participants to buy and sell Shares at prices near the VIIV is dependent upon their assessment that the VIIV is a reliable, indicative real-time value for a Fund's underlying holdings. Market participants are expected to accept the VIIV as a reliable, indicative real-time value because (1) the VIIV will be calculated and disseminated based on a Fund's actual portfolio holdings, (2) the

securities in which the Funds plan to invest are generally highly liquid and actively traded and therefore generally have accurate real time pricing available, and (3) market participants will have a daily opportunity to evaluate whether the VIIV at or near the close of trading is indeed predictive of the actual NAV.

The real-time dissemination of a Fund's VIIV, together with the ability of APs to create and redeem each day at the NAV, will be crucial for market participants to value and trade Shares in a manner that will not lead to significant deviations between the Shares' Bid/Ask Price and NAV.⁴⁶

In a typical index-based ETF, it is standard for APs to know what securities must be delivered in a creation or will be received in a redemption. For Managed Portfolio Shares, however, APs do not need to know the securities comprising the portfolio of a Fund since creations and redemptions are handled through the Confidential Account mechanism. The Adviser represents that the in-kind creations and redemptions through a Confidential Account will preserve the integrity of the active investment strategy and reduce the potential for "free riding" or "front-running," while still providing investors with the advantages of the ETF structure.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of an issue of Managed Portfolio Shares that the NAV per share of a fund will be calculated daily and that the NAV will be made available to all market participants at the same time. Investors can also obtain a fund's SAI, shareholder reports, and its Form N-CSR, Form N-Q and Form N-SAR. A fund's SAI and shareholder reports will be available free upon request from the applicable fund, and those documents and the Form N-CSR, Form N-Q and Form N-SAR may be viewed on-screen or downloaded from the Commission's website. In addition, with respect to the Funds, a large amount of information will be publicly available regarding the Funds and the Shares, thereby promoting market transparency. Quotation and last sale information for the Shares will be available via the CTA high-speed line. Information regarding the intra-day value of the Shares of a

Fund, which is the VIIV as defined in proposed NYSE Arca Rule 8.900-E (c)(3), will be widely disseminated every second throughout the Exchange's Core Trading Session by one or more major market data vendors. The website for the Funds will include a form of the prospectus for the Funds that may be downloaded, and additional data relating to NAV and other applicable quantitative information, updated on a daily basis. Moreover, prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Trading in Shares of a Fund will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12-E have been reached or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Trading in the Shares will be subject to NYSE Arca Rule 8.900-E (d)(2)(C), which sets forth circumstances under which Shares of the Funds will be halted. In addition, as noted above, investors will have ready access to the VIIV, and quotation and last sale information for the Shares. The Shares will conform to the initial and continued listing criteria under proposed Rule 8.900-E. The Funds will not invest in futures, forwards or swaps. Each Fund's investments will be consistent with its investment objective and will not be used to enhance leverage. While a Fund may invest in inverse ETFs, a Fund will not invest in leveraged (e.g., 2X, -2X, 3X or -3X) ETFs. The Funds will not invest in non-U.S. listed securities.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of actively-managed exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding the VIIV and quotation and last sale information for the Shares.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose

⁴⁴ Price correlation trading is used throughout the financial industry. It is used to discover both trading opportunities to be exploited, such as currency pairs and statistical arbitrage, as well as for risk mitigation such as dispersion trading and beta hedging. These correlations are a function of differentials, over time, between one or multiple securities pricing. Once the nature of these price deviations have been quantified, a universe of securities is searched in an effort to, in the case of a hedging strategy, minimize the differential. Once a suitable hedging basket has been identified, a trader can minimize portfolio risk by executing the hedging basket. The trader then can monitor the performance of this hedge throughout the trade period, making corrections where warranted.

⁴⁵ With respect to trading in Shares of the Funds, market participants would manage risk in a variety of ways. It is expected that market participants will be able to determine how to trade Shares at levels approximating the VIIV without taking undue risk by gaining experience with how various market factors (e.g., general market movements, sensitivity of the VIIV to intraday movements in interest rates or commodity prices, etc.) affect VIIV, and by finding hedges for their long or short positions in Shares using instruments correlated with such factors. The Adviser expects that market participants will initially determine the VIIV's correlation to a major large capitalization equity benchmark with active derivative contracts, such as the Russell 1000 Index, and the degree of sensitivity of the VIIV to changes in that benchmark. For example, using hypothetical numbers for illustrative purposes, market participants should be able to determine quickly that price movements in the Russell 1000 Index predict movements in a Fund's VIIV 95% of the time (an acceptably high correlation) but that the VIIV generally moves approximately half as much as the Russell 1000 Index with each price movement. This information is sufficient for market participants to construct a reasonable hedge—buy or sell an amount of futures, swaps or ETFs that track the Russell 1000 equal to half the opposite exposure taken with respect to Shares. Market participants will also continuously compare the intraday performance of their hedge to a Fund's VIIV. If the intraday performance of the hedge is correlated with the VIIV to the expected degree, market participants will feel comfortable they are appropriately hedged and can rely on the VIIV as appropriately indicative of a Fund's performance.

⁴⁶ The statements in the Statutory Basis section of this filing relating to pricing efficiency, arbitrage, and activities of market participants, including market makers and APs, are based on representations by the Adviser and review by the Exchange.

any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposed rule change would permit listing and trading of another type of actively-managed ETF that has characteristics different from existing actively-managed and index ETFs, and would introduce additional competition among various ETF products to the benefit of investors.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove the proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEArca-2018-04 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-NYSEArca-2018-04. 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](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-NYSEArca-2018-04 and should be submitted on or before February 16, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁷

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018-01364 Filed 1-25-18; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15434 and #15435; WASHINGTON Disaster Number WA-00069]

Administrative Declaration of a Disaster for the State of Washington

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an administrative declaration of a disaster for the state of Washington dated 01/18/2018.

Incident: Auburn Heritage Building Fire.

Incident Period: 12/26/2017.

DATES: Issued on 01/18/2018.

Physical Loan Application Deadline Date: 03/19/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 10/18/2018.

ADDRESSES: Submit completed loan applications to: U.S. Small Business

Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: King

Contiguous Counties:

Washington: Chelan, Kitsap, Kittitas, Pierce, Snohomish, Yakima

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	3.500
Homeowners without Credit Available Elsewhere	1.750
Businesses with Credit Available Elsewhere	6.770
Businesses without Credit Available Elsewhere	3.385
Non-Profit Organizations with Credit Available Elsewhere ...	2.500
Non-Profit Organizations without Credit Available Elsewhere	2.500
<i>For Economic Injury:</i>	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	3.385
Non-Profit Organizations without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 15434 5 and for economic injury is 15435 0.

The State which received an EIDL Declaration # is Washington.

(Catalog of Federal Domestic Assistance Number 59008)

Dated: January 18, 2018.

Linda E. McMahon,
Administrator.

[FR Doc. 2018-01399 Filed 1-25-18; 8:45 am]

BILLING CODE 8025-01-P

⁴⁷ 17 CFR 200.30-3(a)(12).

DEPARTMENT OF STATE**[Public Notice: 10288]****Meeting of the United States-Jordan Joint Forum on Environmental Technical Cooperation and Request for Comments on the Meeting Agenda and the 2018–2021 Work Program****AGENCY:** Department of State.**ACTION:** Announcement of meeting; solicitation of comments; invitation to public session.

SUMMARY: The Department of State is providing notice that the governments of the United States and the Hashemite Kingdom of Jordan (the governments) intend to hold a Joint Forum on Environmental Technical Cooperation (Joint Forum) and a public session in Amman, Jordan, on February 12, 2018.

The governments created the Joint Forum pursuant to the United States-Jordan Joint Statement on Environmental Technical Cooperation (Joint Statement) in concert with the United States-Jordan Free Trade Agreement (FTA), both concluded on October 24, 2000. During the Joint Forum, the governments will discuss how the United States and Jordan can cooperate to protect the environment, review past bilateral environmental cooperation, and approve a 2018–2021 Work Program on Environmental Technical Cooperation (Work Program). The Department of State invites members of the public to submit written comments on items to include on the meeting agenda or in the 2018–2021 Work Program.

The Department of State also invites interested persons to attend a public session to learn more about the work of the Joint Forum and the new Work Program and provide advice or comments on its implementation.

DATES: The public session will be held on February 12, 2018, in Amman, Jordan. Comments on the Joint Forum meeting agenda and/or the 2018–2021 Work Program should be provided no later than February 8, 2018, to facilitate consideration.

ADDRESSES: Those interested in attending the public session should email Tiffany Prather at PratherTA@state.gov. Comments on the Joint Forum meeting agenda and/or the 2018–2021 Work Program should be emailed to PratherTA@state.gov or faxed to Tiffany Prather at (202) 647–5947, with the subject line “United States-Jordan Environmental Cooperation.”

FOR FURTHER INFORMATION CONTACT: Tiffany Prather, (202) 647–4548.

SUPPLEMENTARY INFORMATION: The United States and Jordan announced the establishment of the Joint Forum in the Joint Statement done on October 24, 2000, along with the FTA. The Joint Forum meets regularly and advances environmental protection in Jordan by developing technical cooperation initiatives, which take into account environmental priorities, and which are agreed to by the governments.

The Joint Forum has met four times since 2000, in 2004, 2009, 2012, and 2014, and issued Work Programs to implement the Joint Statement. The United States anticipates the 2018–2021 Work Program will build upon this prior cooperation.

Members of the public, including non-governmental organizations, educational institutions, private sector enterprises, and all other interested persons, are invited to submit written comments regarding items for inclusion in the meeting agenda or in the new Work Program. Please include your full name and identify any organization or group you represent. We encourage submitters to refer to:

- United States-Jordan Joint Statement on Environmental Technical Cooperation;
- United States-Jordan 2014–2017 Work Program on Environmental Technical Cooperation;
- United States-Jordan 2012–2013 Work Program on Environmental Technical Cooperation;
- United States-Jordan 2008–2011 Work Program on Environmental Technical Cooperation;
- Article 5 of the United States-Jordan Free Trade Agreement; and
- Environmental Review of the United States-Jordan Free Trade Agreement.

These documents are available at: <http://www.state.gov/e/oes/eqt/trade/jordan/index.htm>.

Carol Volk,

Acting Director, Office of Environmental Quality and Transboundary Issues, U.S. Department of State.

[FR Doc. 2018–01458 Filed 1–25–18; 8:45 am]

BILLING CODE 4710–09–P**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****Twenty Third Meeting of the NextGen Advisory Committee (NAC)**

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

ACTION: Twenty Third Meeting of the NextGen Advisory Committee (NAC).

SUMMARY: The FAA is issuing this notice to advise the public of the Twenty Third Meeting of the NextGen Advisory Committee. The NAC is a subcommittee to RTCA.

DATES: The meeting will be held March 14, 2018, 9:00 a.m.–2:00 p.m.

ADDRESSES: The meeting will be held at: Harris Corporation, 1395 Troutman Blvd., Palm Bay, FL 32905.

FOR FURTHER INFORMATION CONTACT: Andy Cebula, NAC Secretariat, 202–330–0652, acebula@rtca.org, 1150 18th Street NW, Suite 910, Washington, DC 20036, or by fax at (202) 833–9434, or website at <http://www.rtca.org>.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Twenty Third Meeting of the NextGen Advisory Committee (NAC). The agenda will include the following:

March 14, 2018, 9:00 a.m.–2:00 p.m.

1. Opening of Meeting/Introduction of NAC Members—Chairman David Bronczek
2. Official Statement of Designated Federal Officer—Dan Elwell, FAA Acting Administrator
3. Review and Approval of October 4, 2017 Meeting Summary
4. Chairman’s Report—Chairman Bronczek
5. FAA Report—FAA
6. NextGen Priorities Status—NextGen Integration Working Group (NIWG) Northeast Corridor Phase Two; Action Item: Consideration for Approval of Northeast Corridor Phase Two Report
7. NextGen Priorities Status—NextGen Integration Working Group (NIWG): Data Communications, Multiple Runway Operations (including Wake ReCategorization), Performance Based Navigation (PBN), Surface Operations & Data Sharing
8. Comm/Nav/Surveillance Equipage Status
9. Drone Advisory Committee Report
10. Other Business
11. Summary of Meeting and Next Steps
12. Closing Comments—DFO and NAC Chairman
13. Adjourn

In order to attend the NAC Meeting at Harris Corporation, you must complete the registration and security form at <https://www.harris.com/event-registration/nac-meetingpublic> by February 27, 2018. Due to security requirements, all guests must provide credentials in advance to attend the event. Please enter your complete name

as it appears on your government-issued photo identification (U.S. driver's license or passport for non-U.S. citizens). Federal PIV cards will not be accepted as a valid form of identification. You will need to show the same identification upon check-in. Please contact HTC@harris.com should you have questions or difficulties with the form. (This submission form is encrypted to protect your personal information.)

With the approval of the Chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on January 23, 2018.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG-A17 NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2018-01481 Filed 1-25-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-1999-5578; FMCSA-1999-5748; FMCSA-2000-7918; FMCSA-2004-17984; FMCSA-2005-20027; FMCSA-2005-20560; FMCSA-2005-21254; FMCSA-2005-21711; FMCSA-2007-27897; FMCSA-2007-29019; FMCSA-2009-0086; FMCSA-2009-0206; FMCSA-2011-0057; FMCSA-2011-0124; FMCSA-2011-0189; FMCSA-2013-0029; FMCSA-2014-0298; FMCSA-2014-0302; FMCSA-2014-0304; FMCSA-2015-0055; FMCSA-2015-0056]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 60 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirements in one eye.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in

the discussions below. Comments must be received on or before February 26, 2018.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, 202-366-4001, fmcamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA-1999-5578; FMCSA-1999-5748; FMCSA-2000-7918; FMCSA-2004-17984; FMCSA-2005-20027; FMCSA-2005-20560; FMCSA-2005-21254; FMCSA-2005-21711; FMCSA-2007-27897; FMCSA-2007-29019; FMCSA-2009-0086; FMCSA-2009-0206; FMCSA-2011-0057; FMCSA-2011-0124; FMCSA-2011-0189; FMCSA-2013-0029; FMCSA-2014-0298; FMCSA-2014-0302; FMCSA-2014-0304; FMCSA-2015-0055; FMCSA-2015-0056 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.
- *Hand Delivery:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal Holidays.
- *Fax:* 1-202-493-2251.

Instructions: Each submission must include the Agency name and the docket number(s) for this notice. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to <http://www.regulations.gov> at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day,

e.t., 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments online.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for five years if it finds “such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.” The statute also allows the Agency to renew exemptions at the end of the five-year period. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding vision found in 49 CFR 391.41(b)(10) states that a person is physically qualified to driver a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

The 60 individuals listed in this notice have requested renewal of their exemptions from the vision standard in 49 CFR 391.41(b)(10), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable two-year period.

II. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of

the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

III. Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 60 applicants has satisfied the renewal conditions for obtaining an exemption from the vision requirement (64 FR 27027; 64 FR 40404; 64 FR 51568; 64 FR 66962; 65 FR 66286; 66 FR 13825; 66 FR 63289; 68 FR 13360; 68 FR 64944; 69 FR 33997; 69 FR 61292; 70 FR 12265; 70 FR 16887; 70 FR 17504; 70 FR 2701; 70 FR 30997; 70 FR 30999; 70 FR 46567; 70 FR 48797; 70 FR 61493; 70 FR 67776; 71 FR 55820; 72 FR 11426; 72 FR 39879; 72 FR 40359; 72 FR 40362; 72 FR 52419; 72 FR 54971; 72 FR 58362; 72 FR 62896; 72 FR 64273; 72 FR 67344; 73 FR 65009; 74 FR 19267; 74 FR 28094; 74 FR 34074; 74 FR 34394; 74 FR 41971; 74 FR 43217; 74 FR 43221; 74 FR 49069; 74 FR 57551; 74 FR 57553; 74 FR 62632; 74 FR 8302; 76 FR 12216; 76 FR 18824; 76 FR 29024; 76 FR 32016; 76 FR 34136; 76 FR 4413; 76 FR 44653; 76 FR 53708; 76 FR 54530; 76 FR 55463; 76 FR 55465; 76 FR 62143; 76 FR 66123; 76 FR 67246; 76 FR 70212; 76 FR 70215; 78 FR 18667; 78 FR 32703; 78 FR 34143; 78 FR 52602; 78 FR 64280; 78 FR 77782; 78 FR 78477; 79 FR 24298; 79 FR 4531; 79 FR 69985; 80 FR 12248; 80 FR 14223; 80 FR 16500; 80 FR 25768; 80 FR 29152; 80 FR 33011; 80 FR 44188; 80 FR 50917; 80 FR 53383; 80 FR 59225; 80 FR 59230; 80 FR 62161; 80 FR 8927; 81 FR 1284). They have submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements. These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315, the following groups of drivers received renewed exemptions in the month of November and are discussed below:

As of November 3, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 31 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (65 FR 66286; 66 FR 13825; 68 FR 13360; 70 FR 12265; 70 FR 16887; 70 FR 2701; 70 FR 30999; 70 FR 46567; 70 FR 48797; 70 FR 61493; 72 FR 11426; 72 FR 40359; 72 FR 54971; 72 FR 62896; 74 FR 19267; 74 FR 28094; 74 FR 34074; 74 FR 43221; 74 FR 49069; 74 FR 8302; 76 FR 12216; 76 FR 32016; 76 FR 44653; 76 FR 53708; 76 FR 62143; 78 FR 18667; 78 FR 32703; 78 FR 34143; 78 FR 52602; 78 FR 77782; 78 FR 78477; 79 FR 4531; 79 FR 69985; 80 FR 12248; 80 FR 14223; 80 FR 16500; 80 FR 25768; 80 FR 29152; 80 FR 33011; 80 FR 44188; 80 FR 50917; 80 FR 53383; 80 FR 59225; 80 FR 59230; 80 FR 62161; 80 FR 8927; 81 FR 1284):

Steven B. Anderson (ID)
Harjot S. Aujla (WA)
Gregory W. Babington (MA)
Brian M. Bowman (TN)
Robert J. Burns (KY)
Kevin R. Cowger (ID)
Kenneth D. Daniels (PA)
Mark P. Davis (ME)
Kenneth W. Dunn (TN)
John A. Gartner (MN)
Elias Gomez, Jr. (TX)
Keith N. Hall (UT)
Steven E. Hayes (IN)
Amos S. Hostetter (OH)
Stephen C. Linardos (FL)
Daniel C. Linares (CA)
Ray J. Liner (LA)
Robert E. Mayers (MN)
Ross E. McCleary (NE)
James G. Miles (TN)
Pablo R. Murillo (TX)
Vincent E. Perkins (MA)
Alonzo K. Rawls (NJ)
Berry A. Rodrigue (LA)
Roger D. Rogers (PA)
Juan M. Rosas (AZ)
Dale R. Sweigart (PA)
Charles D. Theademan (WA)
Arnulfo J. Valenzuela (TX)
Danny L. Watson (TN)
William E. Zzulka (MN)

The drivers were included in docket numbers FMCSA-2000-7918; FMCSA-2005-20027; FMCSA-2005-21254; FMCSA-2005-21711; FMCSA-2009-0086; FMCSA-2013-0029; FMCSA-2014-0298; FMCSA-2014-0302; FMCSA-2014-0304; FMCSA-2015-0055; FMCSA-2015-0056. Their exemptions are applicable as of November 3, 2017, and will expire on November 3, 2019.

As of November 6, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 13 individuals

have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (70 FR 17504; 70 FR 30997; 70 FR 48797; 70 FR 61493; 72 FR 39879; 72 FR 40362; 72 FR 52419; 72 FR 54971; 74 FR 34394; 74 FR 41971; 74 FR 43217; 74 FR 49069; 74 FR 57551; 76 FR 18824; 76 FR 29024; 76 FR 34136; 76 FR 54530; 76 FR 55463; 76 FR 55465; 76 FR 66123; 76 FR 67246; 78 FR 34143; 78 FR 52602; 78 FR 77782; 78 FR 78477; 79 FR 24298; 80 FR 63869):

James J. Doan (PA)
James E. Fix (SC)
James P. Greene (NY)
Michael A. Lawson (KY)
Steven R. Lechtenberg (NE)
Joseph L. Mast (OR)
Jesse R. McClary, Sr. (MO)
Roy L. Morgan (IL)
Steven D. O'Donnell (NJ)
Gerald J. Shamla (MN)
Halman Smith (DE)
Jerry W. Stanfill (AR)
Scott C. Teich (MN)

The drivers were included in docket numbers FMCSA-2005-20560; FMCSA-2005-21711; FMCSA-2007-27897; FMCSA-2009-0206; FMCSA-2011-0057; FMCSA-2011-0124; FMCSA-2011-0189; FMCSA-2013-0029. Their exemptions are applicable as of November 6, 2017, and will expire on November 6, 2019.

As of November 28, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following eight individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (69 FR 33997; 69 FR 61292; 70 FR 48797; 70 FR 61493; 71 FR 55820; 72 FR 54971; 72 FR 58362; 72 FR 67344; 73 FR 65009; 74 FR 49069; 74 FR 57553; 76 FR 4413; 76 FR 70212; 80 FR 63869):

Robert W. Bequeaith (IA)
Clarence N. Florey, Jr. (PA)
Loren H. Geiken (SD)
Michael A. Hershberger (OH)
Patrick J. Hogan, Jr. (DE)
Amilton T. Monterio (MA)
David G. Oakley (SC)
Brent L. Seaux (LA)

The drivers were included in docket numbers FMCSA-2004-17984; FMCSA-2005-21711; FMCSA-2007-29019. Their exemptions are applicable as of November 28, 2017, and will expire on November 28, 2019.

As of November 30, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following eight individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (64 FR 27027; 64

FR 40404; 64 FR 51568; 64 FR 66962; 66 FR 63289; 68 FR 64944; 70 FR 48797; 70 FR 61493; 70 FR 67776; 72 FR 64273; 74 FR 62632; 76 FR 70215; 78 FR 64280; 80 FR 63869);

Terry J. Aldrige (MS)
Lennie D. Baker, Jr. (NC)
Jerry D. Bridges (TX)
Gary R. Gutschow (WI)
James J. Hewitt (WI)
James R. Murphy (NY)
Thomas E. Walsh (CA)
Kevin P. Weinhold (MA)

The drivers were included in docket numbers FMCSA–1999–5578; FMCSA–2005–21711. Their exemptions are applicable as of November 30, 2017, and will expire on November 30, 2019.

IV. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must undergo an annual physical examination (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a certified Medical Examiner, as defined by 49 CFR 390.5, who attests that the driver is otherwise physically qualified under 49 CFR 391.41; (2) each driver must provide a copy of the ophthalmologist's or optometrist's report to the Medical Examiner at the time of the annual medical examination; and (3) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file or keep a copy of his/her driver's qualification if he/her is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

V. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VI. Conclusion

Based upon its evaluation of the 60 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the vision requirement in 49 CFR 391.41(b)(10), subject to the

requirements cited above. In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for two years unless revoked earlier by FMCSA.

Issued on: January 19, 2018.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2018–01401 Filed 1–25–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2017–0342]

Hours of Service of Drivers: Application for Exemption; SikhsPAC and the North American Punjabiz Trucker Association

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that it has received a joint application from SikhsPAC and the North American Punjabiz Trucker Association (applicants) on behalf of their members for an exemption from the electronic logging device (ELD) requirements. The exemption would allow members involved in segments of America's agricultural transportation industry to delay using ELDs. The applicants expressed their concerns about how the ELD mandate would negatively impact their industry if the exemption is not granted. According to the applicants, granting the exemption would achieve a level of safety equivalent to the level achieved by the ELD mandate. FMCSA requests public comment on the applicants' application for exemption.

DATES: Comments must be received on or before February 26, 2018.

ADDRESSES: You may submit comments identified by Federal Docket Management System (FDMS) Number FMCSA–2017–0342 by any of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. See the *Public Participation and Request for Comments* section below for further information.

- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* 1–202–493–2251

- Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to www.regulations.gov, including any personal information included in a comment. Please see the *Privacy Act* heading below.

Docket: For access to the docket to read background documents or comments, go to www.regulations.gov at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line FDMS is available 24 hours each day, 365 days each year.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT: For information concerning this notice, contact Mr. Thomas Yager, Chief, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 614–942–6477. Email: MCPSPD@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2017–0342), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comments online, go to www.regulations.gov and put the docket number, “FMCSA–2017–0342”

in the "Keyword" box, and click "Search." When the new screen appears, click on "Comment Now!" button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period and may grant or not grant this application based on your comments.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Request for Exemption

In addition to this exemption request, applicants have filed a request for a delay in ELD enforcement and a request for an ELD waiver. Those issues are being addressed through separate processes and will not be discussed further in this notice.

The applicants request an exemption from the ELD requirements on behalf of their members (fresh produce shippers

and small truck businesses). According to the applicants, many of their members are not fully prepared to meet the December 18, 2017, compliance date. Additionally, the current ELD retail marketplace does not accommodate the needs of the applicant's industry segment, and does not factor in existing HOS exemptions currently used by members. The applicants question whether any ELD self-certified device would fully function given the lack of access to broadband in many rural areas. The applicants also expressed their concern about ELD security against cyberattacks, enforcement, cost, and training.

The applicants assert that the exemption, if granted, would give the marketplace time necessary to develop cost-effective and practical solutions for the specific needs of impacted stakeholders and would allow FMCSA to properly address necessary training programs with compliant ELD options. The applicants believe that if the exemption is not granted the ELD rule will cause significant challenges and harm to fresh produce shippers and small truck businesses. According to the applicants, granting the exemption will achieve a level of safety equivalent to the level achieved by the ELD requirements.

A copy of the applicants' application for exemption is available for review in the docket for this notice.

Issued on: January 19, 2018.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2018-01402 Filed 1-25-18; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2017-0197]

Hours of Service of Drivers: National Asphalt Pavement Association, Inc.; Application for Exemptions

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition; grant of application for exemptions.

SUMMARY: FMCSA announces its decision to grant the National Asphalt Pavement Association, (Inc.) (NAPA) request for exemptions from two requirements of the hours-of-service (HOS) regulations for all drivers of certain commercial motor vehicles (CMVs): (1) The 30-minute rest break provision and (2) the requirement that

short-haul drivers utilizing the record of duty status (RODS) exception return to their work-reporting location within 12 hours of coming on duty. The first exemption will enable drivers engaged in the transportation of asphalt and related materials to use 30 minutes or more of on-duty "waiting time" to satisfy the requirement for the 30-minute rest break, provided they do not perform any other work during the break. The second exemption will allow these drivers to use the short-haul exception but return to their work-reporting location within 14 hours instead of the usual 12 hours.

DATES: This exemption is applicable January 26, 2018 and expires January 25, 2023.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Yager, Chief, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 614-942-6477. Email: MCPSD@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to www.regulations.gov and insert the docket number, FMCSA-2017-0197, in the "Keyword" box and click "Search." Next, click the "Open Docket Folder" button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from certain Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the

exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period (up to 5 years) and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Request for Exemptions

NAPA seeks two exemptions for all drivers transporting asphalt and related materials and equipment from the HOS 30-minute rest break provision in 49 CFR 395.3(a)(3)(ii) and the restriction of the RODS exception for short-haul operations available to drivers who return to their normal work-reporting location within 12 hours [49 CFR 395.1(e)(1)(ii)(A)].

NAPA requested the first exemption from the HOS rest break provision to allow drivers engaged in the transportation of asphalt and related materials to use 30 minutes or more of on-duty “waiting time” to satisfy the requirement for the 30-minute rest break, provided they do not perform any other work during the break. According to NAPA, asphalt is a highly perishable product. It is loaded into the delivery truck at 280–300 degrees Fahrenheit and begins to cool immediately. If the asphalt is not delivered and placed on the paving site within two hours, the product hardens and is no longer viscous enough to be useable. Drivers of asphalt delivery vehicles typically drive approximately one-third of their workday; the rest of their day is spent waiting to load or unload their vehicles and in other non-driving duties such as paperwork and cleaning their trucks after each load.

NAPA requested the second exemption to allow some drivers to use the short-haul RODS exception but with a 14-hour duty period instead of 12 hours. NAPA advises that while some short-haul drivers will be able to take advantage of the exception from the 30-minute break, other drivers are often required to be on duty more than 12 hours in a day and therefore are not eligible to use the short-haul exception.

NAPA mentioned that drivers of ready-mixed concrete delivery vehicles were granted an exemption from the minimum 30-minute rest break

provision.¹ NAPA states that “the same reasoning supporting the exemptions from the 30-minute break time rule and allowing a 14-hour daily on duty-period for drivers of ready-mixed concrete vehicles applies to drivers engaged in the transportation of asphalt and related materials and equipment. Both are perishable products that are not useable if they are not dropped and spread within a brief delivery window. Because of this short delivery window, the routes from the production facility to the delivery site for both products are limited to less than 40 miles, and the time spent actually driving a CMV is typically only a few hours per day. Thus in both cases, the drivers do not face the same fatigue factors as drivers of long-haul trucks, and therefore do not pose the same risk of a fatigue-related accident as long-haul drivers.”

NAPA requested that the operation of certain vehicles and equipment (Water Truck, Tack (tar) Distributor, Equipment Hauler and Pick-Sweeper (Street Sweeper)) be included in the definition of “transportation of asphalt and related materials and equipment” for purposes of these exemptions.

NAPA stated in its application that drivers would remain subject to the HOS regulations and would receive sufficient rest due to the nature of their operations that limit driving to an average of six to seven hours per day or less during the paving season. NAPA believes that granting these exemptions would achieve the same level of safety provided by the two HOS rules. The requested exemptions are for 5 years with renewals. A copy of NAPA’s application for exemptions is available for review in the docket for this notice.

V. Public Comments

On September 7, 2017, FMCSA published notice of this application and requested public comment (82 FR 42415). The Agency received 70 comments representing individuals and various transportation interests in response to the proposed exemptions. The majority of the respondents in

support of the requested exemptions were companies, associations, and individuals affiliated with the asphalt industry.

For example, Nu Rock Asphalt Coatings supported the exemptions and stated, “[i]t seems it would be advantageous for those involved in asphalt work to have HOS regulations in line with those found in the ready-mix concrete business. We feel this could be done without compromising safety.”

Wiregrass Construction wrote, “[s]ince the ready-mix industry parallels the asphalt industry in terms of operational limitations with highly perishable, nonhazardous product, it seems perfectly logical that the asphalt industry should be subject to the same exemption from the 30 minute break requirement and 12 hour limit on Short Haul Exception.”

NAPA was among the many respondents commenting about its application and wrote to specifically clarify the record and provide additional comment concerning its application. NAPA explained that their petition for relief from the specific HOS requirements were not restricted to NAPA members and also provided additional rationale to support the need for both exemptions.

Four respondents made comments about the regulations but took no position on the application. One individual, Mr. Richard Elliott, wrote, “I do not oppose them using wait time in line as the 30 minute rest period but I do oppose extending any duty hours or exceptions.”

An anonymous respondent and the Advocates for Highway and Auto Safety (Advocates) opposed the requested exemptions. Advocates provided several reasons for not granting the exemptions. According to Advocates, “the Application seeks to exempt an untold number of motor carriers and drivers from safety regulations and provides no justification for the exemptions requested.”

VI. FMCSA Decision

FMCSA has evaluated NAPA’s application and the public comments and decided to grant the exemptions. The Agency believes that all drivers transporting asphalt and related materials and equipment will likely achieve a level of safety that is equivalent to or greater than, the level of safety achieved without the exemption [49 CFR 381.305(a)].

The first exemption from the HOS 30-minute break provision will allow drivers engaged in the transportation of asphalt and related materials to use 30 minutes or more of on-duty “waiting

¹ More precisely, section 5521 of the Fixing America’s Surface Transportation (FAST) Act, exempts a “driver of a ready mixed concrete delivery vehicle” from the reporting, recordkeeping, or documentation requirements under the hours-of-service regulations if the driver operates within a 100 air-mile radius of his/her normal work reporting location, returns to the work reporting location and is released within 14 hours, and meets certain other requirements [Pub. L. 114–94, 129 Stat. 1312, 1559, Dec. 4, 2015, codified at 49 U.S.C. 31502(f)]. In addition, FMCSA granted drivers of ready mixed concrete trucks an exemption from the 30-minute break requirement [80 FR 17819, April 2, 2015], which section 5206(b)(1)(A) of the FAST Act required to be made permanent [129 Stat. 1312, 1537].

time” to satisfy the requirement for the 30-minute rest break, provided they do not perform any other work during the break. The second exemption will allow drivers to use the short-haul RODS exception but with a 14-hour duty period instead of 12 hours.

VII. Terms and Conditions for the Exemption

- Drivers must have a copy of this notice or equivalent signed FMCSA exemption document in their possession while operating under the terms of the exemptions. The exemption document must be presented to law enforcement officials upon request.

- Drivers must return to the work reporting location and be released from work within 14 consecutive hours.

Preemption

In accordance with 49 U.S.C. 31315(d), during the period these exemptions are in effect, no State shall enforce any law or regulation that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemptions.

Notification to FMCSA

Exempt motor carriers must notify FMCSA within 5 business days of any accident (as defined in 49 CFR 390.5), involving any of its CMVs operating under the terms of the exemptions. The notification must include the following information:

- Name of the exemption: “NAPA”
- Name of the operating motor carrier,
- Date of the accident,
- City or town, and State, in which the accident occurred, or closest to the accident scene,
- Driver’s name and license number,
- Vehicle number and State license number,
- Number of individuals suffering physical injury,
- Number of fatalities,
- The police-reported cause of the accident,
- Whether the driver was cited for violation of any traffic laws, motor carrier safety regulations, and
- The driver’s total driving time and total on-duty time period prior to the accident.

Reports filed under this provision shall be emailed to MCPSD@DOT.GOV.

Termination

FMCSA does not believe the drivers covered by this exemption will experience any deterioration of their safety record.

Interested parties or organizations possessing information that would

otherwise show that any or all of these motor carriers are not achieving the requisite statutory level of safety should immediately notify FMCSA. The Agency will evaluate any information submitted and, if safety is being compromised or if the continuation of the exemptions are inconsistent with 49 U.S.C. 31315(b)(4) and 31136(e), FMCSA will immediately take steps to revoke the exemptions of the company or companies and drivers in question.

Issued on: January 19, 2018.

Cathy F. Gautreaux,
Deputy Administrator.

[FR Doc. 2018–01400 Filed 1–25–18; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2016–0128]

Pipeline Safety: Meeting of the Voluntary Information-Sharing System Working Group

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice.

SUMMARY: This notice announces a public meeting of the Voluntary Information-Sharing System (VIS) Working Group. The VIS Working Group will convene to discuss and identify recommendations to establish a voluntary information-sharing system.

DATES: The meeting will be held on February 28, 2018, from 8:30 a.m. to 5:00 p.m. ET. Members of the public who wish to attend in person should register no later than February 23, 2018. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, may notify PHMSA by February 23, 2018. For additional information, see the **ADDRESSES** section.

ADDRESSES: The meeting will be held at a location yet to be determined in the Washington, DC Metropolitan area. The meeting location, agenda and any additional information will be published on the following VIS Working Group and registration page at: <https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=130>. The meetings will not be webcast; however, presentations will be available on the meeting website and posted on the E-Gov website, <https://www.regulations.gov/>, under docket number PHMSA–2016–0128 within 30 days following the meeting.

Public Participation: These meetings will be open to the public. Members of the public who attend in person will also be provided an opportunity to make a statement during the meetings.

Written comments: Persons who wish to submit written comments on the meetings may submit them to the docket in the following ways:

E-Gov website: <https://www.regulations.gov>. This site allows the public to enter comments on any **Federal Register** notice issued by any agency.

Fax: 1–202–493–2251.

Mail: Docket Management Facility; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590–0001.

Hand Delivery: Room W12–140 on the ground level of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except on Federal holidays.

Instructions: Identify the docket number PHMSA–2016–0128 at the beginning of your comments. Note that all comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided.

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). Therefore, consider reviewing DOT’s complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, (65 FR 19477), or view the Privacy Notice at <https://www.regulations.gov> before submitting comments.

Docket: For docket access or to read background documents or comments, go to <https://www.regulations.gov> at any time or to Room W12–140 on the ground level of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 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 PHMSA–2016–0128.” The docket clerk will date stamp the postcard prior to returning it to you via the U.S. mail.

Privacy Act Statement

In accordance with 5 U.S.C. 553(c), the DOT solicits comments from the public to better inform its rulemaking process. The DOT posts these

comments, without edit, including any personal information the commenter provides, to www.regulations.gov as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

Services for Individuals with Disabilities: The public meeting will be physically accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Cheryl Whetsel at cheryl.whetsel@dot.gov.

FOR FURTHER INFORMATION CONTACT: For information about the meeting, contact Cheryl Whetsel by phone at 202-366-4431 or by email at cheryl.whetsel@dot.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The VIS Working Group is a recently created advisory committee established in accordance with Section 10 of the Protecting our Infrastructure of Pipelines and Enhancing Safety Act of 2016 (Pub. L. 114-183), the Federal Advisory Committee Act of 1972 (5 U.S.C., App. 2, as amended), and 41 CFR 102-3.50(a).

II. Meeting Details and Agenda

The VIS Working Group agenda will include briefings on topics such as mandate requirements, integrity management, data types and tools, in-line inspection repair and other direct assessment methods, geographic information system implementation, subcommittee considerations, lessons learned, examples of existing information-sharing systems, safety management systems, and more. As part of its work, the committee will ultimately provide recommendations to the Secretary, as required and specifically outlined in Section 10 of Public Law 114-183, addressing:

(a) The need for, and the identification of, a system to ensure that dig verification data are shared with in-line inspection operators to the extent consistent with the need to maintain proprietary and security-sensitive data in a confidential manner to improve pipeline safety and inspection technology;

(b) Ways to encourage the exchange of pipeline inspection information and the development of advanced pipeline inspection technologies and enhanced risk analysis;

(c) Opportunities to share data, including dig verification data between operators of pipeline facilities and in-line inspector vendors to expand

knowledge of the advantages and disadvantages of the different types of in-line inspection technology and methodologies;

(d) Options to create a secure system that protects proprietary data while encouraging the exchange of pipeline inspection information and the development of advanced pipeline inspection technologies and enhanced risk analysis;

(e) Means and best practices for the protection of safety and security-sensitive information and proprietary information; and

(f) Regulatory, funding, and legal barriers to sharing the information described in paragraphs (a) through (d).

The Secretary will publish the VIS Working Group's recommendations on a publicly available DOT website and in the docket. The VIS Working Group will fulfill its purpose once its recommendations are published online. PHMSA will publish the agenda on the PHMSA meeting page <https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=130>, once it is finalized.

Issued in Washington, DC, on January 23, 2018, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2018-01476 Filed 1-25-18; 8:45 am]

BILLING CODE 4910-60-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Joint Report: Differences in Accounting and Capital Standards Among the Federal Banking Agencies as of September 30, 2017; Report to Congressional Committees

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Report to Congressional Committees.

SUMMARY: The OCC, the Board, and the FDIC (collectively, the agencies) have prepared this report pursuant to section 37(c) of the Federal Deposit Insurance Act. Section 37(c) requires the agencies to jointly submit an annual report to the Committee on Financial Services of the

U.S. House of Representatives and to the Committee on Banking, Housing, and Urban Affairs of the U.S. Senate describing differences among the accounting and capital standards used by the agencies. Section 37(c) requires that this report be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

OCC: Benjamin Pegg, Risk Expert, Capital Policy, (202) 649-7146, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

Board: Elizabeth MacDonald, Manager, Capital and Regulatory Policy, (202) 475-6316, Division of Supervision and Regulation, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

FDIC: Benedetto Bosco, Chief, Capital Policy Section, (202) 898-6853, Division of Risk Management Supervision, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: The text of the report follows:

Report to the Committee on Financial Services of the U.S. House of Representatives and to the Committee on Banking, Housing, and Urban Affairs of the U.S. Senate Regarding Differences in Accounting and Capital Standards Among the Federal Banking Agencies

Introduction

Under section 37(c) of the Federal Deposit Insurance Act (section 37(c)), the Office of the Comptroller of the Currency (OCC), the Board of Governors of the Federal Reserve System (Board), and the Federal Deposit Insurance Corporation (FDIC) (collectively, the agencies) must jointly submit an annual report to the Committee on Financial Services of the U.S. House of Representatives and the Committee on Banking, Housing, and Urban Affairs of the U.S. Senate that describes any differences among the accounting and capital standards established by the agencies for insured depository institutions (institutions).¹

In accordance with section 37(c), the agencies are submitting this joint report, which covers differences among their accounting or capital standards existing as of September 30, 2017, applicable to institutions. In recent years, the agencies have acted together to harmonize their accounting and capital standards and eliminate as many

¹ See 12 U.S.C. 1831n(c). This report must be published in the **Federal Register**. See 12 U.S.C. 1831n(c)(3).

differences as possible. As of September 30, 2017, the agencies have not identified any material differences among themselves in the accounting standards applicable to institutions.

In 2013, the agencies revised the risk-based and leverage capital rules for institutions (capital rules),² which harmonized the agencies' capital rules in a comprehensive manner.³ Only a few differences remain, which are statutorily mandated for certain categories of institutions or which reflect certain technical, generally nonmaterial differences among the agencies' capital rules.

As revised in 2013, the agencies' capital rules generally have increased the quantity and quality of regulatory capital. For example, these revised capital rules include a minimum common equity tier 1 capital ratio of 4.5 percent, raise the minimum tier 1 capital ratio from 4 percent to 6 percent, and establish additional capital buffer amounts for institutions: The capital conservation buffer, and, for advanced approaches institutions,⁴ the countercyclical capital buffer. These revised capital rules also require all institutions to meet a 4 percent minimum leverage ratio measured as an institution's tier 1 capital to average total consolidated assets (generally applicable leverage ratio) and require advanced approaches institutions to meet a 3 percent minimum supplementary leverage ratio, measured as an institution's tier 1 capital to the sum of on- and off-balance sheet exposures (supplementary leverage ratio).⁵

² See 78 FR 62018 (October 11, 2013) (final rule issued by the OCC and the Board); 78 FR 55340 (September 10, 2013) (interim final rule issued by the FDIC). The FDIC later issued its final rule in 79 FR 20754 (April 14, 2014). The agencies' respective capital rules are at 12 CFR part 3 (OCC), 12 CFR part 217 (Board), and 12 CFR part 324 (FDIC). These capital rules apply to institutions, as well as to certain bank holding companies, and savings and loan holding companies. 12 CFR 217.1(c).

³ The capital rules reflect the scope of each agency's regulatory jurisdiction. For example, the Board's capital rule includes requirements related to bank holding companies, savings and loan holding companies, and state member banks, while the FDIC's capital rule includes provisions for state nonmember banks and state savings associations, and the OCC's capital rule includes provisions for national banks and federal savings associations.

⁴ Generally, these are institutions, bank holding companies, and savings and loan holding companies that are subject to the capital rules with total consolidated assets of \$250 billion or more or total consolidated on-balance sheet foreign exposures of at least \$10 billion.

⁵ Under the auspices of the Federal Financial Institutions Examination Council, the agencies have developed the Consolidated Reports of Condition and Income, or "Call Report," where institutions report their respective capital and leverage ratios.

Differences in Capital Standards Among the Federal Banking Agencies

Below are summaries of the technical differences remaining among the capital standards of the agencies' capital rules.⁶

Definitions

The agencies' capital rules largely contain the same definitions.⁷ The differences that exist generally serve to accommodate the different scope of jurisdiction of each agency. Set forth below are two definitional differences among the agencies. Each agency's definitional provisions provide that a "corporate exposure is an exposure to a company that is not" one of 11 separate other types of exposures.⁸ The Board's capital rule provides that two additional items are not corporate exposures: a policy loan and a separate account.⁹ Unlike the OCC's and FDIC's capital rules, the Board's capital rule covers bank holding companies and savings and loan holding companies, which may engage in insurance underwriting activities¹⁰ in which institutions cannot engage,¹¹ and these additional items in the Board's capital rule are relevant for insurance underwriting activities. Thus, these additional items are only relevant to bank holding companies and savings and loan holding companies under the terms of the Board's capital rule.

The agencies' capital rules also have differing definitions of a pre-sold construction loan. All three agencies provide that a pre-sold construction loan means any "one-to-four family residential construction loan to a builder that meets the requirements of section 618(a)(1) or (2) of the Resolution Trust Corporation Refinancing, Restructuring, and Improvement Act of 1991 (12 U.S.C. 1831n), and, in addition to other criteria, the purchaser has not terminated the contract."¹² The Board's definition provides further clarification that, if a purchaser has terminated the contract, the institution must immediately apply a 100 percent risk weight to the loan and report the revised risk weight in the next quarterly Call Report.¹³ Similarly, if the purchaser has terminated the contract, the OCC and FDIC capital rules would immediately

⁶ Certain minor differences, such as terminology specific to each agency for the institutions that they supervise, are not included in this report.

⁷ See 12 CFR 3.2 (OCC); 12 CFR 217.2 (Board); 12 CFR 324.2 (FDIC).

⁸ *Id.*

⁹ 12 CFR 217.2. The Board's rule separately defines policy loan and separate account. *Id.*

¹⁰ 78 FR 62127 (October 11, 2013).

¹¹ See 12 U.S.C. 1831a.

¹² 12 CFR 3.2 (OCC), 12 CFR 217.2 (Board), 12 CFR 324.2 (FDIC).

¹³ 12 CFR 217.2.

disqualify the loan from receiving a 50 percent risk weight, and would apply a 100 percent risk weight to the loan. The change in risk weight would be reflected in the next quarterly Call Report. Thus, the minor wording difference between the agencies should have no practical consequence.

Capital Components and Eligibility Criteria for Regulatory Capital Instruments

While the capital rules generally provide uniform eligibility criteria for regulatory capital instruments, there are two textual differences among the agencies' capital rules. First, the OCC's and FDIC's capital rules require that additional tier 1 capital instruments not be subject to a "limit" imposed by the contractual terms governing the instrument, while the Board's capital rule does not include this requirement.¹⁴ Second, only the Board's capital rule states that "[s]tate member banks are subject to certain other legal restrictions on reductions in capital resulting from cash dividends, including out of the capital surplus account, under 12 U.S.C. 324 and 12 CFR 208.5."¹⁵ The Board's capital rule also includes similar language relating to distributions on additional tier 1 capital instruments.¹⁶ However, the agencies apply the criteria for determining eligibility of regulatory capital instruments to ensure consistent outcomes.

Capital Deductions

There is a technical difference between the FDIC's capital rule and the OCC's and Board's capital rules with regard to an explicit requirement for deduction of examiner-identified losses. The agencies require their examiners to determine whether their respective supervised institutions have appropriately identified losses. The FDIC's capital rule, however, explicitly requires FDIC-supervised institutions to deduct identified losses from common equity tier 1 capital elements, to the extent that the institution's common equity tier 1 capital would have been reduced if the appropriate accounting entries had been recorded.¹⁷ Generally, identified losses are those items that an examiner determines to be chargeable against income, capital, or general valuation allowances.

For example, identified losses may include, among other items, assets

¹⁴ 12 CFR 3.20 (OCC); 12 CFR 217.20 (Board); 12 CFR 324.20 (FDIC).

¹⁵ 12 CFR 217.20.

¹⁶ *Id.*

¹⁷ 12 CFR 324.22(a)(9).

classified as loss, off-balance-sheet items classified as loss, any expenses that are necessary for the institution to record in order to replenish its general valuation allowances to an adequate level, and estimated losses on contingent liabilities. The Board and the OCC expect their supervised institutions to promptly recognize examiner-identified losses, but the requirement is not explicit under their capital rules. Instead, the Board and the OCC apply their supervisory authorities to ensure that their supervised institutions charge off any identified losses.

Subsidiaries of Savings Associations

There are special statutory requirements for the agencies' capital treatment of a savings association's investment in or credit to its subsidiaries as compared with the capital treatment of such transactions between other types of institutions and their subsidiaries. Specifically, the Home Owners' Loan Act (HOLA) distinguishes between subsidiaries of savings associations engaged in activities that are permissible for national banks and those engaged in activities that are not permissible for national banks.¹⁸ When subsidiaries of a savings association are engaged in activities that are not permissible for national banks,¹⁹ the parent savings association generally must deduct the parent's investment in and extensions of credit to these subsidiaries from the capital of the parent savings association. If a subsidiary of a savings association engages solely in activities permissible for national banks, no deduction is required and investments in and loans to that organization may be assigned the risk weight appropriate for the activity.²⁰ As the appropriate federal banking agencies for federal and state savings associations, respectively, the OCC and the FDIC apply this capital treatment to those types of institutions. The Board's regulatory capital framework does not apply to savings associations and therefore does not include this requirement.

Tangible Capital Requirement

Federal statutory law subjects savings associations to a specific tangible capital requirement but does not similarly do so with respect to banks. Under section

5(t)(2)(B) of HOLA, savings associations are required to maintain tangible capital in an amount not less than 1.5 percent of total assets.²¹ The capital rules of the OCC and the FDIC include a requirement that covered savings associations maintain a tangible capital ratio of 1.5 percent.²² This statutory requirement does not apply to banks and, thus, there is no comparable regulatory provision for banks. The distinction is of little practical consequence, however, because under the Prompt Corrective Action (PCA) framework, all institutions are considered critically undercapitalized if their tangible equity falls below 2 percent of total assets.²³ Generally speaking, the appropriate federal banking agency must appoint a receiver within 90 days after an institution becomes critically undercapitalized.²⁴

Enhanced Supplementary Leverage Ratio

The agencies adopted enhanced supplementary leverage ratio standards that take effect beginning on January 1, 2018.²⁵ These standards require certain bank holding companies to exceed a 5 percent supplementary leverage ratio to avoid limitations on distributions and certain discretionary bonus payments and also require the subsidiary institutions of these bank holding companies to meet a 6 percent supplementary leverage ratio to be considered "well capitalized" under the PCA framework.²⁶ The rule text establishing the scope of application for the enhanced supplementary leverage ratio differs among the agencies. However, the distinction is of little practical consequence at this time because the rules of each agency apply the enhanced supplementary leverage ratio to the same set of bank holding companies. The Board applies the enhanced supplementary leverage ratio standards to bank holding companies identified as global systemically important bank holding companies as defined in 12 CFR 217.2 and those bank holding companies' Board-supervised, institution subsidiaries.²⁷ The OCC and the FDIC apply enhanced

supplementary leverage ratio standards to the institution subsidiaries under their supervisory jurisdiction of a top-tier bank holding company that has more than \$700 billion in total assets or more than \$10 trillion in assets under custody.²⁸

Dated: January 11, 2018.

Grace E. Dailey,

Senior Deputy Comptroller and Chief, National Bank Examiner, Office of the Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System, January 11, 2018.

Ann E. Misback,

Secretary of the Board.

Dated at Washington, DC, this 19th day of January 2018.

By order of the Board of Directors, Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2018-01434 Filed 1-25-18; 8:45 am]

BILLING CODE 4810-33-P; 6210-01-P; 6714-01-P

UNITED STATES SENTENCING COMMISSION

Sentencing Guidelines for United States Courts

AGENCY: United States Sentencing Commission.

ACTION: Notice of proposed amendments to sentencing guidelines, policy statements, and commentary. Request for public comment, including public comment regarding retroactive application of any of the proposed amendments. Notice of public hearing.

SUMMARY: Pursuant to section 994(a), (o), and (p) of title 28, United States Code, the United States Sentencing Commission is considering promulgating amendments to the sentencing guidelines, policy statements, and commentary. This notice sets forth the proposed amendments and, for each proposed amendment, a synopsis of the issues addressed by that amendment. This notice also sets forth several issues for comment, some of which are set forth together with the proposed amendments, and one of which (regarding retroactive application of proposed amendments) is set forth in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: (1) *Written Public Comment.*—Written public comment regarding the proposed amendments and issues for comment set forth in this notice,

²¹ See 12 U.S.C. 1464(t)(1)(A)(ii) and (t)(2)(B).

²² See 12 CFR 3.10(a)(6) (OCC); 12 CFR 324.10(a)(6) (FDIC). The Board's regulatory capital framework does not apply to savings associations and, therefore, does not include this requirement.

²³ See 12 U.S.C. 1831o(c)(3); see also 12 CFR 6.4 (OCC); 12 CFR 208.45 (Board); 12 CFR 324.403 (FDIC).

²⁴ 12 U.S.C. 1831o(h)(3)(A).

²⁵ See 79 FR 24528 (May 1, 2014).

²⁶ See 12 CFR 6.4(c)(1)(iv)(B) (OCC); 12 CFR 208.43(b)(1)(iv)(B) (Board); 12 CFR 324.403(b)(1)(v) (FDIC).

²⁷ See 80 FR 49082 (August 14, 2015).

¹⁸ See 12 U.S.C. 1464(t)(5).

¹⁹ Subsidiaries engaged in activities not permissible for national banks are considered non-includable subsidiaries.

²⁰ A deduction from capital is only required to the extent that the savings association's investment exceeds the generally applicable thresholds for deduction of investments in the capital of an unconsolidated financial institution.

²⁸ See 12 CFR 6.4(c)(1)(iv)(B) (OCC); 12 CFR 324.403(b)(1)(v) (FDIC).

including public comment regarding retroactive application of any of the proposed amendments, should be received by the Commission not later than March 6, 2018. Written reply comments, which may only respond to issues raised during the original comment period, should be received by the Commission not later than March 28, 2018. Public comment regarding a proposed amendment received after the close of the comment period, and reply comment received on issues not raised during the original comment period, may not be considered.

(2) *Public Hearing.*—The Commission may hold a public hearing regarding the proposed amendments and issues for comment set forth in this notice. Further information regarding any public hearing that may be scheduled, including requirements for testifying and providing written testimony, as well as the date, time, location, and scope of the hearing, will be provided by the Commission on its website at www.ussc.gov.

ADDRESSES: All written comment should be sent to the Commission by electronic mail or regular mail. The email address for public comment is *PublicComment@ussc.gov*. The regular mail address for public comment is United States Sentencing Commission, One Columbus Circle NE, Suite 2–500, Washington, DC 20002–8002, Attention: Public Affairs.

FOR FURTHER INFORMATION CONTACT: Christine Leonard, Director, Office of Legislative and Public Affairs, (202) 502–4500, *pubaffairs@ussc.gov*.

SUPPLEMENTARY INFORMATION: The United States Sentencing Commission is an independent agency in the judicial branch of the United States Government. The Commission promulgates sentencing guidelines and policy statements for federal courts pursuant to 28 U.S.C. 994(a). The Commission also periodically reviews and revises previously promulgated guidelines pursuant to 28 U.S.C. 994(o) and submits guideline amendments to the Congress not later than the first day of May each year pursuant to 28 U.S.C. 994(p).

Publication of a proposed amendment requires the affirmative vote of at least three voting members of the Commission and is deemed to be a request for public comment on the proposed amendment. *See* USSC Rules of Practice and Procedure 2.2, 4.4. In contrast, the affirmative vote of at least four voting members is required to promulgate an amendment and submit it to Congress. *See id.* 2.2; 28 U.S.C. 994(p).

The proposed amendments in this notice are presented in one of two formats. First, some of the amendments are proposed as specific revisions to a guideline, policy statement, or commentary. Bracketed text within a proposed amendment indicates a heightened interest on the Commission's part in comment and suggestions regarding alternative policy choices; for example, a proposed enhancement of [2][4][6] levels indicates that the Commission is considering, and invites comment on, alternative policy choices regarding the appropriate level of enhancement. Similarly, bracketed text within a specific offense characteristic or application note means that the Commission specifically invites comment on whether the proposed provision is appropriate. Second, the Commission has highlighted certain issues for comment and invites suggestions on how the Commission should respond to those issues.

In summary, the proposed amendments and issues for comment set forth in this notice are as follows:

(1) A multi-part proposed amendment to § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy), including (A) amending the Drug Equivalency Tables in § 2D1.1 to (i) set forth a class-based marijuana equivalency applicable to synthetic cathinones (except Schedule III, IV, and V substances) of 1 gram = [200]/[380]/[500] grams of marijuana, bracketing the possibility of making this class-based marijuana equivalency also applicable to methcathinone, and (ii) establish a minimum base offense level of [12] for cases involving synthetic cathinones (except Schedule III, IV, and V substances), and related issues for comment; (B) amending the Drug Equivalency Tables in § 2D1.1 to (i) set forth a class-based marijuana equivalency applicable to synthetic cannabinoids (except Schedule III, IV, and V substances) of 1 gram = [167]/[334]/[500] grams of marijuana, (ii) provide a definition for the term “synthetic cannabinoid,” and (iii) bracket the possibility of establishing a minimum base offense level of [12] for cases involving synthetic cannabinoids (except Schedule III, IV, and V substances), and related issues for comment; and (C) amending § 2D1.1 to (i) provide penalties for offenses involving fentanyl equivalent to the higher penalties currently provided for offenses involving fentanyl analogues, (ii) provide a definition for the term “fentanyl analogue,” set forth a single marijuana equivalency applicable to

any fentanyl analogue of 1 gram = 10 kilograms of marijuana, and specify in the Drug Quantity Table that the penalties relating to “fentanyl” apply to the substance identified as “N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propenamide,” and (iii) provide an enhancement in cases in which fentanyl or a fentanyl analogue is misrepresented or marketed as another substance, and related issues for comment;

(2) a multi-part proposed amendment to § 2L1.2 (Unlawfully Entering or Remaining in the United States) to respond to miscellaneous guidelines application issues, including (A) amending § 2L1.2(b)(2) so that its applicability turns on whether the defendant “engaged in criminal conduct” before he or she was ordered deported or ordered removed from the United States for the first time, rather than whether the defendant sustained the resulting conviction or convictions before that event, and a related issue for comment; and (B) amending Application Note 2 of the Commentary to § 2L1.2 to clarify that, consistent with the meaning of “sentence of imprisonment” under § 4A1.2 (Definitions and Instructions for Computing Criminal History), the phrase “sentence imposed” in § 2L1.2 includes any term of imprisonment given upon revocation of probation, parole, or supervised release, regardless of when the revocation occurred; and

(3) a proposed amendment to make various technical changes to the *Guidelines Manual*, including (A) technical changes to provide updated references to certain sections in Title 16, United States Code, that were restated, with minor revisions, when Congress enacted a new Title 54; (B) technical changes to reflect the editorial reclassification of certain provisions bearing on crime control and law enforcement, previously scattered throughout various parts of the United States Code, to a new Title 34; and (C) a clerical change to § 8C2.1 (Applicability of Fine Guidelines) to delete an outdated reference to § 2C1.6, which was deleted by consolidation with § 2C1.2 (Offering, Giving, Soliciting, or Receiving a Gratuity) effective November 1, 2004.

In addition, the Commission requests public comment regarding whether, pursuant to 18 U.S.C. 3582(c)(2) and 28 U.S.C. 994(u), any proposed amendment published in this notice should be included in subsection (d) of § 1B1.10 (Reduction in Term of Imprisonment as a Result of Amended Guideline Range (Policy Statement)) as an amendment that may be applied retroactively to previously sentenced defendants. The

Commission lists in § 1B1.10(d) the specific guideline amendments that the court may apply retroactively under 18 U.S.C. 3582(c)(2). The background commentary to § 1B1.10 lists the purpose of the amendment, the magnitude of the change in the guideline range made by the amendment, and the difficulty of applying the amendment retroactively to determine an amended guideline range under § 1B1.10(b) as among the factors the Commission considers in selecting the amendments included in § 1B1.10(d). To the extent practicable, public comment should address each of these factors.

The text of the proposed amendments and related issues for comment are set forth below. Additional information pertaining to the proposed amendments and issues for comment described in this notice may be accessed through the Commission's website at www.ussc.gov.

Authority: 28 U.S.C. 994(a), (o), (p), (x); USSC Rules of Practice and Procedure 2.2, 4.3, 4.4.

William H. Pryor, Jr.,
Acting Chair.

Proposed Amendments to the Sentencing Guidelines, Policy Statements, and Official Commentary

1. Synthetic Drugs

Synopsis of Proposed Amendment: This proposed amendment is a result of the Commission's multiyear study of offenses involving synthetic cathinones (such as methylone, MDPV, and mephedrone) and synthetic cannabinoids (such as JWH-018 and AM-2201), as well as tetrahydrocannabinol (THC), fentanyl, and fentanyl analogues, and consideration of appropriate guideline amendments, including simplifying the determination of the most closely related controlled substance under Application Note 6 of the Commentary to § 2D1.1. See U.S. Sentencing Comm'n, "Notice of Final Priorities," 82 FR 39949 (Aug. 22, 2017). The proposed amendment contains three parts (Parts A through C). The Commission is considering whether to promulgate any or all of these parts, as they are not mutually exclusive.

Part A of the proposed amendment would amend the Drug Equivalency Tables in § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) to adopt a class-based approach to account for synthetic cathinones. It sets forth a single marihuana equivalency applicable to synthetic cathinones (except Schedule

III, IV, and V substances) of 1 gram = [200]/[380]/[500] grams of marihuana. Part A of the proposed amendment also brackets the possibility of making this class-based marihuana equivalency also applicable to methcathinone, by deleting the specific reference to this controlled substance in the Drug Equivalency Tables. Finally, Part A of the proposed amendment establishes a minimum base offense level of [12] for cases involving synthetic cathinones (except Schedule III, IV, and V substances). Issues for comment are also provided.

Part B of the proposed amendment would amend the Drug Equivalency Tables in § 2D1.1 to adopt a class-based approach to account for synthetic cannabinoids. It sets forth a single marihuana equivalency applicable to synthetic cannabinoids (except Schedule III, IV, and V substances) of 1 gram = [167]/[334]/[500] grams of marihuana. It also adds a provision defining the term "synthetic cannabinoid." Finally, Part B of the proposed amendment brackets for comment a provision establishing a minimum base offense level of [12] for cases involving synthetic cannabinoids (except Schedule III, IV, and V substances). Issues for comment are also provided.

Part C of the proposed amendment would amend § 2D1.1 in several ways to account for fentanyl and fentanyl analogues. First, it provides penalties for offenses involving fentanyl that are equivalent to the higher penalties currently provided for offenses involving fentanyl analogues. Second, the proposed amendment revises § 2D1.1 to provide a definition of the term "fentanyl analogue," set forth a single marihuana equivalency applicable to any fentanyl analogue of 1 gram = 10 kilograms of marihuana, and specify in the Drug Quantity Table that the penalties relating to "fentanyl" apply to the substance identified as "N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide." Finally, Part C of the proposed amendment amends § 2D1.1 to provide an enhancement in cases in which fentanyl or a fentanyl analogue is misrepresented or marketed as another substance. Issues for comment are also provided.

(A) Synthetic Cathinones

Synopsis of the Proposed Amendment: Synthetic cathinones are human-made drugs chemically related to cathinone, a stimulant found in the khat plant. See National Institute on Drug Abuse, DrugFacts: Synthetic Cathinones ("Bath Salts") (January 2016), available at [https://](https://www.drugabuse.gov/publications/drugfacts/synthetic-cathinones-bath-salts)

www.drugabuse.gov/publications/drugfacts/synthetic-cathinones-bath-salts. According to the National Institute on Drug Abuse, synthetic variants of cathinone can be much stronger than the natural cathinone and, in some cases, very dangerous. *Id.* Abuse of synthetic cathinones, sometimes referred to as "bath salts," has become more prevalent over the last decade.

Currently, § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) specifically lists only one synthetic cathinone, Methcathinone. Because other synthetic cathinones are not specifically listed in either the Drug Quantity Table or the Drug Equivalency Tables in § 2D1.1, cases involving these substances require courts to use Application Note 6 of the Commentary to § 2D1.1 to "determine the base offense level using the marihuana equivalency of the most closely related controlled substance referenced in [§ 2D1.1]." The Commission has received comment suggesting that questions regarding "the most closely related controlled substance" arise frequently in cases involving synthetic cathinones, and that the Application Note 6 process requires courts to hold extensive hearings to receive expert testimony on behalf of the government and the defendant.

The Commission has also received comment indicating that a large number of synthetic cathinones are currently available on the illicit drug market and that new varieties are regularly developed for illegal trafficking. Given this information, it would likely be difficult and impracticable for the Commission to provide individual marihuana equivalencies for each synthetic cathinone in the *Guidelines Manual*. Testimony received by the Commission indicates that whether a substance is properly classified as a synthetic cathinone is not generally subject to debate, as there appears to be broad agreement that the basic chemical structure of cathinone remains present throughout all synthetic cathinones.

Part A of the proposed amendment would amend the Drug Equivalency Tables in § 2D1.1 to adopt a class-based approach to account for synthetic cathinones. It sets forth a single marihuana equivalency applicable to synthetic cathinones (except Schedule III, IV, and V substances) of 1 gram = [200]/[380]/[500] grams of marihuana. The proposed amendment also establishes a minimum base offense level of [12] for cases involving synthetic cathinones (except Schedule III, IV, and V substances). Finally, the

proposed amendment brackets the possibility of making this class-based marihuana equivalency also applicable to methcathinone, by deleting the specific reference to this controlled substance in the Drug Equivalency Tables.

Issues for comment are also provided.

Proposed Amendment

The Commentary to § 2D1.1 captioned “Application Notes” is amended in Note 8(D)—

[in the table under the heading “Cocaine and Other Schedule I and II Stimulants (and their immediate precursors) **”, by striking the following:

“1 gm of Methcathinone = 380 gm of marihuana”;

and] by inserting after the table under the heading “Cocaine and Other Schedule I and II Stimulants (and their immediate precursors) **” the following new table:

“*Synthetic Cathinones (except Schedule III, IV, and V Substances)* * 1 gm of a synthetic cathinone (except a Schedule III, IV, or V substance) = [200]/[380]/[500] gm of marihuana

* *Provided*, that the minimum offense level from the Drug Quantity Table for any synthetic cathinone (except a Schedule III, IV, or V substance) individually, or in combination with another controlled substance, is level [12].”.

Issues for Comment

1. Part A of the proposed amendment would amend the Drug Equivalency Tables in § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) to adopt a class-based approach to account for synthetic cathinones. It sets forth a single marihuana equivalency applicable to synthetic cathinones (except Schedule III, IV, and V substances) of 1 gram = [200]/[380]/[500] grams of marihuana. The Commission seeks comment on how, if at all, the guidelines should be amended to account for synthetic cathinones.

Should the Commission provide a class-based approach to account for synthetic cathinones? Are synthetic cathinones sufficiently similar to one another in chemical structure, pharmacological effects, potential for addiction and abuse, patterns of trafficking and abuse, and/or associated harms, to support the adoption of a class-based approach for sentencing purposes? Are there any synthetic cathinones that should not be included as part of a class-based approach and for

which the Commission should provide a marihuana equivalency separate from other synthetic cathinones? If so, what equivalency should the Commission provide for each such synthetic cathinone, and why? If the Commission were to provide a different approach to account for synthetic cathinones in the guidelines, what should that different approach be?

Which, if any, of the proposed [1:200]/[1:380]/[1:500] marihuana equivalency ratios is appropriate for synthetic cathinones (except Schedule III, IV, and V substances) as a class? Should the Commission establish a different equivalency applicable to such a class? If so, what equivalency should the Commission provide and on what basis?

2. Part A of the proposed amendment brackets the possibility of making the marihuana equivalency applicable to synthetic cathinones also applicable to methcathinone by deleting the specific reference to this controlled substance in the Drug Equivalency Tables. Is methcathinone sufficiently similar to other synthetic cathinones in chemical structure, pharmacological effects, potential for addiction and abuse, patterns of trafficking and abuse, and/or associated harms to be included as part of a class-based approach for synthetic cathinones? Should the Commission instead continue to provide a marihuana equivalency for methcathinone separate from other synthetic cathinones?

3. The Commission seeks comment whether it should amend the Commentary to § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) to provide guidance on how to apply the new class-based marihuana equivalency for synthetic cathinones. What guidance, if any, should the Commission provide on the application of the proposed class-based marihuana equivalency? Should the Commission define the term “synthetic cathinone” for purposes of this class-based approach? If so, what definition should the Commission provide for such term? What factors should the Commission account for if it considers providing a definition for “synthetic cathinone”?

(B) Synthetic Cannabinoids

Synopsis of the Proposed Amendment: Synthetic cannabinoids are human-made, mind-altering chemicals developed to mimic the effects of tetrahydrocannabinol (THC), the main psychoactive chemical found in the marihuana plant. Like THC, synthetic cannabinoids act as an agonist

at a specific part of the central nervous system known as the cannabinoid receptors, binding to and activating these receptors to produce psychoactive effects. However, the available scientific literature on this subject suggests that some synthetic cannabinoids bind more strongly to cell receptors affected by THC, and may produce stronger effects. See National Institute of Drug Abuse, DrugFacts: Synthetic Cannabinoids (Revised November 2015) available at <https://www.drugabuse.gov/publications/drugfacts/synthetic-cannabinoids>.

The Commission has received comment indicating that the synthetic cannabinoids encountered on the illicit market are predominantly potent cannabinoid agonists that are pharmacologically similar to THC, but may cause a more severe toxicity and more serious adverse effects than THC. According to commenters, THC is only a partial agonist at type 1 cannabinoid receptors (CB₁ receptors) and produces 30 to 50 percent (or less) of the highest possible response in receptor activation. Synthetic cannabinoids are full agonists at CB₁ receptors that elicit close to 100 percent response in receptor activation. Some commenters have argued that this high activation response may contribute to the increased toxicity and more severe adverse effects of synthetic cannabinoids when compared with THC. According to commenters, some of the adverse effects of synthetic cannabinoids are more prevalent or more severe than those produced by marihuana and THC, and may be produced at lower doses. The Commission was also informed by commenters that drug discrimination data is available on at least 26 different synthetic cannabinoids. JWH-018, one of the substances included in the Commission’s study, was shown in the drug discrimination assay to be approximately three times as potent as THC. Another substance included in the Commission’s study, AM-2201, was shown to be approximately five times as potent as THC using the same assay. Newer synthetic cannabinoids have been shown to be even more potent than these substances. According to the Drug Enforcement Administration, on rare occasions synthetic cannabinoids have been shown to be less potent than THC, as substances with a lower potency are often abandoned by manufacturers following negative user reports relating to their effects.

Currently, § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) specifically lists

only one synthetic cannabinoid, synthetic THC. Synthetic THC has a marihuana equivalency of 1 gram = 167 grams of marihuana. Because other synthetic cannabinoids are not specifically listed in either the Drug Quantity Table or the Drug Equivalency Tables in § 2D1.1, cases involving these substances require courts to use Application Note 6 of the Commentary to § 2D1.1 to “determine the base offense level using the marihuana equivalency of the most closely related controlled substance referenced in [§ 2D1.1].” Although courts often rely on the synthetic THC equivalency in cases involving synthetic cannabinoids, the Commission has received comment suggesting that questions regarding “the most closely related controlled substance” arise frequently in such cases, and that the Application Note 6 process requires courts to hold extensive hearings to receive expert testimony on behalf of the government and the defendant.

The Commission has also received comment suggesting that, like synthetic cathinones, a large number of synthetic cannabinoids are currently available on the illicit drug market and new varieties are regularly developed for illegal trafficking. Given this information, it would likely be difficult and impracticable for the Commission to provide individual marihuana equivalencies for each synthetic cannabinoid in the *Guidelines Manual*. Unlike synthetic cathinones, synthetic cannabinoids cannot be defined as a single class based on a common chemical structure. Synthetic cannabinoids regularly developed for illegal trafficking come from several different structural classes. However, the Commission received testimony from experts indicating that, while synthetic cannabinoids may differ in chemical structure, these substances all produce the same pharmacological effects: They act as an agonist at type 1 cannabinoid receptors (CB₁ receptors).

Part B of the proposed amendment would amend the Drug Equivalency Tables in § 2D1.1 to adopt a class-based approach to account for synthetic cannabinoids. It sets forth a single marihuana equivalency applicable to synthetic cannabinoids (except Schedule III, IV, and V substances) of 1 gram = [167]/[334]/[500] grams of marihuana. The proposed amendment would also add a provision defining “synthetic cannabinoid” as “any synthetic substance (other than synthetic tetrahydrocannabinol) that [acts as an agonist at]/[binds to and activates] type 1 cannabinoid receptors (CB₁ receptors).”

Finally, Part B of the proposed amendment brackets for comment a provision establishing a minimum base offense level of [12] for cases involving synthetic cannabinoids (except Schedule III, IV, and V substances).

Issues for comment are also provided.

Proposed Amendment

The Commentary to § 2D1.1 captioned “Application Notes” is amended in Note 8(D) by inserting after the table under the heading “Schedule I Marihuana” the following new table:

“*Synthetic Cannabinoids (except Schedule III, IV, and V Substances)*[*]

1 gm of a synthetic cannabinoid (except a Schedule III, IV, or V substance) = [167]/[334]/[500] gm of marihuana

[**Provided*, that the minimum offense level from the Drug Quantity Table for any synthetic cannabinoid (except a Schedule III, IV, or V substance) individually, or in combination with another controlled substance, is level [12].] “Synthetic cannabinoid,” for purposes of this guideline, means any synthetic substance (other than synthetic tetrahydrocannabinol) that [acts as an agonist at]/[binds to and activates] type 1 cannabinoid receptors (CB₁ receptors).”.

Issues for Comment

1. Part B of the proposed amendment would amend the Drug Equivalency Tables in § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) to adopt a class-based approach to account for synthetic cannabinoids. It sets forth a single marihuana equivalency applicable to synthetic cannabinoids (except Schedule III, IV, and V substances) of 1 gram of such a synthetic cannabinoid = [167]/[334]/[500] grams of marihuana. The Commission seeks comment on how, if at all, the guidelines should be amended to account for synthetic cannabinoids.

Should the Commission provide a class-based approach to account for synthetic cannabinoids? Are synthetic cannabinoids sufficiently similar to one another in chemical structure, pharmacological effects, potential for addiction and abuse, patterns of trafficking and abuse, and/or associated harms to support the adoption of a class-based approach for sentencing purposes? Are there any synthetic cannabinoids that should not be included as part of a class-based

approach and for which the Commission should provide a marihuana equivalency separate from other synthetic cannabinoids? If so, what equivalency should the Commission provide for each such synthetic cannabinoid, and why? If the Commission were to provide a different approach to account for synthetic cannabinoids in the guidelines, what should that different approach be?

Which, if any, of the proposed [1:167]/[1:334]/[1:500] marihuana equivalency ratios is appropriate for synthetic cannabinoids (except Schedule III, IV, and V substances) as a class? Should the Commission establish a different equivalency applicable to such a class? If so, what equivalency should the Commission provide and on what basis?

2. The Commission seeks comment on whether the Commission should make a distinction between a synthetic cannabinoid in “actual” form (*i.e.*, as a powder or crystalline substance) and a synthetic cannabinoid as part of a mixture (*e.g.*, sprayed on or soaked into a plant or other base material, or otherwise mixed with other substances), by establishing a different marihuana equivalency for each of these forms in which synthetic cannabinoids are trafficked. If so, what equivalencies should the Commission provide and on what basis? Are there differences in terms of pharmacological effects, potential for addiction and abuse, patterns of trafficking and abuse, and/or associated harms between the various forms in which synthetic cannabinoids are trafficked that would support this distinction? Is the use of the term “actual” appropriate in cases involving synthetic cannabinoids? If not, what term should the Commission use to refer to a synthetic cannabinoid as a powder or crystalline substance that has not been mixed with other substances (*e.g.*, sprayed on or soaked into a plant or other base material)?

3. Part B of the proposed amendment would include in the Commentary to § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) a provision defining the term “synthetic cannabinoid” as “any synthetic substance (other than synthetic tetrahydrocannabinol) that [acts as an agonist at]/[binds to and activates] type 1 cannabinoid receptors (CB₁ receptors).” Is this definition appropriate? If not, what definition, if any, should the Commission provide? Are there any synthetic cannabinoids that would not be included under this definition but should be? Are there any

substances that would be included in this definition but should not be? What factors should the Commission take into account in defining “synthetic cannabinoid”? What additional guidance, if any, should the Commission provide on how to apply the proposed class-based marijuana equivalency for synthetic cannabinoids?

4. Part B of the proposed amendment brackets the possibility of establishing a minimum base offense level of [12] for cases involving synthetic cannabinoids (except Schedule III, IV, and V substances) individually, or in combination with another substance. Should the Commission provide a minimum base offense level for such cases? What minimum base offense level, if any, should the Commission provide for cases involving synthetic cannabinoids, and under what circumstances should it apply?

5. The Commission seeks comment on whether, if the Commission were to adopt a 1:167 equivalency ratio for synthetic cannabinoids, this class-based marijuana equivalency should also be applicable to synthetic tetrahydrocannabinol (THC). If so, should the Commission delete the specific reference to this controlled substance in the Drug Equivalency Tables and expand the proposed definition of “synthetic cannabinoid” to include “any synthetic substance that [acts as an agonist at]/[binds to and activates] type 1 cannabinoid receptors (CB₁ receptors)”? Is synthetic THC covered by this definition of “synthetic cannabinoid”? Is synthetic THC sufficiently similar to other synthetic cannabinoids in chemical structure, pharmacological effects, potential for addiction and abuse, patterns of trafficking and abuse, and/or associated harms, to be included as part of a class-based approach for synthetic cannabinoids? Should the Commission instead continue to provide a marijuana equivalency for synthetic THC separate from other synthetic cannabinoids?

(C) Fentanyl and Fentanyl Analogues

Synopsis of Proposed Amendment: Fentanyl is a powerful synthetic opioid analgesic that is similar to morphine but 50 to 100 times more potent. See National Institute on Drug Abuse, DrugFacts: Fentanyl (June 2016), available at <https://www.drugabuse.gov/publications/drugfacts/fentanyl>. Fentanyl is a prescription drug that can be diverted for illicit use. Fentanyl and analogues of fentanyl are also produced in clandestine laboratories for illicit use. See, e.g., U.N. Office on Drugs & Crime, *Fentanyl and Its Analogues—50 Years On*, Global Smart Update 17 (March

2017), available at https://www.unodc.org/documents/scientific/Global_SMART_Update_17_web.pdf. These substances are sold on the illicit drug market as powder, pills, absorbed on blotter paper, mixed with or substituted for heroin, or as tablets that may mimic the appearance of prescription opioids. While most fentanyl analogues are typically about as potent as fentanyl itself, some analogues, such as sufentanil and carfentanil, are reported to be many times more potent than fentanyl.

The Statutory and Guidelines Framework

The Controlled Substances Act (21 U.S.C. 801 *et seq.*) classifies fentanyl as a Schedule II controlled substance, along with other opiates. While there is no other specific reference to the term “fentanyl” in Title 21, United States Code, a subsequent section establishes a mandatory minimum penalty for a substance identified as “N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide.” 21 U.S.C. 841(b)(1)(A)(vi). A Department of Justice regulation explains that N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide is the substance “commonly known as fentanyl.” 28 CFR 50.21(d)(4)(vii). The Controlled Substances Act prescribes a mandatory minimum penalty of five years for trafficking 40 or more grams of the substance, or ten or more grams of an analogue of the substance. 21 U.S.C. 841(b)(1)(A)(vi); (b)(1)(B)(vi).

The Drug Quantity Table in § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) contains entries for both “fentanyl” and “fentanyl analogue,” at severity levels that reflect the mandatory minimum penalty structure. The Drug Equivalency Tables in the Commentary to § 2D1.1 clearly identify fentanyl with the specific substance associated with the statutory minimum penalty by providing a marijuana equivalency for 1 gm of “Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide)” equal to 2.5 kg of marijuana (*i.e.*, a 1:2,500 ratio). The Drug Equivalency Tables also set forth the marijuana equivalencies for two other substances, alpha-methylfentanyl and 3-methylfentanyl. Both substances have the same marijuana equivalency ratio, 1:10,000, which corresponds with the penalties for fentanyl analogues. Alpha-methylfentanyl and 3-methylfentanyl are pharmaceutical analogues of fentanyl that were developed in the 1960s or 1970s. See,

e.g., T.J. Gillespie, *et al.*, *Identification and Quantification of Alpha-Methylfentanyl in Post Mortem Specimens*, 6(3) J. of Analytical Toxicology 139 (May–June 1982).

Higher Penalties for Offenses Involving Fentanyl

First, Part C of the proposed amendment would revise § 2D1.1 to increase penalties for offenses involving fentanyl. The Commission has received comment indicating that the proliferation and ease of availability of multiple varieties of fentanyl and fentanyl analogues has resulted in an increased number of deaths from overdoses. Commenters have argued that § 2D1.1 does not adequately reflect the serious dangers posed by fentanyl and its analogues, including their high potential for abuse and addiction. Public health data shows that the harms associated with abuse of fentanyl and fentanyl analogues far exceed those associated with other opioid analgesics.

Part C of the proposed amendment would amend § 2D1.1 to provide penalties for fentanyl that are equivalent to the higher penalties currently provided for fentanyl analogues. The proposed amendment would accomplish this objective by changing the base offense levels for fentanyl in the Drug Quantity Table at § 2D1.1(c) to parallel the base offense levels established for fentanyl analogues. It would also amend the Drug Equivalency Tables in the Commentary to § 2D1.1 to change the marijuana equivalency ratio for fentanyl to the same ratio, 1:10,000, provided for fentanyl analogues.

Issues Relating to “Fentanyl Analogues”

Second, Part C of the proposed amendment would revise § 2D1.1 to address several issues relating to offenses involving fentanyl analogues. The Commission has received comment that the penalty for “fentanyl analogue” set forth in the guidelines interacts in a potentially confusing way with the guideline definition of the term “analogue.” Although the term “fentanyl analogue” is not defined by the guidelines, Application Note 6 states that, for purposes of § 2D1.1, “analogue” has the meaning given the term “controlled substance analogue” in 21 U.S.C. 802(32). Section 802(32) defines “controlled substance analogue” to exclude “a controlled substance”—that is, a substance that has been scheduled. Thus, once the Drug Enforcement Administration (or Congress) schedules a substance that is a “fentanyl analogue” in the scientific sense, that substance may not qualify as a “fentanyl analogue” for purposes of the Drug

Quantity Table. Hence, in cases involving a scheduled “fentanyl analogue” other than the two fentanyl analogues listed by name in the Drug Equivalency Tables, courts would be required by Application Note 6 of the Commentary to § 2D1.1 to “determine the base offense level using the marihuana equivalency of the most closely related controlled substance referenced in [§ 2D1.1].”

The Commission has received comment suggesting that the Application Note 6 process requires courts to hold extensive hearings to receive expert testimony on behalf of the government and the defendant. This process is likely to determine that fentanyl, rather than one of the two listed variants in the guideline, is the most closely related controlled substance to a scheduled “fentanyl analogue.” This will result in a substance that would scientifically be considered a fentanyl analogue being punished under the 1:2,500 fentanyl ratio, rather than the 1:10,000 “fentanyl analogue” ratio.

Part C of the proposed amendment would address this situation by revising § 2D1.1 to define “fentanyl analogue” as “any substance (including any salt, isomer, or salt of isomer thereof), whether a controlled substance or not, that has a chemical structure that is [substantially] similar to fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide).” It would also amend the Drug Equivalency Tables in § 2D1.1 to provide a single marihuana equivalency applicable to any fentanyl analogue of 1 gram = 10 kilograms of marihuana. The proposed amendment brackets the possibility of making this new marihuana equivalency also applicable to alpha-methylfentanyl and 3-methylfentanyl by deleting the specific references to these controlled substances in the Drug Equivalency Tables. In addition, the proposed amendment would amend the Drug Quantity Table to specify that the penalties relating to “fentanyl” apply to the substance identified in the statute as “N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide.”

Increased Penalties for Offenses Involving Fentanyl and Fentanyl Analogues Misrepresented as Another Substance

Finally, Part C of the proposed amendment would amend § 2D1.1 to address cases involving fentanyl and fentanyl analogues misrepresented as another substance. The Commission has received comment that fentanyl and fentanyl analogues are being mixed with, and in some instances substituted

for, other drugs, such as heroin and cocaine. According to commenters, fentanyl and fentanyl analogues are also being pressed into pills that resemble prescription opioids, such as oxycodone and hydrocodone. Commenters have also suggested that the harms associated with the use of fentanyl and fentanyl analogues are heightened by the fact that users may unknowingly consume fentanyl or fentanyl analogues in products misrepresented or sold as other substances, such as heroin or counterfeit prescription pills. Because such users may be unaware that what they believe to be a certain substance, such as heroin, is either fentanyl or has been laced with fentanyl, they may not mitigate against the added risks of use, including overdose.

Part C of the proposed amendment would add a new specific offense characteristic at § 2D1.1(b)(13) providing an enhancement of [2][4] levels to address these cases. It provides two alternatives for such an enhancement. Under the first alternative, the enhancement would apply if the offense involved a mixture or substance containing a detectable amount of fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide) or a fentanyl analogue that was misrepresented or marketed as another substance. Under the second alternative, the enhancement would apply if the offense involved a mixture or substance containing fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide) or a fentanyl analogue and the defendant knowingly misrepresented or knowingly marketed that mixture or substance as another substance.

Issues for comment are also provided. Proposed Amendment

Section 2D1.1(b) is amended by redesignating paragraphs (13) through (17) as paragraphs (14) through (18), respectively, and by inserting the following new paragraph (13):

“(13) [If the offense involved a mixture or substance containing fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide) or a fentanyl analogue that was misrepresented or marketed as another substance][If the offense involved a mixture or substance containing fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide) or a fentanyl analogue and the defendant knowingly misrepresented or knowingly marketed that mixture or substance as another substance], increase by [2][4] levels.”

Section 2D1.1(c)(1) is amended by striking “36 KG or more of Fentanyl;” and inserting the following: “[9] KG or more of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

Section 2D1.1(c)(2) is amended by striking “At least 12 KG but less than 36 KG of Fentanyl;” and inserting the following: “At least [3] KG but less than [9] KG of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

Section 2D1.1(c)(3) is amended by striking “At least 4 KG but less than 12 KG of Fentanyl;” and inserting the following: “At least [1] KG but less than [3] KG of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

Section 2D1.1(c)(4) is amended by striking “At least 1.2 KG but less than 4 KG of Fentanyl;” and inserting the following: “At least [300] G but less than [1] KG of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

Section 2D1.1(c)(5) is amended by striking “At least 400 G but less than 1.2 KG of Fentanyl;” and inserting the following: “At least [100] G but less than [300] G of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

Section 2D1.1(c)(6) is amended by striking “At least 280 G but less than 400 G of Fentanyl;” and inserting the following: “At least [70] G but less than [100] G of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

Section 2D1.1(c)(7) is amended by striking “At least 160 G but less than 280 G of Fentanyl;” and inserting the following: “At least [40] G but less than [70] G of Fentanyl ((N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

Section 2D1.1(c)(8) is amended by striking “At least 40 G but less than 160 G of Fentanyl;” and inserting the following: “At least [10] G but less than [40] G of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

Section 2D1.1(c)(9) is amended by striking “At least 32 G but less than 40

G of Fentanyl;” and inserting the following:

“At least [8] G but less than [10] G of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

Section 2D1.1(c)(10) is amended by striking “At least 24 G but less than 32 G of Fentanyl;” and inserting the following:

“At least [6] G but less than [8] G of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

Section 2D1.1(c)(11) is amended by striking “At least 16 G but less than 24 G of Fentanyl;” and inserting the following:

“At least [4] G but less than [6] G of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

Section 2D1.1(c)(12) is amended by striking “At least 8 G but less than 16 G of Fentanyl;” and inserting the following:

“At least [2] G but less than [4] G of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

Section 2D1.1(c)(13) is amended by striking “At least 4 G but less than 8 G of Fentanyl;” and inserting the following:

“At least [1] G but less than [2] G of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

Section 2D1.1(c)(14) is amended by striking “Less than 4 G of Fentanyl;” and inserting the following:

“Less than [1] G of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide);”.

The annotation to § 2D1.1(c) captioned “Notes to Drug Quantity Table” is amended by inserting at the end the following new Note (J):

“(J) Fentanyl analogue, for the purposes of this guideline, means any substance (including any salt, isomer, or salt of isomer thereof), whether a controlled substance or not, that has a chemical structure that is [substantially] similar to fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide).”.

The Commentary to § 2D1.1 captioned “Application Notes” is amended—in Note 6 by striking “Any reference to a particular controlled substance in these guidelines” and inserting “Except as otherwise provided, any reference to a particular controlled substance in these guidelines”, and by striking “For

purposes of this guideline ‘analogue’ has the meaning” and inserting “Unless otherwise specified, ‘analogue,’ for purposes of this guideline, has the meaning”;

and in note 8(D), in the table under the heading “Schedule I or II Opiates*”—[by striking the following two lines:

“1 gm of Alpha-Methylfentanyl = 10 kg of marihuana”

“1 gm of 3-Methylfentanyl = 10 kg of marihuana”

and] by inserting after the line referenced to Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide) the following:

“1 gm of a Fentanyl Analogue = [10] kg of marihuana”.

Issues for Comment

1. Part C of the proposed amendment would amend the “Notes to Drug Quantity Table” in § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) to include a provision defining “fentanyl analogue” as “any substance (including any salt, isomer, or salt of isomer thereof), whether a controlled substance or not, that has a chemical structure that is [substantially] similar to fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide).” Is this definition appropriate? If not, what definition, if any, should the Commission provide? For example, should the Commission specify that to qualify as a “fentanyl analogue,” a substance, whether a controlled substance or not, must (A) have a chemical structure that is [substantially] similar to fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide) and (B) either (i) have an effect on the central nervous system that is substantially similar to [or greater than] fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide), or (ii) be represented or intended to have such an effect?

2. The proposed amendment would amend § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) to adopt a class-based approach to account for all fentanyl analogues, whether they are controlled substances or not. Are fentanyl analogues sufficiently similar to one another in chemical structure, pharmacological effects, potential for addiction and abuse, patterns of trafficking and abuse, and/or associated harms to support such class-based approach for sentencing purposes? If so,

are the penalties set forth in the Drug Quantity Table and the proposed 1:10,000 marihuana equivalency ratio appropriate for fentanyl analogues as a class? Should the Commission establish different penalties or a different equivalency applicable to such substances? If so, what penalties should the Commission provide and on what basis? Are there any fentanyl analogues that should not be included as part of a class-based approach and for which the Commission should provide penalties separate from other fentanyl analogues? If so, what penalties should the Commission provide for each such fentanyl analogue, and why? If the Commission were to provide a different approach to account for fentanyl analogues in the guidelines, what should that different approach be?

The proposed amendment brackets the possibility of making the marihuana equivalency applicable to all fentanyl analogues that are commonly regarded as analogues of “Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide” also applicable to alpha-methylfentanyl and 3-methylfentanyl by deleting the specific references to these controlled substances in the Drug Equivalency Tables. Are alpha-methylfentanyl and 3-methylfentanyl sufficiently similar to other fentanyl analogues in chemical structure, pharmacological effects, potential for addiction and abuse, patterns of trafficking and abuse, and/or associated harms, to be included as part of a class-based approach for fentanyl analogues? Should the Commission instead continue to provide marihuana equivalencies for alpha-methylfentanyl and 3-methylfentanyl separate from other fentanyl analogues?

3. According to the Drug Enforcement Administration (DEA) and other sources, fentanyl and fentanyl analogues are typically manufactured in China and then shipped via freight forwarding companies or parcel post to the United States or to other places in the Western Hemisphere. Additionally, fentanyl and fentanyl analogues are available for purchase online through the “dark net” (commercial websites functioning as black markets) and regular websites, and commonly shipped into the United States. According to the DEA, the improper handling of fentanyl and fentanyl analogues presents grave danger to individuals who may inadvertently come into contact with such substances. Those at risk include law enforcement and emergency personnel who may unknowingly encounter these substances during arrests, searches, or emergency calls.

The Commission seeks comment on whether the guidelines provide appropriate penalties for cases in which fentanyl or a fentanyl analogue may create a substantial threat to the public health or safety (including the health or safety of law enforcement and emergency personnel). If not, how should the Commission revise the guidelines to provide appropriate penalties in such cases? Should the Commission provide new enhancements, adjustments, or departure provisions to account for such cases? If the Commission were to provide such a provision, what specific offense conduct, harm, or other factor should be the basis for applying the provision? What penalty increase should be provided?

2. Illegal Reentry Guideline Enhancements

Synopsis of Proposed Amendment: This proposed amendment is a result of the Commission's consideration of miscellaneous guidelines application issues. See U.S. Sentencing Comm'n, "Notice of Final Priorities," 82 FR 39949 (Aug. 22, 2017). It responds to issues that have arisen regarding application of the illegal reentry guideline at § 2L1.2 (Unlawfully Entering or Remaining in the United States). The proposed amendment contains two parts (Part A and Part B). The Commission is considering whether to promulgate either or both of these parts, as they are not mutually exclusive.

Part A of the proposed amendment responds to an issue brought to the Commission's attention by the Department of Justice. See Annual Letter from the Department of Justice to the Commission (July 31, 2017), available at <https://www.ussc.gov/sites/default/files/pdf/amendment-process/public-comment/20170731/DOJ.pdf>. In its annual letter to the Commission, the Department suggested that the illegal reentry guideline's enhancements for prior convictions (other than convictions for illegal reentry) contain a gap in coverage. Subsection (b)(2) of the guideline provides for an increase in the defendant's offense level if, before the defendant was ordered deported or ordered removed from the United States for the first time, the defendant "sustained . . . a conviction" for a felony offense (other than an illegal reentry offense) or "three or more convictions" for certain misdemeanor offenses. Subsection (b)(3) of the guideline provides for an increase in the defendant's offense level, if after the defendant was ordered deported or ordered removed from the United States

for the first time, the defendant "engaged in criminal conduct resulting in" such a felony conviction or three or more such misdemeanor convictions. Neither subsection (b)(2) nor subsection (b)(3), however, provides for an increase in the defendant's offense level in the situation where a defendant engaged in criminal conduct before being ordered deported or ordered removed from the United States for the first time but did not sustain a conviction or convictions for that criminal conduct until after he or she was first ordered deported or ordered removed.

Part A of the proposed amendment would amend § 2L1.2 to cover this situation by revising subsection (b)(2) so that its applicability turns on whether the defendant "engaged in criminal conduct" before he or she was first ordered deported or order removed, rather than whether the defendant sustained the resulting conviction or convictions before that event. Part A would also make non-substantive, conforming changes to the language of subsection (b)(3).

An issue for comment is also provided.

Part B of the proposed amendment responds to an issue that has arisen in litigation concerning how § 2L1.2's enhancements for prior convictions apply in the situation where a defendant's prior conviction included a term of probation, parole, or supervised release that was subsequently revoked and an additional term of imprisonment imposed.

As described above, subsections (b)(2) and (b)(3) of § 2L1.2 provide for increases in a defendant's offense level for prior convictions (other than convictions for illegal reentry). The magnitude of the offense level increase that the subsections provide for a prior felony conviction varies depending on the length of the "sentence imposed." Application Note 2 of the Commentary to § 2L1.2 states that "[s]entence imposed" has the meaning given the term 'sentence of imprisonment' in Application Note 2 and subsection (b) of § 4A1.2 (Definitions and Instructions for Computing Criminal History)." Under § 4A1.2, the "sentence of imprisonment" includes not only the original term of imprisonment imposed but also any term of imprisonment imposed upon revocation of probation, parole, or supervised release. See USSG § 4A1.2, comment. (n.11). Consistent with that approach, Application Note 2 of the Commentary to § 2L1.2 states that, under § 2L1.2, "[t]he length of the sentence imposed includes any term of imprisonment given upon revocation of probation, parole, or supervisory

release." Two courts of appeals have held, however, that, under § 2L1.2(b)(2), the "sentence imposed" does not include a period of imprisonment imposed upon revocation of probation, parole, or supervisory release if that revocation occurred after the defendant was ordered deported or ordered removed from the United States for the first time. See *United States v. Martinez*, 870 F.3d 1163 (9th Cir. 2017); *United States v. Franco-Galvan*, 846 F.3d 338 (5th Cir. 2017).

Part B of the proposed amendment would revise the definition of "sentence imposed" in Application Note 2 of the Commentary to § 2L1.2 to clarify that, consistent with the meaning of "sentence of imprisonment" under § 4A1.2, the phrase "sentence imposed" in § 2L1.2 includes any term of imprisonment given upon revocation of probation, parole, or supervised release, regardless of when the revocation occurred.

Proposed Amendment

(A) Closing the Coverage Gap

Section 2L1.2(b)(2) is amended by striking "the defendant sustained" and inserting "the defendant engaged in criminal conduct that, at any time, resulted in".

Section 2L1.2(b)(3) is amended by striking "If, at any time after the defendant was ordered deported or ordered removed from the United States for the first time, the defendant engaged in criminal conduct resulting in" and inserting "If, after the defendant was ordered deported or ordered removed from the United States for the first time, the defendant engaged in criminal conduct that, at any time, resulted in".

Issue for Comment

1. The Commission has received comments indicating that the enhancements for prior convictions (other than convictions for illegal reentry) in § 2L1.2 (Unlawfully Entering or Remaining in the United States) currently do not apply in the situation where a defendant engaged in criminal conduct before being ordered deported or ordered removed from the United States for the first time but did not sustain a conviction or convictions for that criminal conduct until after he or she was first ordered deported or ordered removed. Part A of the proposed amendment would address this situation by revising the language of § 2L1.2(b)(2) so that its applicability would turn on when the defendant "engaged in criminal conduct resulting in" one or more of the covered convictions, rather than when the

defendant “sustained” that “conviction” or “convictions.”

Should the Commission amend § 2L1.2 to cover the situation where a defendant engages in criminal conduct before a first order of removal or deportation but does not sustain a conviction or convictions for the criminal conduct until after that order? How frequently does this situation occur? Does Part A of the proposed amendment appropriately address this situation? Should the Commission address the situation differently? If so, how?

(B) Treatment of Revocations of Probation, Parole, or Supervised Release

The Commentary to § 2L1.2 captioned “Application Notes” is amended in Note 2 in the paragraph that begins “‘Sentence imposed’ has the meaning” by striking “term of imprisonment given upon revocation of probation, parole, or supervised release” and inserting “term of imprisonment given upon revocation of probation, parole, or supervised release, regardless of when the revocation occurred”.

3. Technical Amendment

Synopsis of the Proposed Amendment: This proposed amendment makes various technical changes to the *Guidelines Manual*.

First, the proposed amendment makes technical changes to provide updated references to certain sections in the United States Code that were restated in legislation. As part of an Act to codify existing law relating to the National Park System, Congress repealed numerous sections in Title 16 of the United States Code, and restated them in Title 18 and a newly enacted Title 54. *See* Public Law 113–287 (Dec. 19, 2014). The proposed amendment amends the Commentary to § 2B1.5 (Theft of, Damage to, or Destruction of, Cultural Heritage Resources or Paleontological Resources; Unlawful Sale, Purchase, Exchange, Transportation, or Receipt of Cultural Heritage Resources or Paleontological Resources) to correct outdated references to certain sections in Title 16 that were restated, with minor revisions, when Congress enacted

Title 54. It also deletes from the Commentary to § 2B1.5 the provision relating to the definition of “historic resource,” as that term was omitted from Title 54. In addition, the proposed amendment makes a technical change to Appendix A (Statutory Index), to correct an outdated reference to 16 U.S.C. 413 by replacing it with the appropriate reference to 18 U.S.C. 1865(c).

Second, the proposed amendment also makes technical changes to reflect the editorial reclassification of certain sections in the United States Code. Effective September 1, 2017, the Office of Law Revision Counsel transferred certain provisions bearing on crime control and law enforcement, previously scattered throughout various parts of the United States Code, to a new Title 34. To reflect the new section numbers of the reclassified provisions, Part B of the proposed amendment makes changes to—

- (1) The Commentary to § 2A3.5 (Failure to Register as a Sex Offender);
 - (2) the Commentary to § 2X5.2 (Class A Misdemeanors (Not Covered by Another Specific Offense Guideline));
 - (3) subsection (a)(10) of § 5B1.3 (Conditions of Probation);
 - (4) subsection (a)(8) of § 5D1.3 (Conditions of Supervised Release); and
 - (5) Appendix A (Statutory Index), by updating references to certain sections in Title 42 to reflect their reclassified section numbers in the new Title 34.
- Finally, the proposed amendment revises subsection (a) of § 8C2.1 (Applicability of Fine Guidelines) by deleting an outdated reference to § 2C1.6, which was deleted by consolidation with § 2C1.2 (Offering, Giving, Soliciting, or Receiving a Gratuity) effective November 1, 2004.

Proposed Amendment

The Commentary to § 2A3.5 captioned “Application Notes” is amended in Note 1—

in the paragraph that begins “‘Sex offense’ has the meaning” by striking “42 U.S.C. 16911(5)” and inserting “34 U.S.C. 20911(5)”;

and in the paragraph that begins “‘Tier I offender’, ‘Tier II offender’, and ‘Tier

III offender’ have the meaning” by striking “42 U.S.C. 16911” and inserting “34 U.S.C. 20911”.

The Commentary to § 2B1.5 captioned “Application Notes” is amended—

in Note 1(A) by striking clause (ii) and redesignating clauses (iii) through (vii) as clauses (ii) through (vi), respectively;

in Note 1(A)(i) by striking “16 U.S.C. 470w(5)” and inserting “54 U.S.C. 300308”;

in Note 3(C) by striking “16 U.S.C. 470a(a)(1)(B)” and inserting “54 U.S.C. 302102”;

in Note 3(E) by striking “the Antiquities Act of 1906 (16 U.S.C. 431)” and inserting “54 U.S.C. 320301”;

and in Note 3(F) by striking “16 U.S.C. 1c(a)” and inserting “54 U.S.C. 100501”.

The Commentary to § 2X5.2 captioned “Statutory Provisions” is amended by striking “42 U.S.C. 14133” and inserting “34 U.S.C. 12593”.

Section 5B1.3(a)(10) is amended by striking “42 U.S.C. 14135a” and inserting “34 U.S.C. 40702”.

Section 5D1.3(a)(8) is amended by striking “42 U.S.C. 14135a” and inserting “34 U.S.C. 40702”.

Section 8C2.1(a) is amended by striking “§§ 2C1.1, 2C1.2, 2C1.6;” and inserting “§§ 2C1.1, 2C1.2;”.

Appendix A (Statutory Index) is amended—

by striking the line referenced to 16 U.S.C. 413;

by inserting after the line referenced to 18 U.S.C. 1864 the following:

“18 U.S.C. 1865(c) 2B1.1”;

by inserting after the line referenced to 33 U.S.C. 3851 the following:

“34 U.S.C. 10251 2B1.1

34 U.S.C. 10271 2B1.1

34 U.S.C. 12593 2X5.2

34 U.S.C. 20962 2H3.1

34 U.S.C. 20984 2H3.1”;

and by striking the lines referenced to 42 U.S.C. 3791, 42 U.S.C. 3795, 42 U.S.C. 14133, 42 U.S.C. 16962, and 42 U.S.C. 16984.

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Part II

Department of Health and Human Services

45 CFR Part 88

Protecting Statutory Conscience Rights in Health Care; Delegations of Authority; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 88

[Docket No.: HHS–OCR–2018–0002]

RIN 0945–ZA03

Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION: Proposed rule.

SUMMARY: In the regulation of health care, the United States has a long history of providing conscience-based protections for individuals and entities with objections to certain activities based on religious belief and moral convictions. Multiple such statutory protections apply to the Department of Health and Human Services (HHS, or the Department) and the programs or activities it funds or administers. The Department proposes to revise regulations previously promulgated to ensure that persons or entities are not subjected to certain practices or policies that violate conscience, coerce, or discriminate, in violation of such Federal laws. Through this rulemaking, the Department proposes to grant overall responsibility to its Office for Civil Rights (OCR) for ensuring that the Department, its components, HHS programs and activities, and those who participate in HHS programs or activities comply with Federal laws protecting the rights of conscience and prohibiting associated discriminatory policies and practices in such programs and activities. In addition to conducting outreach and providing technical assistance, OCR will have the authority to initiate compliance reviews, conduct investigations, supervise and coordinate compliance by the Department and its components, and use enforcement tools otherwise available in civil rights law to address violations and resolve complaints. In order to ensure that recipients of Federal financial assistance and other Department funds comply with their legal obligations, the Department will require certain recipients to maintain records; cooperate with OCR's investigations, reviews, or other enforcement actions; submit written assurances and certifications of compliance to the Department; and provide notice to individuals and entities about their conscience and associated anti-discrimination rights, as applicable.

DATES: Submit comments on or before March 27, 2018.

ADDRESSES: You may send comments, identified by RIN 0945–ZA03 or Docket HHS–OCR–2018–0002, by any of the following methods:

- *Federal eRulemaking Portal.* You may submit electronic comments at <http://www.regulations.gov> by searching for the Docket ID number HHS–OCR–2018–0002. Follow the instructions for sending comments.
- *Regular, Express, or Overnight Mail:* U.S. Department of Health and Human Services, Office for Civil Rights, Attention: Conscience NPRM, RIN 0945–ZA03, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW, Washington, DC 20201.
- *Hand Delivery/Courier:* Department of Health and Human Services, Office for Civil Rights, Attention: Conscience NPRM, RIN 0945–ZA03, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW, Washington, DC 20201.

Instructions: All submissions received must include “Department of Health and Human Services, Office for Civil Rights RIN 0945–ZA03” for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Further instructions are available under PUBLIC PARTICIPATION.

Docket: For complete access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and search for Docket ID number HHS–OCR–2018–0002.

FOR FURTHER INFORMATION CONTACT: Sarah Bayko Albrecht at (800) 368–1019 or (800) 537–7697 (TDD).

SUPPLEMENTARY INFORMATION:

I. Introduction

The freedoms of conscience and of religious exercise are foundational rights protected by the First Amendment to the U.S. Constitution and by Federal statutes. These laws ensure, for example, that Americans are not compelled to speak, to salute the flag, to join a national church, or to vote for a particular candidate.¹ They also ensure that, as a general matter, the Federal government may not discriminate against its citizens for the views they hold.² Congress has passed laws protecting conscience and religious

freedom with particular force in the health care context, and it is these statutes that are the subject of this proposed rule. Specifically, this proposed rule concerns Federal laws that provide:

- Conscience protections related to abortion, sterilization, and certain other health services to participants in programs—and their personnel—funded by the Department (the Church Amendments, 42 U.S.C. 300a–7);
- Conscience protections for health care entities related to abortion provision or training, referral for such abortion or training, or accreditation standards related to abortion (the Coats-Snowe Amendment, 42 U.S.C. 238n);
- Protections from discrimination for health care entities and individuals who object to furthering or participating in abortion under programs funded by the Department's yearly appropriations acts (e.g., Consolidated Appropriations Act, 2017, Pub. L. 115–31, Div. H, Tit. V, sec. 507(d) (the Weldon Amendment) and at Div. H, Tit. II, sec. 209);
- Conscience protections under the Patient Protection and Affordable Care Act (ACA) related to assisted suicide (42 U.S.C. 18113), the ACA individual mandate (26 U.S.C. 5000A(d)(2)), and other matters of conscience (42 U.S.C. 18023(c)(2)(A)(i)–(iii), (b)(1)(A) and (b)(4));
- Conscience protections for objections to counseling and referral for certain services in Medicaid or Medicare Advantage (42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B));
- Conscience protections related to the performance of advanced directives (42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406);
- Conscience protections related to Global Health Programs to the extent administered by the Secretary (22 U.S.C. 7631(d); Consolidated Appropriations Act, 2017, Pub. L. 115–31, Div. J, Tit. VII, sec. 7018 (Helms Amendment));
- Exemptions from compulsory health care or services generally (42 U.S.C. 1396f & 5106i(a)(1)), and under specific programs for hearing screening (42 U.S.C. 280g–1(d)), occupational illness testing (29 U.S.C. 669(a)(5)); vaccination (42 U.S.C. 1396s(c)(2)(B)(ii)), and mental health treatment (42 U.S.C. 290bb–36(f)); and
- Protections for religious nonmedical health care (e.g., 42 U.S.C. 1320a–1, 1320c–11, 1395i–5 and 1397j–1(b)).

(These laws will be collectively referred to as “Federal health care conscience and associated anti-discrimination laws” for purposes of this Notice of Proposed Rulemaking.)

¹ U.S. Const., amend. I; see also, e.g., *West Virginia State Board of Education v. Barnette*, 319 U.S. 624 (1943); 18 U.S.C. 594.

² See e.g., *Turner Broad. Sys. Inc. v. FCC*, 512 U.S. 622 (1994); *Rust v. Sullivan*, 500 U.S. 173 (1991); *Kingsley Int'l Corp. v. Regents of the Univ. of N.Y.*, 360 U.S. 684 (1954).

With this proposed regulation, the Department seeks to more effectively and comprehensively enforce Federal health care conscience and associated anti-discrimination laws. Specifically, the Department proposes to grant its Office for Civil Rights (OCR) overall responsibility for ensuring that the Department, its components, HHS programs and activities, and those who participate in HHS programs or activities comply with these Federal laws. In addition to conducting outreach and providing technical assistance, OCR will have the authority to initiate compliance reviews, conduct investigations, supervise and coordinate compliance by the Department and its component(s), and use enforcement tools comparable to those available under other civil rights laws to more effectively address violations and resolve complaints. In order to ensure that recipients of Department funds comply with their legal obligations, as it does with other civil rights laws within its purview, the Department will require certain funding recipients to maintain records; cooperate with OCR's investigations, reviews, or enforcement actions; submit written assurances and certifications of compliance to the Department; and provide notice to individuals and entities about conscience and associated anti-discrimination rights (as applicable).

II. America's Tradition of Conscience Protection, Religious Freedom, and the Right to be Free From Unlawful Discrimination

Congress has a long history of protecting conscience, religious beliefs, and moral convictions in law in a variety of contexts. *See, e.g.*, 1864 Draft Act, 13 Stat. 9 (exempting religious objectors opposed to bearing arms from military service); 50 U.S.C. 3806(j) (exempting conscientious objectors from combat training or military service); 18 U.S.C. 3597(b) (exempting law enforcement employees from participating in executions "if such participation is contrary to the moral or religious convictions of the employee"); 20 U.S.C. 1681(a)(3) (exempting educational institutions from sex discrimination bans under Title IX of the Education Amendments of 1972 where such ban "would not be consistent with the religious tenets" of the institution); 42 U.S.C. 300a-8 (prohibiting the coercion of persons to undergo abortion or sterilization procedures by threatening loss of benefits and attaching a criminal punishment of a fine of not more than \$1000, imprisonment for not more than one year, or both, to violations of that

prohibition); *see also* the Religious Freedom Restoration Act, 42 U.S.C. 2000bb *et seq.* (preventing the Federal government from imposing substantial burdens on religious exercise absent a compelling government interest pursued in the manner least restrictive of that exercise).

The need and justification for these types of laws was aptly explained by the Supreme Court in 1965:

[B]oth morals and sound policy require that the State should not violate the conscience of the individual. All our history gives confirmation to the view that liberty of conscience has a moral and social value which makes it worthy of preservation at the hands of the state. So deep in its significance and vital, indeed, is it to the integrity of man's moral and spiritual nature that nothing short of the self-preservation of the state should warrant its violation; and it may well be questioned whether the state which preserves its life by a settled policy of violation of the conscience of the individual will not in fact ultimately lose it by the process.

United States v. Seeger, 380 U.S. 163, 170 (1965), quoting Harlan Fiske Stone, *The Conscientious Objector*, 21 Col. Univ. Q. 253, 269 (1919).

For decades,³ Congress has also respected the conscience of taxpayers who object to paying for abortion by legislating prohibitions on the Federal funding of abortion. Specifically, the Hyde Amendment, which Congress has routinely attached to appropriations acts, generally prohibits Federal funding of abortion.⁴ *See, e.g.*, Consolidated Appropriations Act, 2017, Public Law 115-31, Div. H, sec. 506, 507, 131 Stat. 562 (May 5, 2017). *See also id.* at Div. E, sec. 613, 131 Stat. 372 (using Hyde language to prohibit funding of abortions through Federal employee health benefits or coverage); *id.* at Div. E, sec. 810, 131 Stat. 393 (applying Hyde language to the District of Columbia); and 20 U.S.C. 1688 (including language in Title IX to prohibit recipients of Federal education funding from requiring any person, or public or private entity, to pay for any

benefit or service, including the use of facilities, related to an abortion).⁵

In a May 4, 2017, Executive Order entitled "Promoting Free Speech and Religious Liberty," the President declared that the Executive Branch will "vigorously enforce Federal law's robust protections for religious freedom." E.O. 13798, 82 FR 21675 (May 8, 2017). Pursuant to that Executive Order, the Attorney General of the United States issued guidance on religious liberty clarifying that Federal law "protects not just the right to believe or the right to worship; it protects the right to *perform or abstain from performing certain physical acts in accordance with one's beliefs*." Memorandum from the Attorney General, Federal Law Protections for Religious Liberty at 2 (Oct. 6, 2017) (emphasis added). Pursuant to the President's Executive Order and Executive Branch policy, and in keeping with the Attorney General's religious liberty guidance, HHS proposes this rule to enhance the awareness and enforcement of Federal health care conscience and associated anti-discrimination laws, to further conscience and religious freedom, and to protect the rights of individuals and entities to abstain from certain activities related to health care services without discrimination or retaliation.

III. The Federal Health Care Conscience and Associated Anti-Discrimination Laws Applicable to Government, Providers, Patients, Insurers, and Other Entities That Benefit From or Administer Federally Funded Health Care Programs or Activities

As noted above, Congress has recognized that modern health care practices may give rise to conflicts with the religious beliefs and moral convictions of providers and patients alike. The existence of moral and ethical qualms on the part of health care clinicians about participating in, assisting, referring for, or otherwise being morally complicit in certain procedures is well documented by ethicists.⁶ Religious institutions and

³ *See* E.O. 13535, 75 FR 15599 (Mar. 29, 2010) (establishing enforcement mechanism to "ensure that Federal funds are not used for abortion services (except in cases of rape or incest, or when the life of the woman would be endangered), consistent with a longstanding Federal statutory restriction that is commonly known as the Hyde Amendment").

⁴ In *Harris v. McRae*, 448 U.S. 297, 315 (1980), the Supreme Court held that Congress has the power to limit or prohibit the funding of abortion. In *Maher v. Roe*, 432 U.S. 464, 474 (1977), the court held that the Constitution empowers Congress to make a "value judgment favoring childbirth over abortion" that it may implement "by the allocation of public funds." *See also Rust v. Sullivan*, 500 U.S. 173, 192-193, 201 (1991).

⁵ *See* Mark L. Rienzi, *The Constitutional Right Not to Kill*, 62 Emory L.J. 121, 152 (2012) ("[L]egislators acted quickly, decisively, and at times nearly unanimously to protect conscience rights in the wake of *Roe*. . . . The speedy passage and near ubiquity of these laws demonstrate that a great majority of Americans at the time—regardless of their famously intense disputes as to the merits of the underlying abortion question—agreed that the government should not have the power to compel participation in abortions by unwilling individuals and institutions.").

⁶ *See, e.g.*, Stephen J. Genuis & Chris Lipp, *Ethical Diversity and the Role of Conscience in Clinical Medicine*, 2013 Int'l. J. Family Med. 1, 9 (2013); Armand H. Matheny Antommara, *Adjudicating*

entities, too, have expressed qualms about the provision of, participation in, or provision of insurance coverage for, certain procedures or services. To address these problems, Congress has repeatedly legislated conscience protections for the institutions and individuals providing health care to the American public, as outlined below.

A. The Church Amendments

The Church Amendments were enacted at various times during the 1970s in response to debates over whether judicially recognized rights to abortions or sterilizations might lead to the requirement that individuals or entities participate in activities to which they have religious or moral objections. The Church Amendments consist of five provisions, codified at 42 U.S.C. 300a–7, that protect those who hold religious beliefs or moral convictions respecting certain health care procedures from discrimination by entities that receive Federal funding.

First, subsection (b) of the Church Amendments provides that no court, public official, or other public authority can use an individual's receipt of certain Federal funding as grounds to require the individual to perform, or assist in, sterilizations or abortions, if doing so would be contrary to his or her religious beliefs or moral convictions. 42 U.S.C. 300a–7(b)(1). Subsection (b) further prohibits those public authorities from requiring an entity, based on the entity's receipt of Federal funds under certain HHS programs, (1) to permit sterilizations or abortions in the entity's facilities if the entity otherwise prohibits the performance of such procedures on the basis of religious beliefs or moral convictions, or (2) to make its personnel available for such procedures if contrary to the personnel's religious beliefs or moral convictions. 42 U.S.C. 300a–7(b)(2)(A) and (b)(2)(B). The individuals and entities protected by this provision are recipients of a grant, contract, loan, or loan guarantee under the Public Health Service Act (42 U.S.C. 201 *et seq.*) and their personnel.⁷

Second, subsection (c)(1) of the Church Amendments applies to decisions on employment, promotion, or termination of employment, as well as extension of staff or other privileges with respect to physicians and other health care personnel. 42 U.S.C. 300a–7(c)(1)(A)–(B). This subsection prohibits certain entities from discriminating in these decisions based on an individual's refusal to perform or assist in an abortion or sterilization because of religious beliefs or moral convictions. 42 U.S.C. 300a–7(c)(1). It also prohibits those entities from discriminating in such decisions based on an individual's performance of a lawful abortion or sterilization procedure, or on an individual's religious beliefs or moral convictions about such procedures more generally. *Id.* Like subsection (b), recipients of a grant, contract, loan, or loan guarantee under the Public Health Service Act must comply with subsection (c)(1).

Third, subsection (c)(2) of the Church Amendments applies to the recipients of the Department's grants or contracts for biomedical or behavioral research under any program administered by the Secretary of Health and Human Services. 42 U.S.C. 300a–7(c)(2). This subsection prohibits discrimination against physicians or other health care personnel in employment, promotion, or termination of employment, as well as discrimination in the extension of staff or other privileges because of an individual's performance or assistance in any lawful health service or research activity, refusal to perform or assist in any such service or activity based on religious beliefs or moral convictions, or the individual's religious beliefs or moral convictions respecting such services or activities more generally. 42 U.S.C. 300a–7(c)(2)(A)–(B).

Fourth, subsection (d) of the Church Amendments applies to any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary. For these programs, no individual shall be required to perform or assist in the performance of part of the program or research activity if doing so would be contrary to his or her religious beliefs or moral convictions. 42 U.S.C. 300a–7(d).

Fifth, subsection (e) of the Church Amendments applies to health care training or study, such as internships and residencies. Subsection (e) prohibits any entity receiving certain funds from denying admission to, or otherwise discriminating against, applicants for training or study based on the applicant's reluctance or willingness to counsel, suggest, recommend, assist, or

in any way participate in the performance of abortions or sterilizations contrary to or consistent with the applicant's religious beliefs or moral convictions. 42 U.S.C. 300a–7(e). Recipients of a grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 *et seq.*) must comply with subsection (e). Notably, the Church Amendments contain provisions protecting the rights of individuals and entities explicitly.

B. The Coats-Snowe Amendment (Section 245 of the Public Health Service Act)

Enacted in 1996, section 245 of the Public Health Service Act (also known as the “Coats-Snowe Amendment” or “Coats-Snowe”) applies nondiscrimination requirements to Federal, State, or local governments receiving Federal financial assistance. 42 U.S.C. 238n. As a condition of receiving such funding, those governments may not discriminate against “health care entities,” including individual physicians; participants in programs of training in the health professions; and postgraduate physician training programs, including residency training programs, that refuse to undergo training in, require or provide training in, or perform abortions; refer for abortions or abortion training; or make arrangements for any of those activities. 42 U.S.C. 238n(a)(1)–(2). Furthermore, those governments may not discriminate against a health care entity because the entity attends or attended a health care training program that does not (or did not) perform abortions; require, provide, or refer for training in the performance of abortions; or make arrangements for any such training. 42 U.S.C. 238n(a)(3).

In addition, Coats-Snowe applies to accreditation of postgraduate physician training programs. Therefore, governments receiving the specified Federal funds may not deny a legal status (including a license or certificate) or financial assistance, services, or other benefits to a health care entity (which, as defined in 42 U.S.C. 238n(c)(2), includes individual physicians, postgraduate physician training programs, and participants in programs of training in the health professions) based on an applicable physician training program's lack of accreditation due to the accrediting agency's requirements that a health care entity perform induced abortions; require, provide, or refer for training in the performance of induced abortions; or

Rights or Analyzing Interests: Ethicists' Role in the Debate Over Conscience in Clinical Practice, 29 *Theor. Med. Bioeth.* 201, 206 (2008); William W. Bassett, *Private Religious Hospitals: Limitations Upon Autonomous Moral Choices in Reproductive Medicine*, 17 *J. Contemp. Health L. & Pol'y* 455, 529 (2001); Peter A. Clark, *Medical Ethics at Guantanamo Bay and Abu Ghraib: The Problem of Dual Loyalty*, 34 *J.L. Med. & Ethics* 570 (2006).

⁷ The Community Mental Health Centers Act, Public Law 88–164, 77 Stat. 282 (1963), and the Developmental Disabilities Services and Facilities Construction Amendments of 1970, Public Law 91–517, 84 Stat. 1316 (1970), were repealed by subsequent statute and accordingly are not referenced here.

make arrangements for such training. 42 U.S.C. 238n(b)(1).

C. The Weldon Amendment

The Weldon Amendment (or “Weldon”) was originally adopted in 2004 and has been readopted (or incorporated by reference) in each subsequent appropriations act for the Departments of Labor, Health and Human Services, and Education. *See, e.g.*, Consolidated Appropriations Act, 2017, Public Law 115–31, Div. H, sec. 507(d), 131 Stat. 135. Weldon provides that “[n]one of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.” Consolidated Appropriations Act, 2017, Public Law 115–31, Div. H, sec. 507(d)(1), 131 Stat. 135. Weldon defines “health care entity” to “include[] an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.” *Id.* at sec. 507(d)(2).

D. Conditions on Federally Appropriated Funds Requiring Compliance With Federal Health Care Conscience and Associated Anti-Discrimination Laws

In addition to Weldon, the Consolidated Appropriations Act of 2017 includes other health care conscience protections. For example, a provision, using the same language as the Weldon Amendment, prohibits the Department from denying participation in Medicare Advantage to an otherwise eligible health care entity, such as a provider-sponsored organization, on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortion. Consolidated Appropriations Act, 2017, Public Law 115–31, Div. H, sec. 209, 131 Stat. 135.

E. The Patient Protection and Affordable Care Act’s Conscience and Associated Anti-Discrimination Protections

Passed in 2010, the Patient Protection and Affordable Care Act (ACA) also includes several conscience and associated anti-discrimination protections.

Section 1553 of the ACA prohibits Federal, State, or local governments; health care providers that receive

Federal financial assistance under the ACA; and ACA health plans from discriminating against an individual or institutional health care entity because of the individual or entity’s objection to providing any health care items or service for the purpose of causing or assisting in causing death, such as by assisted suicide, euthanasia, or mercy killing. 42 U.S.C. 18113. Section 1553 designates the HHS Office for Civil Rights (OCR) to receive complaints of discrimination on that basis. *Id.*

Section 1303 declares that the ACA does not require health plans to provide coverage of abortion services as part of “essential health benefits for any plan year.” 42 U.S.C. 18023(b)(1)(A). Furthermore, no qualified health plan offered through an ACA exchange may discriminate against any individual health care provider or health care facility because of the facility or provider’s unwillingness to provide, pay for, provide coverage of, or refer for abortions. 42 U.S.C. 18023(b)(4). And section 1303 of the ACA makes clear that nothing in that Act should be construed to undermine “Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.” 42 U.S.C. 18023(c)(2)(A)(i)–(iii).

Finally, Internal Revenue Code sec. 5000A, as added by section 1501 of the ACA, provides a religious conscience exemption from the individual mandate to maintain minimum essential coverage (and avoid its corresponding tax penalty) for any member of an exempt religious organization or division or for a “health care sharing ministry.” 26 U.S.C. 5000A(d)(2). Exempt religious organizations or individuals are those who adhere to established tenets or teachings in opposition to acceptance of the benefits of any private or public insurance. 26 U.S.C. 1402(g)(1). A “health care sharing ministry” is an organization, described in section 501(c)(3) and taxed under section 501(a) of the Internal Revenue Code, comprising members who share a common set of ethical or religious beliefs and who share medical expenses among members in accordance with those beliefs without regard to the State in which a member resides or is employed. 26 U.S.C. 5000A(d)(2)(B). Under Section 1411 of the ACA (42 U.S.C. 18081), HHS is responsible for issuing certifications to individuals who are entitled to an exemption from the individual responsibility requirement or the associated tax penalties imposed

under Internal Revenue Code sec. 5000A, including when such individuals are exempt by reason of membership in an exempt religious organization or health care sharing ministry. 42 U.S.C. 18081(a)(4), (b)(5).

F. Other Protections Related to the Performance of Advance Directives or Assisted Suicide

Even before the ACA, Congress had passed conscience protections related to assisting or causing death. Section 7 of the Assisted Suicide Funding Restriction Act of 1997 (Pub. L. 105–12, 111 Stat. 23) clarified that the Patient Self-Determination Act’s provisions stating that Medicare and Medicaid beneficiaries have certain self-determination rights do not: (1) Require any provider, organization, or any employee of such provider or organization participating in the Medicare or Medicaid program to inform or counsel any individual about a right to any item or service furnished for the purpose of causing or assisting in death, such as assisted suicide, euthanasia, or mercy killing; or (2) apply to or affect any requirement with respect to a portion of an advance directive that directs the purposeful causing of, or assistance in causing, the death of an individual, such as by assisted suicide, euthanasia, or mercy killing. 42 U.S.C. 14406 (by cross-reference to 42 U.S.C. 1395cc(f) (Medicare) and 1396a(w) (Medicaid)); *see also* 42 U.S.C. 1396a(w)(3), 1396a(a)(57); 1396b(m)(1)(A); 1396r(c)(2)(E); and 1395cc(f)(4) (by cross-reference to 42 U.S.C. 14406).⁸ Those protections extend to Medicaid and Medicare providers, such as hospitals, nursing facilities, home health or personal care service providers, hospice programs, Medicaid managed care organizations, health maintenance organizations, Medicare+Choice (now Medicare Advantage) organizations, and prepaid organizations.

G. Protections Related to Counseling and Referrals Under Medicare Advantage Plans, Medicaid Plans, and Managed Care Organizations

Certain Federal protections extend beyond the context of advance

⁸ Similar protections exist under the Department’s regulations applicable to hospitals, nursing facilities, and other medical facilities, 42 CFR 489.102(c)(2); Medicare Advantage, 42 CFR 422.128(b)(2)(ii); and Medicare Health Maintenance Organizations and Comprehensive Medical Plans, 42 CFR 417.436 (such organizations, plans, and their agents are not required to implement advance directives if the provider cannot do so “as a matter of conscience” and State law allows such conscientious objection).

directives. For example, Federal law prohibits organizations offering Medicare+Choice (now Medicare Advantage) plans and Medicaid managed care organizations from being compelled to provide, reimburse for, or cover any counseling or referral service in plans over an objection on moral or religious grounds. 42 U.S.C. 1395w–22(j)(3)(B) (Medicare+Choice); 42 U.S.C. 1396u–2(b)(3)(B) (Medicaid managed care organization). Department regulations provide that this conscience provision for managed care organizations also applies to prepaid inpatient health plans and prepaid ambulatory health plans under the Medicaid program. 42 CFR 438.102(a)(2).

H. Conscience and Associated Anti-Discrimination Protections Applying to Global Health Programs

The Department administers certain programs under the President's Emergency Program for AIDS Relief (PEPFAR), to which additional conscience protections apply. Specifically, recipients of foreign assistance funds for HIV/AIDS prevention, treatment, or care authorized by section 104A of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2), 22 U.S.C. 7601–7682, or under any amendment made by the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (Pub. L. 110–293), cannot be required, as a condition of receiving such funds, (1) to “endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS,” or (2) to “endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.” 22 U.S.C. 7631(d)(1)(B). The government also cannot discriminate against such recipients in the solicitation or issuance of grants, contracts, or agreements for the recipients' refusal to do any such actions. 22 U.S.C. 7631(d)(2).

I. Exemptions From Compulsory Medical Screening, Examination, Diagnosis, or Treatment

In addition to these provider protections, multiple Federal health programs contain conscience protections for patients and parents of children who have objections to certain tests or treatments. Congress provided, for example, that neither Medicaid nor the Children's Health Insurance Program (CHIP) should be interpreted to require any State “to compel any person

to undergo any medical screening, examination, diagnosis, or treatment” against their religious objection. 42 U.S.C. 1396f. Similarly, although Congress granted HHS authority to conduct research, experiments, and demonstrations related to occupational illnesses in the Occupational Safety and Health Act of 1970, such authority did not include the power to require “medical examination, immunization, or treatment for those who object thereto on religious grounds, except where such is necessary for the protection of the health or safety of others.” 29 U.S.C. 669(a)(5).

As relevant here, four other statutory provisions protect parents who conscientiously object to their children being forced to receive certain treatments or health interventions. First, under the Public Health Service Act, certain suicide prevention programs are not to be construed to require “suicide assessment, early intervention, or treatment services for youth” if their parents or legal guardians have religious or moral objections to such services. 42 U.S.C. 290bb–36(f); Section 3(c) of the Garrett Lee Smith Memorial Act (Pub. L. 108–355, 118 Stat. 1404, reauthorized by Pub. L. 114–255 at Sec. 9008). Second, Health Resources and Services Administration (HRSA) grants may not be used to preempt or prohibit State laws, including laws which do not require hearing loss screening for newborn infants or young children where their parents object to such screening based on religious belief. 42 U.S.C. 280g–1(d). Third, providers of pediatric vaccines funded by Federal medical assistance programs must comply with any State laws relating to any religious or other exemptions. 42 U.S.C. 1396s(c)(2)(B)(ii). Fourth, certain State and local child abuse prevention and treatment programs funded by HHS are not to be construed as creating a Federal requirement that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of that parent or legal guardian. 42 U.S.C. 5106i(a)(1).

J. Conscience Clauses Related to Religious Nonmedical Health Care

Since 1965, Congress has provided accommodations in Medicare and Medicaid for persons and institutions objecting to the acceptance or provision of medical care or services based on a belief in a religious method of healing through approval of religious nonmedical health care institutions (RNHCIs). RNHCIs object to providing many standard medical items and services, such as screenings, examination, diagnosis, prognosis,

treatment, or the administration of medications. 42 U.S.C. 1395x(ss)(1). Instead, RNHCIs furnish nonmedical items and services such as room and board, unmedicated wound dressings, and walkers,⁹ and they provide care exclusively through nonmedical nursing personnel assisting with nutrition, comfort, support, moving, positioning, ambulation, and other activities of daily living.¹⁰

Congress has supported RNHCIs through several statutes. For example, although such institutions would not otherwise meet the medical criteria for Medicare providers, *see* 42 U.S.C. 1395x(e) (definition of “hospital”), 1395x(y)(1) (definition of “skilled nursing facility”), 1395x(k), and 1320cb–11 (exemptions from other medical criteria and standards), Congress expressly included them within the definition of designated Medicare providers. Congress prohibited States from excluding RNHCIs from licensure through implementation of State definitions of “nursing home” and “nursing home administrator,” 42 U.S.C. 1396g(e), and Congress exempted RNHCIs from certain Medicaid requirements for medical criteria and standards. 42 U.S.C. 1396a(a)(83) (exempting RNHCIs from 42 U.S.C. 1396a(a)(9)(A), 1396a(a)(31), 1396a(a)(33), and 1396b(i)(4)). Finally, Congress permitted patients at RNHCIs to file an election with HHS stating that they are “conscientiously opposed to acceptance of” medical treatment on the basis of “sincere religious beliefs” (42 U.S.C. 1395ib–5) yet will remain eligible for the nonmedical care and services ordinarily covered under Medicare, Medicaid, and CHIP. 42 U.S.C. 1395x(e), 1395x(y), and 1396g(e). Federal courts have upheld the constitutionality of such religious accommodations. *See e.g., Children's Healthcare v. Min De Parle*, 212 F.3d 1084 (8th Cir. 2000) and *Kong v. Min De Parle*, No. C 00–4285 CRB, 2001 WL 1464549 (N.D.Cal. Nov. 13, 2001).

Congress has also provided particular accommodations for persons and institutions that object to medical services and items. Section 6703(a) of the Elder Justice Act of 2009 (Pub. L. 111–148, 124 Stat. 119) provides that Elder Justice and Social Services Block Grant programs may not interfere with or abridge a person's “right to practice his or her religion through reliance on

⁹ <https://www.medicare.gov/coverage/rnhci-items-and-services.html>.

¹⁰ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/RNHCIs.html>.

prayer alone for healing,” when the preference for such reliance is contemporaneously expressed, previously set forth in a living will or similar document, or unambiguously deduced from the elder’s life history. 42 U.S.C. 1397j–1(b). Additionally, the Child Abuse Prevention and Treatment Act (CAPTA) specifies that it does not require (though it also does not prevent) a State finding of child abuse or neglect in cases in which a parent or legal guardian relies solely or partially upon spiritual means rather than medical treatment, in accordance with religious beliefs. 42 U.S.C. 5106i(a)(2).

IV. The Original Version and Current Version of the Rule

The Department has engaged in rulemaking to enforce some of these Federal health care conscience and associated anti-discrimination provisions on two previous occasions: in the 2008 Federal Health Care Conscience Rule, and in the revocation and replacement of that Rule in 2011. This Part briefly summarizes each action.

A. 2008 Federal Health Care Conscience Rule

The Department issued a notice of proposed rulemaking in 2008 to clarify and enforce the Church, Coats-Snowe, and Weldon Amendments. 73 FR 50274 (Aug. 26, 2008). That notice recognized: (1) The inconsistent awareness of Federal health care nondiscrimination protections among Federally funded recipients and protected persons and entities; and (2) the unavailability of remedies for victims of discrimination under the above-referenced Amendments.

The Department received a “large volume” of comments on the 2008 proposed rule. *See* 73 FR 78072, 78074 (2008 Rule). Comments came from a wide variety of individuals and organizations, including private citizens, individual and institutional health care providers, religious organizations, patient advocacy groups, professional organizations, universities and research institutions, consumer organizations, and State and Federal agencies and representatives. Comments dealt with a range of issues surrounding the proposed rule, including whether the rule was needed, what individuals would be protected by the proposed rule, what services would be covered by the proposed rule, whether health care workers would use the regulation to discriminate against patients, what significant implementation issues could be associated with the rule, what legal arguments could be made for and

against the rule, and what cost impacts of the proposed rule could be anticipated. Many comments confirmed the need to promulgate a regulation to raise awareness of Federal nondiscrimination protections and provide for their enforcement.

The Department responded to those substantive comments and issued a final rule on December 19, 2008, 45 CFR part 88, consisting of six sections:

Section 88.1 stated that the purpose of the 2008 Rule was “to provide for the implementation and enforcement” of the Church, Coats-Snowe, and Weldon Amendments. It specified that those Amendments and the implementing regulations “[w]ere to be interpreted and implemented broadly to effectuate their protective purposes.”

Section 88.2 of the 2008 Rule defined several terms used in Part 88 and applicable to various provider nondiscrimination protections, namely, the terms “Assist in the Performance,” “Entity,” “Health Care Entity,” “Health Service Program,” “Individual,” “Instrument,” “Recipient,” “Sub-recipient,” and “Workforce.”

Section 88.3 of the 2008 Rule set forth the scope of applicability of the sections and subsections of Part 88 as they related to each conscience law subject to the 2008 Rule.

Section 88.4 of the 2008 Rule set forth the substantive requirements and applications of the Church Amendments, Coats-Snowe, and the Weldon Amendment.

Section 88.5 of the 2008 Rule required covered Federally funded entities to provide written certification of compliance with the laws on conscience protection subject to the 2008 Rule.

Section 88.6 of the 2008 Rule designated HHS OCR to receive complaints based on the provider conscience laws and directed OCR to coordinate handling those complaints with the Departmental components with respect to which the covered entity receives funding.

B. Proposed Changes in 2009 Resulting in New Final Rule in 2011

On March 10, 2009, with the advent of a new Administration, the Department proposed to rescind, in its entirety, the 2008 Rule. 74 FR 10207 (Mar. 10, 2009) (2009 Proposed Rule). The Department declared that certain comments on the August 2008 Proposed Rule raised a number of questions warranting further review of the 2008 Rule to ensure its consistency with that Administration’s policy. The Department invited further comments to reevaluate the necessity for regulations implementing the conscience protection

and provider nondiscrimination laws. In response to the proposal to rescind the 2008 Rule, the Department received comments stating that health care workers should not be required to violate their religious or moral convictions; expressing concern that health care providers would be coerced into violating their consciences; and identifying the 2008 Rule as protecting First Amendment religious freedom rights, the capacity to uphold the tenets of the Hippocratic Oath, and the ethical integrity of the medical profession. Numerous commenters identified concerns that there would be no regulatory scheme to protect the rights afforded to health care providers, including medical students. 76 FR 9968, 9971 (Feb. 23, 2011) (2011 Rule).

On February 23, 2011, the Department rescinded most of the 2008 Rule and finalized the present rule. 76 FR 9968 (Feb. 23, 2011) (2011 Rule). The 2011 Rule left in place section “88.1 Purpose,” but removed the word “implementation,” describing the Rule’s purpose as “provid[ing] for the enforcement” of the Church, Coats-Snowe, and Weldon Amendments. It then removed the 2008 Rule’s sections 88.2 through 88.5, redesignated the 2008 Rule’s section 88.6 as section 88.2, and modified that section to read, in its entirety: “The Office for Civil Rights (OCR) of the Department of Health and Human Services is designated to receive complaints based on the Federal health care provider conscience protection statutes. OCR will coordinate the handling of complaints with the Departmental funding component(s) from which the entity, to which a complaint has been filed, receives funding.”

The preamble to the 2011 Rule stated, “The Department supports clear and strong conscience protections for health care providers who are opposed to performing abortions.” 76 FR at 9969. The Department recognized, “The comments received suggested that there is a need to increase outreach efforts to make sure providers and grantees are aware of these statutory protections. It is also clear that the Department needs to have a defined process for health care providers to seek enforcement of these protections.” 76 FR at 9969. Accordingly, the summary of the 2011 Rule stated that “enforcement of the Federal statutory health care provider conscience protections will be handled by the Department’s Office for Civil Rights, in conjunction with the Department’s funding components.” 76 FR at 9968. The Department announced that OCR was beginning to lead “an initiative designed to increase the

awareness of health care providers about the protections provided by the health care provider conscience statutes, and the resources available to providers who believe their rights have been violated.” 76 FR at 9969. The 2011 Rule provided that OCR would “collaborate with the funding components of the Department to determine how best to inform health care providers and grantees about health care conscience protections, and the new process for enforcing those protections.” *Id.*

V. History of OCR Enforcement of Federal Health Care Conscience Laws

Since the designation of OCR as the agency with authority to enforce Federal health care conscience laws in 2008, OCR has received a total of forty-four complaints, the large majority of which (thirty-four) were filed since the November 2016 election.¹¹ Of these forty-four complaints, thirty-five currently remain open. OCR closed six of the complaints after investigation and three on administrative grounds.

The first of the closed complaints, filed on March 8, 2010,¹² by a nurse at a private hospital, alleged that the hospital had forced her to assist in an abortion in 2009 in violation of the Church Amendments. OCR conducted an investigation and closed the complaint less than a year later after OCR determined that the hospital had agreed to sufficient corrective action in a resolution agreement. The hospital had agreed to: (1) Comply with the Church Amendments; (2) continue to make best efforts to ensure that non-objecting health care personnel are available to perform job duties with respect to abortion procedures, including any abortion procedures that occur over the weekend; (3) revise its human resources policy concerning nondiscrimination as set forth in subsection (c)(1) of the Church Amendments; (4) continue to post notices of that policy on the hospital’s intranet and on the operating room notice board; and (5) train personnel about the hospital’s obligations under the Church Amendments to ensure proper recording of staff’s objecting or non-objecting status. In addition, the hospital incorporated technical assistance from OCR regarding its process for identifying employees’

objection status and the hospital’s grievance procedures. OCR directed the hospital to ensure that no adverse action was taken against the complainant or others for participating in the investigation.

In January 2011,¹³ OCR closed two other complaints alleging that a university violated the Church Amendments by requiring applicants to a nurse residency program to sign a form agreeing to assist in abortion procedures. Specifically, the application form declared, “If you are chosen for the Nurse Residency Program in the Women’s Health track, you will be expected to care for women undergoing termination of pregnancy. . . . If you feel you cannot provide care to women during this type of event, we encourage you to apply to a different track of the Nurse Residency Program to explore opportunities that may best fit your skills and career goals.” The form further provided, “By signing this letter, I acknowledge that I am aware that I may be providing nursing care for women who are having the procedures listed above.” OCR closed these two complaints after it determined that the university had engaged in adequate corrective action—which included a public announcement that the university would no longer require an applicant to the nursing program to sign the form if doing so would be inconsistent with the applicant’s religious or moral beliefs.

Members of Congress raised concerns following OCR’s closure of three additional complaints filed on September 10, October 1, and October 9, 2014,¹⁴ alleging that the State of California violated the Weldon Amendment by requiring insurance plans to cover elective abortions. Those complaints were filed by eighteen different complainants: one religious organization, seven churches, one church school, two religiously affiliated universities, and seven employees of one of those universities who participated in the university’s health plan. Each complaint alleged that the California Department of Managed Health Care (CDMHC) had contacted seven insurers offering plans without abortion coverage on August 22, 2014, and stated that those insurers were required to include abortion coverage in order to maintain certification as insurance companies in California. All seven insurers changed their policies in

response to the letter. OCR closed the complaints on the stated ground that the seven insurers did not object to providing abortion coverage on religious or moral grounds and that the Weldon Amendment required such objection.¹⁵

OCR at that time took the view that a protected entity must assert a religious or moral objection in order to merit protection under the Weldon Amendment, although the express language of the law does not require that a health care entity claim a religious or moral objection to merit protection. OCR’s closures prompted 133 Members of Congress to express concern to the HHS Secretary that the Department failed to enforce the Weldon Amendment.¹⁶ Senior leaders of the House of Representatives also scheduled a meeting with the HHS Secretary and OCR Director to request information from OCR about these closures.¹⁷

Since that time, OCR has closed three more complaints on administrative grounds. The first, filed on May 5, 2016, alleged that a hospital center violated the Church Amendments by discriminating against a health care professional who performed and supported the performance of abortions,¹⁸ but the complainant withdrew that complaint nine months later. The second, filed October 25, 2016, alleged a covered entity discriminated against the complainant when it refused to perform a sterilization procedure. Though technically not a conscience complaint itself, the covered entity’s answer, filed before OCR undertook any investigation, raised conscience-based defenses, specifically citing the Church Amendments. Following the complainant’s request to withdraw the complaint, OCR administratively closed the case. The third, filed on January 17, 2017, concerned literature the complainant received from his employer’s pharmacy benefit management company, and to which the employee had a religious or moral objection.¹⁹ OCR determined that the complainant had failed to raise sufficient facts to support a claim under the Federal health care conscience and anti-discrimination laws.

Of the ten complaints filed before November 2016, two (one filed August

¹¹ After OCR proposed rescission of the 2008 Rule, forty-six members of Congress, including the Chairman of the House Energy and Commerce Committee with oversight over HHS, raised concerns about whether HHS was fully enforcing the Federal health care conscience laws. See Rep. Mike Pence, House Energy and Commerce Committee Chairman Joseph Pitts, et al., Letter to HHS Secretary Kathleen Sebelius (Feb. 11, 2011).

¹² OCR Complaint No. 10–109676.

¹³ OCR Complaint No. 11–122388; OCR Complaint No. 11–122387.

¹⁴ OCR Complaint No. 14–193604; OCR Complaint No. 15–193782; OCR Complaint No. 15–195665.

¹⁵ Letter from OCR Director to Complainants (June 21, 2016), <http://www.adfmedia.org/files/CDMHCInvestigationClosureLetter.pdf>.

¹⁶ Letter from Reps. John Fleming, M.D., Diane Black, et al. to HHS Secretary Kathleen Sebelius (Nov. 25, 2014).

¹⁷ House Majority Whip Kevin McCarthy, et al., Letter to Secretary Sebelius (June 22, 2016).

¹⁸ OCR Complaint No. 15–238113.

¹⁹ OCR Complaint No. 17–259696.

15, 2014 and the other filed November 4, 2015) remain open. Although OCR received on average only approximately 1.25 complaints per year from the 2008 Rule until November 2016, OCR has received *thirty-four* complaints between November 2016 and mid-January 2018.

VI. Reasons for the Proposed Rule

After reviewing the previous rulemakings, comments from the public, and OCR's enforcement activities, the Department has concluded that there is a significant need to amend the 2011 Rule to ensure knowledge, compliance, and enforcement of the Federal health care conscience and associated anti-discrimination laws. The 2011 Rule created confusion over what is and is not required under Federal health care conscience laws and narrowed OCR's enforcement authority. Since November 2016, there has been a significant increase in complaints filed with OCR alleging violations of these conscience and associated anti-discrimination laws. The increase underscores the need for the Department to have the proper enforcement tools available to appropriately enforce Federal health care conscience and associated anti-discrimination laws.²⁰

A. Allegations and Evidence of Discrimination and Coercion Have Existed Since the 2008 Rule and Increased Over Time

The 2008 Rule sought to address an environment of discrimination toward, and attempted coercion of, those who object to certain health care procedures based on religious or moral convictions.²¹ Yet in February 2009, the Department announced its intent to rescind the 2008 Rule just one month after its effective date.²² And it completed that rescission in 2011 despite significant evidence of an environment of discrimination and coercion, including thousands of public comments during the 2008 and 2011 rulemakings describing the same.

²⁰ Since 2011, conscience and coercion in health care have been the subjects of significant litigation on the State and local level. Recently, the Supreme Court agreed to determine whether certain disclosures required by a state law violate the Free Speech rights of pregnancy resource centers that do not refer for abortions. See *National Institute of Family and Life Advocates v. Becerra*, No. 16-1140 (*certiorari* granted November 13, 2017).

²¹ 73 FR 78072, 78073 (Dec. 19, 2008) (2008 Rule).

²² Rob Stein, *Obama Plans to Roll Back 'Conscience' Rule Protecting Health Care Qf Workers Who Object to Some Types of Care*, The Washington Post (Feb. 28, 2009) <http://www.washingtonpost.com/wp-dyn/content/article/2009/02/27/AR2009022701104.html> (writing that "The administration's plans, revealed quietly with a terse posting on a Federal website, unleashed a flood of heated reaction").

Indeed, a 2009 article in the *New England Journal of Medicine* argued, "Qualms about abortion, sterilization, and birth control? Do not practice women's health."²³ In a 2009 survey of 2,865 members of faith-based medical associations, 39% reported having faced pressure or discrimination from administrators or faculty based on their moral, ethical, or religious beliefs.²⁴ Additionally, 32% of survey respondents reported having been pressured to refer a patient for a procedure to which they had moral, ethical, or religious objections. Some 20% of medical students in that poll said that they would not pursue a career in obstetrics/gynecology because of perceived discrimination and coercion in that specialty against their beliefs. In total, 91% of respondents reported that they "would rather stop practicing medicine altogether than be forced to violate [their] conscience."

Comments received during the 2011 rulemaking were consistent with this survey. Multiple commenters reported that some hospitals had forced health care providers to sign affidavits agreeing to participate in abortions if asked.²⁵ One obstetrician/gynecologist commented that, during his entire time in health care—from medical school, through his residency, and to private practice—he had been pressured to participate in abortions and abortion counseling.²⁶ Medical and nursing students, in twenty-five comments, expressed their reluctance to enter the health care field as a whole, and particularly specialties such as obstetrics, family medicine, and elder care, where their objections to abortion or euthanasia might not be respected.²⁷

²³ Julie D. Cantor, M.D., J.D., "Conscientious Objection Gone Awry—Restoring Selfless Professionalism in Medicine," 360 *New England J. Med.* 1484–85 (April 9, 2009).

²⁴ The Polling CompanyTM, Inc./WomanTrend, *Highlights of The Polling Company, Inc. Phone Survey of the American Public*, fielded March 31, 2009 through April 3, 2009, <https://www.cmda.org/library/doclib/pollingsummaryhandout.pdf> (last visited Jan. 18, 2018); see also Memorandum from Jonathan Imbody, Christian Medical Association, Vice President for Government Relations to Office of Public Health and Science, Department of Health and Human Services (Apr. 9, 2009).

²⁵ Comment Nos. HHS-OPHS-2009-0001-0739, -52648, -52677.

²⁶ Comment No. HHS-OPHS-2009-0001-0868.

²⁷ Comment Nos. HHS-OPHS-2009-0001-0026, -1035, -10522, -12117, -14427, -34439, -11404 ("future physician" concerned about shortages), -35236 (granddaughter entering the medical profession will change career path), -11579 (son entering the medical profession), -14435 (concerned mother of medical student), -18783 (spoke to student who is distraught and may leave), -5571, -41431 (sister is a medical student), -5638, -0068, -1791 (student would quit job), -2750 (exacerbates healthcare issues), -5255 (opposed and has used exemption), -7058, -7276, -7671, -5270

At least ninety commenters said that, if forced to choose between their careers or violating their conscience, they would quit their jobs.²⁸ Tens of thousands of comments to the proposed 2011 Rule expressed concern that, without robust enforcement of Federal health care conscience laws, individuals with conscientious objections simply would not enter the health care field at all or would leave the profession, and hospitals would shut down, contributing to the shortage of health care providers or affecting the quality of care provided.²⁹ Thousands also feared

(has already seen others leave the profession over pressure for their beliefs), -5638, -5566 (nurse who chose not to specialize in obstetrics and gynecology for fear of pressure), -5566 (nurse who chose not to enter obstetrics and gynecology because of pressure to perform abortions).

²⁸ Almost 90 comments are cited here, but this is merely a sample of the total. See comment Nos. HHS-OPHS-2009-0001-0540, -0017, -0264, -0350, -0356, -0485, -0540, -0880, -0881, -0902, -0917, -0932, -10154, -15148, -20381 (woman in California whose daughter is a nurse), -23290 (already left the profession), -32951, -9188, -47007 (patient's doctor said he would retire), -14287, -19128, -9873, -29603 (physician stating many will retire), -50498 (patient's doctor said he would retire), -27384, -44458, -18837, -14216, -18015, -18015, -34140 (already retired but would have retired earlier), -32593, -15341, -14837, -8582, -16541, -11579 (patient's doctor said he would retire), -0229, -51896 (children would be forced to leave), -32009 (other physicians will be driven out), -10280 (physician with objections), -19029, -33116, -50663, -3675, -24456, -11327, -19221, -34888 (nurse saying others will leave), -14535 (daughter will leave the profession), -21679 (four members in the family who may leave), -0283, -0340, -0905, -9272, -0055 (will give up serving underserved population), -10862 (two sisters who are nurses will leave, hospital shut down), -17401, -29674 (son who is a physician will be forced out), -26795 (physician who says doctors will be forced out), -25742, -49731, -15087, -13138, -17563, -0006 (refuse to accept violation of beliefs in practice), -0815, -7665, -8091, -2598 (private family physician who intentionally avoided obstetrics because it was made clear that "pro-life candidates need not apply." Also cites strong pressure in universities and organizations in favor of abortion provision. Concerned physicians will leave the practice more.), -3564, -0199, -5230 (discrimination already present), -6603, -1397 (nurse who has been forced to do things against her conscience in the past before the 2008 rule came into effect, and who will quit if put in that scenario again), -1100 (nurse who says others will leave the practice), -6669, -0272, -0925, -0125, -4668, -6709, -7900, -2544, -3535, -1852, -7684, -1381.

²⁹ Comment Nos. HHS-OPHS-2009-0001-20613, -43039, -27699, -42804, -6001, -10850, -27147, -50621, -52878, -19586, -40775, -4824, -27384, -11138, -52997, -53001, -4460, -12878, -12575, -43364, -27262, -42942, -26426, -38158, -43672, -52381, -32173, -16541, -19751, -2697, -52935, -6369, -44571, -53022, -48387, -21990, -50837, -42069, -14662, -51974, -45449, -17364, -5370, -2922, -15005, -18783, -23376, -50685, -17401, -52946, -11206, -33828, -38997, -3925, -21036, -50894, -27155, -10529, -47113, -7266, -22291, -4016, -0204, -8788, -25608, -52932, -39199, -12340, -52950 (form letter with 1,916 copies), -31897, -52984 (form letter with 62 copies), -53081 (form letter with 22 copies), -52968 (form letter with 9,532 copies), -52961 (patients concerned

Continued

personnel with objections would be terminated or otherwise unable to find employment, training, or opportunities to advance in their field.³⁰ Commenters identified a culture of hostility to conscience concerns in health care.³¹ Some expressed concern that the rescission of the 2008 Rule would contribute to these problems by inappropriately politicizing, and interfering in, the practice of medicine and individual providers' judgment.³² Thousands of comments from medical personnel stated their disagreement with the rescission, often stating that they had requested exemptions in the past and were concerned rescission would make it harder to request exemptions in the future.³³ Hundreds of commenters expressed concern over the exclusion and marginalization of health care entities and employees holding religious or moral convictions, and fears that the moral agency of the medical profession was eroding.³⁴

According to news reports, in 2010, Nassau University Medical Center disciplined eight nurses when they raised objections to assisting in the performance of abortions.³⁵ Nurses in Illinois and New York filed lawsuits against private hospitals alleging they had been coerced to participate in abortions. *Mendoza v. Martell*, No. 2016-6-160 (Winnebago County Cir. Ill. June 8, 2016); *Cenzon-DeCarlo v. Mount Sinai Hospital*, 626 F.3d 695 (2d Cir.

2010). A nurse-midwife in Florida alleged she had been denied the ability to apply for a position at a hospital due to her objections to prescribing certain medications. *Hellwege v. Tampa Family Health Centers*, 103 F. Supp. 3d 1303 (M.D. Fla. 2015). Twelve nurses in New Jersey sued a public hospital over a policy allegedly requiring them to assist in abortions and for disciplining one nurse who raised a conscientious objection to the same. *Danquah v. University of Medicine and Dentistry of New Jersey*, No. 2:11-cv-6377 (D.N.J. Oct. 31, 2011). Many religious health care personnel and faith-based medical entities have further alleged that health care personnel are being targeted for their religious beliefs.³⁶

In 2016, the American Congress of Obstetricians and Gynecologists (ACOG) reaffirmed a prior ethics opinion that recommended, "[i]n an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections."³⁷

B. Recently Enacted State and Local Government Health Care Laws and Policies Have Resulted in Numerous Lawsuits by Conscientious Objectors

The Department has witnessed an increase in lawsuits against State and local laws that complainants allege violate conscience. For example, many State and local governments have enacted legislation requiring pregnancy resource centers to post notices related to abortion that plaintiffs have objected to on First Amendment and analogous grounds. Courts preliminarily or permanently enjoined ordinances in

New York City, Austin, Montgomery County, Baltimore, and Illinois. *Greater Baltimore Center for Pregnancy Concerns, Inc. v. Mayor and City Council of Baltimore*, No. 16-2325 (4th Cir. Jan. 5, 2018) (affirming freedom of speech claim to strike down Baltimore ordinance requiring pregnancy resource center to state abortion services are not available in their facilities); *Evergreen Association, Inc. v. City of New York*, 740 F.3d 233 (2d Cir. 2014) (striking down under the First Amendment ordinance provisions requiring disclosures about whether pregnancy resource centers refer for abortion and conveying city health department's recommendation to consult a licensed medical provider); *Austin LifeCare v. City of Austin*, No. 1:11-cv-00875-LY (W.D. Tex. Jun. 23, 2014) (permanently enjoining enforcement of ordinance as void for vagueness); *Centro Tepeyac v. Montgomery County*, 5 F.Supp.3d 745 (D. Md. Mar. 7, 2014) (applying strict scrutiny in finding that ordinance violated pregnancy resource center's First Amendment rights); *Pregnancy Care Center of Rockford v. Rauner*, No. 2016-MR-741 (Ill. 17th Jud. Cir. Dec. 20, 2016) (preliminary injunction entered on free speech grounds); *National Institute of Family and Life Advocates v. Rauner*, No. 3:16-cv-50310 (N.D. Ill. filed Sept. 29, 2016) (preliminary injunction entered on free speech grounds). But litigation continues in a case filed against Hawaii. *See Calvary Chapel Pearl Harbor v. Chin*, No. 1:17-cv-00326-DKW-KSC (D. Haw., filed July 12, 2017) (stayed pending Supreme Court's review of *NIFLA v. Becerra*). And several courts rejected challenges to California's law, *see, e.g., Mountain Right to Life v. Harris*, No. 5:16-cv-00119 (C.D. Calif. July 8, 2016) (denying preliminary injunction); *A Woman's Friend Pregnancy Resource Clinic v. Harris*, 153 F.Supp.3d 1168 (E.D. Cal. Dec. 21, 2015); *Livingwell Medical Clinic v. Harris*, No. 3:15-cv-04939, 2015 WL 13187682 (N.D. Cal. Dec. 18, 2015).

Some of these ordinances also require that pregnancy resource centers or medical professionals provide information about where abortion services can be obtained or whether facilities have licensed medical staff. The Supreme Court issued a writ of certiorari in one such case challenging California's A.B. 775 on free speech grounds. *See NIFLA v. Becerra*, No. 16-1140 (Nov. 13, 2017).

Some States have also sought to require health insurance plans to cover abortions, triggering additional conscience-related lawsuits. California, for example, sent a letter to seven

about access to pro-life doctors: Form letter with 3,272 copies), -53098 (patients concerned effort to push people out: Form letter with 976 copies), -52977 (form letter with 3,516 copies), -53021 (form letter with 4,842 copies), -52949 (form letter with 688 copies), -53039 (form letter with 742 copies), -0476.

³⁰ Comment Nos. HHS-OPHS-2009-0001-0558, -10144, -53026 (claims documentation of unaddressed discrimination), -52985 (claims documentation of unaddressed discrimination), -52960 (claims documentation of unaddressed discrimination), -52735 (lack of knowledge about rights), -53048 (evidence of discrimination), -53047 (evidence of discrimination: Form letter with 3,196 copies), -52960 (evidence of discrimination: Form letter with 1,685 copies), -53028 (evidence of discrimination: Form letter with 2,002 copies).

³¹ Comment Nos. HHS-OPHS-2009-0001-0739, -52677, -26812, -53013 (form letter with 8,472 copies).

³² Comment No. HHS-OPHS-2009-0001-10280, -2486, -46903, -19125, -36940, -12020, -41551.

³³ Comment Nos. HHS-OPHS-2009-0001-3107, -15617, -19496, -27506, -9586, -35721, -49748, -1650, -19965, -18365, -23095, -6332, -3405, -1762, -4395, -4569, -6890, -0729, -0943, -1490, -2994, -3248, -3419, -5341, -6479, -7079, -4525, -7093, -2486, -2039, -7750, -6270, -1903, -3293, -3405, -1127, -5505, -1823, -4939, -5881, -4529, -5829, -1773, -2220, -2345, -3089, -7163, -7471, -3840, -0389, -1933, -3493, -3088, -5088, -5702.

³⁴ Comment Nos. HHS-OPHS-2009-0001-52974 (form letter with 428 copies).

³⁵ *LI Hospital issues abortion apology to nurses*, N.Y. Post (Apr. 28, 2010), <http://nypost.com/2010/04/28/li-hospital-issues-abortion-apology-to-nurses>.

³⁶ *See, e.g., Roman Catholic Diocese of Albany v. Vullo*, No. 02070-16 (N.Y. Albany County S. Ct. May 4, 2016); *Means v. U.S. Conference of Catholic Bishops*, No. 1:15-CV-353, 2015 WL 3970046 (W.D. Mich. 2015); *ACLU v. Trinity Health Corporation*, 178 F.Supp.3d 614 (E.D. Mich. 2016); *Minton v. Dignity Health*, No. 17-558259 (Calif. Super. Ct. Apr. 19, 2017); *Chamorro v. Dignity Health*, No. 15-549626 (Calif. Super. Ct. Dec. 28, 2015). *See also* U.S. Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Services* (Nov. 17, 2009) (identifying Catholic objections to performing abortions, tubal ligations, and hysterectomies).

³⁷ <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/The-Limits-of-Conscientious-Refusal-in-Reproductive-Medicine> (reaffirming ACOG, *The Limits of Conscientious Refusal in Medicine*, Committee Opinion No. 385, 110 Obstet Gyn. 1479 (2007)) The 2007 ACOG opinion had, at least in part, prompted the 2008 Rule. Then-HHS Secretary Leavitt wrote to ACOG and the American Board of Obstetrics and Gynecology (ABOG) and noted that the combination of the ACOG opinion and ABOG certification requirements could constitute a violation of Federal health care conscience laws.

insurance companies requiring insurers to include abortion coverage in plans used by persons who objected to such coverage. See Letter from California Department of Managed Health Care, *Re: Limitations or Exclusions of Abortion Services* (Aug. 22, 2014).³⁸ The state of California estimates that at least 28,000 individuals subsequently lost their abortion-free health plans, and multiple churches have challenged California's policy in court. See *Foothill Church v. Rouillard*, 2:15-cv-02165-KJM-EFB, 2016 WL 3688422 (E.D. Calif. July 11, 2016); *Skyline Wesleyan Church v. California Department of Managed Health Care*, No. 3:16-cv-00501-H-DHB (S.D. Calif. 2016). The New York State Department of Financial Services required individual and small group employers, irrespective of the number of employees or any religious affiliation, to provide insurance coverage for abortions, see New York Department of Financial Services, Outpatient and Professional Services Model Language, Section IX[M], prompting additional lawsuits, see, e.g., *Roman Catholic Diocese of Albany v. Vullo*, No. 02070-16 (N.Y. Albany County S. Ct. May 4, 2016).

Over the past several years, an increasing number of jurisdictions in the United States have also legalized assisted suicide. See District of Columbia B21-0038 (Feb. 18, 2017), Colorado Prop. 106 (Dec. 16, 2016); California ABX2-15 (June 9, 2016); 18 Vermont Act 39 (May 20, 2013) ("Act 39"). Act 39 states that health care professionals must inform patients "of all available options related to terminal care." 18 Vt. Stat. Ann. § 5282. When the Vermont Department of Health construed Act 39 to require all health care professionals to counsel for assisted suicide, individual health care professionals and associations of religious health care providers sued Vermont, alleging a violation of their conscience rights. *Vermont Alliance for Ethical Health Care, Inc. v. Hoser*, No. 5:16-cv-205 (D. Vt. Apr. 5, 2017) (dismissed by consent agreement). More recently still, the family of a California cancer patient sued UCSF Medical Center for elder abuse because the cancer patient died after the oncologists on staff declined to participate in assisted suicide and before she could obtain a new physician.³⁹

Finally, some States have passed laws requiring health care professionals to provide referrals for implementation of advance directives. See Iowa Code Ann. section 144D.3(5) (2012) (requiring that provider take "all reasonable steps to transfer the patient to another health care provider, hospital, or health care facility" even when there is an objection based on "religious beliefs, or moral convictions"); Idaho Code Ann. 39-4513(2) (2012) (requiring that a provider "make[] a good faith effort to assist the person in obtaining the services of another physician or other health care provider who is willing to provide care for the person in accordance with the person's expressed or documented wishes").

The Department has not opined on or judged the legal merits or sufficiency of any of the above-cited lawsuits or challenged laws. They are discussed here only to illustrate that recent disputes alleging violations of conscience, broadly understood, by state and local governments exist to a notable degree, and to illustrate the need for greater clarity concerning the scope and operation of the Federal conscience and associated anti-discrimination laws that are the subject of this regulation. The Department anticipates that the proposed regulation will result in greater public familiarity with Federal health care conscience and associated anti-discrimination protections and may inform both potential plaintiffs and future State and local legislators.

C. Confusion Exists About Conscience Laws' Scope and Applicability

Even though Federal health care conscience and associated anti-discrimination laws are currently in effect, the public has sometimes been confused about their applicability in relation to other Federal, State, or local laws. One of the purposes of the 2008 Rule was to address confusion about the interaction between Federal health care conscience protections and other Federal statutes.

For instance, some advocacy organizations have filed lawsuits claiming that Federal or State laws require private religious entities to perform abortions and sterilizations despite the existence of longstanding conscience and associated anti-discrimination protections on this topic. See *Means v. U.S. Conference of Catholic Bishops*, No. 1:15-CV-353, 2015 WL 3970046 (W.D. Mich. 2015) (abortion); *ACLU v. Trinity Health Corporation*, 178 F.Supp.3d 614 (E.D. Mich. 2016) (abortion); *Minton v. Dignity Health*, No. 17-558259 (Calif. Super. Ct. Apr. 19, 2017)

(hysterectomy); *Chamorro v. Dignity Health*, No. 15-549626 (Calif. Super. Ct. Dec. 28, 2015) (tubal ligation). A patient also recently sued a secular public hospital for accommodating doctors' and nurses' religious objections to abortion in alleged violation of a State law, Washington's Reproductive Privacy Act. *Coffey v. Public Hospital Dist. No. 1*, 20-15-2-00217-4 (Wash. 2015).

Congress has exercised the broad authority afforded to it under the Spending Clause to attach conditions on Federal funds for respect of conscience, and such conscience conditions supersede conflicting provisions of State law and must be harmonized and given effect with "cross-cutting" anti-discrimination laws, as in many other contexts. See e.g., Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et seq.* The Department seeks to clarify the scope and application of Federal health care conscience and associated anti-discrimination laws in the proposed rule.

D. Courts Have Found No Alternative Private Right of Action To Remedy Violations

In lawsuits filed by health care providers for alleged violations of certain Federal health care conscience and associated anti-discrimination laws, courts have held that such laws do not contain an implied private right of action to seek relief from such violations by non-governmental covered entities. Adequate governmental enforcement mechanisms are therefore critical to the enforcement of these laws.

The case of a New York nurse who alleged that a private hospital forced her to assist in an abortion over her religious objections illustrates the point. The nurse filed a lawsuit in Federal court in 2009, but her case was dismissed on the ground that she did not have a private right to file a civil action against such a hospital under the Church Amendments. *Cenzon-DeCarlo v. Mount Sinai Hospital*, 626 F.3d 695 (2d Cir. 2010). The Second Circuit affirmed the dismissal, holding that the Church Amendments "may be a statute in which Congress conferred an individual right" but that Congress *had not implied a remedy* to file suit against private entities in Federal court. *Id.* at 698-699. After the dismissal of the Federal lawsuit, the nurse then filed a case in State court, but that case too was dismissed for lack of a private right of action. *Cenzon-DeCarlo v. Mount Sinai Hospital*, 962 N.Y.S.2d 845 (S. Ct. Kings County 2010). The nurse then filed a complaint with OCR on January 1, 2011, and, as discussed above, OCR resolved the complaint when the hospital

³⁸ <https://www.dmhc.ca.gov/Portals/0/082214letters/abc082214.pdf>.

³⁹ Bob Egelko, *California's assisted-dying loophole: Some doctors won't help patients die*, San Francisco Chronicle (Aug. 12, 2017), <http://www.sfgchronicle.com/news/article/California-s-assisted-dying-loophole-Some-11761312.php>.

changed its written policy for health care professionals going forward.

Similar results were obtained in a Federal lawsuit brought by a nurse in 2014, alleging that a health center had violated subsection (d) of the Church Amendments when it denied her the ability to apply for a position as a nurse because she objected to prescribing abortifacients. *Hellwege v. Tampa Family Health Centers*, 103 F. Supp. 3d 1303 (M.D. Fla. 2015). Like the court in New York, the court held that the Church Amendments “recognize important individual rights” but did not confer a remedy to bring suit against a private entity in Federal court. *Id.* at 1310. In July of this year, a Federal district court in Illinois held that there is no private right of action for a doctor who alleges that the State required her to refer for abortions in violation of the Coats-Snowe Amendment. *National Institute of Family and Life Advocates, et al. v. Rauner*, No. 3:16-cv-50310, at 4 (N.D. Ill. July 19, 2017).

E. Addressing Confusion Caused by OCR Sub-Regulatory Guidance

In light of these decisions and the increase in conscience-based challenges to State and local laws in the health care context, OCR has a singular and critical responsibility to provide clear and appropriate interpretation of Federal health care conscience and associated anti-discrimination laws, to engage in outreach to protected parties and covered entities, to conduct compliance reviews, to investigate alleged violations, and to vigorously enforce those laws.

This proposed regulation intends to clear up confusion caused by OCR sub-regulatory guidance issued through OCR’s high-profile closing of three Weldon Amendment complaints against the state of California filed in 2014.⁴⁰ On June 21, 2016, OCR declared it found no violation stemming from California’s policy requiring that health insurance plans include coverage for abortion based on the facts alleged in the three complaints it had received.⁴¹ OCR’s closure letter concluded that the Weldon Amendment’s protection of health insurance plans included issuers of health insurance plans but not institutions or individuals who purchase or are insured by those plans. Even though California’s policy resulted in complainants losing abortion-free insurance that was consistent with their beliefs, because none of the

complainants were insurance issuers, the letter concluded that none qualified as an entity or person protected under the Weldon Amendment. Relying on legislative history instead of the Weldon Amendment’s text, OCR also declared that health care entities are not protected under Weldon unless they possess a “religious or moral objection to abortion,” as opposed to some other reason for refusing to facilitate abortion, and concluded that the insurance issuers at issue did not merit protection because they had not raised any religious or moral objections. Finally, OCR called into question its ability to enforce the Weldon Amendment against a State *at all* because, according to the letter, to do so could “potentially” require the revocation of Federal funds to California in such a magnitude as to violate the Constitution’s prohibition on the Federal government infringing State sovereignty through its Spending Clause power.⁴²

The Department does not opine upon, and has not made a judgment on, the compatibility of California’s policy with the Weldon Amendment. But clarifications are in order with respect to the general interpretations of the Weldon Amendment offered in OCR’s previous closure of complaints against California’s abortion coverage requirement. The Department has engaged in further consideration of these general matters and has also further reviewed the Federal health care conscience statutes, the legislative history, and the record of rulemaking and public comments under Part 88. Based on this review, the Department has concluded that the above-mentioned sub-regulatory guidance issued by OCR with respect to interpretation of the Weldon Amendment no longer reflects the current position of HHS, OCR, or the HHS Office of the General Counsel.

Specifically, and first, HHS does not believe that the “potential” constitutional concerns cited in the letter relieve HHS of the obligations Congress imposed on it to not make certain funding available to covered entities that discriminate in violation of the Weldon Amendment. Instead, HHS must diligently enforce the Weldon Amendment according to its text and to the extent allowed by the Constitution. It is a bedrock principle that the Federal government is to presume that statutes

passed by Congress are constitutional. Additionally, if conflicts with the Constitution are clearly present, saving constructions should be employed to avoid interpreting statutes as dead letters. The Weldon Amendment’s funding remedies in cases of violation can and should be read and applied consistently with the Constitution.

Second, in contrast to OCR’s previous position, HHS concludes that the Weldon Amendment’s protection for health insurance and any other kind of plans is not a protection that may only be invoked or complained of by issuers.⁴³ Per the amendment, “the term ‘health care entity’ includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or *any other kind of* health care facility, organization, or plan.” Consolidated Appropriations Act, 2017, Public Law 115–31, Div. H, Tit. V, sec. 507(d) (emphasis added). The amendment’s broad and non-exhaustive definition indicates that the amendment takes an inclusive approach with respect to the health care entities it protects and should not be interpreted narrowly. Because the Weldon Amendment protects not only the health insurance issuer, but also the health plan itself, it can also be raised, at minimum, by the plan sponsor on behalf of the plan, as well as by the issuer. Such an interpretation is not foreclosed by either the statute or the regulation. *Cf.* Department of Justice Title VI Legal Manual (“The financial assistance does not have to relate to a program in which the complainant participates or seeks to participate or [to a program] used for the complainant’s benefit. Rather, an agency only has to prove that the entity received Federal financial assistance when the alleged discrimination occurred.”).

Finally, the plain text of the Weldon Amendment prohibits discrimination against protected individuals and entities for being unwilling to take certain actions or to provide certain support in relation to abortion without requiring a specifically religious or moral motive for that decision or position.⁴⁴ The Weldon Amendment

⁴³ HHS believes health insurance issuers are health care entities by that term’s plain meaning in the Weldon Amendment. But, notably, while the Weldon Amendment explicitly protects plans, it does not explicitly mention issuers. This further undermines OCR’s previous conclusion that the amendment protects issuers, but not plans distinct from issuers.

⁴⁴ As seen by the compilation of the Federal health care conscience and associated anti-discrimination laws that are the subject of this proposed Rule, Congress uses the phrase “religious

⁴⁰ OCR Complaint Nos. 14–193604, 15–193782, and 15–195665.

⁴¹ Letter from OCR Director to Complainants (June 21, 2016) available at <http://www.adfmedia.org/files/CDMHCIInvestigationClosureLetter.pdf>.

⁴² In reaching this conclusion, the letter cited advice from “HHS’ Office of General Counsel, after consulting with the Department of Justice,” but HHS believes this advice may have been relayed orally as it has not located any written legal analysis from either the HHS Office of the General Counsel or the Department of Justice despite a diligent search.

states that funding shall not be available to an agency, program, or government if that “agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.” *See, e.g., Consolidated Appropriations Act, 2017, Public Law 115–31, sec. 507(d).* While Weldon certainly protects objections based on conscience or religion, nothing in the text *limits* its protection to those contexts. The legislative history of the Weldon Amendment cannot be used to contradict or limit the plain text of the statute. In any event, the legislative history in the form of a floor statement from the Amendment’s sponsor, Representative Dave Weldon, reinforces the plain meaning of the amendment. Representative Weldon stated that his amendment “simply states you cannot force the unwilling” to participate in abortion, and that it protects those “who choose not to provide abortion services,” including health professionals who say they are pro-choice and supportive of *Roe v. Wade*, but would rather not perform abortions themselves.⁴⁵

The Department is concerned that segments of the public have been dissuaded from complaining about religious discrimination in the health care setting to OCR, at least in part, as the result of these previous unduly narrow interpretations of the Weldon Amendment. For example, Foothill Church in Glen Morrow, California, expressed concern that filing a complaint with OCR about California’s abortion-coverage requirement was pointless because the Department had already closed three similar complaints finding no violation of Federal health care conscience laws. *See Foothill Church v. Rouillard*, No. 2:15-cv-02165-KJM-EFB, 2016 WL 3688422 (E.D. Calif. July 11, 2016).

With the proposed rule, the Department seeks to educate protected entities and covered entities as to their legal rights and obligations; to encourage individuals and organizations with religious beliefs and moral convictions to enter, or remain in, the health care industry; and, by clarifying the Department’s general views regarding the operation and

applicability of the Weldon Amendment, to prevent others from being similarly dissuaded from filing complaints due to OCR sub-regulatory guidance that is no longer reflective of the views of the Department.

F. Additional Federal Health Care Conscience and Associated Anti-Discrimination Laws

Finally, in addition to all of the concerns discussed above that support the proposed rulemaking, the Department proposes to use this rulemaking to address various other Federal health care conscience and associated anti-discrimination laws not discussed in the 2008 and 2011 Rules. These provisions include the Consolidated Appropriations Act, 2017, Public Law 115–31, Div. H, sec. 209; *Id.*, Div. E, sec. 726 and 808; 22 U.S.C. 7631(d); 29 U.S.C. 669(a)(5); 42 U.S.C. 1396f, 5106i(a)(1) and (2), 280g–1(d), 290bb–36(f), 1396s(c)(2)(B)(ii), 1395w–22(j)(3)(B), 1396u–2(b)(3)(B), 1395cc(f), 1396a(w)(3), 1320a–1, 1320c–11, 1395i–5, 1395x(e), 1395x(y)(1), 1396a(a), 1397j–1(b), and 14406. Some of these provisions were enacted after 2008. All provide additional protections for health care providers, patients, beneficiaries of human services, or providers of human services from coercion and discrimination because of moral convictions or religious beliefs.

VII. Summary of the Proposed Rule

This proposed rule would generally reinstate the structure of the 2008 Rule, supplemented with further definition of Federal health care conscience and associated anti-discrimination laws and robust notice and enforcement provisions. Specifically, the proposed rule would require certain recipients of Federal financial assistance from the Department or of Federal funds from the Department to both notify individuals and entities who are protected under the Federal health care conscience and associated anti-discrimination laws (such as employees, applicants, or students) of their rights and also to assure and certify to the Department their compliance with the requirements of these laws. It would also set forth in more detail the investigative and enforcement responsibility of OCR, along with the tools at OCR’s disposal in carrying out its responsibility with respect to those Federal health care conscience and associated anti-discrimination laws.

By virtue of Congress’s enactment of all the Federal health care conscience and associated anti-discrimination laws cited herein, the Department is required to ensure its own compliance with those

statutes, and the compliance of its funding recipients. In 2008 and 2011, the Secretary delegated to OCR the authority to receive complaints of discrimination under the Church, Coats-Snowe, and Weldon Amendments, in coordination with Departmental components that provide Federal financial assistance. Congress later designated OCR as having enforcement authority under Section 1553 of the ACA. Many of the remaining statutes that are the subject of the proposed rule do not have any implementing regulations. With the publication of this proposed rule in the **Federal Register**, the Secretary thus provides notice of the delegation to OCR of full enforcement authority over a significantly larger universe of Federal statutes compared to the 2008 and 2011 Rules.

The compliance and enforcement sections specify in much greater detail than either the 2008 or 2011 Rule how OCR will enforce the Federal health care and associated anti-discrimination laws beyond the receipt and handling of complaints and the coordination with other Department components. Implementation of the requirements set forth in this proposed rule would be conducted in the same way that OCR implements other civil rights requirements (such as the prohibition of discrimination on the basis of race, color, or national origin), which includes outreach, investigation, compliance, technical assistance, and enforcement practices. Enforcement would be based on complaints, referrals, news reports, and OCR-initiated compliance reviews and communications activities. If OCR were to become aware of a potential violation of Federal health care conscience and associated anti-discrimination laws, OCR would assist or require such government or entity to come into compliance. If, despite the Department’s assistance, compliance were not achieved, the Department would consider all legal options available to overcome the effects of such discrimination or violations. Enforcement mechanisms would include termination of relevant funding in whole or in part, claw backs, referral to the Department of Justice, or other measures. This proposed rule clarifies that recipients are liable for their own compliance with Federal health care conscience and associated anti-discrimination laws and implementing regulations, as well as for ensuring their sub-recipients comply with these laws. The rule also clarifies that parties subject to OCR investigation have a duty to cooperate and preserve documents

or moral convictions” (or an equivalent) when it wants to exempt only persons asserting those motivations, and does not include such language when it wants to exempt persons and institutions without any inquiry into their motivation. *See, e.g., 42 U.S.C. 238n* (Coats-Snowe Amendment).

⁴⁵ 150 Cong. Rec. H10090 (Statement of Rep. Weldon) (Nov. 20, 2004); 151 Cong. Rec. H177 (Statement of Rep. Weldon) (Jan. 25, 2005).

and to report that they if they are subject to an OCR enforcement action or investigation to their funding agency. Finally, the rule grants OCR authority to remedy claims of intimidation and retaliation against those who file a complaint or assist in an OCR investigation.

VIII. Section-by-Section Descriptions of the Proposed Rule

Proposed Section 88.1 Purpose

The “Purpose” section of the regulation sets forth the objective that the proposed regulation would, when finalized, provide for the implementation and enforcement of Federal health care conscience and associated anti-discrimination laws. It also states that the statutory provisions and regulations contained in this part are to be interpreted and implemented broadly to effectuate their protective purposes.

Proposed Section 88.2 Definitions

Administered by the Secretary: The Department proposes that a Federally funded program or activity is “administered by the Secretary” when it is “subject to the responsibility of the Secretary of the U.S. Department of Health and Human Services, as established via statute or regulation.” This term was used but not defined in the 2008 Rule, and is defined here in order to add clarity.

Assist in the Performance: The Department proposes that “assist in the performance” means “to participate in any activity with an articulable connection to a procedure, health service or health service program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity. This includes counseling, referral, training, and other arrangements for the procedure, health service, or research activity.” This definition mirrors the definition used for this term in the 2008 Rule.

In interpreting the term “assist in the performance,” the Department seeks to provide broad protection for individuals, consistent with the plain meaning of the statutes. The Department believes that a more narrow definition of the statutory term “assist in the performance,” such as a definition restricted to those activities that constitute direct involvement with a procedure, health service, or research activity, would fall short of implementing the protections Congress provided. But the Department acknowledges that the rights in the statutes are not unlimited, and it

proposes to limit the definition of “assist in the performance” to activities with an articulable connection to the procedure, health service, health service program, or research activity in question.

Department: The Department proposes to define “the Department” to mean the U.S. Department of Health and Human Services and any component thereof.

Discriminate or Discrimination: The Department proposes to define “discriminate” or “discrimination” to mean, as applicable and as permitted by the applicable statute, (1) to withhold, reduce, exclude, terminate, restrict, or otherwise make unavailable or deny any grant, contract, subcontract, cooperative agreement, loan, license, certification, accreditation, employment, title, or other similar instrument, position, or status; (2) to withhold, reduce, exclude, terminate, restrict, or otherwise make unavailable or deny any benefit or privilege; (3) to utilize any criterion, method of administration, or site selection, including the enactment, application, or enforcement of laws, regulations, policies, or procedures directly or through contractual or other arrangements, that tends to subject individuals or entities protected under this part to any adverse effect described in this definition, or to have the effect of defeating or substantially impairing accomplishment of a health program or activity with respect to individuals, entities, or conduct protected under this part; or (4) to otherwise engage in any activity reasonably regarded as discrimination, including intimidating or retaliatory action. The 2008 Rule did not define this term—it is defined here in order to provide clearer notice to the public about what sort of conduct certain provisions of this proposed rule would prohibit.

A functional concept of “discrimination” in this context must account for the various forms that violations of the right of conscience can take. One way Federal law prohibits such violations is by requiring that religious individuals or institutions be allowed a level playing field, and that their beliefs not be held to disqualify them from participation in a program or benefit. For example, a medical school that receives a grant under the Public Health Service Act may not deny admission to an applicant based on that applicant’s conscientious objection to participating in an abortion. 42 U.S.C. 300a–7(e). This form of discrimination, broadly conceived—denial of participation in a program, service, or benefit—parallels the type of discrimination typically prohibited with

respect to other protected characteristics such as race, color, or national origin. See 45 CFR 80.3 (HHS regulations implementing Title VI nondiscrimination requirements and prohibiting, inter alia, “Deny[ing] an individual any service . . .”, “Subject[ing] an individual to segregation or separate treatment . . .”, “Treat[ing] an individual differently from others in determining whether he satisfies any admission . . . requirement . . .”, etc., on the basis of race, color, or national origin). HHS believes it appropriate to apply the general principles of nondiscrimination enshrined in Title VI with full force to discrimination on the basis of religious belief or moral conviction.

Freedom from discrimination on the basis of religious belief or moral conviction, however, does not just mean the right not to be treated differently or adversely; it also means being free not to act contrary to one’s beliefs. To that end, Federal law carves out exemptions based on religious and/or conscientious objection to otherwise generally applicable requirements that compel certain conduct. For instance, as discussed infra, although the ACA’s individual mandate compels, via force of a tax penalty, the purchase of minimum essential health coverage, that mandate exempts certain religious organizations and individuals who conscientiously oppose acceptance of the benefits of any private or public insurance. 26 U.S.C. 1402(g)(1). OCR solicits comments regarding the impact on the proposed regulation of the planned elimination of the penalty for failure to carry ACA-mandated health insurance as set forth in the major tax reform legislation passed at the end of 2017.

The intersection of religion and health care may also create the more unusual and insidious circumstance in which governmental authorities unlawfully seek to target religious organizations or individuals for additional legal or regulatory burdens, precisely because of their exercise of a particular religious belief or moral conviction. See *Church of the Lukumi Babalu Aye, Inc. v. Hialeah*, 508 U.S. 520 (1993) (striking down facially neutral ordinance gerrymandered to apply only to religiously motivated conduct). The Supreme Court has made clear that governmental burdens on speech targeting particular viewpoints are presumptively unconstitutional. *Matal v. Tam*, 137 S.Ct. 1744, 1766 (2017) (“A law found to discriminate based on viewpoint is an egregious form of content discrimination, which is presumptively unconstitutional.”

(internal citations and quotations omitted)). Thus, within OCR's regulatory ambit, and to the extent permitted by law, OCR will regard as presumptively discriminatory any law, regulation, policy, or other such exercise of authority that has as its purpose, or explicit or otherwise clear application, the targeting of religious or conscience-motivated conduct. In determining the purpose or justification of such an exercise of authority, OCR will consider all relevant factors and proposes to include in that analysis, when supported by the applicable statute, whether or not the exercise of authority has a disparate impact on religious believers or those who share a particular religious belief or moral conviction. The Department solicits comment on whether disparate impact analysis is appropriate, as a policy or legal matter, to apply to any of the statutes implemented by this rule; whether it is appropriately included in the definition of discrimination, and, if so, how disparate impact analysis would be best performed in the context of applicable Federal health care conscience and associated anti-discrimination laws (e.g., how groups suffering the disparate impact can be described under the various statutes).

Entity: The Department proposes to define the term "entity" consistent with the definition of "person" in 1 U.S.C. 1 and also to include any State, political subdivision of any State, instrumentality of any State or political subdivision thereof, and any public agency, public institution, public organization, or other public entity in any State or political subdivision of any State. The 2008 Rule provided identical definitions for both "entity" and "health care entity." Here, the Department proposes this definition of "entity," distinct from the definition of "health care entity" set out *infra*, to better fit the use of these terms in the statutes at issue in this proposed rule.

Federal Financial Assistance: The Department proposes to define the term "Federal financial assistance" to include "(1) the grant or loan of Federal funds; (2) the grant or donation of Federal property and interests in property; (3) the detail of Federal personnel; (4) the sale or lease of, and the permission to use (on other than a casual or transient basis), Federal property or any interest in such property without consideration or at a nominal consideration, or at a consideration which is reduced for the purpose of assisting the recipient or in recognition of the public interest to be served by such sale or lease to the recipient; and (5) any Federal

agreement, arrangement, or other contract which has as one of its purposes the provision of assistance." Note that Federal financial assistance includes forms of non-cash assistance. The 2008 Rule did not use the term "Federal financial assistance." It is employed here to provide greater clarity about what sort of Federal assistance triggers obligations under this part. The Department notes that this term will likely be familiar to much of the health care industry, and is intended in the proposed rule to carry its traditional meaning, such as that provided in the Department's regulations implementing Title VI of the Civil Rights Act of 1964. See 45 CFR 80.13.

Not all of the statutes that the proposed rule would enforce use the term "Federal financial assistance." This is reflected in the text of the various provisions in § 88.3 of the proposed rule, which set out the proposed rule's terms regarding the applicability of the statutes being enforced. However, the proposed rule would establish separate requirements regarding assurance and certification of compliance with applicable Federal health care conscience and associated antidiscrimination laws, and regarding the posting of notices regarding those laws. The proposed rule employs the term "Federal financial assistance" in order to help define who must comply with those separate requirements regarding assurance and certification of compliance and notices.

Health Care Entity: The Department proposes to define the term "health care entity" to include an individual physician or other health care professional, health care personnel, a participant in a program of training in the health professions, an applicant or participant for training or study in the health professions, a postgraduate physician training program, a hospital, a laboratory, an entity engaging in biomedical or behavioral research, a provider-sponsored organization, a health maintenance organization, a health insurance plan (including group or individual plans), a plan sponsor, issuer, or third-party administrator, or any other kind of health care organization, facility, or plan. It may also include components of State or local governments.

The Department's proposed definition is an illustrative, not exhaustive, list. Like the statutory definitions in the Weldon Amendment and Public Health Service Act, the Department uses the words "include" and "any other kind" to indicate that the list is illustrative. Thus, the Department's proposed inclusion of the terms "health care

professional" and "health care personnel" is intended, for example, to cover pharmacists, nurses, occupational therapists, public-health workers, and technicians, as well as psychiatrists, psychologists, counselors, and other mental health providers, but the definition does not enumerate these health care job categories because they are reasonably included in such terms. To attempt to employ an exhaustive list would run the risk of inadvertently omitting certain types of health care professionals or health care personnel.

With regard to the term "health insurance plan," the Department proposes that it include the sponsors, issuers, and third-party administrators of health care plans or insurance. The Weldon Amendment specifically includes in its definition of the term "health care entity" "a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of . . . plan" and protects such health care entities from being subject to discrimination on the basis that they do not provide, pay for, cover, or refer for abortions. Thus, to ensure that Congress's explicit protection for health insurance plans and health care organizations is fully enforced, the Department considers it appropriate to include plan sponsors not primarily engaged in the business of health care as "health care entities" for purposes of the proposed regulation.

We ask for comment on this proposed approach. We also ask for comment on whether the terms "entity" and "health care entity," as we propose to employ them in relation to the various statutes that this rule implements, clearly and accurately reflect the intent and scope of each of those statutes.

Health Program or Activity: The Department proposes to define "health program or activity" to include the provision or administration of any health-related services, health service programs and research activities, health-related insurance coverage, health studies, or any other service related to health or wellness whether directly, through payments, grants, contracts, or other instruments, through insurance, or otherwise. In developing an appropriate definition for "health program or activity," HHS looked at Section 1128B(f)(1) of the Social Security Act, 42 U.S.C. 1320a-7b(f)(1), which defines a similar term, "Federal health care program," as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government." This term was not used

in the 2008 Rule, and is added here in order that this proposed rule may correspond more precisely to the intended application of the statutes at issue, where the term “health service program” may not suffice.

Health Service Program: For the purposes of this part, the Department proposes to define “health service program” to include any plan or program that provides health benefits, whether directly, through insurance, or otherwise, and is funded, in whole or part, by the Department. It may also include components of State or local programs. This definition mirrors the definition used for this term in the 2008 Rule.

Because subsection (d) of the Church Amendments covers health service programs or research activities administered by the Secretary, these programs include those where the Department provides care or health services directly (e.g., Indian Health Service, NIH Clinical Center); programs administered by the Secretary that provide health services through grants, cooperative agreements, or otherwise (e.g., Administration for Children and Families programs such as the Unaccompanied Alien Children program, and HRSA programs such as community health centers); programs where the Department reimburses another entity that provides care (e.g., Medicare); and health insurance programs where Federal funds are used to provide access to health coverage (e.g., CHIP, Medicaid, and Medicare Advantage). It may also include components of State or local governments. The Department believes this definition would appropriately effectuate Congress’s intent to protect health service programs and research activities funded in whole or in part by, and/or administered by the Secretary.

We have proposed definitions for both “health program or activity” and “health service program” because the phrases are used in different statutes that are the subject of this proposed rule. We ask for comment on whether the terms mean the same thing and should or could be defined interchangeably for purposes of this regulation.

Individual: For purposes of this part, the Department proposes to define “individual” as a member of the workforce of an entity or health care entity. The Department adopts the concept of “workforce” from the Health Insurance Portability and Accountability Act Rules, where it includes volunteers, trainees, or other members or agents of a covered entity, broadly defined, when the conduct of

the person is under the control of such entity. This definition mirrors the definition used for this term in the 2008 Rule.

Instrument: The Department proposes to define “instrument” to be the means by which Federal funds are conveyed to a recipient, and to include grants, cooperative agreements, contracts, grants under a contract, memoranda of understanding, loans, loan guarantees, stipends, and any other funding or employment instrument or contract. There are a variety of means by which the Department conveys Federal financial assistance or other Federal funds from the Department to organizations, including: Grants, cooperative agreements, contracts, grants under a contract, and memoranda of understanding. The definition of “instrument” is intended to include all means by which the Department conveys funding and resources. Save for the addition of the phrase “loans, loan guarantees, stipends,” this definition mirrors the definition used for this term in the 2008 Rule.

OCR: The Department proposes to define OCR to signify the Office for Civil Rights of the Department of Health and Human Services.

Recipient: The Department proposes to define “recipient” to mean “any State, political subdivision of any State, instrumentality of any State or political subdivision thereof, and any person or any public or private agency, institution, organization, or other entity in any State including any successor, assign, or transferee thereof, to whom Federal financial assistance is extended directly from the Department or a component of the Department, or who otherwise receives Federal funds directly from the Department or a component of the Department, but such term does not include any ultimate beneficiary.” The term would include State and local governments, public and private institutions of higher education, public and private hospitals, commercial organizations, and other quasi-public and private nonprofit organizations such as, but not limited to, community action agencies, research institutes, educational associations, and health centers. The term may include foreign or international organizations (such as agencies of the United Nations). This definition differs from the definition used for this term in the 2008 Rule in part because this proposed rule employs the term “Federal financial assistance,” whereas the 2008 Rule did not. Other changes made in this definition are intended to provide clarity about the types of entities that may qualify as recipients.

As discussed elsewhere in this notice of proposed rulemaking, recipients would be subject to this part’s requirements regarding assurances and certifications of compliance. The Department seeks to minimize the financial and administrative burdens of the proposed rule by accomplishing the assurances and certifications required of recipients through the forms that recipients are already filing to assure or certify compliance with other applicable nondiscrimination laws. The Department anticipates that the vast majority, if not all, of recipients will be able to fulfill their assurance and certification requirements by using the modified versions of the forms already in use. Accordingly, if an entity is currently required to file an HHS-690 Form, HHS-5161-1 Form, or another similar form assuring or certifying compliance with nondiscrimination requirements in connection with Federal financial assistance from or through the Department, that entity can reliably assume that it is a “recipient” for the purposes of this part.

Referral or Refer for: The Department proposes to define “referral”⁴⁶ or “refer for” as including the provision of any information (including but not limited to name, address, phone number, email, or website) by any method (including but not limited to notices, books, disclaimers, or pamphlets online or in print) pertaining to a service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or direction that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, when the entity or health care entity making the referral sincerely understands that particular health care

⁴⁶ Various ethicists have discussed how referral constitutes moral cooperation with a conscientiously objected activity. See, e.g., William W. Basset, *Private Religious Hospitals: Limitations Upon Autonomous Moral Choices in Reproductive Medicine*, 17 J. Contemp. Health L. & Pol’y 455, 529 (2001) (“The moral principle involved in the cooperation and referral situations is called the principle of moral cooperation”); Armand H. Matheny Antommara, *Adjudicating Rights or Analyzing Interests: Ethicists’ Role in the Debate Over Conscience in Clinical Practice*, 29 Theor. Med. Bioeth. 201, 206 (2008) (“not contravening one’s conscience through illicit cooperation is a significant interest that may obligate one to forego other important interests, such as one’s job or even career”); Stephen J. Genuis & Chris Lipp, *Ethical Diversity and the Role of Conscience in Clinical Medicine*, 2013 Int’l. J. Family Med. 1, 9 (2013) (“Facilitating a clinical course of action that the health provider sincerely deems to be ill-advised, unethical, or against the patient’s best interests may compromise the integrity of the professional role and may violate fundamental tenets of such ethical codes”).

service, activity, or procedure to be a purpose or possible outcome of the referral. This term was not used in the 2008 Rule. It is added here to address confusion the Department perceives among the public about what sorts of actions may be properly regarded as referrals for the purposes of protecting rights of conscience under the statutes at issue in this proposed rule.

The Weldon Amendment prohibits discrimination on the basis that a health care entity does not “refer for abortions.” The Coats-Snowe Amendment prohibits discrimination on the basis that an entity refuses to “provide referrals for [induced abortions],” “refuses to make arrangements for” such referrals, or attends a health profession training program that does not “refer for training in the performance of induced abortions.” Section 1303 of the ACA prohibits qualified health plans offered through an exchange from discriminating against any individual health care provider or health care facility because of its unwillingness to refer for abortions. 42 U.S.C. 18023(b)(4). Medicare Advantage contains a protection for entities that inform HHS that they will not provide referrals for abortions. Consolidated Appropriations Act of 2017, Public Law 115–31, 131 Stat. 502, Div. H, sec. 209 (2017). Certain recipients of funds administered by Secretary under the Foreign Assistance Act cannot be required to make a referral to a program or activity to which the recipient has a religious or moral objection. 22 U.S.C. 7631(d). Medicare Advantage plans and Medicaid managed care organizations are protected from being required to provide certain referral services. 42 U.S.C. 1395w–22(j)(3); 42 U.S.C. 1396u–2.

The Department believes that Congress provided, in these Federal health care statutes, protections for entities from discrimination in a broad way related to referring for abortions or abortion training, or, as specified in applicable statutes, for other kinds of services. In the Coats-Snowe Amendment, for example, Congress protected not only the refusal to provide referrals for abortion, but also the refusal to make arrangements to provide referrals for abortion. This protects entities that object not just to making referrals, but to rendering aid to anyone else who is reasonably likely to make an abortion referral. Likewise, in the Weldon Amendment and Section 1303 of the ACA, Congress specified that it did not merely protect the action of declining to refer to an abortion provider, but of declining to refer “for”

abortions generally. This more broadly protects a decision not to provide contact information or guidance likely to assist a patient in obtaining an abortion elsewhere.

Under the proposed definition, to provide an abortion referral, refer for abortion, or make arrangements for an abortion referral, would include such activities as providing to a patient seeking abortion contact information of a physician or clinic that may provide an abortion, or telling a patient that funding is available for abortion and providing a phone number where she can be referred to abortion services or funding. It would include such activities by any method, such as orally, in writing, digitally, or through the posting of notices. The Department believes defining referral or refer in a more narrow way, for example to only mean an endorsement, recommendation, facilitated referral to a physician, or transfer of records to a specific provider, would fail to implement Congress’s broad protection for entities unwilling to be complicit in the provision of items or services they cannot in good conscience themselves provide.

State: The Department proposes to define “State” to include, in addition to the several States, the District of Columbia. For those provisions in this part related to or relying upon the Public Health Service Act, the term “State” is proposed to include the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands. For those provisions in this part related to or relying upon the Social Security Act, the term “State” is proposed to incorporate the definition of “State” found at 42 U.S.C. 1301. This term was not defined in the 2008 Rule but is added here to reflect that the term carries different meanings in certain statutes at issue in this proposed rule. The Department seeks comment on whether this definition fully and accurately implements the scope of the statutes that are the subject of this proposed rule, especially with regard to statutes that cover State and local government or other public authorities.

Sub-recipient: The Department proposes to define “sub-recipient” to mean “any political subdivision of any State, any instrumentality of any State or political subdivision thereof, and any person or any public or private agency, institution, organization, or other entity in any State, including any successor, assign, or transferee thereof, to whom Federal financial assistance is extended

through another recipient or another sub-recipient, or who otherwise receives Federal funds from the Department or a component of the Department indirectly through a recipient or another sub-recipient, but such term does not include any ultimate beneficiary.” The term includes State and local governments, public and private institutions of higher education, public and private hospitals, commercial organizations, and other quasi-public and private nonprofit organizations such as, but not limited to, community action agencies, research institutes, educational associations, and health centers. The term may include foreign or international organizations (such as agencies of the United Nations). As with the definition of “recipient,” this definition differs from the 2008 Rule’s definition of this term in part because of the use of the term “Federal financial assistance,” and also in order to provide greater clarity about the types of potentially covered entities.

Workforce: The Department proposes to define “workforce” to consist of employees, volunteers, trainees, contractors, and other persons whose conduct in the performance of work for an entity or health care entity is under the direct control of such entity or health care entity, whether or not they are paid by the entity or health care entity, as well as health care providers holding privileges with the entity or health care entity. This definition substantially mirrors the definition used for this term in the 2008 Rule.

Proposed Section 88.3 Applicable Requirements and Prohibitions

The proposed “Applicability” section outlines the specific requirements of the Federal health care conscience and associated anti-discrimination laws that apply to various persons and entities. These provisions are taken from the relevant statutory language and would direct covered entities to the appropriate sections that contain the relevant requirements that form the basis of this regulation.

The “Requirements and Prohibitions” section explains the obligations that the Federal health care conscience and associated anti-discrimination statutes impose on the Department and on entities that receive applicable Federal financial assistance and other Federal funding from the Department. These provisions are taken from the relevant statutory language.

We intend for the proposed requirements and prohibitions to be interpreted using the definitions proposed in section 88.2.

Proposed Section 88.4 Assurance and Certification of Compliance Requirements

In the “Assurance and Certification of Compliance” section, the Department would require certain recipients to submit written assurances and certifications of compliance with the Federal health care conscience and associated anti-discrimination laws, as applicable, as a condition of the terms of acceptance of the Federal financial assistance or other Federal funding from the Department. While the 2008 Rule required only the submission of a certification of compliance, the Department believes that both an assurance and certification provide important protections to persons and entities under these laws and would be consistent with requirements under other civil rights laws. We are concerned that there is a lack of knowledge on the part of States, local governments, and the health care industry of the rights of protected persons and entities, and the corresponding obligations on covered entities provided by the Federal health care conscience and associated anti-discrimination laws. Certifications provide a demonstrable way of ensuring that applicants for such funding know of, and attest that they will comply with, applicable Federal health care conscience and associated anti-discrimination laws.

Applicants for Department grants, loans, contracts, Federal financial assistance, or other Federal funds from the Department are currently required to sign assurances and certifications of compliance with several specific civil rights laws, such as Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975. See HHS–690 Form, OMB No. 0945–0006 (Medicare Part A); HHS–5161–1 Form, OMB No. 0930–0367 (HHS Grant Applications). The assurances and certifications of compliance required by this part would be accomplished via submission of modified versions of the applicable civil rights clearance forms, such as the HHS–5161–1 Form, HHS–690 Form, or similar forms that may be developed and implemented in the future.

The HHS–690 Form (Assurance of Compliance) briefly identifies the prohibited discriminatory conduct covered by each civil rights law. Although many Federal health care conscience and associated anti-discrimination laws were enacted at approximately the same time as those

other civil rights laws, such as conscience laws are not specifically mentioned in Form HHS–690 Form or HHS–5161–1 Form. Adding the above-referenced laws to these forms would increase awareness of the Federal health care conscience and associated anti-discrimination laws and demonstrate the Department’s commitment to consistently enforcing all civil rights protections on an equal basis. The certification form serves to provide a formal statement by the recipient, generally subsequent to the submission of the assurance that the recipient actually is currently in compliance with the referenced requirements.

Given this backdrop, section 88.4 proposes to require certain applicants for Federal financial assistance or other Federal funds from the Department to which this part applies to submit assurances and certifications of compliance with Federal health care conscience and associated anti-discrimination provisions and this part. Consistent with current practice, we propose covered applicants file the HHS–690 Form once per year and incorporate such filing by reference in all other applications submitted that year, rather than for every application that year. To this end, and as consistent with other civil rights regulations, proposed § 88.4(b)(6) permits an applicant to incorporate the assurance by reference in subsequent applications to the Department. The proposed rule explains that both the assurance and certification shall constitute a condition of continued receipt of Federal financial assistance or other Federal funds from the Department. With respect to the certification required in proposed § 88.4(a)(2), proposed § 88.4(b)(7) clarifies that a violation of the requirements of the certification may result in enforcement by the Department, as provided in section 88.7 of this part.

The Department believes that requiring assurances and certifications of compliance by applicants for and recipients of Federal financial assistance and other Federal funds from the Department would provide an important vehicle for increasing awareness of Federal health care conscience and associated anti-discrimination laws and thereby increasing compliance. While many people in the health care field may have general knowledge that Federal health care conscience and associated anti-discrimination protections exist for persons and health care providers, the scope of these protections is not always widely understood. Because Congress has enacted several different protections, a

person or entity may be aware that, for instance, a physician may not be compelled to perform abortions, but may not be aware of other aspects of the statutes providing Federal health care conscience and associated anti-discrimination protections. Others may become aware of these laws, at least in detail, only when a dispute arises and a person, provider, or entity attempts to assert their Federal health care conscience rights, and there may be subsequent disagreement over the nature of the rights asserted.

The Department recognizes that it needs to undertake significant outreach efforts in order for the rule to be maximally effective. Thus, the Department will consider all avenues available for increasing public awareness of Federal health care conscience laws. The Department welcomes public comment on the various options available for public education and outreach.

Paragraph (b) identifies specific requirements for the proposed assurance and compliance requirements: (b)(1) Addresses the timing to submit the assurance for current applicants or recipients as of the effective date of this part; (b)(2) addresses the form and manner of such submittals; and (b)(3) addresses the duration of obligations for both the assurance and certification. In regard to the form and manner of the submission, the Department is committed to leveraging existing grant, contract, and other Departmental forms where possible rather than creating additional, separate forms for recipients to sign. To this end, § 88.5(4)(2) explains that applicants shall submit assurance and certification forms in an efficient manner specified by OCR, in coordination with the relevant Department component, or alternatively in a separate writing. Such certifications should be clearly written so that applicants and recipients know, by means of the certification, which provisions they must comply with based on the nature of the recipient or the funding mechanism through which it receives funds.

Department components will be given discretion to phase in the written assurance and certification requirement by no later than the beginning of the next fiscal year following the effective date of the regulation. The Department intends to work with recipients of Federal financial assistance or other Federal funds from the Department to ensure compliance with the requirements or prohibitions promulgated in this regulation. If the applicant or recipient fails or refuses to furnish a required assurance or

certification, OCR, in coordination with the relevant Department component, may effect compliance by any of the remedies provided in § 88.7.

While both recipients and sub-recipients, as defined herein, must comply with the substantive requirements of Federal health care conscience and associated anti-discrimination laws, as applicable, sub-recipients are not subject to the requirements of section 88.4 regarding assurance and certifications of compliance. This approach departs from the 2008 Rule, which required certifications of compliance to be submitted by both recipients and sub-recipients. By exempting sub-recipients from this requirement, the Department seeks to cut down on administrative burdens. The Department invites comment on whether this approach strikes the appropriate balance between achievement of this rulemaking's policy objectives and avoidance of undue burden on the health care industry.

Section 88.4(c) also contains several important exceptions from the proposed requirements for written assurance and certification of compliance, including: (1) Physicians, physician offices, and other health care practitioners participating in Part B of the Medicare program; (2) recipients of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration for Children and Families, whose purpose is unrelated to health care provision as specified; (3) recipients of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration on Community Living, whose purpose is unrelated to health care provision as specified; and (4) Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the Indian Self-Determination and Education Assistance Act.

Requiring the large number of entities in these four categories to submit assurance and certification requirements would pose significant implementation hurdles for Departmental components, programs, and services. Furthermore, the Department believes that, due primarily to their generally smaller size, several of the excepted categories of recipients of Federal financial assistance or other Federal funds from the Department are less likely to encounter the types of issues sought to be addressed in this regulation. For example, State Medicaid programs are already responsible for ensuring the compliance of their sub-recipients as

part of ensuring that the State Medicaid program is operated consistently with applicable nondiscrimination provisions. Similarly, certain programs currently administered by the Administration for Children and Families and the Administration on Community Living involve the provision of grants to States and other governments, or cash assistance or vouchers rather than direct services, and they are not likely to involve medical research, the participation of health care providers, or referral to health care providers.

Excepted providers, however, may become subject to the assurance and certification requirement if they receive Federal financial assistance or Federal funds from the Department through a mechanism or in a manner not excepted by this section. For example, a physician office participating in Medicare Part B may become subject to the written certification requirement by receiving Department funds to conduct clinical research. And it is important to emphasize that no exemption from the requirements of this regulation regarding notice, assurances, or certifications relieves the Department, recipients, or sub-recipients, and State and local governments, of their obligations to comply with these longstanding Federal health care conscience laws.

The Department seeks public comment on whether further exceptions should be made to the requirements of § 88.4 in contexts where the requirements would be unduly burdensome or in contexts unrelated to health care or medical research.

Proposed Section 88.5 Notice Requirement

The proposed rule adds a "Notice" section that was not contained in the 2008 Rule. This section requires the Department and recipients to notify the public, patients, and employees, which may include students or applicants for employment or training, of their protections under the Federal health care conscience and associated anti-discrimination statutes and this regulation.

For consistency with other notice requirements in civil rights regulations, paragraph (a) of § 88.5 proposes to require the Department and recipients to post the notice in Appendix A within 90 days of the effective date of this part. This notice advises persons and entities about their rights and the Department's and recipients' obligations under Federal health care conscience and associated anti-discrimination laws. The notice provides information about how

to file a complaint with OCR. We seek comment on whether there are categories of recipients that should be exempted from this requirement to post such notices.

The proposed rule requires all Department components and recipients to use the notice text in Appendix A. This approach maximizes efficiency and economies of scale by enabling recipients to leverage the text of an HHS-authored notice. We invite comment on whether the proposed rule should permit recipients to draft their own notices for which the content meets certain criteria and does not compromise the intent of § 88.5.

Proposed paragraph (b) sets forth two categories of locations where the notice must appear: On the Department's and recipient's website(s), and in a physical location of each Department and recipient establishment where notices to the public and notices to their workforce are customarily posted. With regard to the physical posting, paragraph (b)(2) imposes readability requirements without identifying prescriptive font-size or other display requirements. The proposed readability specifications advance the goal for the notice content to appear sufficiently conspicuous and visible that persons observing it could reasonably be expected to see and be able to read the information.

Proposed paragraph (c) incentivizes recipients to display the notice in locations other than their websites and physical establishments. In the event that the OCR Director, pursuant to the proposed enforcement authority in section 88.7 of this part, investigates or initiates a compliance review of a recipient, the OCR Director will consider as one of many factors in compliance whether the recipient posted the notice in the documents described in paragraphs (c)(1)–(3), as applicable. Because this part regulates a diverse range of recipients, we identified three categories of documents most common across all recipients. We seek comment on the proposed approach of paragraph (c) and on the categories of documents identified in paragraphs (c)(1)–(3).

Finally, we recognize that recipients may be subject to other notice requirements under Federal and State law. Paragraph (d) of § 88.5 proposes to permit recipients to combine the text of the notice required in paragraph (a) with other notices under the condition that the recipient retains all of the language provided in Appendix A of this part in an unaltered state. Instead of regulating the manner of compliance, we considered permitting recipients to

integrate and revise the text of the notice required in paragraph (a) with other notices. Although this approach permits greater flexibility, it invites potential unintentional misrepresentation of Federal health care conscience and associated anti-discrimination rights. We request comment on whether paragraph (d) strikes the best balance based on recipients' experiences.

Proposed Section 88.6 Compliance Requirements

This section identifies specific requirements for compliance with the Federal health care conscience and associated anti-discrimination laws. Recipients and other agency components must maintain records evidencing compliance with these laws and the proposed regulation and are required to cooperate with OCR in the enforcement process. If a recipient or sub-recipient is subject to an OCR compliance review, investigation, or complaint filed with OCR regarding the recipient's or sub-recipient's compliance with Federal health care conscience and associated anti-discrimination laws, the recipient or sub-recipient must inform any Departmental funding component of such review, investigation, or complaint. The recipient or sub-recipient must also, in any application for new or renewed Federal financial assistance or Departmental funding, disclose the existence of such compliance review or investigation, and must also report on such applications the existence of any complaints filed with OCR if a complaint had been filed in the previous five years before the recipient's or sub-recipient's application. This section also addresses claims in the event a covered entity intimidates or retaliates against those who complain to OCR or participate in or assist in an OCR enforcement action.

Proposed Section 88.7 Enforcement Authority

This section reaffirms the delegation to OCR of the Department's authority to enforce the Federal health care conscience laws, in collaboration with the relevant Department components. OCR has been expressly delegated the authority to enforce the Church, Coats-Snowe, and Weldon Amendments since the 2008 Rule. Enforcement of section 1553 is expressly delegated to OCR in the ACA. Each of the Federal health care conscience laws, by virtue of Congressional enactment, requires compliance by the Department and covered entities. This NPRM provides notice that the Secretary has delegated

to OCR the authority to enforce all Federal health care conscience and associated anti-discrimination laws that are the subject of the proposed rule. This section also includes retaliation claims in the event a covered entity takes any such retaliatory actions against those who participate in or assist an OCR enforcement action.

This section also specifies that OCR's enforcement authority includes the authority to handle complaints, perform compliance reviews, investigate, and seek appropriate action (in coordination with the leadership of any relevant HHS component) that the Director deems necessary to remedy the violation of Federal health care conscience and associated anti-discrimination laws and the proposed regulation, as allowed by law. The current text of § 88.7 of this part grants OCR discretion in choosing the means of enforcement, from informal resolution to more rigorous enforcement leading to, for example, funding termination, as appropriate to the particular facts, law, and availability of resources. The Director may, in coordination with a relevant Department component, restrict funds for noncompliant entities in whole or in part, including by limiting funds to certain programs and particular covered entities, or by restricting a broader range of funds or broader categories of covered entities, as allowed by law to effectuate the Federal health care conscience laws. In addition to withdrawal of funding, possible corrective actions include settlements or voluntary resolution agreements where allowed. OCR can also refer cases to the Department of Justice for additional enforcement, and in coordination with the relevant Department component.

The proposed rule would also make explicit the Department's authority to investigate and handle violations and conduct compliance reviews whether or not a formal complaint has been filed. That language is consistent with OCR's enforcement practices under other civil rights laws, and with the Department's obligation to enforce Federal health care conscience and associated anti-discrimination laws. Under the proposed rule, OCR would also be explicitly authorized to investigate "whistleblower" complaints, or complaints made on behalf of others, whether or not the particular complainant is a person or entity protected by conscience and associated antidiscrimination laws.

This section adopts the enforcement procedures for other civil rights laws, such as Title VI and Section 504 of the Rehabilitation Act. *See, e.g.*, 45 CFR 80.8 through 80.10 and 84.7. If the

Department becomes aware that a State or local government or an entity may have undertaken activities in violation of statutory conscience and associated antidiscrimination laws, the Department will work with such government or entity to provide assistance and guidance to recipients to help them comply voluntarily with the law and this part. For compliance, recommended best practices (as identified in the Department's other civil rights regulations) include such procedures as: (1) The designation of at least one employee responsible for compliance, (2) the adoption of internal grievance procedures to provide for prompt and equitable resolution of complaints, and (3) the preparation of internal compliance reports by recipients, sub-recipients, participants, and beneficiaries.

If, despite the Department's assistance, compliance is not achieved, the Department will consider all legal options, up to and including termination of funding and return of funds, as applicable. Remedial measures include the temporary withholding of cash payments in whole or part, pending correction of the deficiency, the denial of funds and any applicable matching credit in whole or in part, the suspension or termination of the Federal award in whole or in part, the withholding of new Federal financial assistance or other Federal funds from the Department, referral of the matter to the Attorney General for enforcement proceedings, and any other remedies that may be legally available.

The Department solicits comments on what administrative procedures or opportunities for due process the Department should, as a matter of policy, or must, as a matter of law, provide. (1) with respect to the remedial and enforcement measures that the Department may consider imposing or utilizing in response to a failure or threatened failure to comply with Federal health care conscience and associated antidiscrimination laws or this part, (2) before the Department may terminate Federal financial assistance or other Federal funds from the Department, or (3) before the Department may implement any or all of the remedial measures identified in § 88.7(j)(3) of the proposed rule. For example, comment is requested on whether the proposed rule should establish notice, hearing, and appeal procedures similar to those established in the Department's regulations implementing Title VI of the Civil Rights Act of 1964, at 45 CFR 80.8–80.10. We also request comment on whether and in what circumstances it is

appropriate to require remedies against a recipient for the violations of a sub-recipient, or against entities whose subsidiaries are found to be in violation of any Federal health care conscience and associated antidiscrimination law or the proposed regulation.

Proposed Section 88.8 Relationship to Other Laws

This section clarifies the relationship between this part and other Federal, State, and local laws that protect religious freedom and moral convictions. Many State laws provide additional conscience protections for providers who have objections to abortion, fertility treatments, sterilization, capital punishment, assisted suicide, and euthanasia.⁴⁷ The

Department proposes to uphold the maximum protection for the rights of conscience and the broadest prohibition on discrimination provided by Federal, State, or local law, as consistent with the Constitution. Where a State or local law provides as much or greater protection than Federal law for religious freedom and moral convictions, the Department will not construe Federal law to preempt or impair the application of that law, unless expressly provided.

This section is new to this proposed rule with no analog in the 2008 Rule.

The proposed rule does not relieve OCR of its obligation to enforce other civil rights authorities, such as Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, Section 504 of the Rehabilitation Act of 1973, and the Americans with Disabilities Act of 1990. OCR will enforce all civil rights laws consistent with the Constitution and the statutory language.

Proposed Section 88.9 Rule of Construction

This section ensures that the protections for religious freedom and moral conviction provided by this part shall be construed broadly and to the maximum extent permitted by law and the Constitution.

Proposed Section 88.10 Severability

This section is a “severability clause” for the proposed regulation that provides that, if any provision or part of a provision of the proposed regulation is held to be invalid or unenforceable, either facially or as applied, the provision in question will be construed in a manner that allows it to remain in force to the maximum extent permitted by law. Furthermore, if a provision of the proposed regulation is held to be invalid or unenforceable, that provision is severable from the rest of the proposed regulation, which remains in full force and effect to the maximum

extent permitted by law. A severed provision shall not affect the remainder of the proposed regulation, and where possible the severed provision remains in effect as applied to other persons or situations not similarly situated, or to other dissimilar circumstances.

IX. Request for Comment

In addition to the requests for comments mentioned elsewhere in this notice of proposed rulemaking, the Department, in order to draft its final rule to best reflect the experiences and concerns of those most impacted, seeks comment on this Proposed Rule. In particular, the Department seeks the following:

- Comment on all issues raised by the proposed regulation.

- Information, including any facts, surveys, audits, or reports, about the occurrence or nature of coercion, discriminatory conduct, or other violations of the Federal health care conscience and associated anti-discrimination laws.

- Information, including any facts, surveys, audits, or reports, with regard to the general knowledge, or lack thereof, of the protections established by the Federal health care conscience and associated anti-discrimination provisions among the general public, as well as within the health care field, health care insurance industry, and employment law field.

- Information, including any facts, surveys, audits, or reports, on whether public authorities continue to claim that the receipt of Federal funds is a sufficient basis for entities to be required to participate in abortions or sterilizations. If so, comment on how the Department should address this problem.

- Information, including any facts, surveys, audits, or reports, about whether parents or legal guardians are discriminated against based on objections to testing or treatment of their minor children.

- Information, including any facts, surveys, audits, or reports, about whether individuals or entities have been coerced or discriminated against based on their religious or moral objection to counseling or referral.

- Information, including any facts, surveys, audits, or reports, about whether health care insurers, health plan sponsors, and health plan participants have religious or moral objections to certain health insurance coverage.

- Information, including any facts, surveys, audits, or reports, about whether applicants for Federal financial assistance from the Department, who

⁴⁷ See, e.g., Ala. Code 15–18–82.1(i) (2017); Alaska Stat. 18.16.010(b), 13.52.060(e) (2017); Ariz. Rev. Stat. Ann. 20–826(Z), 20–1057.08(B), 20–1402(M), 20–1404(V), 20–2329(B), 20–2329(C), 36–3205(C)(1), 36–2154 (2017); Ark. Code Ann. 20–13–1403(b), 20–16–304(4)–(5), 20–16–601, 23–79–1103(b), 23–79–1104(b)(3) (2017); Cal. Prob. Code 4734 (West 2017); Cal. Penal Code 3605(c) (West 2017); Cal. Bus. & Prof. Code 733(b)(3) (West 2017); Cal. Health & Safety Code 443.14(b), (e), 443.15, 1367.25(c), 1374.55(e)–(f), 123420 (West 2017); Cal. Ins. Code 10119.6(d)–(e), 10123.196(e) (West 2017); Colo. Rev. Stat. 25–6–102(9), 25–6–207, 25–3–110(3) (2017); Conn. Gen. Stat. 38a–503e(b), (e), 38a–536(c), 38a–509(c), 38a–530e(b), (e) (2017); Del. Code Ann. tit. 24, 1791, tit. 18, § 3559(d) (2017); Fla. Stat. 381.0051(5), 390.0111(8), 409.973(1)(h), 765.1105, 922.105(9) (2017); Ga. Code Ann. 16–12–142, 17–10–38(d), 31–20–6, 49–7–6 (2017); Haw. Rev. Stat. 431:10A–116.7, 453–16(e), 327E–7(e) (2017); Idaho Code Ann. 18–611, 18–612, 39–3915 (2017); 745 Ill. Comp. Stat. 70/1–70/14 (2017); 215 Ill. Comp. Stat. § 5/356m(b)(2) (2017); 720 Ill. Comp. Stat. § 510/13 (2017); 745 Ill. Comp. Stat. § 30/1 (2017); Ind. Code 16–34–1–3 to –7 (2017); Iowa Code 146.1–2 (2017); Kan. Stat. Ann. 65–443, –444, 65–446, –447, 65–1637(n), 65–6737 (2017); Ky. Rev. Stat. Ann. § 311.800(3)–(5) (West 2017); La. Rev. Stat. Ann. 15:569(C), 15:570(C), 40:1061.2–.3, 40:1061.4(C), 40:1061.20 (2017); Me. Rev. Stat. tit. 18–A, 5–807(e), tit. 32, 13795(2–3), tit. 22, 1591–1592, 1903(4), tit. 24, 2332–J(2), tit. 24–A, 2756(2), 2847–G(2), 4247(2), tit. 34–B, § 7016 (2017); Md. Code Ann., Health–Gen. 20–214 (West 2017); Md. Code Ann., Ins. 15–810(i), 15–826(c) (West 2017); Mass. Gen. Laws ch. 112, 12f, ch. 272, 21B, ch. 175, 47W(f), ch. 176A, 8W(f), ch. 176B, 4W(f), ch. 176G, 4C(c) (2017); Mich. Comp. Laws Serv. 333.20181 to 333.20184 (2017); Minn. Stat. 145.414, 145.42, 145.925(6) (2017); Miss. Code Ann. 41–41–215(5), 41–107–5 to –9 (2017); Mo. Rev. Stat. 188.105–.110, 191.724, 197.032, 338.255 (2017); Mont. Code Ann. § 50–20–111, 50–5–502 to –505 (2017); Neb. Rev. Stat. 28–337 to –341 (2017); Nev. Rev. Stat. 449.191, 632.475, 689A.0415(5), 689A.0417(5), 689B.0376(5), 689B.0377(5), 695B.1916(5), 695B.1918(5), 695C.1694(5), 695C.1695(5) (2017); N.J. Stat. Ann. 26A:65A–1, to –3, 17B:27–46.1x(b), 17:48A–7w(b), 17:48–6x(b), 17:48E–35.22(b), 26:2J–4.23(b), 17:48–6ee, 17:48A–7bb, 17:48E–35.29, 17B:27–46.1ee, 17B:26–2.1y, 26:2J–4.30, 17B:27A–19.15, 17:48F–13.2, 17B:27A–7.12 (West 2017); N.M. Stat. Ann. 24–8–6(A)(2), 24–7A–7(E), 30–5–2, 59A–22–42(D), 59A–46–44(C) (2017); N.Y. Civ. Rights Law § 79–i (McKinney 2017); N.Y. Ins. Law 3221(l)(16)(A), 4303(cc)(1) (McKinney 2017); N.C. Gen. Stat. § 14–45.1(f)–(j), 58–3–178(e) (2017); N.D. Cent. Code § 23–16–14 (2017); Ohio Rev. Code Ann. § 4731.91

(West 2017); Okla. Stat. tit. 63, 1–568, 1–728c to –728f, 1–741 (2017); Or. Rev. Stat. 127.625, 127.885, 435.225, 435.475, 435.485 (2017); 43 Pa. Cons. Stat. 955.2 (2017); 18 Pa. Cons. Stat. 3213(d) (2017); R.I. Gen. Laws 23–17–11, 27–18–57, 27–19–48, 27–20–43, 27–41–59 (2017); S.C. Code Ann. 44–41–40, 44–41–50 (2017); S.D. Codified Laws 34–23A–11 to –14, 36–11–70 (2017); Tenn. Code Ann. 39–15–204 to –205, 68–34–104(5) (2017); Tex. Ins. Code Ann. 1271.007, 1366.006, 1369.108 (West 2017); Tex. Occ. Code Ann. 103.001–.004 (West 2017); Utah Code Ann. sec. 76–7–306 (West 2017); Vt. Stat. Ann. tit. 18, 5285–5286 (2017); Va. Code Ann. sec. 32.1–134, 18.2–75, 54.1–2957.21 (2017); Wash. Rev. Code Ann. 9.02.150, 48.43.065(2), 70.47.160(2), 70.245.190 (2017); W. Va. Code 16–2B–4, 16–11–1, 16–30–12 (2017); Wis. Stat. 253.07(3)(b), 253.09, 441.06(6), 448.03(5)(A) (2017); Wyo. Stat. Ann. 42–5–101(d)–102, 35–6–105 to –106 (2017).

would otherwise been eligible for such assistance, have been discriminated against based on their religious or moral objections.

- Information, including any facts, surveys, audits, or reports, about whether individuals did not enter a health care field or a certain specialty because of concerns that their conscientious objections would not be accommodated.

- Information, including any facts, surveys, audits, or reports, about whether certain populations in the health care field, such as students or nurses, face or are vulnerable to discrimination in violation of the Federal health care conscience and associated anti-discrimination laws, and how outreach and enforcement might be tailored to respond to those needs.

- Information, including any facts, surveys, audits, or reports, about the occurrence of coercion or discrimination against health care practitioners or professionals related to the implementation of advance directives.

- Information, including any facts, surveys, audits, or reports, about coercion or discrimination against religious nonmedical health care institutions and their patients.

- Information, including any facts, surveys, audits, or reports, about whether the existence or expansion of rights to exercise religious beliefs or moral convictions in health care improves or worsens patient outcomes and access to health care.

- Comment on whether particular circumstances might exist that present a higher risk of undetected unlawful discrimination, such as the medical residency application process, and how the rule might address such problems.

- Comment on whether the voicing of health care conscience and associated anti-discrimination objections protected by Federal law is chilled by State laws, State agency action, lack of perceived remedies, threat of litigation, or threat of losing legal status, such as a medical license.

- Comment on whether the definition of “individual” in relation to “workforce” artificially circumscribes the scope of protections afforded by the Church Amendments that protect individuals and individual rights.

- Comment on whether the definition of “recipient” appropriately defines the scope of entities that should be subject to the rule’s requirements regarding notice and assurances or certifications, including whether those requirements should be extended to sub-recipients.

- Comment on whether the definition of “referral or refer for” appropriately

defines the scope of activities that should be encompassed by the rule’s protections.

- Comment on whether the definition of “assist in the performance” appropriately defines the scope of activities that should be encompassed by the rule’s protections.

- Comment on whether written certifications of compliance with nondiscrimination laws should contain additional language.

- Comment on the appropriateness of exceptions to the certification requirements.

- Comment on what constitutes the most effective method of educating recipients of Department funds and their employees about the protections of the Federal health care conscience and associated anti-discrimination laws.

- Comment on what constitutes the most effective method for recipients of Department funds to provide notice about the requirements and prohibitions in the Federal health care conscience and associated anti-discrimination laws to employees, students, applicants, and sub-recipients.

- Comment on whether State or local government laws, policies, or enforcement activities conflict with or make it difficult to ensure compliance with Federal health care conscience and associated anti-discrimination laws.

- Comment on whether policies and practices at covered entities appear to conflict with the health care conscience and associated anti-discrimination laws or make it difficult to ensure compliance with those laws.

- Comment on whether the rule provides adequate clarity regarding the respective obligations of recipients and sub-recipients, and regarding the potential consequences of noncompliance with those obligations.

- Comment on whether the exemptions in section 88.4(c) for certain grant programs currently administered by the Administration for Children and Families and the Administration for Community Living are meaningful given the requirement that the grant program involve no significant likelihood of referral for the provision of health care.

- Comment on whether, and how, the proposed rule should address the scheduled elimination of the penalty under the Patient Protection and Affordable Care Act for an individual’s failure to carry minimum essential health coverage.

- Comment on whether alternate remedies, such as lawsuits, have been sufficient to protect individuals and entities from discrimination, coercion, or other treatment prohibited by the

health care conscience and associated anti-discrimination laws.

- Comment on whether any provisions in the proposed rule would result in an unjustified limitation on access to health care or treatments.

- Comment on which enforcement tools OCR, as a policy matter, ought to employ, such as compliance reviews, investigations, and alternate disbursement of funds.

- Comment on whether the proposed rule avoids “tribal implications” and does not “impose substantial direct compliance costs on Indian tribal governments” as stated in Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, sec. 5(b) (Nov. 9, 2000), and whether the rule clearly and appropriately addresses its application to Federal funds that are contracted or compacted out to tribal nations.

- Comment on whether Urban Indian organizations, as defined by 25 U.S.C. 1603(29), operating a Title V Urban Indian Health Program that currently has a grant or contract with the IHS under Title V of the Indian Health Care Improvement Act, (Pub. L. 93–437), should be exempted from the proposed rule’s requirements regarding assurances and certifications of compliance.

- Comment on whether the proposed rule should apply to Tribes, which are recipients of Federal financial assistance through compact agreements or are awarded Federal contracts. Furthermore, the Department requests comment on exemptions for any Indian Tribes under the notice and certification requirements. Additionally, the Department solicits comment on the rule’s impact on Tribal sovereignty.

- Comment on whether the notice text provided in Appendix A to this rule strikes the appropriate balance between, on the one hand, affirming rights of conscience in a simple and reader-friendly manner, in general terms suitable for use by all recipients; and on the other, reflecting the complexities and variations in the application of Federal health care conscience and associated anti-discrimination laws to different covered entities and protected parties in different contexts.

- Consistent with the Paperwork Reduction Act, comments regarding the burden of the requirement for covered entities to report if they are the subject of an OCR investigation the Department in any requests for new or renewed Federal financial assistance or Federal funds in the five years subsequent to the filing of the relevant OCR complaint.

- Consistent with the Paperwork Reduction Act, comments regarding the

burden and cost estimates, or regarding any other aspect of the collection of information proposed in this rule as discussed below.

X. Public Participation

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments that are received by the date and time specified in the **DATES** section of the Preamble.

Written comments mailed or hand delivered must include one original and two copies. Mailed comments may be subject to security delays due to security procedures. Please allow sufficient time for mailed comments to be timely received in the event of delivery delays. Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the lobby of the building. Electronic comments with attachments should be in Microsoft Word or Excel; however, we prefer Microsoft Word. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.

XI. Delegations of Authority

Notice is hereby given that I have delegated to the Director of the Office for Civil Rights (OCR), with authority to redelegate, the authority to enforce the following Federal health care conscience and associated anti-discrimination laws:

- Conscience protections related to abortion, sterilization, and other lawful health services among recipients of funds and participants in programs, and their personnel, where funded by the Department (the Church Amendments, 42 U.S.C. 300a–7);
- Conscience protections for health care entities related to abortion, training, or accreditation (the Coats-Snowe Amendment, section 245 of the Public Health Service Act, 42 U.S.C. 238n);
- Provisions protecting health care entities and individuals that do not act to further abortion or other practices from discrimination by recipients of funding under the Department's annual appropriations acts (e.g., Consolidated Appropriations Act, 2017, Pub. L. 115–31, Div. H, sec. 507(d) (the Weldon Amendment); Div. H, sec. 209);
- Patient Protection and Affordable Care Act protections related to assisted suicide (42 U.S.C. 18113), the

requirement to issue certifications of exemption from the individual mandate with respect to membership in exempt religious sects or divisions or health care sharing ministries (26 U.S.C. 5000A(d)(2)), and the conscience provisions with respect to abortion (42 U.S.C. 18023(c)(2)(A), (b)(1)(A), and (b)(4));

- Protections for objections to counseling and referral for certain services in Medicaid or Medicare Advantage (42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B));
- Protections related to the performance of advanced directives in Medicare and Medicaid (42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406);
- Protections related to Global Health Programs to the extent administered by the Secretary (22 U.S.C. 7631(d); Consolidated Appropriations Act, 2017, Pub. L. 115–31, Div. J, sec. 7018 (Helms Amendment));
- Exemptions from compulsory health care or services generally (42 U.S.C. 1396f & 5106i(a)(1)), and under specific programs for hearing screening (42 U.S.C. 280g–1(d)), occupational illness testing (29 U.S.C. 669(a)(5)); vaccination (42 U.S.C. 1396s(c)(2)(B)(ii)), and mental health treatment (42 U.S.C. 290bb–36(f)); and
- Protections for religious nonmedical care in the Medicare, Medicaid, and CHIP programs (42 U.S.C. 1320a–1; 1320c–11; 1395i–5; 1395x(e); 1395x(y)(1); 1396a(a); 1396b(i)(4); 1397j–1(b); and 5106i(a)(2)).

Pursuant to these delegations, the OCR Director shall have the authority:

To receive and handle complaints of discrimination or any other potential violation of the Federal health care conscience and associated anti-discrimination laws and/or these regulations at 45 CFR part 88 by recipients, sub-recipients, or Department components;

To initiate and conduct compliance reviews and investigate incidents of discrimination or any other potential violation of the Federal health care conscience and associated anti-discrimination laws and/or these regulations by recipients, sub-recipients, or Department components;

To supervise and coordinate OCR's investigations or compliance reviews with the relevant Department components;

To delegate responsibilities to other officials of the Department in connection with the effectuation of Federal health care conscience and associated anti-discrimination laws and these regulations, including the achievement of effective coordination

and maximum uniformity within the Department; and

To take remedial action as the Director of OCR deems necessary and as allowed by law to overcome the effects of violations of Federal health care conscience and associated anti-discrimination laws and this part, in coordination with the relevant component or components of the Department.

If there appears to be a failure or threatened failure to comply with Federal health care conscience and associated anti-discrimination laws or this part, compliance with these laws and this part may be effected by the following actions, taken in coordination with the funding component:

Temporarily withholding cash payments, in whole or in part, pending correction of the deficiency;

Denying use of Federal financial assistance or other Federal funds from the Department, including any applicable matching credit, in whole or in part;

Wholly or partly suspending award activities;

Terminating Federal financial assistance or other Federal funds from the Department, in whole or in part;

Withholding new Federal financial assistance or other Federal funds from the Department, in whole or in part, administered by or through the Secretary for which an application or approval is required, including renewal or continuation of existing programs or activities or authorization of new activities;

Referring the matter to the Attorney General for proceedings to enforce any rights of the United States, or obligations of the recipient or sub-recipient, created by Federal law; and

Taking any other remedies that may be legally available.

This delegation is effective upon signature. I hereby affirm and ratify any actions taken by the OCR Director or the Director's subordinates which involved the exercise of the authorities delegated herein from April 1, 2017, to the effective date of this delegation.

XII. Regulatory Impact Analysis

A. Introduction and Summary

The Department has examined the impacts of the proposed rule as required under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017), the Regulatory

Flexibility Act (September 19, 1980, Pub. L. 96–354, 5 U.S.C. 601–612), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–04), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), the Assessment of Federal Regulation and Policies on Families (Pub. L. 105–277, section 654, 5 U.S.C. 601 (note)), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

This rule proposes to revise the regulation that allows OCR to accept

and coordinate the handling of complaints alleging violations of the Weldon, Church, and Coats-Snowe Amendments that collectively protect conscience, prohibit coercion, and require nondiscrimination in certain programs and activities operated by recipients or sub-recipients or that are administered by the Secretary. Specifically, the proposed rule:

(1) Aligns the regulation's scope to comport with the full panoply of Federal health care conscience and associated anti-discrimination laws that exist across the Department and that the

Secretary has delegated to OCR to enforce,

(2) Expands the scope of enforcement mechanisms available to OCR to be consistent with mechanisms used by OCR to enforce similar civil rights laws, as appropriate,

(3) Requires certain persons and entities covered by this proposed rule to adhere to certain procedural and administrative requirements that aim to elevate awareness of Federal health care conscience and associated anti-discrimination rights and certain obligations of persons and entities.

TABLE 1—ACCOUNTING TABLE OF BENEFITS AND COSTS OF ALL PROPOSED CHANGES

	Present value over 5 years by discount rate (millions of 2016 dollars)		Annualized value over 5 years by discount rate (millions of 2016 dollars)	
	3 Percent	7 Percent	3 Percent	7 Percent
Benefits:				
Quantified Benefits
<i>Non-quantified Benefits:</i> Balance of personal freedom and moral commitment; more diverse and inclusive workforces; improved provider patient relationships; equity, fairness, nondiscrimination.				
Costs:				
Quantified Costs	692.1	562.7	165.1	168.1
<i>Non-quantified Costs:</i> Any ancillary costs resulting from a protection of conscience rights.				

The Department estimates that the benefits of this rule, although not quantifiable or monetized, justify the burdens of the regulatory action. The Department estimates that implementation of this rule will, on average, cost \$312.3 million in year one and \$125.5 million annually in years two through five. Considering the number of entities affected and excluding the costs to OCR, this rule is estimated to cost each affected person, entity, and health care entity, on average, \$665 in year one, which drops by 60% to about \$266 annually in years two through five.

Analysis of Economic Impacts: Executive Orders 12866 and 13563

HHS has examined the economic implications of this proposed rule as required by Executive Orders 12866 and 13563. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity).

B. Executive Order 12866

Section 6(3)(C) of Executive Order 12866 requires agencies to prepare a regulatory impact analysis (RIA) for major rules that are significant. Section 3(f) of Executive Order 12866 defines a regulatory action as significant if it is likely to result in a rule that meets one of four conditions: (1) Is economically significant, (2) creates a serious inconsistency or otherwise interferes with an action taken or planned by another agency, (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of the recipients of these grants and programs, or (4) raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. A rule is likely to be economically significant where the agency estimates that it will (a) have an annual effect on the economy of \$100 million or more in any one year, or (b) adversely and materially affect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities. The Department has determined that this rule will have an annual effect on the economy of \$100

million or more in one year and, thus, is economically significant.

C. Executive Order 13563

Executive Order 13563 supplements and reaffirms the principles of Executive Order 12866. Section 1(b) of Executive Order 13563 requires agencies to:

- “propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs,”
- “tailor its regulations to impose the least burden on society,”
- “select . . . regulatory approaches that maximize net benefits,”
- “[as] feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt,” and
- “identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior . . . or providing information upon which the public can make choices.”

Executive Order 13563 encourages agencies to promote innovation; avoid creating redundant, inconsistent, or overlapping requirements applicable to already highly-regulated industries and sectors; and consider approaches that maintain flexibility and freedom of choice for the public.

Finally, Executive Order 13563 requires that agencies use the best reasonably obtainable scientific, technical and economic information available in evaluating the burdens and benefits of a regulatory action.

As discussed throughout this impact analysis, the Department considered these objectives in its analyses of this proposed rule. In doing so, the Department used the best reasonably obtainable technical and economic information to determine that this proposed rule: Creates net benefits, is tailored to impose the least burden on society, incentivizes the desired behavior, and maximizes flexibility. This impact analysis also strives to promote transparency in how the Department derived the estimates. To this end, this RIA notes the extent to which key uncertainties in the data and assumptions affect the Department's analytic conclusions.

1. Need for the Proposed Rule

(i) Problems That the Proposed Rule Seeks To Address

In developing regulatory actions, “[e]ach agency shall identify the problem that it intends to address (including . . . the failures of private markets or public institutions . . .) as well as assess the significance of the problem.” E.O. 12866, sec. 1(b)(1). In identifying the problem warranting agency regulatory action, “[e]ach agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem . . .” E.O. 12866, sec. 1(b)(2).

This proposed rule seeks to address two categories of problems: (1) Inadequate enforcement tools to address discrimination and coercion associated with conscience objections by persons, entities, or health care entities, and (2) intolerance for certain Federal health care conscience and associated anti-discrimination rights, in part due to confusion about the law, leading to possible violations of law and increased complaints. The array of issues described *supra* in Parts IV (The Original Version and Current Version of the Rule) and Part VI (Reasons for the Proposed Rule) fall into one or both of these two overarching categories.

Protection of religious beliefs and moral convictions not only serves individual rights, it serves society as a whole. Protections for conscience help ensure a society free from discrimination and more respectful of personal freedom. Although the boundaries of protection for conscience may be tested when that protection appears to impede other public goods, it

is in those cases where fidelity to the law becomes paramount.⁴⁸

Despite the longstanding nature of the Federal health care conscience and associated anti-discrimination laws that this rule proposes to enforce, discrimination and coercion continue to occur. Relevant situations where persons, entities, and health care entities with religious beliefs or moral convictions may be coerced or suffer discrimination include:

- Being asked to perform, participate in, pay for, counsel or refer for abortion, sterilization, euthanasia, or other health services;
- engaging in health professions training that pressures students, residents, fellows, etc., to perform, assist in the performance of, or counsel for abortion;
- considering a career in obstetrics, family medicine, or elder care, when one has a religious or moral objection to abortion, sterilization, or euthanasia;
- raising religious or moral objections to participating in certain services within the scope of one's employment; and,
- being required to administer or receive certain vaccinations derived from aborted fetal tissues as a condition of work or receipt of educational services.

Discrimination, coercion, and intolerance for religious beliefs or moral convictions continue to occur due to (1) the poor functioning of Federal government frameworks to enforce Federal health care conscience and associated anti-discrimination laws and (2) inadequate information and understanding about the obligations of persons and entities and the rights of persons, entities, and health care entities under these laws. These deficiencies in Federal governing frameworks include:

An inadequate, minimalistic regulatory scheme at part 88 of 45 CFR due to the Department's 2011 Rule that rescinded the comprehensive 2008 Rule, *see supra* Part IV.A–B (describing content of the existing and prior versions of the rule) and Part VI.C (identifying confusion about conscience laws' scope and applicability);

An unduly narrow Departmental interpretation of the Weldon Amendment adopted by OCR in connection with the 2011 Rule that limited the scope of discrimination contrary to the language that Congress passed, *see supra* Part VI.E (addressing confusion caused by OCR sub-regulatory guidance); and

A lack of strategic coordination across the Department to address the enforcement of Federal health care conscience and associated anti-discrimination laws set forth in authorizing statutes of programs that the Department's components conduct, *see supra* Part III.F (identifying additional Federal health care conscience and associated anti-discrimination laws).

The absence of adequate Federal governing frameworks to remedy discrimination may have undermined incentives for covered persons and entities proactively to institute measures to protect conscience, prohibit coercion, and promote nondiscrimination.

OCR is aware that persons who are unlawfully coerced to violate their consciences or otherwise discriminated against because they have acted in accord with their moral convictions or religious beliefs experience real harm that is significant psychologically, emotionally, and financially. Such persons claim that their harm amounts to an actionable violation of the Federal health care conscience and associated anti-discrimination laws that OCR can remedy through administrative enforcement.⁴⁹ Indeed, since November of 2016, OCR has received thirty-four complaints concerning Federal health care conscience and associated anti-discrimination laws. *See supra* Part V (identifying when OCR complaints were received).

(ii) How the Proposed Rule Seeks To Address Those Problems

This proposed regulatory action corrects those problems. First, the Department proposes to revise 45 CFR part 88 from a minimal regulatory scheme to one comparable to the regulatory schemes implementing other civil rights laws. Such schemes typically include a dozen provisions, addressing a range of conduct. These provisions typically restate the substantive requirements and obligations of the laws and often impose procedural requirements (*e.g.*, assurances of compliance, notices to the public) to further compliance with those substantive rights and obligations. In addition, such schemes outline the enforcement procedures to provide regulated entities notice of the enforcement tools available to OCR and the type of remedies OCR may seek. Part 88, by contrast, is currently only three sentences long and therefore provides

⁴⁸ See Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals*, 49 Ariz. St. L.J. 549, 550–51 (2017).

⁴⁹ As discussed earlier, several courts have declined to recognize a private right of action for persons protected under certain Federal health care conscience and associated anti-discrimination laws. In such cases, persons must rely on OCR for enforcement.

considerably less notice and clarity about the conduct prohibited under Federal law and the enforcement mechanisms available to OCR.

Department components, recipients, and sub-recipients must comply with the Federal laws that are the subject of this proposed rulemaking. In addition to conducting outreach and providing technical assistance, OCR would have the authority to initiate compliance reviews, conduct investigations, and supervise and coordinate appropriate action with the relevant Department component to assure compliance.

To assist OCR in ensuring compliance with and enforcement of the Federal health care conscience and associated anti-discrimination laws, the proposed rule would require certain persons and entities: To maintain records; cooperate with OCR investigations, reviews, interviews, or other parts of OCR's enforcement process; submit written assurances and certifications of compliance to the Department; and provide notice to persons, entities, and health care entities about Federal health care conscience and associated anti-discrimination protections, as applicable. These procedural and administrative requirements are similar to those in other civil rights regulations and have a proven record of improving compliance with, and enforcement of, other Federal civil rights laws. Together, these requirements would support the Department's renewed effort for strategic coordination with respect to the compliance and enforcement of the Federal health care conscience and associated anti-discrimination laws that exist across the Department.

Second, this proposed rule seeks to promote voluntary compliance with laws governing the ability of persons, entities, and health care entities to act in accord with their religious beliefs or moral convictions by ensuring that persons and entities are aware of and understand Federal health care conscience and associated anti-discrimination laws. Persons and entities would be more likely to accommodate conscience and associated anti-discrimination rights if persons and entities understand that they are legally obligated to do so. Persons and entities would also be in a better position to accommodate these rights if they understand these rights to be akin to other civil rights to be free from discrimination on the basis of race, national origin, disability, etc.—rights that recipients and sub-recipients are already familiar with respecting.

The Department anticipates, as anticipated with the 2008 Rule, that this proposed rule would promote

accommodation of protected persons, entities, and health care entities. *See e.g.*, 73 FR 78074, 78081 (2008 Rule). Greater transparency of practices through open communication of recipient and sub-recipient policies “should strengthen relationships between patients and providers, as well as those between entities and their . . . [workforce members].” *Id.* at 78074. The Department intends that OCR's outreach and guidance, investigations, compliance reviews, and enforcement actions, would provide institutions with an incentive to review their compliance with Federal health care conscience and associated anti-discrimination laws, as applicable, resulting in increased voluntary compliance.

2. Affected Persons and Entities

The proposed rule affects: (1) Persons and entities obligated to comply with 45 CFR part 88 because they are subject to the Weldon Amendment, Coats-Snowe Amendment, or Church Amendments (or a combination thereof); and (2) persons and entities obligated to comply with at least one of the nearly two dozen Federal laws that this revision of part 88 proposes to enforce.

(i) Scope of Persons and Entities That 45 CFR Part 88 Covers

This proposed rule affects persons and entities obligated to comply with the Weldon, Church, and Coats-Snowe Amendments of which 45 CFR part 88 provides for the enforcement.

Current part 88 extends:

- To almost every program and activity administered by the Secretary;
- To all State and local governments that receive Federal financial assistance as recipients or sub-recipients; and
- To recipients that operate a health service program or research activity or biomedical or behavioral research administered by the Secretary, or for the implementation of programs or activities authorized in the Public Health Service Act (“PHS Act”) or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (“DD Act”) through specified instruments. As described in the following paragraphs, the current part 88 thus covers a synthesis of actors subject to the Church, Coats-Snowe, and Weldon Amendments.

(A) The Department

Part 88 applies to the Department because the Weldon and Coats-Snowe Amendments, as well as specific paragraphs of the Church Amendments, apply to the Department.

The Weldon Amendment states that “[n]one of the funds made available in

this Act may be made available to a Federal agency or program . . . if such agency [or] program . . . subjects any institutional or individual health care entity to discrimination . . .”⁵⁰ The Department is a Federal agency that receives substantial funds made available in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act (“Labor/HHS/ Education Appropriation”), which are the funds addressed in Weldon.⁵¹ To continue to receive those funds, the Department cannot discriminate on a basis prohibited by Weldon.

The Coats-Snowe Amendment states that “[t]he Federal Government . . . may not subject any health care entity to discrimination on the [bases]” listed in paragraphs (a)(1)–(3) of 42 U.S.C. 238n. The Department, as part of the Federal Government, must comply with the Coats-Snowe Amendment in all of the Department's operations.

Paragraphs (d) and (c)(2) of the Church Amendments apply to certain programs administered by the Secretary. Paragraph (d) applies to all health service programs or research activities funded in whole or part under programs administered by the Secretary regardless of the source of funding. Paragraph (c)(2) applies to entities that receive grants or contracts “for biomedical or behavioral research under any program administered by the Secretary.”⁵² The Department administers many such programs, either directly or through its components. Examples include:

- The Health Resources and Services Administration (HRSA) administers grant programs, such as the operation of a grant program for community health centers,
- The National Institute of Health operates grant programs to fund research,
- The Centers for Medicare & Medicaid Services (CMS) administers Medicare and Federally-facilitated Health Insurance Marketplaces,⁵³ and CMS jointly administers Medicaid with States,⁵⁴ and

The Indian Health Service (IHS) operates a system of direct health care for certain Tribes and Tribal organizations and also administers contracts and self-governance compacts under the Indian Self-Determination and Education Assistance Act

⁵⁰ *E.g.*, Consolidated Appropriations Act, 2017, Public Law 115–31, Div. H, Tit. V, sec. 507(d), 131 Stat. 135, 562 (May 5, 2017).

⁵¹ *See id.*

⁵² 42 U.S.C. 300a–7(c)(2) and (d).

⁵³ <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/fje.html>.

⁵⁴ <https://www.medicare.gov/>.

(ISDEAA),⁵⁵ as amended, which allows Tribes and Tribal Organizations to assume control and management of health care that IHS would otherwise provide.⁵⁶

(B) State and Local Governments

Part 88 applies to all State and local governments that receive HHS Federal financial assistance by virtue of several statutory provisions. First, the Weldon Amendment applies to State and local governments that receive funds made available in the Labor/HHS/Education Appropriation.⁵⁷ Second, the Coats-Snowe Amendment applies to State and local governments that receive HHS Federal financial assistance (regardless of funding source), “includ[ing] governmental payments provided as reimbursement for carrying out health-related activities.”⁵⁸

Third, several paragraphs of the Church Amendments apply to State and local governments. Paragraph (b) of the Church Amendments prohibits coercion by a “public authority,” and thereby includes States and local governments. Paragraphs (c) and (e) of the Church Amendments apply to State and local governments to the extent that such governments receive funds to implement programs authorized in the public laws cited in such paragraphs.

Finally, paragraph (d) of the Church Amendments applies to a State or local government to the extent that such State or local government receives partial or full funding for a health service program or research activity under a program administered by the Secretary.⁵⁹

State and local governments (such as counties or cities) and instrumentalities of governments (such as State health and human services agencies) subject to current part 88 receive Federal financial assistance or Federal funds from the Department from a variety of financing streams as recipients or sub-recipients. Examples of these financing streams, which include reimbursement for health-related activities, include:

- Medicaid and the Children’s Health Insurance Program,
- public health and prevention programs, HIV/AIDS and STD prevention and education, and substance abuse screening,
- biomedical and behavioral research at State institutions of higher-education,
- services for older Americans,
- medical assistance to refugees, and
- adult protection services to combat elder justice abuse.

(C) Persons and Entities

Part 88 applies to recipients and sub-recipients that operate “any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary;”⁶⁰ receive a grant, contract, loan, or loan guarantee under the PHS Act or the DD Act; or receive an interest subsidy under the DD Act. Several statutory provisions support this application. First, paragraphs (c)(1)–(2) of the Church Amendments apply to entities that receive a “grant, contract, loan, or loan guarantee under the [PHS Act],” or a “grant or contract for biomedical or behavioral research.” Second, paragraph (e) of the Church Amendments applies to entities that receive a “grant, contract, loan, or loan guarantee, or interest subsidy” under the [PHS Act] or the DD Act.⁶¹ Third, paragraph (d) of the Church Amendments applies to “any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services.”⁶²

⁶⁰ 42 U.S.C. 300a–7(d).

⁶¹ 42 U.S.C. 300a–7(c)(1)(B) (“No entity which receives a grant, contract, loan, or loan guarantee under the Public Health Service Act . . .”), 300a–7(e) (“No entity which receives . . . any grant, contract, loan, [or] loan guarantee . . . under the Public Health Service Act . . . or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 may . . .”). In addition to the PHS Act, paragraphs (c)(1) and (e) of the Church Amendments apply to entities that receive funding under the Community Mental Health Centers Act, 42 U.S.C. 2689 *et seq.* Paragraph (c)(1) of the Church Amendments additionally applies to entities that receive funding under the Developmental Disabilities Services and Facilities Construction Act, 42 U.S.C. 6000 *et seq.* Congress repealed both of these laws; thus, there are no entities receiving funds under programs authorized by these statutes to consider in this RIA. See Omnibus Reconciliation Act of 1981, Public Law 97–35, Title IX, sec. 902(e)(2)(B), 95 Stat. 560 (1981); Developmental Disabilities Assistance and Bill of Rights Act of 2000, Public Law 106–402, Title IV, sec. 401(a), 114 Stat. 1737 (2000).

⁶² *Id.* at 300a–7(d) (“No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services . . .”).

The broad array of recipients and sub-recipients in this category is a function of two statutory features. First, paragraph (d) of the Church Amendment does not tie the funding source to a particular appropriation, instrument, or authorizing statute. Second, the PHS Act contains thirty titles and authorizes dozens of programs. Examples of entities that receive funds under programs authorized by the PHS Act include:

- Health facilities, including hospitals, Federally qualified health centers, community health centers, and mental health clinics;
- Health-related schools and other education entities that provide health professions training for medicine, oral health, behavioral health, geriatric care, nursing, etc.;
- Community-based organizations that provide substance abuse screening, HIV/AIDS prevention and treatment, and domestic violence screening;
- Private non-profit and for-profit agencies that provide medical care to unaccompanied minors;
- Interdisciplinary university centers or public or nonprofit entities associated with universities that receive financial assistance to implement the DD Act;⁶³ and
- State Councils on Developmental Disabilities⁶⁴ and States’ Protection and Advocacy Systems that receive funds to implement the DD Act.⁶⁵

(ii) Persons and Entities Obligated To Comply With Additional Federal Laws That This NPRM Proposes To Enforce

This proposed rule would affect persons and entities obligated to comply with at least one of the approximately two dozen Federal laws that this revision of part 88 proposes to enforce. There is substantial overlap between persons and entities obligated to comply with the current part 88 and persons and entities subject to at least one of the additional Federal laws that this revision of part 88 proposes to enforce. This overlap occurs because such persons and entities should already be subject to 45 CFR part 88 by virtue of their coverage by the Weldon Amendment, Coats-Snowe Amendment, or Church Amendments (or a combination thereof), the coverage of which the Department explained in the immediately preceding part—Part XI.C.2.i. Because of this overlap, the Department estimates that the proposed

⁶³ E.g., <https://www.acl.gov/node/466>.

⁶⁴ E.g., <https://www.acl.gov/node/110>. <https://www.acl.gov/sites/default/files/about-acl/2017-12/DDC-2017.pdf>.

⁶⁵ E.g., <https://www.acl.gov/sites/default/files/about-acl/2017-06/PADD-2017.pdf>.

⁵⁵ Public Law 93–638, 88 Stat. 2203 (Jan. 4, 1975).

⁵⁶ IHS FY 2018 Congressional Justification of Estimates to the Appropriations Committees 199, 203 (2017), https://www.ihs.gov/budget/formulation/includes/themes/responsive2017/display_objects/documents/FY2018CongressionalJustification.pdf

⁵⁷ Public Law 115–31, Div. H, Tit. V, sec. 507(d), 131 Stat. at 562 (“None of the funds made available in this Act may be made available to a . . . State or local government[] if such . . . government . . .”).

⁵⁸ 42 U.S.C. 238n(a), (c)(1).

⁵⁹ *Id.* at § 300a–7(d) (“No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services . . .”).

delegation of authority to OCR to enforce the following laws would not add any new persons and entities to the coverage of part 88:

Provider conscience laws related to abortion (the Weldon Amendment for Medicare Advantage, *e.g.* Public Law 115–31, Div. H, sec. 209, 131 Stat. 135, 539 (2017));

Certain provisions of the Affordable Care Act applying Federal conscience protections of providers with respect to abortion (42 U.S.C. 18023(b)(4)), regarding assisted suicide (42 U.S.C. 18113), and providing a conscience exemption to the individual mandate (26 U.S.C. 5000A(d)(2));

Certain laws governing provider counseling, referral, and implementation of directives (counseling and referral in Medicare Advantage ((42 U.S.C. 1395w–22(j)(3)(B))), counseling and referral in Medicaid (42 U.S.C. 1396u–2(b)(3)(B)), and performance of advanced directives in the Medicare and Medicaid programs (42 U.S.C. 1396a(w)(3), and 14406));

Laws providing for patient objections to receiving health care services, including medical screening, examination, diagnosis, treatment, or other health care (42 U.S.C. 1396f), occupational illness testing (29 U.S.C. 669(a)(5)), pediatric vaccination (42 U.S.C. 1396s(c)(2)(B)(ii)), youth suicide prevention and treatment (42 U.S.C. 290bb–36(f)), and newborn health screening (42 U.S.C. 280g–1(d)); and

Laws protecting religious nonmedical health care, by exempting religious non-medical institutions from health facility review (42 U.S.C. 1320a–1), peer review (42 U.S.C. 1320c–11), certain health standards (42 U.S.C. 1396a(a)(9)(A)), medical evaluation (42 U.S.C. 1396a(a)(31)), medical licensing review (42 U.S.C. 1396a(a)(33)), and utilization review plan requirements (42 U.S.C. 1396b(i)(4)), and by protecting the exercise of religious nonmedical health care in the Elder Justice Block Grant Program (42 U.S.C. 1397j–1(b)) and in the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106i(a)(2)).

The Department estimates that the proposed delegation of authority to OCR to enforce the following laws would probably add new persons and entities to the coverage of part 88:

- Global Health Programs for HIV/AIDS Prevention, Treatment, or Care (22 U.S.C. 7631(d)), and

- The Helms Amendment (*e.g.*, Consolidated Appropriations Act, 2017, Pub. L. 115–31, Div. J, sec. 7018).

The persons and entities subject to 22 U.S.C. 7631(d) and the Helms Amendment may not be currently subject to part 88 because the persons

and entities are recipients and sub-recipients of funds that HHS administers for Global Health programs where those funds are appropriated to the U.S. Department of State and USAID but awarded from HHS. Thus, the financing streams to which these laws apply likely do not overlap with the financial streams to which the Weldon, Coats-Snowe, and Church Amendments apply. However, paragraph (d) of the Church Amendments applies to a “health service program or research activity funded in whole or in part under a program administered by the Secretary.” Paragraph (d) does not require that the funding for the health service program or research activity be appropriated to HHS, but only that it be “funded in whole or part under a program administered by the Secretary.” Consequently, paragraph (d) of the Church Amendments (and, thus, part 88) would arguably apply to recipients and sub-recipients of Federal funds from (or administered by) the Department with respect to such Global Health programs because if the Department administers the funds, it administers the program.

(iii) Methodology

Although the Department has qualitatively summarized the new persons and entities covered by this proposed rule, the Department has also quantitatively estimated those persons and entities to understand the likely impact of the proposed rule. To do so, the Department primarily relied on the latest data available from the U.S. Census Bureau’s Statistics of U.S. Businesses,⁶⁶ supplemented with other sources. The Department determined that no one data source could supply an unduplicated count of the persons or entities that receive an award through an instrument covered within the scope of this proposed rule. But in assessing the available methodologies, the Department concluded that the U.S. Census Bureau data, supplemented with other sources, was the most reasonable way to estimate the number of persons and entities that this proposed rule would affect.

The U.S. Census Bureau’s Statistics of U.S. Businesses is based on the North American Industry Classification System (NAICS).⁶⁷ The NAICS classifies

all economic activity into 20 sectors and breaks that information down into sub-sectors and industries.⁶⁸ Essentially, the NAICS groups physical business establishments together based on how similar the locations’ processes are for producing goods or services.⁶⁹ The NAICS provides information on how many singular physical locations exist for a particular business or industry (called an “establishment”),⁷⁰ how many of those establishments are under common ownership or control of a business organization or entity (called a “firm”),⁷¹ and the number of people who work in a particular business or industry, among other types of information. For instance, a hospital system that has common ownership and control over multiple hospital facilities is a firm, and each hospital facility is an establishment.

For the vast majority of the recipient and sub-recipient types, the Department assumes that only a portion of the industry captured in the Statistics of U.S. Businesses receives Federal funds. For instance, not all physician offices accept Medicare, Medicaid, or both. In fact, about 68.9% of physician offices accepted new Medicaid patients based on 2013 data from the National Electronic Health Records Survey.⁷² Approximately 83.7% of physicians accepted new Medicare patients based on the same data.⁷³ Because current part 88 applies to physicians receiving reimbursement for Medicare Part B and to physicians participating in Medicaid, the Department assumed that the lower of these two percentages (69%) represents the lower-bound of physicians nationwide subject to current part 88. In the absence of evidence with which to generate a refined upper-bound estimate, the Department assumed that current part 88 covers all physicians nationwide as the upper-bound.

The Department used this same percentage range (69% to 100%) in estimating the coverage for other health care industry sector types, such as hospitals and various outpatient care facilities. For the social services and

⁶⁶ FAQ 5, <https://www.census.gov/eos/www/naics/faqs/faqs.html#q5>.

⁶⁹ FAQ 1, <https://www.census.gov/eos/www/naics/faqs/faqs.html#q1>.

⁷⁰ <https://www.census.gov/eos/www/naics/faqs/faqs.html#q2>.

⁷¹ https://www.census.gov/glossary/#term_Firm.

⁷² Esther Hing et al., Nat’l Ctr. For Health Statistics, Centers for Disease Control and Prevention, U.S. Dep’t of Health and Human Servs., Acceptance of New Patients with Public and Private Insurance by Office-Based Physicians: United States, 2013, Data Brief No. 195, 1 (Mar. 2015).

⁷³ *Id.*

⁶⁶ <https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html>. The Department relied on the data file titled “U.S. & State, NAICS, detailed employment sizes (U.S., 6-digit and states, NAICS sectors).” The latest data available is from 2015 that the Bureau made available in September of 2017, and this data relied on the 2012 NAICS codes. *Id.*

⁶⁷ <https://www.census.gov/programs-surveys/susb/technical-documentation/methodology.html>.

education industries, which generally have principal purposes other than health and patient care, the Department adopted ranges more appropriate for those industries. For the social services industries, the Department adopted a range with 25% as the lower-bound and 100% as the upper-bound to cover 62.5% of the industry on average).

To estimate the number of local governments and educational institutions, the Department supplemented its use of data from the U.S. Census Bureau's Statistics of U.S. Businesses with Census data from other statistical programs or with available award data available through the HHS Tracking Accountability in Government Grants System (TAGGS).⁷⁴ For instance, in estimating the number of counties nationwide, the Department relied on U.S. Census Bureau's 2010 Census Geographic Entity Tallies by State and Type to identify the total counties and equivalent areas for the U.S., Puerto Rico, the U.S. Territories, and the Island Areas.⁷⁵

As another example, the Department relied on data from TAGGS to derive a lower-bound percentage of colleges and universities that are recipients. (The upper-bound assumes all educational institutions industry-wide are recipients.) Although most colleges and universities receive Federal financial assistance from the U.S. Department of Education, not all universities are recipients of HHS funds; thus, the Department wanted a lower-bound estimate to reflect that assumption.

Using the "Advanced Search" function in TAGGS, HHS identified all awards to Junior Colleges, Colleges, and Universities for FY 2016 and de-duplicated the results to obtain a singular list of unique awardees from the Department, which totaled 615. Because these awardees included

satellite campuses of college or university systems, the total awardee number was akin to the number of "establishments" rather than "firms" as those terms are used in the U.S. Census Bureau's Statistics of U.S. Businesses. Similar to how an "establishment" is a location of a "firm" that has common ownership and control, a satellite campus is one location of a university system with common ownership and control of multiple campus locations.

To derive an estimate of educational institutions at the "firm" level, the Department computed the ratio between firms and establishments from the U.S. Census Bureau's Statistics of U.S. Businesses.⁷⁶ This ratio is 51.32% (2,457 firms/4,788 establishments). The Department applied that ratio to the total number of Junior Colleges, Colleges, and Universities that received HHS funding as "establishments" (0.5132×615 awardee establishments) to get an estimate of 316 firms. Despite this method's potential complexity, the Department found it the most reasonable method for estimating the lower-bound number of colleges and universities that are Department recipients.

The Department considered other methodologies for estimating the number of impacted persons and entities. For instance, the Department considered primarily relying on award data from TAGGS in lieu of using it as a supplemental data source. In addition, the Department also considered adding together the number of awards to States, local governments, private entities, nonprofit entities, etc., that Department components commonly report on a program-by-program basis on the Web, in ad hoc reports on topic-specific matters, and in their annual Justifications of Estimates to the Appropriations Committees as part of

the President's annual budget request to Congress.

The Department rejected those methodological approaches. In particular, the Department was concerned that those approaches would double-count a substantial number of persons and entities that receive an award from more than one Department component or that receive multiple awards from the same component. Primarily relying on TAGGS would not only double-count some persons and entities but would under-count others because TAGGS does not capture the number of sub-recipients receiving awards from a recipient. Given these considerations, NAICS information, supplemented with Census data from other statistical programs or with publicly available award data from TAGGS, was the best reasonably obtainable source of economic and technical information on which the Department could rely.

The Department seeks comment on the methodology used and whether there are other methodologies that the Department could consider to refine the scope of persons and entities affected by this proposed rule.

(iv) Quantitative Estimate of Persons and Entities Covered by NPRM

Table 1 lists each type of recipient and the estimated number of recipients that this proposed rule covers. Because there is uncertainty as to the universe of persons and entities currently covered by 45 CFR part 88 and the incremental number of new persons and entities that the Department expects this proposed rule will cover, Table 1 captures this uncertainty by reflecting estimated recipients as a range with a lower and an upper-bound. The footnotes detail the assumptions and calculations for each line of the table.

TABLE 1—ESTIMATED NUMBER OF PERSONS AND ENTITIES COVERED BY NPRM

	Type	Covered by current 45 CFR 88?	Covered by NPRM?	Estimated number (low)	Estimated number (high)
1	State and Territorial Governments ⁷⁷	Yes	Yes	58	58
2	Federally recognized Tribes ⁷⁸	Yes	Yes	567	567
3	Counties ⁷⁹	Yes	Yes	3,234	3,234
Hospitals:					
4	General and Medical Surgical Hospitals ⁸⁰	Yes	Yes	1,859	2,694
5	Specialty Hospitals (e.g., psychiatric, substance abuse, rehabilitation, cancer, maternity) ⁸¹	Yes	Yes	553	801
Nursing and Residential Care Facilities:					

⁷⁴ <http://taggs.hhs.gov> (last visited Aug. 24, 2017).

⁷⁵ https://www.census.gov/geo/maps-data/data/tallies/all_tallies.html.

⁷⁶ U.S. Census Bureau, Statistics of U.S. Businesses, 2015, NAICS code 611310 (Colleges, Universities, and Professional Schools).

TABLE 1—ESTIMATED NUMBER OF PERSONS AND ENTITIES COVERED BY NPRM—Continued

	Type	Covered by current 45 CFR 88?	Covered by NPRM?	Estimated number (low)	Estimated number (high)
6	Skilled Nursing Facilities ⁸²	Yes	Yes	6,316	9,153
7	Residential Intellectual and Developmental Disability Facilities ⁸³	Yes	Yes	4,310	6,246
8	Continuing Care Retirement Communities ⁸⁴	Yes	Yes	2,605	3,775
9	Other Residential Care Facilities (e.g., group homes) ⁸⁵ ..	Yes	Yes	2,247	3,256
10	Entities providing Home Health Care Services ⁸⁶	Yes	Yes	15,062	21,829
Entities Providing Ambulatory Health Care Services:					
11	Offices of Physicians (except Mental Health Specialists) ⁸⁷	Yes	Yes	115,673	167,642
12	Offices of Physicians (Mental Health Specialists) ⁸⁸	Yes	Yes	7,324	10,614
13	Offices of Mental Health Practitioners (except Physicians) ⁸⁹	Yes	Yes	14,340	20,782
14	Offices of Dentists ⁹⁰	Yes	Yes	86,874	125,904
15	Offices of Chiropractors ⁹¹	Yes	Yes	26,725	32,535
16	Offices of Optometrists ⁹²	Yes	Yes	13,775	19,964
17	Offices of Physical, Occupational and Speech Therapists, and Audiologists ⁹³	Yes	Yes	17,623	25,540
18	Offices of Podiatrists ⁹⁴	Yes	Yes	5,314	7,701
19	Family Planning Centers ⁹⁵	Yes	Yes	999	1,448
20	Freestanding Ambulatory Surgical and Emergency Centers ⁹⁶	Yes	Yes	2,908	4,214
21	HMO Medical Centers ⁹⁷	Yes	Yes	78	113
22	Kidney Dialysis Centers ⁹⁸	Yes	Yes	305	442
23	Outpatient Mental Health and Substance Abuse Centers ⁹⁹	Yes	Yes	3,776	5,472
24	Diagnostic Imaging Centers ¹⁰⁰	Yes	Yes	3,209	4,651
25	Medical Laboratories ¹⁰¹	Yes	Yes	2,278	3,302
26	Ambulance Services ¹⁰²	Yes	Yes	2,185	3,167
27	All Other Outpatient Care Centers (e.g., centers and clinics for pain therapy, community health, and sleep disorders) ¹⁰³	Yes	Yes	3,880	5,623
28	Entities providing All Other Ambulatory Health Care Services (health screening, smoking cessation, hearing testing, blood banks) ¹⁰⁴	Yes	Yes	2,391	3,465
Insurance Carriers:					
29	Direct Health and Medical Insurance Carriers ¹⁰⁵	Yes	Yes	607	880
Entities Providing Social Assistance Services:					
30	Entities Serving the Elderly and Persons with Disabilities (provision of nonresidential social assistance services to improve quality of life) ¹⁰⁶	Yes	Yes	9,051	36,205
31	Entities providing Other Individual Family Services (e.g., marriage counseling, crisis intervention centers, suicide crisis centers) ¹⁰⁷	Yes	Yes	5,310	21,240
32	Entities providing Child and Youth Services (e.g., adoption agencies, foster care placement services) ¹⁰⁸	Yes	Yes	2,169	8,674
33	Temporary Shelters (e.g., short term emergency shelters for victims of domestic violence, sexual assault, or child abuse; runaway youth; and families caught in medical crises) ¹⁰⁹	Yes	Yes	805	3,219
34	Emergency and Other Relief Services (e.g., medical relief, resettlement, and counseling to victims of domestic or international disasters or conflicts) ¹¹⁰	Yes	Yes	169	675
Other Entities:					
35	Pharmacies and Drug Stores ¹¹¹	Yes	Yes	13,490	19,550
36	Research and Development in Biotechnology ¹¹²	Yes	Yes	2,347	3,402
37	Colleges, Universities, and Professional Schools ¹¹³	Yes	Yes	316	2,457
Subtotal, subject to current part 88				364,575	571,282
38	HHS awarded funds appropriated to the U.S. Department of State & USAID ¹¹⁴	No	Yes	65	130
Subtotal, incremental increase in entities				65	130

TABLE 1—ESTIMATED NUMBER OF PERSONS AND ENTITIES COVERED BY NPRM—Continued

Type	Covered by current 45 CFR 88?	Covered by NPRM?	Estimated number (low)	Estimated number (high)
Total, estimated entities subject to NPRM			364,640	571,412

⁷⁷ Assumes coverage of the 50 States, DC, Puerto Rico, 6 U.S. Territories, and the Island Areas.

⁷⁸ Assumes all Federally-recognized Tribes get HHS funds. Indian Health Service, FY 2018 Justification of Estimates to the Appropriations Committees CJ-1 (2017), https://www.ihs.gov/budgetformulation/includes/themes/responsive2017/display_objects/documents/FY2018CongressionalJustification.pdf.

⁷⁹ U.S. Census Bureau, 2010 Census Geographic Entity Tallies by State and Type, https://www.census.gov/geo/maps-data/data/tallies/all_tallies.html (total counties and equivalent areas for the U.S., Puerto Rico, the U.S. Territories, and the Island Areas). The Department assumed that every county receives Federal funds as a recipient or sub-recipient.

⁸⁰ U.S. Census Bureau, Statistics of U.S. Businesses, 2015 (released Sept. 2017), <https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html> (nationwide count of firms for NAICS Code 622110). Assumes coverage for 69%–100% of the industry.

⁸¹ *Id.* (sum of the nationwide count of firms for NAICS Codes 622210 and 622310). Assumes 69%–100% of industry is covered.

⁸² *Id.* (relying on the nationwide count of firms for NAICS Code 623110). Assumes 69%–100% of industry is covered.

⁸³ *Id.* (nationwide count of firms for NAICS Code 623210). Assumes 69%–100% of industry is covered.

⁸⁴ *Id.* (nationwide count of firms for NAICS Code 623311). Assumes 69%–100% of industry is covered.

⁸⁵ *Id.* (nationwide count of firms for NAICS Code 623990). Assumes 69%–100% of industry is covered.

⁸⁶ *Id.* (nationwide count of firms for NAICS Code 621610). Assumes 69%–100% of industry is covered.

⁸⁷ *Id.* (nationwide count of firms for NAICS Code 621111). Assumes 69%–100% of industry is covered.

⁸⁸ *Id.* (nationwide count of firms for NAICS Code 621112). Assumes 69%–100% of industry is covered.

⁸⁹ *Id.* (nationwide count of firms for NAICS Code 621330). Assumes 69%–100% of industry is covered.

⁹⁰ *Id.* (nationwide count of firms for NAICS Code 621210). Assumes 69%–100% of industry is covered.

⁹¹ *Id.* (nationwide count of firms for NAICS Code 621310). Assumes 69%–100% of industry is covered.

⁹² *Id.* (nationwide count of firms for NAICS Code 621320). Assumes 69%–100% of industry is covered.

⁹³ *Id.* (nationwide count of firms for NAICS Code 621340). Assumes 69%–100% of industry is covered.

⁹⁴ *Id.* (nationwide count of firms for NAICS Code 621391). Assumes 69%–100% of industry is covered.

⁹⁵ *Id.* (nationwide count of firms for NAICS Code 621410). Assumes 69%–100% of industry is covered.

⁹⁶ *Id.* (nationwide count of firms for NAICS Code 621493). Assumes 69%–100% of industry is covered.

⁹⁷ *Id.* (nationwide count of firms for NAICS Code 621491). Assumes 69%–100% of industry is covered.

⁹⁸ *Id.* (nationwide count of firms for NAICS Code 621492). Assumes 69%–100% of industry is covered.

⁹⁹ *Id.* (nationwide count of firms for NAICS Code 621420). Assumes 69%–100% of industry is covered.

¹⁰⁰ *Id.* (nationwide count of firms for NAICS Code 621512). Assumes 69%–100% of industry is covered.

¹⁰¹ *Id.* (nationwide count of firms for NAICS Code 621511). Assumes 69%–100% of industry is covered.

¹⁰² *Id.* (nationwide count of firms for NAICS Code 621910). Assumes 69%–100% of industry is covered.

¹⁰³ *Id.* (nationwide count of firms for NAICS Code 621498). Assumes 69%–100% of industry is covered.

¹⁰⁴ *Id.* (nationwide count of firms for NAICS Code 62199). Assumes 69%–100% of the industry is covered.

¹⁰⁵ *Id.* (nationwide count of firms for NAICS Code 524114). Assumes 69%–100% of industry is covered.

¹⁰⁶ *Id.* (nationwide count of firms for NAICS Code 624120). Assumes 69%–100% of industry is covered.

¹⁰⁷ *Id.* (nationwide count of firms for NAICS Code 624190). Assumes 69%–100% of industry is covered.

¹⁰⁸ *Id.* (nationwide count of firms for NAICS Code 624110). As described *supra* Part XI.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

¹⁰⁹ *Id.* (nationwide count of firms for NAICS Code 624221). As described *supra* Part XI.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

¹¹⁰ *Id.* (nationwide count of firms for NAICS Code 624230). As described *supra* Part XI.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

¹¹¹ *Id.* (nationwide count of firms for NAICS Code 44610). Assumes 69%–100% of industry is covered.

¹¹² *Id.* (nationwide count of firms for NAICS Code 541711). Assumes 69%–100% of industry is covered.

¹¹³ *Id.* (nationwide count of firms for NAICS Code 611310). As described *supra* Part XI.C.2.iii (methodology), the Department assumes 13%–100% of institutions of higher-education are covered. See *supra* XI.C.2.iii for a detailed explanation for how the Department supplemented Statistics of U.S. Businesses data with award data from the Department's Tracking Accountability in Government Grants System.

¹¹⁴ U.S. Dep't of Health & Human Servs., Tracking Accountability in Government Grants System (TAGGS) <http://taggs.hhs.gov> (last visited Dec. 19, 2017). HHS identified unique awardees for FY 2017 from HHS PEPFAR implementing agencies (CDC, HRSA, SAMHSA, NIH, FDA) to foreign nonprofits, foreign governments, and international organizations and used this number as a lower-bound. Because the Department also receives funds

Approximately 364,575 to 571,282 persons and entities are currently subject to part 88 by virtue of the Weldon Amendment, the Coats-Snowe Amendment, and the Church Amendments. The Department estimated that the universe of incremental new persons and entities subject to 22 U.S.C. 7631(d) and the Helms Amendment that this proposed rule would cover is small and, possibly, non-existent. This proposed rule may add 65 to 130 new persons and entities to part 88's coverage.¹¹⁵ With this incremental increase, this proposed rule would cover a total of 364,640 to 571,412 entities.

(A) Estimated Persons and Entities Required To Sign an Assurance and Certification of Compliance

Relative to the persons and entities shown in Table 1, a smaller subset will be subject to proposed 88.4, which requires certain recipients to submit an assurance and certification of compliance. The Department began calculating that subset by removing sub-recipients from the total because proposed 88.4 would apply only to recipients, not sub-recipients. OCR has not found a reliable way to estimate the total number of sub-recipients. For purposes of this calculation, the Department assumed that every county is a sub-recipient but not a recipient and accordingly excluded all 3,234 counties from the total number that must comply with the assurance and certification of compliance requirement. The Department requests information, data sources, studies, or reports that could assist in identifying the number of sub-recipients under this proposed regulation excluded from § 88.4.

The Department next sought to estimate and remove exempted entities from the total. The Department assumed that all physicians would meet the proposed criteria for exemption from the requirement in proposed

appropriated to USAID through one or more reimbursable agreements, the Department assumed that there could be twice as many recipients and sub-recipients after considering the awardees from these reimbursable agreements and thus multiplied and lower-bound by two.

¹¹⁵ But see *supra* Part XI.C.2.ii (discussing the application of paragraph (d) of the Church Amendments to such grantees).

§ 88.4(c)(1).¹¹⁶ Consequently, the Department excluded 255,684 to 370,557 entities, representing the lower and upper-bounds, from the estimate. To the degree that some physicians are recipients of the Department through an instrument other than reimbursement for their participation in Medicare Part B, then the Department overestimated the impact of the exemption.

The Department removed 11,220 to 44,879 persons and entities that provide child and youth services and services for the elderly and persons with disabilities based on the proposed exemption for recipients awarded under grant programs administered by the Administration for Children and Families or the Administration for Community Living. The exemption applies if the program meets certain

regulatory criteria indicating that its purpose is unrelated to health care and certain types of research, does not involve health care providers, and does not involve referral for the provision of health care. See proposed § 88.4(c)(2)–(3).

The Department reasonably anticipated that all persons and entities that provide child and youth services (such as adoption and foster care) would fall into this exemption. The Department also reasonably anticipated that all entities providing services for the elderly and persons with disabilities (by providing nonresidential social assistance services to improve quality of life) would fall within this exemption. The Department considered exempting entities providing Other Individual Family Services (e.g., marriage

counseling, crisis intervention centers, suicide crisis centers), but decided not to do so. Although the provision of these services may not involve health care providers, there is a significant likelihood of referral for the provision of health care at crisis intervention centers and suicide crisis centers.

Finally, the Department excluded 223 Tribes and Tribal Organizations from the total. The number reflects the proposed Tribal exemption. See proposed § 88.4(c)(4). The Department has identified 223 Tribes and Tribal Organizations that operate Title contracts under Title I of the ISDEA Act.

The Department seeks comment on the methods used to estimate the scope of exempted recipients under proposed § 88.4(c)(1)–(4).

TABLE 2—RANGE OF RECIPIENTS SUBJECT TO THE PROPOSED ASSURANCE AND CERTIFICATION REQUIREMENTS (§ 88.4)

	Low-end estimate	Upper-bound estimate
Range of Persons or Entities Subject to the NPRM	364,640	571,412
Range of Recipients Excluded from Proposed § 88.4	– 270,361	– 418,893
Total, Recipients Subject to the Assurance and Certification Requirements	94,279	152,519

(B) Estimated Number of Recipients Required to Provide Notice (§ 88.5)

More persons and entities would be subject to the notice requirement than to the assurance and certification requirements under the proposed rule. Although the Department proposes to exclude certain recipients from the assurance and certification requirements, the Department proposes to require all recipients and the Department to comply with the notice requirement. The Department proposes this policy approach because persons, entities, and health care entities who do not know their rights may not exercise them. The notice is designed to be seen by workforce members of the Department or recipients, beneficiaries of covered programs and activities, and the public. In contrast, assurance and

certification documents are internal facing documents that certain recipients would sign and the public would likely never see.

In an effort to reduce the burden on sub-recipients, proposed § 88.5, similar to proposed § 88.4, does not require sub-recipients to post a notice. The Department requests comment on whether its proposed policy strikes the right balance between reducing the burden on sub-recipients and providing notice of important rights. OCR employed the methods from *supra* Part XI.C.2.iv.A to estimate the total number of sub-recipients (3,234 counties) to exclude from the total count of persons and entities subject to the notice requirement.

The Department counted the number of establishments associated with each recipient type. Unlike the assurance and

certification requirements, which will be implemented at the “firm” level, the Department expects that the notice requirement will be implemented at the “establishment” level because proposed § 88.5 requires recipients to post the notice in all physical locations where notices are commonly posted for members of the workforce or for the public. For instance, a hospital system that has common ownership and control over multiple hospital facilities (a firm) would implement § 88.4 but each hospital facility (an establishment) would implement § 88.5 to display physical notices.

Table 3 employs the same methodology for calculating the number of entities but uses the U.S. Census Bureau’s Statistics of U.S. Businesses data for establishments rather than firms.

TABLE 3—NUMBER OF PHYSICAL ESTABLISHMENTS OF EACH RECIPIENT TYPE REQUIRED TO PROVIDE NOTICE (§ 88.5)

	Type	Estimated number (Low)	Estimated number (High)
1	State and Territorial Governments ¹¹⁷	58	58
2	Federally recognized Tribes ¹¹⁸	567	567
3	Counties ¹¹⁹ (assumed sub-recipient category to which the notice requirement does not apply).	n/a	n/a
4	General and Medical Surgical Hospitals ¹²⁰	3,699	5,361

¹¹⁶ Sum of rows 11, 12, 14–18 of Table 1.

TABLE 3—NUMBER OF PHYSICAL ESTABLISHMENTS OF EACH RECIPIENT TYPE REQUIRED TO PROVIDE NOTICE (§ 88.5)—Continued

	Type	Estimated number (Low)	Estimated number (High)
5	Specialty Hospitals (e.g. psychiatric, substance abuse, rehabilitation, cancer, maternity) ¹²¹	1,139	1,651
6	Skilled Nursing Facilities ¹²²	11,789	17,085
7	Residential Intellectual and Developmental Disability Facilities ¹²³	22,611	32,770
8	Continuing Care Retirement Communities ¹²⁴	3,668	5,316
9	Other Residential Care Facilities (e.g., group homes) ¹²⁵	3,627	5,256
10	Entities providing Home Health Care Services ¹²⁶	21,377	30,981
11	Offices of Physicians (except Mental Health Specialists) ¹²⁷	147,817	214,228
12	Offices of Physicians (Mental Health Specialists) ¹²⁸	7,498	21,867
13	Offices of Mental Health Practitioners (except Physicians) ¹²⁹	15,022	21,771
14	Offices of Dentists ¹³⁰	92,895	134,631
15	Offices of Chiropractors ¹³¹	26,999	39,129
16	Offices of Optometrists ¹³²	15,101	21,885
17	Offices of Physical, Occupational and Speech Therapists, and Audiologists ¹³³	25,213	36,541
18	Offices of Podiatrists ¹³⁴	5,769	8,361
19	Family Planning Centers ¹³⁵	1,584	2,295
20	Freestanding Ambulatory Surgical and Emergency Centers ¹³⁶	4,609	6,679
21	HMO Medical Centers ¹³⁷	560	812
22	Kidney Dialysis Centers ¹³⁸	5,144	7,455
23	Outpatient Mental Health and Substance Abuse Centers ¹³⁹	7,227	10,474
24	Diagnostic Imaging Centers ¹⁴⁰	4,553	6,598
25	Medical Laboratories ¹⁴¹	7,360	10,667
26	Ambulance Services ¹⁴²	3,271	4,740
27	All Other Outpatient Care Centers (e.g., centers and clinics for pain therapy, community health, and sleep disorders) ¹⁴³	8,054	11,672
28	Entities providing All Other Ambulatory Health Care Services (health screening, smoking cessation, hearing testing, blood banks) ¹⁴⁴	3,670	5,319
29	Direct Health and Medical Insurance Carriers ¹⁴⁵	3,712	5,379
30	Entities Serving the Elderly and Persons with Disabilities (provision of nonresidential social assistance services to improve quality of life) ¹⁴⁶	10,475	41,899
31	Entities providing Other Individual Family Services (e.g., marriage counseling, crisis intervention centers, suicide crisis centers) ¹⁴⁷	7,184	28,736
32	Entities providing Child and Youth Services (e.g., adoption agencies, foster care placement services) ¹⁴⁸	2,901	11,604
33	Temporary Shelters (e.g., short term emergency shelters for victims of domestic violence, sexual assault, or child abuse; runaway youth; and families caught in medical crises) ¹⁴⁹	1,013	4,053
34	Emergency and Other Relief Services (e.g., medical relief, resettlement, and counseling to victims of domestic or international disasters or conflicts) ¹⁵⁰	309	1,236
35	Pharmacies and Drug Stores ¹⁵¹	30,450	44,130
36	Research and Development in Biotechnology ¹⁵²	2,505	3,631
37	Colleges, Universities, and Professional Schools ¹⁵³	615	4,788
38	HHS awarded funds appropriated to the U.S. Department of State & USAID ¹⁵⁴	65	130
Total, Subject to the Notice Requirement.	476,539	746,206

Public Comment Requested on Scope of Entities

Given the uncertainty as to the number of recipients covered by this

¹¹⁷ Assumes coverage of the 50 States, DC, Puerto Rico, 6 U.S. Territories, and the Island Areas.

¹¹⁸ Assumes all Federally-recognized Tribes get HHS funds. Indian Health Service, FY 2018 Justification of Estimates to the Appropriations Committees CJ-1 (2017), https://www.ihs.gov/budgetformulation/includes/themes/responsive2017/display_objects/documents/FY2018CongressionalJustification.pdf.

¹¹⁹ U.S. Census Bureau, 2010 Census Geographic Entity Tallies by State and Type, <https://www.census.gov/geo/maps-data/data/tallies/alltallies.html> (total counties and equivalent areas for the U.S., Puerto Rico, the U.S. Territories, and the

Island Areas). The Department assumed that every county is a recipient or a sub-recipient.

¹²⁰ U.S. Census Bureau, Statistics of U.S. Businesses, 2015 (released Sept. 2017), <https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html> (nationwide count of firms for NAICS Code 622110). Assumes coverage for 69%–100% of the industry.

¹²¹ *Id.* (sum of the nationwide count of firms for NAICS Codes 622210 and 622310). Assumes 69%–100% of industry is covered.

¹²² *Id.* (relying on the nationwide count of firms for NAICS Code 623110). Assumes 69%–100% of industry is covered.

¹²³ *Id.* (nationwide count of firms for NAICS Code 623210). Assumes 69%–100% of industry is covered.

¹²⁴ *Id.* (nationwide count of firms for NAICS Code 623311). Assumes 69%–100% of industry is covered.

¹²⁵ *Id.* (nationwide count of firms for NAICS Code 623990). Assumes 69%–100% of industry is covered.

¹²⁶ *Id.* (nationwide count of firms for NAICS Code 621610). Assumes 69%–100% of industry is covered.

¹²⁷ *Id.* (nationwide count of firms for NAICS Code 621111). Assumes 69%–100% of industry is covered.

¹²⁸ *Id.* (nationwide count of firms for NAICS Code 621112). Assumes 69%–100% of industry is covered.

¹²⁹ *Id.* (nationwide count of firms for NAICS Code 621330). Assumes 69%–100% of industry is covered.

¹³⁰ *Id.* (nationwide count of firms for NAICS Code 621210). Assumes 69%–100% of industry is covered.

Continued

NPRM, the Department in particular seeks public comment on ways that HHS could improve the accuracy of the estimates contained in this RIA. Please

specifically provide data, studies, reports, or other documentation to support your comments.

Estimated Burdens

There are six categories of estimated burdens for this proposed rule, as summarized in Table 4.

TABLE 4—SUMMARY OF COSTS

	Cost category	Year 1: Initial costs		Years 2 to 5: Annual recurring costs	
		Total cost (in millions)	Affected (%)	Total cost (in millions)	Affected (%)
1	Familiarization (one-time burden)	\$62.9	100
2	Assurance and Certification.				
	Signing Documents	72.8	26	\$72.8	26
	Reviewing Policies and Procedures	36.4	13	36.4	13
	Update Policies, Procedures, Training	13.8	5	1.4	0.5
Subtotal, Assurance and Cert		123.0	110.6
3	Notice requirement.				
	Mandatory, one-time, posting	92.9	99		
	Voluntary Posting	25.2	50	6.7	24.9
Subtotal, Notice		118.1	6.7
4	Compliance Procedures	0.6	0.01	0.6	.01
5	Voluntary Remedial Efforts	6.8	0.5	6.8	0.5
Subtotal, Non-HHS Costs		311.4	124.6
6	OCR Enforcement	0.9	N/A	0.9	N/A
Total		312.3	125.5

Familiarization Costs

The Department estimates that all persons and entities subject to the proposed rule would spend approximately one hour on average familiarizing themselves with the content of the proposed rule and its requirements. One fundamental reason that the Department publishes this

proposed rule is the lack of awareness of obligations under Federal health care conscience and associated anti-discrimination laws and individuals' rights. This burden is a one-time opportunity cost of staff time to review the proposed rule. The mean hourly wage (including benefits and overhead) for a lawyer (occupation code 23–1011)

is \$134.50 per hour (\$67.25 per hour × 2).¹⁵⁵ The labor cost is approximately \$62.9 million in the first year (\$134.50 per hour × 1 hour × 468,123 entities) and zero dollars in the out-years.

Assurance and Certification (Proposed \$88.4)

The burden for the assurance and certification is the opportunity cost of

¹³¹ *Id.* (nationwide count of firms for NAICS Code 621310). Assumes 69%–100% of industry is covered.

¹³² *Id.* (nationwide count of firms for NAICS Code 621320). Assumes 69%–100% of industry is covered.

¹³³ *Id.* (nationwide count of firms for NAICS Code 621340). Assumes 69%–100% of industry is covered.

¹³⁴ *Id.* (nationwide count of firms for NAICS Code 621391). Assumes 69%–100% of industry is covered.

¹³⁵ *Id.* (nationwide count of firms for NAICS Code 621410). Assumes 69%–100% of industry is covered.

¹³⁶ *Id.* (nationwide count of firms for NAICS Code 621493). Assumes 69%–100% of industry is covered.

¹³⁷ *Id.* (nationwide count of firms for NAICS Code 621491). Assumes 69%–100% of industry is covered.

¹³⁸ *Id.* (nationwide count of firms for NAICS Code 621492). Assumes 69%–100% of industry is covered.

¹³⁹ *Id.* (nationwide count of firms for NAICS Code 621420). Assumes 69%–100% of industry is covered.

¹⁴⁰ *Id.* (nationwide count of firms for NAICS Code 621512). Assumes 69%–100% of industry is covered.

¹⁴¹ *Id.* (nationwide count of firms for NAICS Code 621511). Assumes 69%–100% of industry is covered.

¹⁴² *Id.* (nationwide count of firms for NAICS Code 621910). Assumes 69%–100% of industry is covered.

¹⁴³ *Id.* (nationwide count of firms for NAICS Code 621498). Assumes 69%–100% of industry is covered.

¹⁴⁴ *Id.* (nationwide count of firms for NAICS Code 62199). Assumes 69%–100% of the industry is covered.

¹⁴⁵ *Id.* (nationwide count of firms for NAICS Code 524114). Assumes 69%–100% of industry is covered.

¹⁴⁶ *Id.* (nationwide count of firms for NAICS Code 624120). Assumes 69%–100% of industry is covered.

¹⁴⁷ *Id.* (nationwide count of firms for NAICS Code 624190). Assumes 69%–100% of industry is covered.

¹⁴⁸ *Id.* (nationwide count of firms for NAICS Code 624110). As described *supra* Part XI.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

¹⁴⁹ *Id.* (nationwide count of firms for NAICS Code 624221). As described *supra* Part XI.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

¹⁵⁰ *Id.* (nationwide count of firms for NAICS Code 624230). As described *supra* Part XI.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

¹⁵¹ *Id.* (nationwide count of firms for NAICS Code 44610). Assumes 69%–100% of industry is covered.

¹⁵² *Id.* (nationwide count of firms for NAICS Code 541711). Assumes 69%–100% of industry is covered.

¹⁵³ *Id.* (nationwide count of firms for NAICS Code 611310). As described *supra* Part XI.C.2.iii (methodology), the Department assumes 13%–100% of institutions of higher-education are covered.

¹⁵⁴ U.S. Dep't of Health & Human Servs., Tracking Accountability in Government Grants System (TAGGS) <http://taggs.hhs.gov> (last visited Dec. 19, 2017).

¹⁵⁵ Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm.

recipient staff time (1) to review the HHS-690 Form (assurance), and HHS-5161-1 Form (certification language) as well as the requirements of the underlying Federal health care conscience and associated anti-discrimination laws referenced or incorporated, (2) to review recipient-wide policies and procedures or take other actions to self-assess compliance with applicable Federal health care conscience and associated anti-discrimination laws, and (3) to implement any actions necessary to come into compliance. Examples of actions a recipient may need to take to come into compliance include updating policies and procedures, implementing staffing or scheduling practices that respect an exercise of conscience rights under Federal law, and training staff on relevant Federal laws or the recipient's policies and procedures. Table 5 *infra* summarizes these costs.

The Department estimates that each recipient not excepted will spend an average of 4 hours reviewing the assurance and certification language as well as the requirements of the underlying Federal health care conscience and associated anti-discrimination laws referenced or incorporated through a Web link. In the 2008 Rule, the Department estimated that it would take 30 minutes to certify compliance with three laws: The Church, Weldon, and Coats-Snowe Amendments. 73 FR 78072, 78095 (2008 Rule). In this proposed rule, there are almost two dozen additional laws included. Using the rough guide of 10 minutes per law, the Department estimates that it would take an additional 3.5 hours on average to review the applicability of the additional laws that this rule proposes to enforce, for a total burden of 4 hours per recipient, per year, for the first five years. Some recipients may spend

considerably less time; others may spend considerably more time.

The labor cost is a function of a lawyer spending 3 hours reviewing the assurance and certification and a chief executive spending one hour to review and sign, as proposed § 88.4(b)(2) requires a signature by an individual authorized to bind the recipient. The mean hourly wage (including benefits and overhead) for these occupations is \$134.50 per hour for the lawyer (occupation code 23-1011) (\$67.25 per hour × 2) and \$186.88 for the chief executive (occupation code 11-1011) (\$93.44 per hour × 2).¹⁵⁶ The weighted mean hourly wage (including benefits and overhead) of these two occupations is \$147.60 per hour ((134.50 × .75) + (186.88 × .25)). The labor cost is \$72.8 million each year for the first five years (\$147.60 per hour × 4 hours × 123,302 entities).

The Department estimates that 61,652 recipients, which is half of all recipients required to assure and certify compliance (123,302 entities/2) will review policies and procedures or take other actions to self-assess compliance with applicable Federal health care conscience and associated anti-discrimination laws each year for the first five years of publication. The Department reasonably estimates such action because § 88.4(c)(4) states that the submission of an assurance and certification will not relieve a recipient of the obligation to take and complete actions to come into compliance prior to or after submission of such assurance or certification. The first step to such actions is reviewing organization-wide safeguards that are, or should be, in place.

The Department estimates that recipients that review policies and procedures or otherwise self-assess compliance will spend an average of 4 hours doing so. Some entities will spend more time and others will spend less time. The labor cost is a function of

a lawyer spending 3 hours and a chief executive spending one hour, which produces the weighted mean hourly wage of \$147.60 per hour. The labor cost for self-assessing compliance, such as reviewing policies and procedures, is a total of \$36.4 million each year for the first five years (\$147.60 per hour × 4 hours × 61,652 entities).

The Department estimates that approximately 5% of entities will take an organization-wide action to improve compliance in the first year and 0.5% will take a similar action annually each year in years two through five. This percentage equates to 23,406 recipients in year 1 and 2,341 recipients annually in years two through five. The Department estimates that these recipients would spend 4 hours annually, on average, to take remedial efforts. The Department estimates that recipients will spend an average of 4 hours to update policies and procedures, implement staffing or scheduling practices that respect an exercise of conscience rights under Federal law, or train staff on relevant Federal law or the recipient's policies and procedures. The labor cost is a function of a lawyer spending 3 hours and a chief executive spending one hour, which produces a weighted mean hourly wage of \$147.60 per hour. The labor cost is \$13.8 million in year one (\$147.60 per hour × 4 hours × 23,406 entities) and approximately \$1.4 million annually for years two through five (\$147.60 per hour × 4 hours × 2,341 entities).

The Department is committed to leveraging existing grant, contract, and other Departmental forms where possible rather than creating additional, separate forms for recipients to sign. Sub-recipients are not subject to this requirement; as described in the preamble, the Department seeks comment on this approach taken to reduce burden on small entities.

TABLE 5—SUMMARY OF ASSURANCE AND CERTIFICATION COSTS

Cost categories	Year 1: Initial costs		Years 2–5: recurring costs	
	Total cost	Per entity	Total cost	Per entity
	(in millions)	(dollars)	(in millions)	(dollars)
Review and Sign	\$72.8	\$590	\$72.8	\$590
Review Policies and Procedures	36.4	590	36.4	590
Update Policies and Procedures; Train Workforce	13.8	590	1.4	590
Total Costs	123.0	998	110.6	897

¹⁵⁶ Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment

and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm.

Notice Requirement (Proposed § 88.5)

Proposed § 88.5 requires recipients and the Department to provide notice. Section 88.5 includes a mandatory posting requirement and incentives additional posting. The mandatory posting requirement is a one-time burden with no recurring costs. The Department does not intend for recipients to incur any costs in developing the notice; indeed, proposed § 88.5 would require recipients to post the text of the notice in appendix A to this proposed part. This approach leverages economies of scale by requiring recipients to post the exact text from the notice in Appendix A. The Department is mindful that Executive Order 13562 asks agencies, if feasible, to specify performance objectives for persons and entities rather than the behavior or manner of compliance. The Department has determined that providing a pre-written notice is the most efficient and effective way to provide information to persons, entities, and health care entities while reducing the burden on a recipient. The Department acknowledges that the trade-off regarding this approach is that it limits a recipient's flexibility. On the other hand, the decreased flexibility may be a worthwhile trade-off because, with a pre-written notice from OCR, a recipient need not spend time with counsel or executives in developing the text.

The Department estimates that the burden for the notice is represented in terms of opportunity costs of staff time to download, print, and post the notice, combined with material costs for paper and ink. These costs are a one-time, upfront burden in the first year of implementation. The Department estimates that it will take $\frac{1}{3}$ of an hour for an administrative assistant to download the notice, print notice(s) and post them in physical locations of the establishment where notices are commonly posted. To post the notice on the Web, the Department estimates that it will take 2 hours for a Web developer to execute the design and technical elements to post the notice online. For some establishments, it may take an administrative assistant or Web developer longer to perform this function; for other establishments, it may take less time. The mean hourly wage (including benefits and overhead) for an administrative assistant is \$38.78 per hour (occupation code 43-6010) ($\$19.39$ per hour $\times 2$).¹⁵⁷ The mean

hourly wage (including benefits and overhead) for a Web developer is \$69.38 per hour (occupation code 15-11134) ($\$34.69$ per hour $\times 2$).¹⁵⁸ This labor cost is approximately \$92.7 million ($(\frac{1}{3}$ hr. $\times \$38.78$ per hour $\times 611,372$ establishments) + (2 hours $\times \$63.38$ per hour $\times 611,372$ establishments)).

A key uncertainty with respect to this labor cost is the degree to which each establishment maintains its own website and thus would bear the labor cost for a Web developer to post the notice on the establishment's website. For the purpose of this RIA, the Department has erred on the side of overestimating the burden. Therefore, the Department assumed that a Web developer at each physical location will spend 2 hours to post the notice.

If, however, recipients maintain one website for all of its establishments, a Web developer at the firm-level, rather than Web developers at each establishment, would bear the labor costs to post the notice online. In contrast to 611,372 establishments bearing the labor costs of the Web developer, about 464,792 recipients at the firm-level would bear this cost. This number results from subtracting 3,324 counties from the total number of entities on average subject to the NPRM (468,026 entities). For the purpose of this calculation, the Department assumed all counties are sub-recipients.

The labor costs are the sum of (1) the costs for an administrative assistant at each establishment to post the notice in physical locations ($\frac{1}{3}$ hr. $\times \$38.78$ per hour $\times 611,372$ establishments) and (2) the costs for a Web developer at each firm to post the notice on the entity's website (2 hours $\times \$63.38$ per hour $\times 464,792$), which equals \$72.4 million. This labor cost is \$20 million less, or approximately 22% less, than the labor cost of a Web developer at each establishment of a recipient, rather than at the firm-level, to post the notice on the websites of each recipient establishment.

Another key uncertainty with respect to the estimated burden of the notice requirement is the number of locations where notices are commonly posted in an establishment; the number will vary based on multiple factors. These factors may include the type of recipient, floor plans of the building, the square footage of the common areas, the square footage of the building, the number of floors, the size of the workforce, and the number of ultimate beneficiaries, among other variables. The Department assumes that the average establishment will print and post five notices; larger entities might

post more and smaller entities post fewer. The Department also assumes that the cost of materials (paper and ink) is \$0.05 per page. Based on this assumption, the first-year cost to post 5 notices across all establishments would be \$152,843 (611,372 establishments \times \$.05 per page $\times 5$ pages). Because the Department assumes that this cost is a one-time cost during the first year of this proposed rule's implementation, the cost will not recur in years 2 through 5. The total labor and materials costs for implementing the mandatory component of the notice requirement is \$8 million (\$7.9 million in labor costs and \$152,843 for materials) in year one with zero recurring costs.

Because societal goals for assuring nondiscrimination are often realized through individuals' persistent exercise of protected rights, this proposed rule's notice requirement serves as a gateway to achieve those goals. Section 88.5 intends to incentivize recipients to include the OCR-drafted notice in certain types of documents or publications by rendering such posting as a factor that the OCR Director would consider if the Director investigates or initiates a compliance review of a recipient.

For instance, OCR would take into account whether a recipient has provided the notice in a personnel manual for the recipient's workforce, in applications for membership in the recipient's workforce or to receive a service or benefit, or in a student handbook for students participating in a program for training or study. Because this provision is permissive, the Department assumes that 305,686 establishments will undertake such action in the first year, which is half of all establishments subject to the notice requirement (611,372 establishments \times 50%). Approximately 152,843 establishments (305,686 establishments / 2) will annually undertake such voluntary posting in years 2 through 5. The Department assumes that an administrative assistant paid at \$19.39/hour would identify documents in which to include the notice, revising the documents or their layouts to include the notice, or otherwise printing an insert to include with paper documents. The assistant may spend a total of 2 hours in year one and 1 hour annually in years 2 through 5. The labor cost, adjusted upward for benefits and overhead is \$23.7 million (2 \times \$19.39 per hour $\times 2$ hours $\times 305,686$ establishments) in year one and \$5.9 million annually in years 2 through 5 (2 \times \$19.39 $\times 1 \times 152,843$ establishments).

The Department anticipates that there may be some additional printing costs

¹⁵⁷ Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm.

¹⁵⁸ *Id.*

where inclusion of the notice adds a page to the underlying document. There is a high degree of uncertainty as to the average number of documents in which a recipient may proactively include the notice. There is also uncertainty as to whether a recipient would provide hard-copy publications or house them online.

A recipient that voluntarily includes the notice in certain publications probably would provide some in hard-copy and others online. On balance, a recipient might print approximately 100 extra pages. Given these assumptions, the cost of voluntarily included notices, as proposed § 88.5(c) incentivizes, will cost approximately \$1.5 million in the first year (305,686 entities × 100 pages × \$0.05 per page) and \$764,215 annually in years two through five.

In sum, total first-year costs to implement the mandatory and voluntary components of the notice requirement is estimated at \$118.1 million and \$6.7 million annually in years 2 through 5, which is a 94% decrease in cost from the one-time cost to implement the notice requirement in year 1.

Compliance Procedures (§ 88.6(d))

The information promptly informs applicable Departmental components of OCR's pending investigation to ensure appropriate coordination within the Department during the pendency of the investigation and the obligation to report complaints if the Department modifies existing applications for grants, or in a separate writing with the applications, for five years. OCR estimates that there are 30 recipients on average per year that OCR may investigate and investigate. Thirty recipients is the average between the lower-bound estimate (10 recipients) and the upper-bound estimate (50 recipients).

The Department estimates that the burden is the opportunity cost that recipients and sub-recipients would incur to email the appropriate grants management official(s). The Department assumes that this email would inform the Department component and could also be used as the separate writing to accompany new or renewed applications. This burden is the labor cost associated with an administrative assistant spending approximately 15 minutes to draft and transmit the email. The mean hourly wage for the administrative assistant (occupation code 43-6010) (\$19.39 per hour) (adjusted for benefits and overhead) is \$38.78 per hour. The Department estimates that the administrative assistant would incur this labor cost for each award action for which the

recipients applied, including new funding opportunities, supplemental funding, and non-competing continuations, among others.

Because OCR had no publicly available and reliable data source to know how many total applications for new or renewed funding in a fiscal year a recipient might make to the Department or its component, OCR used actual award data from HHS TAGGS as a proxy. The Department looked at the number of award actions the Department and its components made to State agencies and State universities in FY 2017 to inform the estimate. Award data in HHS TAGGS for FY 2017 indicated that some State universities receive less than 100 awards per fiscal year and others receive nearly 2,000 awards. Some State agencies receive a couple of awards per fiscal year and others receive 80 awards per fiscal year.

The Department erred on the side of overestimating the burden and assumed that each of the 30 recipients would apply for new or renewed funding 2,000 times per year. The annual labor cost is \$0.6 million across all 30 entities (30 recipients × \$39.78 per hour × 0.25 hours × 2,000).

Voluntary Remedial Efforts

The Department anticipates that some recipients will institute a grievance or similar process to handle internal complaints raised to the recipient's or sub-recipient's attention. The proposed rule does not require such a process, but in HHS OCR's enforcement experience, informal resolution of matters at the recipient or sub-recipient level may effectively resolve a beneficiary's or employee's concern. The Department anticipates 0.5% of entities, or 2,340 recipients or sub-recipients, (0.005 × 468,026 recipients), would conduct such internal investigations should complaints come to the recipient's or sub-recipient's attention or undertake remedial efforts.

The burden is the opportunity cost of staff time to handle internal investigations and take remedial action. Uncertainty exists as to how many hours annually a recipient or sub-recipient would devote to this effort per year. On average, the Department anticipates entities spending 20 hours annually: 16 hours of a lawyer's time and 4 hours of a chief executive's time. The mean hourly wage (including benefits and overhead) for these occupations is \$134.50 per hour for the lawyer (occupation code 23-1011) (\$67.25 per hour × 2 to adjust upward for benefits and overhead) and \$186.88 for the chief executive (occupation code 11-1011) (\$93.44 per hour × 2 to adjust

upward for benefits and overhead).¹⁵⁹ The weighted mean hourly wage (including benefits and overhead) is \$72.49 per hour (((\$67.25 × .80) + (\$93.44 × .20)). The labor cost is \$6.8 million (\$144.98 per hour × 20 hours × 2,341 entities).

Some recipients may spend more than 20 hours, and if this is the case, the labor cost will be greater. Other recipients may spend less than 20 hours, and if this is the case, the labor cost will be lower.

OCR Enforcement

The Department anticipates a temporary increase in investigation and enforcement costs to OCR over the five years immediately following publication of the final rule. The Department expects this increase from the synergistic impact of persons' increased awareness of rights; increased confidence in the Department to address those rights through the administrative complaint process; and an increase in the number of Federal health care conscience and associated anti-discrimination laws for which the rule proposes to enforce. The Department expects that after 5 years following publication of the final rule, the number of complaints probably will plateau, but uncertainty exists in this estimated timeframe. The Department hopes that over time, recipients' awareness of their obligations will equate to fewer violations of law and consequently fewer complaints to OCR to address such violations.

OCR will bear the increased cost in the form of the opportunity cost of staff resources for enforcement. In the first five years following publication of the rule, the Department anticipates that the impact of this proposed rule on enforcement is equivalent to an additional 4.5 FTE. The fully loaded labor cost (which includes benefits and overhead) is about \$201,000 per FTE. With these variables, the Department expects OCR's staff costs would increase by \$904,500 annually in years one through five (4.5 FTE × \$201,000/FTE).

Request for Comment on Burden Analysis

The Department seeks public comment on improving the accuracy of the best estimates contained in this RIA. To the extent that more entities are covered or an entity spends more staff time executing or implementing required and/or voluntary actions, the costs will be higher than estimated.

¹⁵⁹ Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm.

Similarly, to the extent that fewer persons and entities are covered, or an entity spends less staff time executing or implementing required and/or voluntary actions, the costs will be lower than estimated.

In particular, the Department would appreciate comment on areas where the public has documentation, data, or other information to support a belief that this RIA over-estimates or under-estimates the implementation costs. For instance, the Department assumes that recipients and sub-recipients maintain records in the course of evidencing compliance with the terms and conditions of a Federal award, which would include not only financial requirements but all applicable Federal laws, including Federal health care conscience and associated anti-discrimination laws. Consequently, the Department has not identified record keeping as a separate burden resulting from this proposed rule because the Department understands that recipients and sub-recipients must document such compliance in the course of receiving a Federal award. To the extent that this assumption does not represent the existing record keeping requirements or practices, please provide comments to inform this assumption.

Moreover, the Department would appreciate information, data, studies, reports, or other documentation to that support what costs, if any, result from ancillary effects of this proposed rule, such as the monetary impact of certain health outcomes that may arise from the increase protection of conscience of medical providers as set forth in the proposed rule.

Estimated Benefits

This proposed rule is expected to remove barriers to the entry of certain health professionals, and to delay the exit of certain types of health professionals from the field, due to discrimination or coercion anticipated or experienced. Second, in supporting a more diverse medical field, the proposed rule would create ancillary benefits for patients. Third, the Department expects that the proposed rule would generate benefits by securing a public good—a society free from discrimination, which permits more personal freedom and removes unfairness. The proposed rule would promote protection of religious beliefs and moral convictions, which is a societal good based on fundamental rights.

Historical Support for Conscience Protections

The people of the United States of America have valued conscience protections since the country's founding. James Madison, the fourth President of the United States and often hailed as the "father of the Constitution" said, "[c]onscience is the most sacred of all property; . . . the exercise of that, being a natural and unalienable right. To guard a man's house as his castle, to pay public and enforce private debts with the most exact faith, can give no title to invade a man's conscience which is more sacred than his castle."¹⁶⁰ George Washington wrote, "Government being, among other purposes, instituted to protect the Persons and Consciences of men from oppression, it certainly is the duty of Rulers, not only to abstain from it themselves, but according to their Stations, to prevent it in others."¹⁶¹ Some scholars have argued that "[p]rotection for individual exercise of rights of conscience was one of the essential purposes for the founding of the United States of America and one of the great motivations for the drafting of the Bill of Rights."¹⁶²

Recruitment and Maintenance of Health Care Professionals

This proposed rule is expected to remove barriers to the entry of certain health professionals, and to delay the exit of certain types of health professionals from the field, due to discrimination or coercion anticipated or experienced. The Department has a significant interest in removing unlawful barriers to careers in the health care field. As numerous studies and comments establish, failure to protect conscience is one such barrier.

A 2011 study released by the American College of Obstetrics and Gynecology revealed that, "while 97% of ob-gyns reported having encountered women seeking an abortion, only 14% said they were willing to perform the service."¹⁶³ Only 1.2% of Evangelical Protestant, 9% of Catholic or Eastern

Orthodox, 10.1% of Non-Evangelical Protestant, 20% of Hindu, 26.5% with no religious affiliation, and 40.2% of Jewish doctors said they would provide abortion.¹⁶⁴ Yet one in six patients is cared for in Catholic hospitals, and Catholic Hospitals employed 523,040 full-time and 216,487 part-time workers in 2015.¹⁶⁵ Another pro-life organization, the Christian Medical & Dental Associations ("CMDA"), boasts 19,000 members.¹⁶⁶ And the American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG"), which boasts 2,500 members and associates,¹⁶⁷ wrote in 2009, "Like pro-life physicians generally, AAPLOG members overwhelmingly would leave the medical profession—or relocate to a more conscience-friendly jurisdiction—before they would accept coercion to participate or assist in procedures that violate their consciences."¹⁶⁸

Protecting the conscience rights of persons, entities, and health care entities is expected to result in the recruitment of diverse health care professionals and the maintenance of such professionals in the field. The medical community and American people as a whole might also benefit from the willing and enthusiastic participation in the field of people with a variety of moral, religious, and philosophical backgrounds. The Department expects that its proposed rule will protect existing participants in the profession and promote more diverse participation over time as the institutional culture at health facilities, and in health-professions training programs, changes.

Patient Benefits From Conscience Protections

In supporting a more diverse medical field, the proposed rule would create ancillary benefits for patients. The proposed rule would assist patients in seeking counselors and other health-care providers who share their deepest

¹⁶⁴ *Id.*

¹⁶⁵ *U.S. Catholic Health Care: The Nation's Largest Group of Not-for-Profit Health Care Providers*, Catholic Health Association of the United States (2017), available at https://www.chausa.org/docs/default-source/default-document-library/cha_2017_miniprofile.pdf?sfvrsn=0.

¹⁶⁶ *History of Our Ministry*, Christian Medical & Dental Associations, <https://www.cmda.org/library/doclib/history-of-cmda.pdf>.

¹⁶⁷ *About Us*, American Association of Pro-Life Obstetricians and Gynecologists, <http://aaplog.org/about-us>.

¹⁶⁸ Letter from Lawrence J. Joseph, on behalf of the American Association of Pro-Life Obstetricians and Gynecologists, to the Office of Public Health & Science, Department of Health & Human Services 2 (April 9, 2009), available at <http://downloads.frc.org/EF/EF09D50.pdf>.

¹⁶⁰ James Madison, Property, The Founders' Constitution (March 29, 1792), <http://press-pubs.uchicago.edu/founders/documents/v1ch16s23.html>.

¹⁶¹ Letter from George Washington, to The Society of Quakers (October 13, 1789), <https://founders.archives.gov/documents/Washington/05-04-02-0188>.

¹⁶² Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals*, 49 *Ariz. St. L.J.* 549, 561 (2017).

¹⁶³ *Abortion is Legal, but What Percentage of Ob-Gyns Will Provide One?*, *Freakonomics* (August 24, 2011, 1:57 p.m.), <http://freakonomics.com/2011/08/24/abortion-is-legal-but-what-percentage-of-ob-gyns-will-provide-one/>.

held convictions. Some patients will appreciate the ability to speak frankly about their own convictions concerning questions that touch upon life and death and treatment preferences with a doctor best suited to provide such treatment. A pro-life woman may seek a pro-life ob-gyn to advise her on decisions relating to her fertility and reproductive choices. A pro-vaccination parent may seek a pediatrician who shares his views. Open communication in the doctor-patient relationship will foster better over-all care for patients.

The benefit of open and honest communication between a patient and her doctor is difficult to quantify. One study showed that even “the quality of communication [between the physician and patient] affects outcomes . . . [and] influences how often, and if at all, a patient will return to that same physician.”¹⁶⁹ But poor communication negatively affects continuity of care and undermines the patient’s health goals. When conscience protections are robust, both patients and their physicians can communicate openly and honestly with one-another at the outset of their relationship.

Facilitating open communication between providers and their patients also helps to eliminate barriers to care, particularly for minorities. Because positions of conscience are often grounded in religious influence, “[d]enying the aspect of spirituality and religion for some patients can act as a barrier. These influences can greatly affect the well-being of people. These influences were reported to be an essential element in the lives of certain migrant women which enabled them to face life with a sense of equality.”¹⁷⁰ It is important for patients seeking care to feel assured that their faith, and the principles of conscience grounded in their faith, will be honored. This will ensure that they feel they are being treated fairly.¹⁷¹ And for some, being able to find health care providers that share the same moral convictions can be a source of personal healing. See *Gonzales v. Carhart*, 550 U.S. 124, 159 (2007) (“Respect for human life finds an ultimate expression in the bond of love the mother has for her child. . . . it seems unexceptionable to conclude some women come to regret their choice

to abort the infant life they once created and sustained.”). The patient benefits that will accrue from respect for provider conscience protections may take time to develop, but the Department anticipates that such benefits will be individualized and long-lasting.

Societal Benefits From Conscience Protections

The proposed rule will also yield lasting societal benefits. The rule will mitigate current misunderstanding about what conduct the Federal government is legally able to support and fund, and it will educate individuals about their Federal health care conscience rights. The proposed rule would provide an enforcement mechanism for individuals and institutions to file complaints with the Department when such individuals and institutions believe that their rights have been curtailed. The Department expects that, as a result of this proposed rule, more individuals, having been apprised of those rights, would assert them, and such assertions would contribute to the general public’s knowledge and appreciation of these protections.

Fostering respect for the existing Federal health care conscience and associated anti-discrimination laws also fosters lawfulness more generally. As one author stated,

[L]aw and conscience are deeply intertwined. . . . But the phenomenon of conscience isn’t important only to legal experts. Just as conscience helps explain why people follow legal rules, it helps explain why people follow other types of rules as well, such as employers’ rules for employees, parents’ rules for children, and schools’ and universities’ rules for students. It may also help explain why people adhere to difficult-to-enforce ethical rules and to the sorts of cultural rules (“social norms”) that make communal life bearable. . . . Twenty-first century Americans still enjoy a remarkably cooperative, law-abiding culture.¹⁷²

Because fostering conscience in individuals contributes to a more lawful and virtuous society, governments and their subdivisions have a significant interest in encouraging expressions of, and fidelity to, conscience. Governments also have an interest in ensuring the implementation and enforcement of existing laws, as part of the greater virtue of the rule of law.

It is difficult to monetize the respect for conscience to the individual and society as a whole, but the benefit is clearly significant. As the Supreme Court has said:

¹⁷² Lynn Stout, *Cultivating Conscience: How Good Laws Make Good People* 17 (2011).

Both morals and sound policy require that the state should not violate the conscience of the individual. All our history gives confirmation to the view that liberty of conscience has a moral and social value which makes it worthy of preservation at the hands of the state. So deep in its significance and vital, indeed, is it to the integrity of man’s moral and spiritual nature that nothing short of the self-preservation of the state should warrant its violation; and it may well be questioned whether the state which preserves its life by a settled policy of violation of the conscience of the individual will not in fact ultimately lose it by the process.

United States v. Seeger, 380 U.S. 163, 169 (1965) quoting Harlan Fisk Stone, *The Conscientious Objector*, 21 Col. Univ. Q. 253, 269 (1919).

The Department seeks comment regarding the benefits of this proposed rule, and how they might be quantified or monetized and specifically seeks supporting data, studies, reports, or other documentation.

Analysis of Regulatory Alternatives

The Department carefully considered alternatives to this proposed rule, but concluded that none struck the appropriate balance between the Administration’s goal of robust enforcement of existing Federal statutory protections for conscience in the health care field without unduly burdening entities in that field.

First, the Department considered maintaining the status quo, enforcing part 88 as it current exists and largely deferring to States to enact and enforce their respective conscience laws, but such an approach would create a significant risk of unaddressed violations of the conscience rights of persons, entities, and health care entities. Specifically, it would leave OCR’s minimal administrative enforcement scheme as the only remedy for alleged violations of the Weldon, Coats-Snowe or Church Amendments. See *supra* Part VI (reasons for the proposed rule). That minimalistic scheme, so different from those that pertain to other civil rights laws, undermines both OCR’s authority and public perception of the value of these protections. And it fails to allow for strategic coordination with respect to the compliance and enforcement of the many Federal health care conscience and associated anti-discrimination protections that exist outside the Weldon, Coats-Snowe or Church Amendments.

Second, the Department also considered alternative approaches to the policies enunciated in the proposed rule. The Department considered developing a rule that specifies

¹⁶⁹ Fallon E. Chipidza, et al., *Impact of the Doctor-Patient Relationship*, 17(5) *The Primary Care Companion for CNS Disorders* (2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4732308/>.

¹⁷⁰ Emmanuel Scheppers, et al., *Potential Barriers to the Use of Health Services Among Ethnic Minorities: A Review*, 23 *Family Practice* 325, 343 (2006), available at <https://academic.oup.com/fampra/article/23/3/325/475515>.

¹⁷¹ *Id.*

performance objectives rather than the manner of compliance to allow persons and entities more flexibility. For instance, instead of providing the text of a notice in Appendix A for recipients to post, the Department considered allowing recipients to develop the text of their own notices, so long as such notices achieved certain substantive objectives. But the Department was sensitive to the time it might take each entity to draft a notice and to obtain the proper legal consultation and executive sign-off. In lieu of requiring, or permitting, each entity to re-create the wheel, the Department proposes that entities use the notice in Appendix A to reduce burden. The Department also considered requiring fewer recipients to execute the assurance and certify compliance, and/or to post notices of individuals' conscience and anti-coercion rights and the recipients' corresponding obligations.

The Department invites comment on our proposed approach, as well as other approaches to achieve robust enforcement of Federal health care conscience laws with minimal regulatory burden.

Executive Order 13771

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations "to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." The Department believes that this proposed rule is a significant regulatory action as defined by Executive Order 12866. If this rule is finalized as proposed, it would be considered a regulatory action under Executive Order 13771. Excluding any ancillary costs attributed to this proposed rule that result from health outcomes or other effects of protecting conscience rights (as this RIA seeks comment on such costs, which have not yet been quantified), the Department estimates that this rule generates \$112 million in annualized costs at a 7% discount rate, discounted relative to year 2016, over a perpetual time horizon.

Regulatory Flexibility Act

HHS has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612). The RFA requires an agency to describe the impact of a proposed rulemaking on small entities by providing an initial regulatory flexibility analysis unless the agency expects that the proposed rule will not have a significant impact on a substantial number of small entities, provides a factual basis for this

determination, and proposes to certify the statement. 5 U.S.C. 603(a), 605(b). If an agency must provide an initial regulatory flexibility analysis, this analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. HHS considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact of revenue on at least five percent of small entities.

Based on its examination, the Department has preliminarily concluded that this proposed rule does not have a significant economic impact on a substantial number of small entities. The entities that would be affected by the proposed rule, in industries described in detail in the RIA, are considered small by virtue of either nonprofit status or having revenues of less than between \$7.5 million and \$38.5 million in average annual revenue, with the threshold varying by industry.¹⁷³ Persons and States are not included in the definition of a small entity. The Department assumes that most, if not all, of the entities affected meet the threshold of a small entity.

Although the proposed rule will apply to and thus affect small entities, the proposed rule's per-entity effects are relatively small. The Department estimates that this rule would impose an average cost of \$665 in the first year of compliance following publication of the final rule and about \$266 per year in subsequent years. Furthermore, these costs would generally be proportional to the size of an entity, suggesting that the smallest affected entities will face lower average costs. Given thresholds discussed above, we believe these average costs are well below those required to have a significant impact on a substantial number of small entities.

Despite this determination, the proposed rule attempts to minimize costs imposed on small entities. For example, the assurance and certification requirements in proposed § 88.4 contain exceptions to relieve many small entities of the requirement to submit an assurance and certification. The Department has further committed to leveraging existing grant, contract, and other Departmental forms where possible to implement § 88.4 rather than create additional, separate forms for recipients to sign. Similarly, in an effort

to reduce economic burden imposed by the notice requirements in proposed § 88.5, HHS has drafted a notice in Appendix A for recipients to use so that the recipients do not have to bear the labor costs of consulting with counsel and executives. In light of this determination, the Secretary proposed to certify that this rule will not result in a significant impact on a substantial number of small entities.

Unfunded Mandates Reform Act

HHS similarly concludes that the requirements of the Unfunded Mandates Reform Act of 1995 are not triggered by the proposed rule. Section 202(a) of that Act requires us to prepare a written statement, including an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. As discussed in this Regulatory Impact Analysis, if finalized as proposed, this rule would not result in an expenditure in any year that meets or exceeds that amount with regard to State, local, or tribal governments but will exceed that amount with regard to the private sector.

Executive Order 13132—Federalism

The Secretary has also preliminarily determined that this proposed rule does not implicate the requirements of Executive Order 13132. That Executive Order requires an agency to meet certain requirements when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct effects on (1) States, including political subdivisions thereof, (2) the relationship between the Federal government and the States, or (3) the distribution of power and responsibilities among the various levels of government. Although this rulemaking is expected to affect State and local governments, the anticipated affect is not substantial.

First, this rulemaking does not impose substantial direct effects on States or political subdivisions of States. The substantive prohibitions and requirements in Federal health care conscience and associated anti-discrimination laws already apply to State and local governments. Moreover, State and local government agencies who are recipients of HHS awards must already assure compliance with applicable Federal laws and certify

¹⁷³ https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.pdf.

compliance with them in the normal course of receiving such awards. And although proposed § 88.5 imposes a new requirement to post a notice about rights and obligations under Federal health care conscience and associated anti-discrimination laws, this requirement involves a minimal one-time opportunity cost on staff time, attaches only to recipients, and is similar to notice requirements already in force for other civil rights laws. Under such circumstances, the notice requirement cannot be understood to impose substantial direct effects on States or their political subdivisions.

Second, this proposed rulemaking does not have substantial direct effects on the relationship between the Federal government and the States. The proposed rule would be promulgated under longstanding Federal laws that leave room for State activity. For example, 42 U.S.C. 280g–1(d) authorizes the Department to provide grants and cooperative agreements for newborn and infant hearing screening, but makes clear that such grants do not preempt or prohibit any State law, including State laws that allow parents to assert religious objections to such screening. Similarly, 42 U.S.C. 1396f clarifies that nothing in that subchapter shall be construed to require a State to compel a person to undergo medical screenings, examination, diagnosis, treatment, health care or services if a person objects on religious grounds (except for discovering and preventing the spread of infection or contagious disease or protecting environmental health). And the requirement in 42 U.S.C. 1396s(c)(2)(B)(ii) for providers to offer pediatric vaccines is subject to applicable State law, including any law relating to any religious or other exemption. Given these provisions, it is no surprise that, as described *supra*, in Part VIII, all fifty States have some protections in place for conscientious objectors to certain health or medical services.¹⁷⁴

The proposed rule makes clear that it is not intended to interfere with the operation of State law, except as required by existing Federal health conscience protections. Thus, proposed § 88.8 states that this proposed rule does not preempt any Federal, State, or local law that is equally as protective of the rights of conscience and against coercion as the regulation. And the proposed § 88.7 borrows from enforcement mechanisms already

available to OCR to enforce similar civil rights laws. States are familiar with such mechanisms from decades of investigations, compliance reviews, and remedial actions taken pursuant to existing civil rights laws (e.g. Title VI, Section 504 of the Rehabilitation Act, and Title II of the Americans with Disabilities Act). HHS believes that this approach does not alter or have any substantial direct effects on the relationship between the Federal government and the States.

The Department invites comments from States and local governments on whether provisions of this proposed rule implicate federalism concerns not identified and ways to minimize any such burden, consistent with meeting the Department's objectives of ensuring (1) knowledge of the obligations imposed, and the rights and protections afforded, by Federal health care conscience and associated anti-discrimination laws; and (2) compliance with their nondiscrimination provisions.

Congressional Review Act

The Congressional Review Act defines a “major rule” as “any rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of \$100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.” 5 U.S.C. 804(2). Based on the analysis of this proposed rule under Executive Order 12866, the Department deems that this proposed rule is a major rule for purposes of the Congressional Review Act.

Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999, Pub. L. 105–277, section 654, 112 Stat. 2681 (1998) (codified at 5 U.S.C. 601 (note)), requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being.¹⁷⁵

Agencies must assess whether the proposed regulatory action: (1) Impacts the stability or safety of the family, particularly in terms of marital commitment; (2) impacts the authority of parents in the education, nurture, and supervision of their children; (3) helps the family perform its functions; (4) affects disposable income or poverty of families and children; (5) if the regulatory action financially impacts families, are justified; (6) may be carried out by State or local government or by the family; and (7) establishes a policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society.¹⁷⁶

It is unlikely that this proposed rule will negatively impact the stability of the family or impact parental authority. In addition, the proposed rule has no bearing on the disposable income or poverty of families and children, and none of the rule's proposed provisions concern the relationship between the behavior and personal responsibility of youth and the norms of society. Finally, the action taken in this proposed rule cannot be carried out by State or local government or by the family because the rule pertains to the enforcement of certain Federal laws. Therefore, this proposed rule probably will have minimal to no impact on family well-being.

If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. The Secretary proposes to certify that this proposed rule has been assessed in accordance with Section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105–277, section 654, 112 Stat. 2681 (1998), and will not negatively affect family well-being.

Paperwork Reduction Act

This notice of proposed rulemaking would call for new collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Congress enacted the Paperwork Reduction Act of 1995 to “maximize the practical utility and public benefit of the information created, collected, disclosed, maintained, used, shared and disseminated by or for the Federal government” and to minimize the burden of this collection. 44 U.S.C. 3501(2). As defined in 5 CFR 1320.3(c),

Agencies, & Independent Establishments Assessment of Federal Regulations and Policies on Families (Jan. 26, 1999) <https://www.fws.gov/policy/library/rglew.pdf>.

¹⁷⁶ Treasury and General Government Appropriations Act of 1999, Public Law 105–277, sec. 654, 112 Stat. 2681 (1998).

¹⁷⁴ See Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals*, 49 Ariz. St. L.J. 549, 575–76, app. I, 587–600 (2017) (summarizing State laws).

¹⁷⁵ This section discusses the assessment required in Executive Order 12606, The Family, which was revoked on April 21, 1997. Memorandum from Jacob Lew, Dir., Office Of Mgmt. & Budget, Exec. Office of the President, To Heads of Exec. Dep'ts,

“collection of information” comprises reporting, record-keeping, monitoring, posting, labeling, and other similar actions.

The collections of information required by the proposed rule relate to § 88.4 (Assurance and Certification), § 88.5 (Notice), and § 88.6(d) (Compliance Requirements).

Information Collection for Proposed § 88.4 (Assurance and Certification)

Summary of the Collection of Information: The proposed rule requires each recipient (or applicant to become a recipient), with limited exception, to assure and certify compliance with Federal conscience and associated anti-discrimination laws. Specifically, proposed § 88.4(a) requires each recipient or applicant to include in its application for Federal funds, or accompany its application with, an assurance and a certification that it will operate applicable projects or programs in compliance with applicable Federal health care conscience and associated anti-discrimination laws. The Federal laws with which recipients would be required to assure compliance, if applicable, are:

Provider conscience laws related to abortion (the Weldon Amendment for Medicare Advantage, *e.g.* Public Law 115–31, Div. H, sec. 209, 131 Stat. 135, 539 (2017));

Certain provisions of the Affordable Care Act applying Federal conscience protections (42 U.S.C. 18023(b)(4)), regarding assisted suicide (42 U.S.C. 18113), and providing a conscience exemption to the individual mandate (26 U.S.C. 5000A(d)(2));

Certain laws governing provider counseling, referral, and implementation of directives (counseling and referral in Medicare Advantage ((42 U.S.C. 1395w–22(j)(3)(B)), counseling and referral in Medicaid (42 U.S.C. 1396u–2(b)(3)(B)), and performance of advanced directives in the Medicare and Medicaid programs (42 U.S.C. 1396a(w)(3), and 14406);

Conscience and anti-coercion laws applicable to Global Health Programs for HIV/AIDS Prevention, Treatment, or Care (22 U.S.C. 7631(d)) and certain funds appropriated to the U.S. Department of State and USAID (the Helms Amendment (*e.g.*, Consolidated Appropriations Act, 2017, Public Law 115–31, Div. J, sec. 7018));

Laws providing for patient objections to receiving health care services, including medical screening, examination, diagnosis, treatment, or other health care (42 U.S.C. 1396f), occupational illness testing (29 U.S.C. 669(a)(5)), pediatric vaccination (42

U.S.C. 1396s(c)(2)(B)(ii)), youth suicide prevention and treatment (42 U.S.C. 290bb–36(f)), and newborn health screening (42 U.S.C. 280g–1(d)); and

Laws protecting religious nonmedical health care by exempting religious non-medical institutions from health facility review (42 U.S.C. 1320a–1), peer review (42 U.S.C. 1320c–11), certain health standards (42 U.S.C. 1396a(a)(9)(A)), medical evaluation (42 U.S.C. 1396a(a)(31)), medical licensing review (42 U.S.C. 1396a(a)(33)), and from utilization review plan requirements (42 U.S.C. 1396b(i)(4)), and protecting the exercise of religious nonmedical health care in the Elder Justice Block Grant Program (42 U.S.C. 1397j–1(b)) and in the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106i(a)(2)).

Need for Information: Requiring certain recipients and applicants to assure and certify compliance serves two purposes. First, through the act of reading and reviewing the statutory requirements to which recipients or applicants assure and certify compliance, recipients would be apprised of their obligations under the applicable Federal health care conscience and associated anti-discrimination laws. Second, a recipient’s or applicant’s awareness of its obligation would increase the likelihood that it would comply with such laws and consequently afford entities and individuals protection of their conscience rights and protection from coercion or discrimination. Because of this awareness, the Department anticipates that this rule may generate changes in the policies, procedures, and operations of the entities that this proposed rule covers.

Proposed Use of Information: The Department and its components awarding Federal funds and OCR would use the signed assurance and certification as documentation of: (1) A recipient’s or applicant’s awareness of its obligations under the Federal health care conscience and associated anti-discrimination laws and the proposed rule, and (2) a recipient’s commitment to comply with such statutes and the proposed rule. This use would most likely occur during an OCR investigation of the recipient’s compliance with Federal health care conscience and associated anti-discrimination laws and this proposed rule.

Description of the Respondents: The respondents are applicants or recipients for Federal financial assistance or Federal funds from the Department to which the proposed § 88.3 applies. Respondents include hospitals, research institutions, health professions training

programs, qualified health plan issuers, Health Insurance Marketplaces, home health agencies, community mental health centers, and skilled nursing facilities.

Number of Respondents: The Department estimates the number of respondents at 123,302 persons or entities. This estimate represents the average between the lower-bound (94,214) and upper-bound (152,389) estimates of entities that will have to sign an assurance or a certification. These figures appear *supra* in Table 2.

Respondents are a subset of the recipients subject to the relevant Federal health care conscience and associated anti-discrimination laws and the proposed rule because proposed § 88.4(c)(1) through (4) excludes certain categories of recipients. Specifically, the proposed rule excludes physicians, as defined in 42 U.S.C. 1395x(r), physician offices, or other health care practitioners who are recipients, as defined in proposed § 88.2, only in the form of reimbursements for participation Medicare Part B. *See* proposed § 88.4(c)(1). The proposed rule also exempts recipients of certain grant programs administered by the Administration for Children and Families or the Administration for Community Living when the program’s purpose is unrelated to health care and certain types of research, does not involve health care providers, and does not involve any significant likelihood of referral for the provision of health care. *See* proposed § 88.4(c)(2) and (3). Finally, the proposed rule excludes Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the Indian Self-Determination and Education Assistance Act. *See* proposed § 88.4(c)(4).

Burden of Response: The Department is committed to leveraging existing grant, contract, and other Departmental forms where possible rather than creating additional, separate forms for recipients to sign. The Department intends to update the HHS–690 Form, which includes several Federal civil rights authorities with which applicants and recipients must assure compliance.¹⁷⁷ The Department would

¹⁷⁷ HHS regulations implementing each of the following civil rights laws require recipients to assure compliance with applicable implementing regulations: Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act. *See* 45 CFR 80.4 (requiring recipients to assure compliance with HHS Title VI regulations), 84.5 (requiring recipients to assure compliance with HHS Section 504 regulations), 86.4 (requiring recipients to assure compliance with

update the form to include a reference to Federal health care conscience and associated anti-discrimination laws, as well as a Web link to information about the requirements. The Department also intends to update HHS-5161-1 Form, OMB No. 0930-0367 (Certification of Compliance).

The burden for the assurance and certification is the opportunity cost of recipient staff time (1) to review the assurance and certification language as well as the requirements of the underlying Federal health care conscience and associated anti-discrimination laws referenced or incorporated, (2) to review entity-wide policies and procedures or take other actions to self-assess compliance with applicable Federal health care conscience and associated anti-discrimination laws, and (3) to implement any actions to come into compliance.

The methods that the Department uses are outlined *supra* in the Assurance and Certification section of this RIA. The only adjustment to those methods for this information collection analysis is to adjust the mean hourly wage downward to exclude benefits and overhead. In doing so, the Department calculates the following labor costs.

The labor cost is a function of a lawyer spending 3 hours reviewing the assurance and certification and a chief executive spending one hour to review and sign, as proposed § 88.4(b)(2) requires a signature by an individual authorized to bind the recipient. The mean hourly wage (not including benefits and overhead) for these occupations is \$67.25 per hour for the lawyer (occupation code 23-1011) and \$93.44 for the chief executive (occupation code 11-1011).¹⁷⁸ The weighted mean hourly wage (not including benefits and overhead) of these two occupations is \$73.80 per hour $((\$67.25 \times .75) + (\$93.44 \times .25))$. The labor cost is \$36 million each year for the first five years $(\$73.80 \text{ per hour} \times 4 \text{ hours} \times 123,302 \text{ entities})$.¹⁷⁹

The Department estimates that 61,652 recipients, which is half of all respondents to this information

collection (123,302 entities/2) will review entity-wide policies and procedures or take other actions to self-assess compliance with applicable Federal health care conscience and associated anti-discrimination laws each year for the first five years of publication, spending an average of 4 hours doing so. The labor cost is a function of a lawyer spending 3 hours and a chief executive spending one hour, which produces the same weighted mean hourly wage of \$73.80 per hour. The labor cost for self-assessing compliance, such as reviewing policies and procedures, is a total of \$18.2 million each year for the first five years $(\$73.80 \text{ per hour} \times 4 \text{ hours} \times 61,652 \text{ entities})$.¹⁸⁰

The Department estimates that approximately 5% of entities will take an organization-wide action to improve compliance in the first year and 0.5% will act each year in years two through five. This percentage equates to 23,406 entities in year 1 and 2,341 entities annually in years two through five. The Department estimates that each year, the entities that engage in this voluntary compliance will spend 4 hours annually, on average. The labor cost is a function of a lawyer spending 3 hours and a chief executive spending one hour, which produces a weighted mean hourly wage of \$73.80 per hour. The labor cost is \$6.9 million in year one $(\$73.80 \times 4 \times 23,406 \text{ entities})$ and approximately \$690,783 annually for years two through five $(\$73.80 \times 4 \times 2,341 \text{ entities})$.¹⁸¹

The Department asks for public comment on the proposed information collection, including the particular issues below.

- Whether the proposed collection of information is necessary for the proper performance of OCR's functions and the Department's and its components' functions to enforce Federal laws on which Federal funding is conditioned, including whether the information will have practical utility.

- Whether the exception for Indian Tribes and tribal Organizations in proposed 45 CFR 88.4(c)(vi) avoids "tribal implications" and does not "impose substantial direct compliance costs on Indian Tribal governments" as stated in Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, sec. 5(b) (Nov. 9, 2000).

- Whether assuring compliance with the Federal health care conscience and associated anti-discrimination statutes would constitute a burden exempt from the Paperwork Reduction Act as a usual and customary business practice incurred by recipients during the ordinary course of business.

- How the quality, utility, and clarity of the information to be collected may be enhanced.

- How the manner of compliance with the assurance and certification requirements could be improved, including through use of automated collection techniques or other forms of information technology.

Information Collection for Proposed § 88.5 (Notice)

Summary of the Collection of Information: Under the proposed rule, each recipient and the Department must post a notice that apprises persons, entities, and health care entities of their rights under Federal health care conscience and associated anti-discrimination laws and this proposed part.

Need for Information: Notice serves three primary purposes. First, persons become apprised of their rights under the applicable Federal health care conscience and associated anti-discrimination laws, including the right to file a complaint with HHS OCR. Second, a person's awareness of his or her rights increases the likelihood that the person will exercise those rights. Third, recipients and their managers and employees will be reminded and be made aware of their own obligations under these laws.

Proposed Use of Information: In the event that the OCR Director investigates or initiates a compliance review of a recipient, the OCR Director will consider as one of many factors whether the recipient posted the notice in the documents described in § 88.5(c)(1) through (3), as applicable.

Description of the Respondents: The respondents are recipients. Respondents include, but are not limited to, hospitals, research institutions, health professions training programs, qualified health plan issuers, Health Insurance Marketplaces, home health agencies, community mental health centers, and skilled nursing facilities.

Number of Respondents: The number of respondents is estimated at 611,372 establishments. This estimate represents the average between the lower and upper-bound estimates of how many recipient establishments must post notices. Respondents are a subset (99.5%) of the total scope of entities subject to this proposed rule because the

HHS Title IX regulations), 91.33 (requiring recipients to assure compliance with the Age Act and HHS implementing regulations), 92.5 (requiring recipients and entities created under Title I of the Affordable Care Act to assure compliance with Section 1557 and the HHS implementing regulation).

¹⁷⁸ Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm.

¹⁷⁹ This total differs from the burden in the RIA because a fully loaded wage that is adjusted upwards for benefits and overhead must be used.

¹⁸⁰ This total differs from the burden in the RIA because a fully loaded wage that is adjusted upwards for benefits and overhead must be used.

¹⁸¹ This total differs from the burden in the RIA because a fully loaded wage that is adjusted upwards for benefits and overhead must be used.

notice requirement does not apply to sub-recipients.

Burden of Response: The Department estimates that the burden for the notice is represented in terms of opportunity costs of staff time to download, print, and post the notice, combined with material costs for paper and ink. These costs are a one-time burden in the first year of this proposed rule's implementation.

The Department estimates that it would take $\frac{1}{3}$ of an hour for an administrative assistant to download the notice, print notice(s) and post them in physical locations of the establishment where notices are commonly posted. To post the notice on the Web, the Department estimates that it will take 2 hours for a Web developer to execute the design and technical elements to post the notice online. For some establishments, it may take an administrative assistant or Web developer longer to perform these functions; for other establishments, it may take less time.

The Department uses the same method for calculating the cost of this requirement *supra* in the RIA but adjusts the hourly wage downward to exclude benefits and overhead. The mean hourly wage (not including benefits and overhead) for an administrative assistant is \$19.39 per hour (occupation code 43-6010).¹⁸² The mean hourly wage (not including benefits and overhead) for a Web developer is \$34.69 per hour (occupation code 15-11134). This labor cost is approximately \$46.4 million ($(\frac{1}{3} \text{ hour} \times \$19.39/\text{hr.} \times 611,372 \text{ establishments}) + (2 \text{ hours} \times \$34.69/\text{hr.} \times 611,372 \text{ establishments})$).¹⁸³

The number of locations where notices are commonly posted in an establishment will vary based on multiple factors. The Department also assumes that the cost of materials (paper and ink) is \$0.05 per page. Based on this assumption, the first-year cost to post 5 notices across all establishments would be $(611,372 \text{ establishments} \times \$0.05 \text{ per page} \times 5 \text{ pages})$, which amounts to about \$152,843. Because the Department assumes that this cost is a one-time, upfront cost, it will not recur in the out-years.

The proposed notice provision at § 88.5(c)(1) through (3) includes language designed to incentivize recipients to include the OCR-drafted

notice in certain types of documents or publications. Because this provision is permissive, the Department assumes that 305,686 establishments will undertake such action in the first year, which is half of all establishments subject to the notice requirement $(611,372 \text{ establishments} \times 50\%)$. Approximately 152,843 establishments $(305,686 \text{ establishments}/2)$ will annually undertake such voluntary posting in years 2 through 5. The Department assumes that an administrative assistant paid at \$19.39/hour would identify documents in which to include the notice, revising the documents or their layouts to include the notice, or otherwise printing an insert to include with paper documents. The assistant may spend a total of 2 hours in year one and 1 hour annually in years 2 through 5. The labor cost in year 1 is \$11.9 million $(\$19.39 \times 2 \times 305,686 \text{ establishments})$ and \$3 million annually in years 2 through 5 $(\$19.39 \times 1 \times 152,843 \text{ establishments})$.

The Department anticipates that there may be some additional printing costs where inclusion of the notice adds a page to the underlying document. There is a high degree of uncertainty as to the average number of documents in which a recipient may proactively include the notice. There is also uncertainty as to whether a recipient would print the publications or house them online. The Department estimates that a recipient that voluntarily includes the notice in publications may print some publications and house others online; on balance, the recipient might print approximately 100 extra pages. With these assumptions, the cost of voluntarily included notices, as proposed § 88.5(c) incentivizes, will cost approximately \$1.5 million in the first year $(305,686 \text{ entities} \times 100 \text{ pages} \times \$0.05 \text{ per page})$ and \$764,216 annually in years two through five.

Total first-year costs (mandatory plus voluntary) for the notice requirement are estimated at \$59.9 million and \$3.7 million annually in years 2 through 5.

The Department asks for public comment on the proposed information collection, including the particular issues below.

- Whether the proposed collection of information is necessary for the proper performance of OCR's functions and the Department's and its components' functions to enforce Federal laws on which Federal funding is conditioned, including whether the information will have practical utility.

- Feedback on the assumptions that form the basis of our cost estimates for the notice provision.

- How the manner of compliance with notice provision could be improved, including through the use of automated collection techniques or other forms of information technology.

Compliance Procedures (§ 88.6(d))

Summary of the Collection of Information: Proposed § 88.6(d) requires any recipient that receives a notice of investigation or compliance review letter from OCR concerning Federal health care conscience and associated anti-discrimination laws to report this fact to each of the Departmental components from which the recipient receives Federal funds. Additionally, this requirement applies to complaints filed with OCR such that the recipient must disclose to the applicable Departmental funding component the existence of the complaint for five years from the date of the filing of the complaint whenever it applies for new or renewed Federal financial assistance or other Federal funds from the Department.

Need for Information: The information promptly informs applicable Departmental components of OCR's pending investigation and historical complaints to ensure appropriate coordination within the Department during the pendency of the investigation and to inform funding decision-making.

Proposed Use of Information: At a minimum, this requirement puts the Departmental component on notice of OCR's investigation and facilitates coordination between the component and OCR on technical or factual matters underlying the recipient's or sub-recipient's extension of Federal funds. The Department component may also use the information to monitor the status of the investigation and history of complaints to incorporate these facts into the component's decision-making when deciding whether to approve or renew or modify Federal funding to the recipient.

Description of the Respondents: The respondents are a subset of recipients and sub-recipients subject to an HHS OCR investigation of Federal health care conscience and associated anti-discrimination laws and this proposed rule. Respondents include State and local governments, physicians, hospitals, research institutions, health professions training programs, qualified health plan issuers, Health Insurance Marketplaces, home health agencies, educational institutions, community mental health centers, and skilled nursing facilities, among others.

Number of Respondents: The number of respondents on average is 30

¹⁸² Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm.

¹⁸³ This total differs from the burden in the RIA because a fully loaded wage that is adjusted upwards for benefits and overhead must be used.

recipients per year, which is the average between the lower-bound (10 recipients) and upper-bound (50 recipients) estimate.

Burden of Response: The Department estimates that the burden is the opportunity cost that recipients will incur to spend 15 minutes to email the appropriate grants management official(s). The Department uses the same methodology used when calculating these costs in the RIA but adjusts the hourly wage down to exclude benefit and overhead. The mean hourly wage for the administrative assistant (not adjusted for benefits and overhead) is \$19.39 per hour. The annual labor cost is \$0.3 million across all 30 entities (30 entities × \$19.39 per hour × 0.25 hours × 2,000 applications or renewals).

The Department asks for public comment on the proposed information collection, including the particular issues below.

- Whether the proposed collection of information is necessary for the proper performance of OCR's functions and the Department's and its components' functions to enforce Federal laws on which Federal funding is conditioned, including whether the information will have practical utility.
- Feedback on the assumptions that form the basis of our cost estimates.
- The automated collection techniques or other forms of information technology that could improve the efficiency of this collection of information.

Comments regarding the collection of information proposed in this rule must refer to the proposed rule by name and docket number and must be submitted to both OMB and the Docket Management Facility where indicated under **ADDRESSES** by the date specified under **DATES**.

When it issues a final rule, the Department plans to publish in the **Federal Register** the control numbers assigned by the Office of Management and Budget (OMB). Publication of the control numbers notifies the public that OMB has approved the final rule's information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 45 CFR Part 88

Abortion, Adult education, Advanced directives, Assisted suicide, Authority delegations, Childbirth, Civil rights, Coercion, Colleges and universities, Community facilities, Contracts, Educational facilities, Employment, Euthanasia, Family planning, Federal-State relations, Government contracts, Government employees, Grant

programs-health, Grants administration, Health care, Health facilities, Health insurance, Health professions, Hospitals, Immunization, Indian Tribes, Insurance, Insurance companies, Laboratories, Manpower training programs, Maternal and child health, Medicaid, Medical and dental schools, Medical research, Medicare, Mental health programs, Mercy killing, Moral convictions, Nondiscrimination, Nursing homes, Nursing schools, Occupational safety and health, Occupational training, Physicians, Prescription drugs, Public assistance programs, Public awareness, Public health, Religious discrimination, Religious beliefs, Religious liberties, Religious nonmedical health care institutions; Reporting and recordkeeping requirements, Rights of conscience, Scholarships and fellowships, Schools, Scientists, State and local governments, Sterilization, Students, Technical assistance, Tribal Organizations.

Proposed Rule

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to revise 45 CFR part 88 to read as follows:

PART 88—ENSURING THAT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES DOES NOT FUND OR ADMINISTER PROGRAMS OR ACTIVITIES THAT VIOLATE CONSCIENCE AND ASSOCIATED ANTI-DISCRIMINATION LAWS

Sec.

88.1 Purpose.

88.2 Definitions.

88.3 Applicable requirements and prohibitions.

88.4 Assurance and certification of compliance requirements.

88.5 Notice requirement.

88.6 Compliance requirements.

88.7 Enforcement authority.

88.8 Relationship to other laws.

88.9 Rule of construction.

88.10 Severability.

Appendix A to Part 88—Notice Concerning Federal Health Care Conscience and Associated Anti-Discrimination Protections

Authority: The Weldon Amendment (e.g., Consolidated Appropriations Act, 2017, Public Law 115–31, sec. 507(d); Div. H, sec. 209); the Helms Amendment (e.g., Consolidated Appropriations Act, 2017, Public Law 115–31, Div. J, sec. 7018); 22 U.S.C. 7631(d); 26 U.S.C. 5000A(d)(2); 29 U.S.C. 669(a)(5); 42 U.S.C. 300a–7 (the Church Amendments); 42 U.S.C. 238n (Coats-Snowe Amendment); 18113 (Section 1553 of the Affordable Care Act), 18023(c)(2)(A)(i)–(iii), 18023(b)(1)(A), 18023(b)(4); 280g–1(d), 290bb–36(f), 1320a–1, 1320c–11, 1395cc(f), 1395i–5, 1395w–22(j)(3)(B), 1395x(e),

1395x(y)(1), 1396a(a), 1396a(w)(3), 1396f, 1396s(c)(2)(B)(ii), 1396u–2(b)(3)(B), 1397j–1(b), 5106i(a), 14406.

§ 88.1 Purpose.

The purpose of this part is to provide for the implementation and enforcement of the Federal health care conscience and associated anti-discrimination laws. Such laws, for example, protect the rights of persons, entities, and health care entities to refuse to perform, assist in the performance of, or undergo health care services or research activities to which they may object for religious, moral, ethical, or other reasons. Such laws, for example, also protect patients from being subjected to certain health care or services over their conscientious objection. Consistent with their objective to comprehensively protect the conscience and associated anti-discrimination rights of persons, entities, and health care entities, the statutory provisions and the regulatory provisions contained in this part are to be interpreted and implemented broadly to effectuate their protective purposes.

§ 88.2 Definitions.

For the purposes of this part:

Administered by the Secretary means to be subject to the responsibility of the Secretary of the U.S. Department of Health and Human Services, as established via statute or regulation, for the administration of Federal funds available to any program or activity.

Assist in the Performance means to participate in any program or activity with an articulable connection to a procedure, health service, health program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity. This includes but is not limited to counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity.

Department means the Department of Health and Human Services and any component thereof.

Discriminate or Discrimination means, as applicable and as permitted by the applicable statute:

(1) To withhold, reduce, exclude, terminate, restrict, or otherwise make unavailable or deny any grant, contract, subcontract, cooperative agreement, loan, license, certification, accreditation, employment, title, or other similar instrument, position, or status;

(2) To withhold, reduce, exclude, terminate, restrict, or otherwise make unavailable or deny any benefit or privilege;

(3) To utilize any criterion, method of administration, or site selection,

including the enactment, application, or enforcement of laws, regulations, policies, or procedures directly or through contractual or other arrangements, that tends to subject individuals or entities protected under this part to any adverse effect described in this definition, or have the effect of defeating or substantially impairing accomplishment of a health program or activity with respect to individuals, entities, or conduct protected under this part; or

(4) To otherwise engage in any activity reasonably regarded as discrimination including intimidating or retaliatory action.

Entity means a “person” as defined in 1 U.S.C. 1 or a State, political subdivision of any State, instrumentality of any State or political subdivision thereof, or any public agency, public institution, public organization, or other public entity in any State or political subdivision of any State.

Federal Financial Assistance includes:

- (1) Grants and loans of Federal funds;
- (2) The grant or loan of Federal property and interests in property;
- (3) The detail of Federal personnel;
- (4) The sale or lease of, and the permission to use (on other than a casual or transient basis), Federal property or any interest in such property without consideration or at a nominal consideration, or at a consideration which is reduced for the purpose of assisting the recipient or in recognition of the public interest to be served by such sale or lease to the recipient; and
- (5) Any Federal agreement, arrangement, or other contract which has as one of its purposes the provision of assistance.

Health care entity includes an individual physician or other health care professional, health care personnel, a participant in a program of training in the health professions, an applicant for training or study in the health professions, a post-graduate physician training program, a hospital, a laboratory, an entity engaging in biomedical or behavioral research, a provider-sponsored organization, a health maintenance organization, a health insurance plan (including group or individual plans), a plan sponsor, issuer, or third-party administrator, or any other kind of health care organization, facility, or plan. It may also include components of State or local governments.

Health program or activity includes the provision or administration of any health-related services, health service

programs and research activities, health-related insurance coverage, health studies, or any other service related to health or wellness whether directly, through payments, grants, contracts, or other instruments, through insurance, or otherwise.

Health service program includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, and is funded, in whole or part, by the Department. It may also include components of State or local programs.

Individual means a member of the workforce of an entity or health care entity.

Instrument is the means by which Federal funds are conveyed to a recipient, and includes grants, cooperative agreements, contracts, grants under a contract, memoranda of understanding, loans, loan guarantees, stipends, and any other funding or employment instrument or contract.

OCR means the Office for Civil Rights of the Department of Health and Human Services.

Recipient means any State, political subdivision of any State, instrumentality of any State or political subdivision thereof, and any person or any public or private agency, institution, organization, or other entity in any State including any successor, assign, or transferee thereof, to whom Federal financial assistance is extended directly from the Department or a component of the Department, or who otherwise receives Federal funds directly from the Department or a component of the Department, but such term does not include any ultimate beneficiary. The term may include foreign or international organizations (such as agencies of the United Nations).

Referral or refer for includes the provision of any information (including but not limited to name, address, phone number, email, website, instructions, or description) by any method (including but not limited to notices, books, disclaimers, or pamphlets, online or in print), pertaining to a health care service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or directions that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, where the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral.

State includes, in addition to the several States, the District of Columbia. For those provisions related to or relying upon the Public Health Service Act, the term “State” includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands. For those provisions related to or relying upon the Social Security Act, such as Medicaid or the Children’s Health Insurance Program, the term “State” follows the definition of “State” found at 42 U.S.C. 1301.

Sub-recipient means any State, political subdivision of any State, instrumentality of any State or political subdivision thereof, and any person or any public or private agency, institution, organization, or other entity in any State including any successor, assign, or transferee thereof, to whom Federal financial assistance is extended through a recipient or another sub-recipient, or who otherwise receives Federal funds from the Department or a component of the Department indirectly through a recipient or another sub-recipient, but such term does not include any ultimate beneficiary. The term may include foreign or international organizations (such as agencies of the United Nations).

Workforce means employees, volunteers, trainees, contractors, and other persons whose conduct, in the performance of work for an entity or health care entity, is under the direct control of such entity or health care entity, whether or not they are paid by the entity or health care entity, as well as health care providers holding privileges with the entity or health care entity.

§ 88.3 Applicable requirements and prohibitions.

(a) *The Church Amendments, 42 U.S.C. 300a–7—(1) Applicability.* (i) The Department is required to comply with paragraphs (a)(2)(i) through (vii) of this section and §§ 88.5 and 88.6 of this part.

(ii) Any State or local government or subdivision thereof and any other public entity are required to comply with paragraphs (a)(2)(i) through (iii) of this section.

(iii) Any entity that receives a grant, contract, loan, or loan guarantee under the Public Health Service Act [42 U.S.C. 201 *et seq.*] after June 18, 1973, is required to comply with paragraph (a)(2)(iv) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(iv) Any entity that receives a grant or contract for biomedical or behavioral research under any program

administered by the Secretary of Health and Human Services after July 12, 1974, is required to comply with paragraph (a)(2)(v) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(v) Any entity that carries out any part of any health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services is required to comply with paragraph (a)(2)(vi) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(vi) Any entity that receives, after September 29, 1979, any grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act, or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 [42 U.S.C. 15001 *et seq.*] is required to comply with paragraph (a)(2)(vii) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 300a–7(b)(1), entities to whom this paragraph (a)(2)(i) applies shall not require any individual who receives a grant, contract, loan, or loan guarantee under the Public Health Service Act to perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions.

(ii) Pursuant to 42 U.S.C. 300a–7(b)(2)(A), entities to whom this paragraph (a)(2)(ii) applies shall not require any entity funded under the Public Health Service Act to make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions.

(iii) Pursuant to 42 U.S.C. 300a–7(b)(2)(B), entities to whom this paragraph (a)(2)(iii) applies shall not require any entity funded under the Public Health Service Act to provide personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedure or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel.

(iv) Pursuant to 42 U.S.C. 300a–7(c)(1), entities to whom this paragraph (a)(2)(iv) applies shall not discriminate against any physician or other health care personnel in the employment, promotion, termination, or extension of staff or other privileges because such physician or other health care personnel performed or assisted in the

performance, or refused to perform or assist in the performance of a lawful sterilization procedure or abortion on the grounds that doing so would be contrary to his or her religious beliefs or moral convictions, or because of his or her religious beliefs or moral convictions concerning abortions or sterilization procedures themselves.

(v) Pursuant to 42 U.S.C. 300a–7(c)(2), entities to whom this paragraph (a)(2)(v) applies shall not discriminate against any physician or other health care personnel in employment, promotion, termination of employment, or extension of staff or other privileges because such physician or other health care personnel performed or assisted in the performance of any lawful health service or research activity or refused to perform or assist in the performance of such service or activity on the grounds that doing so would be contrary to his or her religious beliefs or moral convictions, or because of his or her religious beliefs or moral convictions.

(vi) Pursuant to 42 U.S.C. 300a–7(d), entities to whom this paragraph (a)(2)(vi) applies shall not require any individual to perform or assist in the performance of any part of a health service program or research activity if such performance or assistance would be contrary to the individual's religious beliefs or moral convictions.

(vii) Pursuant to 42 U.S.C. 300a–7(e), entities to whom this paragraph (a)(2)(vii) applies shall not deny admission to or otherwise discriminate against any applicant for training or study because of reluctance or willingness to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to or consistent with the applicant's religious beliefs or moral convictions.

(b) *The Coats-Snowe Amendment (Section 245 of the Public Health Service Act), 42 U.S.C. 238n—(1) Applicability.* (i) The Federal government, including the Department, is required to comply with paragraphs (b)(2)(i) through (ii) of this section and §§ 88.5, and 88.6 of this part.

(ii) Any State or local government or subdivision thereof that receives Federal financial assistance, including Federal payments provided as reimbursement for carrying out health-related activities is required to comply with paragraphs (b)(2)(i) through (ii) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 238n(a)(1), (2), and (3), entities to whom this paragraph (b)(2)(i) applies shall not subject any individual or institutional health care entity to discrimination on the basis that

the individual or institutional health care entity—

(A) Refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions;

(B) Refuses to make arrangements for any of the activities specified in (b)(2)(i)(A); or

(C) Attends or attended a postgraduate physician training program, or any other program of training in the health professions, that does not or did not require attendees to perform induced abortions or require, provide, or refer for training in the performance of induced abortions, or make arrangements for the provision of such training.

(ii) Pursuant to 42 U.S.C. 238n(b), entities to whom this paragraph (b)(2)(ii) applies shall not, for the purposes of granting a legal status to a health care entity (including a license or certificate), or providing such entity with financial assistance, services or benefits, fail to deem accredited any postgraduate physician training program that would be accredited but for the accrediting agency's reliance upon an accreditation standard or standards that require an entity to perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training, regardless of whether such standard provides exceptions or exemptions.

(c) *Weldon Amendment (See, e.g., Pub. L. 115–31, Div. H, sec. 507(d))—(1) Applicability.* (i) The Department, while operating under an appropriations act that contains the Weldon Amendment, is required to comply with paragraph (c)(2) of this section and §§ 88.5, and 88.6 of this part;

(ii) Any State or local government that receives funds under an appropriations act for the Department that contains the Weldon Amendment is required to comply with paragraph (c)(2) of this section and §§ 88.4, 88.5, and 88.6 of this part;

(iii) Any entity that receives funds through a program administered by the Secretary or under an appropriations act for the Department that contains the Weldon Amendment is required to comply with paragraph (c)(2) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Prohibition.* The entities to whom this paragraph (c)(2) applies shall not subject any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for, abortion.

(d) *Medicare Advantage, Consolidated Appropriations Act of 2017, Public Law 115–31, Div. H, Tit. II, sec. 209—(1)*

Applicability. The Department, while operating under an appropriations act that contains a provision under the Medicare Advantage program as set forth by Public Law 115–31, Div. H, Tit. II, sec. 209, is required to comply with paragraph (d)(2) of this section and §§ 88.5, and 88.6 of this part.

(2) *Prohibition.* The entities to whom this paragraph (d)(2) applies shall not deny participation in the Medicare Advantage program to an otherwise eligible entity (including a Provider Sponsored Organization) because that entity will not provide, pay for, provide coverage of, or provide referrals for abortions.

(e) *Section 1553 of the Affordable Care Act, 42 U.S.C. 18113—(1)*

Applicability. (i) The Department is required to comply with paragraph (e)(2) of this section and §§ 88.5, and 88.6 of this part.

(ii) Any State or local government that receives Federal financial assistance under the Patient Protection and Affordable Care Act (or under any amendment made by the Act) is required to comply with paragraph (e)(2) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(iii) Any health care provider that receives Federal financial assistance under the Patient Protection and Affordable Care Act (or under any amendment made by the Act) is required to comply with paragraph (e)(2) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(iv) Any health plan created under the Patient Protection and Affordable Care Act (or under any amendment) is required to comply with paragraph (e)(2) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Prohibition.* The entities to whom this paragraph (e)(2) applies shall not subject an individual or institutional health care entity to discrimination on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing; provided, that nothing in this paragraph shall be construed to apply to, or to affect, any limitation relating to:

(i) The withholding or withdrawing of medical treatment or medical care;

(ii) The withholding or withdrawing of nutrition or hydration;

(iii) Abortion; or

(iv) The use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if

such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason.

(f) *Section 1303 of the Affordable Care Act, 42 U.S.C. 18023—(1)*

Applicability. (i) The Department is required to comply with paragraph (f)(2)(i) of this section and §§ 88.5, and 88.6 of this part.

(ii) Qualified health plans, as defined under 42 U.S.C. 18021, offered on any Exchange created under the Affordable Care Act, are required to comply with paragraph (f)(2)(ii) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 18023(b)(1)(A)(i), entities to whom this paragraph (f)(2)(i) applies shall not require a qualified health plan to provide coverage of abortion or abortion-related services as described in 42 U.S.C. 18023(b)(1)(B) as part of its essential health benefits for any plan year.

(ii) Pursuant to 42 U.S.C. 18023(b)(4), entities to whom this paragraph (f)(2)(ii) applies shall not discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.

(g) *Section 1411 of the Affordable Care Act, 42 U.S.C. 18081—(1)*

Applicability. The Department shall comply with paragraph (g)(2) of this section and §§ 88.5, and 88.6 of this part.

(2) *Requirement.* The Department shall provide a certification documenting a religious exemption from the individual responsibility requirement and penalty under the Affordable Care Act to:

(i) Any individual who is a member of a recognized religious sect or division thereof and is an adherent of established tenets or teachings of such sect or division by reason of which he is conscientiously opposed to acceptance of the benefits of any private or public insurance which, among other things, makes payments toward the cost of, or provides services for, medical care (including the benefits of any insurance system established by the Social Security Act); and

(ii) Any individual for the month for which such individual is a member of a “health care sharing ministry,” as defined in 26 U.S.C. 5000A(2)(B)(ii).

(h) *Counseling and referral provisions of 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B)—(1)*

Applicability. (i) The Department is required to comply with paragraphs (h)(2)(i) through (ii) of

this section and §§ 88.5 and 88.6 of this part.

(ii) Any State agency that administers a Medicaid program is required to comply with paragraph (h)(2)(ii) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 1395w–22(j)(3)(B), entities to whom this paragraph (h)(2)(i) applies shall not require a Medicare Advantage organization to offer a plan that provides, reimburses for, or provides coverage of, a counseling or referral service if the organization objects to the provision of such service on moral or religious grounds.

(ii) Pursuant to 42 U.S.C. 1396u–2(b)(3)(B), entities to whom this paragraph (h)(2)(ii) applies shall not require a Medicaid managed care organization to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization objects to the provision of such service on moral or religious grounds.

(i) *Advance Directives, 42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406—(1)*

Applicability. (i) The Department is required to comply with paragraph (i)(2) of this section and §§ 88.5 and 88.6 of this part with respect to the Medicare and Medicaid programs.

(ii) Any State agency that administers a Medicaid program is required to comply with paragraph (i)(2) of this section and §§ 88.4, 88.5, and 88.6 of this part with respect to its Medicaid program.

(2) *Prohibitions.* The entities to whom this paragraph (i)(2) applies shall not:

(i) Construe 42 U.S.C. 1395cc(f) or 1396a(w) to require any provider or organization, or any employee of such a provider or organization, to inform or counsel any individual regarding any right to obtain an item or service furnished for the purpose of causing, or the purpose of assisting in causing, the death of the individual, such as by assisted suicide, euthanasia, or mercy killing; or to apply to or affect any requirement with respect to a portion of an advance directive that directs the purposeful causing of, or the purposeful assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing; or

(ii) Construe 42 U.S.C. 1396a to prohibit the application of any applicable State law which allows for an objection on the basis of conscience for any health care provider or any agent of such provider which as a matter of conscience cannot implement an advance directive.

(j) *Global Health Programs, 22 U.S.C. 7631(d)—(1)*

Applicability. (i) The Department is required to comply with

paragraph (j)(2) of this section and §§ 88.5 and 88.6 of this part.

(ii) Any entity that receives Federal financial assistance for HIV/AIDS prevention, treatment, or care to the extent administered by the Secretary under section 104A of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2), under Chapter 83 of Title 22 of the U.S. Code or under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, is required to comply with paragraph (j)(2) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Prohibitions.* The entities to whom this paragraph (j)(2) applies shall not:

(i) To the extent administered by the Secretary under section 104A of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2), under Chapter 83 of Title 22 of the U.S. Code, or under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, require applicants for assistance for HIV/AIDS prevention, treatment, or care to:

(A) Endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or

(B) Endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the applicant has a religious or moral objection, as a condition of assistance.

(ii) Discriminate against applicants in the solicitation or issuance of grants, contracts, or cooperative agreements under such provisions of law for refusing to meet any requirement described in this paragraph (j)(2).

(k) *The Helms Amendment (e.g., Consolidated Appropriations Act of 2017, Public Law 115–31, Div. J, Tit. VII, sec. 7018) (codified at 22 U.S.C. 2151b(f))*—(1) *Applicability.* The Department is required to comply with paragraph (k)(2)(i) of this section and §§ 88.5 and 88.6 of this part.

(ii) Any entity that receives Federal financial assistance under Part I of the Foreign Assistance Act of 1961, as amended (22 U.S.C. 2151b–2), to the extent administered by the Secretary, is required to comply with paragraph (k)(2)(ii) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Prohibitions.* (i) The entities to whom this paragraph (k)(2)(i) applies shall not:

(A) Permit Federal financial assistance identified in (k)(1)(ii) to be used in a manner that would violate provisions in paragraphs (k)(2)(ii)(A)(1)

through (5) of this section related to abortions and involuntary sterilizations.

(B) Obligate or expend Federal financial assistance to any country or organization if the President certifies that the use of these funds by any such country or organization would violate provisions in paragraphs (k)(2)(ii)(A)(1) through (5) of this section related to abortions and involuntary sterilizations.

(ii) The entities to whom this paragraph (k)(2)(ii) applies shall not:

(A) Use such Federal financial assistance identified in (k)(1)(ii) to:

(1) Pay for the performance of abortions as a method of family planning;

(2) Motivate or coerce any person to practice abortions;

(3) Pay for the performance of involuntary sterilization as a method of family planning;

(4) Coerce or provide any financial incentive to any person to undergo sterilizations;

(5) Pay for any biomedical research that relates in whole or in part, to methods of, or the performance of, abortions or involuntary sterilization as a means of family planning;

(B) Obligate or expend Federal financial assistance to any country or organization if the President certifies that the use of these funds by any such country or organization would violate provisions in paragraphs (k)(2)(ii)(A)(1) through (5) of this section related to abortions and involuntary sterilizations.

(l) *Newborn and Infant Hearing Loss Screening, 42 U.S.C. 280g–1(d)*—(1) *Applicability.* The Department is required to comply with paragraph (l)(2) of this section and §§ 88.5 and 88.6 of this part.

(2) *Requirement.* The Department shall not construe 42 U.S.C. 280g–1(d) to preempt or prohibit State laws that do not require screening for hearing loss of newborn infants or young children when their parents object to the screening on the grounds that it conflicts with the parents' religious beliefs.

(m) *Medical Screening, Examination, Diagnosis, Treatment, or Other Health Care or Services, 42 U.S.C. 1396f*—(1) *Applicability.* The Department is required to comply with paragraph (m)(2) of this section and §§ 88.5 and 88.6 of this part.

(2) *Requirements and prohibitions.* The Department shall not construe anything in 42 U.S.C. 1396 *et seq.* to require a State agency that administers a State Medicaid Plan to compel any person to undergo any medical screening, examination, diagnosis, or treatment or to accept any other health care or services provided under such

plan for any purpose (other than for the purpose of discovering and preventing the spread of infection or contagious disease or for the purpose of protecting environmental health), if such person objects (or, in case such person is a child, his parent or guardian objects) thereto on religious grounds.

(n) *Occupational Illness Examinations and Tests, 29 U.S.C. 669(a)(5)*—(1) *Applicability.* (i) The Department is required to comply with paragraph (n)(2) of this section and §§ 88.5 and 88.6 of this part.

(ii) Any recipient of grants or contracts under 29 U.S.C. 669, to the extent administered by the Secretary, is required to comply with paragraph (n)(2) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Requirements.* With respect to occupational illness examinations and tests, the entities to whom this paragraph (n)(2) applies shall not deem any provision of 29 U.S.C. 651 *et seq.* to authorize or require medical examination, immunization, or treatment, as provided under 29 U.S.C. 669, for those who object thereto on religious grounds, except where such is necessary for the protection of the health or safety of others.

(o) *Vaccination, 42 U.S.C. 1396s(c)(2)(B)(ii)*—(1) *Applicability.* (i) The Department is required to comply with paragraph (o)(2) of this section and §§ 88.5 and 88.6 of this part.

(ii) Any State agency that administers a pediatric vaccine distribution program under 42 U.S.C. 1396s is required to comply with paragraph (o)(2) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Requirement.* The entities to whom this paragraph (o)(2) applies shall comply with applicable State law, including any such law relating to any religious or other exemption.

(p) *Specific Assessment, Prevention and Treatment Services, 42 U.S.C. 290bb–36(f), 5106i*—(1) *Applicability.* (i) The Department is required to comply with paragraphs (p)(2)(i) through (iii) of this section and §§ 88.5 and 88.6 of this part.

(ii) Any State; part of any State; public organization; or private nonprofit organization, such as a school, educational institution, juvenile justice system, substance use disorder program, mental health program, foster care system, or other child and youth support organization, designated by a State to develop or direct the State-sponsored Statewide youth suicide early intervention and prevention strategy under 42 U.S.C. 290bb–36 and that receives a grant or cooperative agreement thereunder is required to

comply with paragraph (p)(2)(iii) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(iii) Any Federally recognized Indian tribe or tribal organization (as defined in the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 *et seq.*]) or an urban Indian organization (as defined in the Indian Health Care Improvement Act [25 U.S.C. 1601 *et seq.*]) that is actively involved in the development and continuation of a tribal youth suicide early intervention and prevention strategy under 42 U.S.C. 290bb–36 and that receives a grant or cooperative agreement thereunder is required to comply with paragraph (p)(2)(iii) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(iv) Any entity that receives funds under 42 U.S.C. Chapter 67, Subchapters I or III is required to comply with paragraphs (p)(2)(i) and (ii) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Entities to whom this paragraph (p)(2)(i) applies shall not construe the receipt of funds under or anything in 42 U.S.C. Chapter 67, Subchapters I or III as establishing any Federal requirement that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of the parent or legal guardian.

(ii) Entities to whom this paragraph (p)(2)(ii) applies shall not construe the receipt of funds under or anything in 42 U.S.C. Chapter 67, Subchapters I or III as requiring a State to find, or prohibiting a State from finding, child abuse or neglect in cases in which a parent or legal guardian relies solely or partially upon spiritual means rather than medical treatment, in accordance with the religious beliefs of the parent or legal guardian.

(iii) Entities to whom this paragraph (p)(2)(iii) applies shall not require suicide assessment, early intervention, or treatment services for youth whose parents or legal guardians object based on the parents' or legal guardians' religious beliefs or moral objections.

(q) *Religious nonmedical health care, 42 U.S.C. 1320a–1, 1320c–11, 1395i–5, 1395x(e), 1395x(y)(1), 1396a(a), 1397j–1(b), and 5106i(a)(2)—(1) Applicability.*

(i) The Department is required to comply with paragraphs (q)(2)(i), through (iii) of this section and §§ 88.5 and 88.6 of this part.

(ii) Any State agency that administers a Medicaid or CHIP program is required to comply with paragraph (q)(2)(ii) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(iii) Any entity, including a State or local government or subdivision thereof,

receiving Federal financial assistance from Social Services Block Grant is required to comply with paragraphs (q)(2)(i) and (iv) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(iv) Any entity, including a State or local government or subdivision thereof, receiving Federal financial assistance from the Elder Justice Block Grants is required to comply with paragraph (q)(2)(iii) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) The entities to whom this paragraph (q)(2)(i) applies shall not fail or refuse to exempt a religious nonmedical health care institution from the Medicare requirement for peer review under 42 U.S.C. 1320cc and the Medicare requirements under 42 U.S.C. 1320a–1, for evaluation by advisory boards on capability to provide comprehensive health care services.

(ii) The entities to whom this paragraph (q)(2)(ii) applies shall not fail or refuse to exempt a religious nonmedical health care institution from the Medicaid requirements to:

(A) Meet State medical standards, under 42 U.S.C. 1396a(a)(9)(A);

(B) Be evaluated under 42 U.S.C. 1396a(a)(33), on the appropriateness and quality of medical care and services;

(C) Undergo a regular program, under 42 U.S.C. 1396(a)(31), of independent professional review, including medical evaluation, of services in an intermediate care facility for persons with mental disabilities; and

(D) Establish a utilization review plan under 42 U.S.C. 1395x(k); or the Medicare, Medicaid, and Children's Health Insurance Program requirements, under 42 U.S.C. 1320a–1, for evaluation by advisory boards on capability to provide comprehensive health services.

(iii) Pursuant to 42 U.S.C. 1397j–1(b), the entities to whom this paragraph (q)(2)(iii) applies shall not interfere with or abridge an elder's right to practice his or her religion through reliance on prayer alone for healing when this choice:

(A) Is contemporaneously expressed, either orally or in writing, with respect to a specific illness or injury which the elder has at the time of the decision by an elder who is competent at the time of the decision;

(B) Is previously set forth in a living will, health care proxy, or other advance directive document that is validly executed and applied under State law; or

(C) May be unambiguously deduced from the elder's life history.

(iv) Pursuant to 42 U.S.C. 1395i–5, the entities to whom this paragraph

(q)(2)(iv) applies shall not prohibit coverage of inpatient hospital services or post-hospital extended care services furnished an individual in a religious nonmedical health care institution or home health services furnished an individual by a religious nonmedical health care institution if an individual makes an election providing that:

(A) Such individual is conscientiously opposed to acceptance of conventional or unconventional medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs); and

(B) Acceptance of such medical treatment would be inconsistent with such individual's sincere religious beliefs.

§ 88.4 Assurance and certification of compliance requirements.

(a) *In general*—(1) *Assurance.* Except for an application or recipient to which paragraph (c) of this section applies, every application for Federal financial assistance or Federal funds from the Department to which § 88.3 of this part applies shall, as a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department pursuant to the application, provide, contain, or be accompanied by an assurance that the applicant or recipient will comply with applicable Federal health care conscience and associated anti-discrimination laws and this part.

(2) *Certification.* Except for an application or recipient to which paragraph (c) of this section applies, every application for Federal financial assistance or Federal funds from the Department to which § 88.3 of this part applies, shall, as a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department pursuant to the application, provide, contain, or be accompanied by, a certification that the applicant or recipient will comply with applicable Federal health care conscience and associated anti-discrimination laws and this part.

(b) *Specific requirements*—(1) *Timing.* Applicants or recipients who are already recipients as of the effective date of this part shall submit the assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section as a condition of any reapplication for funds to which this part applies, through any instrument or as a condition of an amendment or modification of the instrument that extends the term of such instrument or adds additional funds to it. Submission

may be required more frequently if the applicant or recipient fails to meet a requirement of this part.

(2) *Form and manner.* Applicants or recipients shall submit the assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section in the form and manner that OCR, in coordination with the relevant Department component, specifies, or shall submit them in a separate writing signed by the applicant's or recipient's officer or other person authorized to bind the applicant or recipient.

(3) *Duration of obligation.* The assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section will obligate the recipient for the period during which the Department extends Federal financial assistance or Federal funds from the Department to a recipient.

(4) *Compliance requirement.* Submission of an assurance or certification required under this section will not relieve a recipient of the obligation to take and complete any action necessary to come into compliance with Federal health care conscience and associated anti-discrimination laws and this part prior to, or at the time of, or subsequent to, the submission of such assurance or certification.

(5) *Condition of continued receipt.* Provision of a compliant assurance and certification shall constitute a condition of continued receipt of Federal financial assistance or Federal funds from the Department and is binding upon the applicant or recipient, its successors, assigns, or transferees for the period during which such Federal financial assistance or Federal funds from the Department are provided.

(6) *Assurances in applications.* An applicant or recipient may incorporate the assurances by reference in subsequent applications to the Department or Department component if prior assurances are initially provided in the same year.

(7) *Enforcement of assurances and certifications.* The Department, Department components, and OCR shall have the right to seek enforcement of the assurances and certifications required in this section.

(8) *Remedies for failure to make assurances and certifications.* If an applicant or recipient fails or refuses to furnish an assurance or certification required under this section, OCR, in coordination with the relevant Department component, may effect compliance by any of the remedies provided in § 88.7.

(c) *Exceptions.* The following persons or entities shall not be required to comply with paragraphs (a)(1) and (2) of this section, provided that such persons or entities are not recipients of Federal financial assistance or other Federal funds from the Department through another instrument, program, or mechanism, other than those set forth in paragraphs (c)(1) through (4) of this section:

(1) A physician, as defined in 42 U.S.C. 1395x(r), physician office, or other health care practitioner participating in Part B of the Medicare program;

(2) A recipient of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration for Children and Families, the purpose of which is either solely financial assistance unrelated to health care or which is otherwise unrelated to health care provision, and which, in addition, does not involve—

- (i) Medical or behavioral research;
- (ii) Health care providers; or
- (iii) Any significant likelihood of referral for the provision of health care;

(3) A recipient of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration on Community Living, the purpose of which is either solely financial assistance unrelated to health care or which is otherwise unrelated to health care provision, and which, in addition, does not involve—

- (i) Medical or behavioral research;
- (ii) Health care providers; or
- (iii) Any significant likelihood of referral for the provision of health care.

(4) Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the Indian Self-Determination and Education Assistance Act.

§ 88.5 Notice requirement.

(a) *In general.* The Department and each recipient shall post the notice text located in Appendix A to this part in accordance with paragraph (b) of this section by April 26, 2018, or with respect to new recipients, within 90 days after becoming a recipient.

(b) *Specific requirements.* The notice text required in paragraph (a) of this section shall appear:

- (1) On the Department's and each recipient's website(s), and
- (2) In a prominent and conspicuous physical location in every Department and recipient establishment where notices to the public and notices to their workforce are customarily posted to permit ready observation. The text of

the notice shall be large enough to be easily read. The Department and each recipient shall take steps to ensure that such notices are not altered, defaced, or covered by other material.

(c) *Factors in evaluation of compliance.* In evaluating a recipient's compliance with the requirements of this part, OCR will take into account whether the recipient has provided the notice text in paragraph (a) of this section:

(1) In a personnel manual or other substantially similar document for members of the recipient's workforce;

(2) In applications for membership in the recipient's workforce or for participation in a service, benefit, or other program, including for training or study; and

(3) In a student handbook or other substantially similar document for students participating in a program of training or study, including for post-graduate interns, residents, and fellows.

(d) *Combined nondiscrimination notices.* The Department and each recipient may post the notice text provided in appendix A of this part along with the content of other notices only if it retains all of the language provided in appendix A of this part in an unaltered state.

§ 88.6 Compliance requirements.

(a) *In general.* The Department and each recipient has primary responsibility to ensure that it is in compliance with Federal health care conscience and associated anti-discrimination laws and this part, and shall take steps to eliminate any violations of the Federal health care conscience and associated anti-discrimination laws and this part. If a sub-recipient is found to have violated the Federal health care conscience and associated anti-discrimination laws, the recipient from whom the sub-recipient received funds shall be subject to the imposition of funding restrictions and other appropriate remedies available under this part.

(b) *Records and information.* The Department, each recipient, and each sub-recipient shall maintain complete and accurate records evidencing compliance with Federal health care conscience and associated anti-discrimination laws and this part, and afford OCR, upon request, reasonable access to such records and information in a timely manner to the extent OCR finds necessary to determine compliance with the Federal health care conscience and associated anti-discrimination laws and this part.

(c) *Cooperation.* The Department, each recipient, and each sub-recipient

shall cooperate with any compliance review, investigation, interview, or other part of OCR's enforcement process, which may include the production of documents, the participation in interviews, the response to data requests, and the making available of premises for inspection where relevant. Failure to cooperate may result in an OCR referral to the Department of Justice for further enforcement in Federal court or otherwise.

(d) *Reporting requirement.* If a recipient or sub-recipient is subject to an OCR compliance review, investigation, or complaint filed with OCR regarding the recipient's or sub-recipient's compliance with Federal health care conscience and associated anti-discrimination laws, the recipient or sub-recipient must inform any Departmental funding component of such review, investigation, or complaint and must, in any application for new or renewed Federal financial assistance or Departmental funding, disclose the existence of such compliance review or investigation, and must also report on such applications, or in a separate writing with such applications, the existence of any such complaints filed with OCR for five years from such complaints' filing.

(e) *Intimidating or retaliatory acts prohibited.* Neither the Department nor any recipient or sub-recipient shall intimidate, threaten, coerce, or discriminate against any person, entity, or health care entity for the purpose of interfering with any right or privilege under the Federal health care conscience and associated anti-discrimination laws or this part, or because such person, entity, or health care entity has made a complaint or participated in any manner in an investigation or review under the Federal health care conscience and associated anti-discrimination laws or this part.

§ 88.7 Enforcement authority.

(a) *In general.* OCR has been delegated the authority to enforce the Federal health care conscience and associated anti-discrimination laws, which includes the authority to:

- (1) Receive and handle complaints;
- (2) Initiate compliance reviews;
- (3) Conduct investigations;
- (4) Supervise and coordinate compliance within the Department;
- (5) In coordination with the relevant component or components of the Department, make enforcement referrals to the Department of Justice; and
- (6) In coordination with the relevant component or components of the

Department, take other appropriate remedial action as the Director of OCR deems necessary and as allowed by law to overcome the effects of violations of Federal health care conscience and associated anti-discrimination laws and this part.

(b) *Complaints.* Any entity, health care entity, or any person, individually, as a member of a class, on behalf of others, or on behalf of an entity, may file a complaint with OCR alleging any potential violation of Federal health care conscience and associated anti-discrimination laws or this part. OCR shall coordinate handling of complaints with the relevant Department component. The complaint filer is not required to be the person, entity, or health care entity whose rights under the Federal health care conscience and associated anti-discrimination laws or this part have been potentially violated.

(c) *Periodic compliance reviews.* OCR may from time to time conduct compliance reviews or use other similar procedures as necessary to permit OCR to investigate and review the practices of the Department, Department components, recipients, and sub-recipients to determine whether they are complying with Federal health care conscience and associated anti-discrimination laws and this part. OCR may conduct these reviews in the absence of a complaint.

(d) *Investigations.* OCR shall make a prompt investigation, whenever a compliance review, report, complaint, or any other information found by OCR indicates a threatened, potential, or actual failure to comply with Federal health care conscience and associated anti-discrimination laws or this part. The investigation should include, where appropriate, a review of the pertinent practices, policies, communications, documents, compliance history, the circumstances under which the possible noncompliance occurred, and other factors relevant to determining whether the Department, Department component, recipient, or sub-recipient has failed to comply. OCR shall use fact-finding methods including, but not limited to, site visits, interviews with complainants, the Department component, recipients, sub-recipients, or third-parties, and written data or discovery requests. OCR may seek the assistance of any State agency.

(e) *Destruction of evidence.* Consistent with § 88.6(b) and (c), a Department component, recipient, or sub-recipient that knowingly or recklessly destroys evidence potentially relevant to an OCR investigation or compliance review that is ongoing or reasonably anticipated shall be in violation of this part.

(f) *Failure to respond.* Absent good cause, a party's failure to respond to a request for information or a data or document request within 45 days of OCR's request, shall constitute a violation of this part.

(g) *Related administrative or judicial proceeding.* Consistent with other applicable Federal laws, testimony and other evidence obtained in an investigation or compliance review conducted under this part may be used by the Department for, and offered into evidence in, any administrative or judicial proceeding related to this part.

(h) *Supervision and coordination.* If as a result of an investigation, compliance review, or other enforcement activity, OCR determines that a Department component appears to be in noncompliance with its responsibilities under Federal health care conscience and associated anti-discrimination laws or this part, OCR will undertake appropriate action with the component to assure compliance. In the event that OCR and the Department component are unable to agree on a resolution of any particular matter, the matter shall be submitted to the Secretary for resolution. OCR may from time to time delegate to officials of the Department responsibilities in connection with the effectuation of Federal health care conscience and associated anti-discrimination laws and this part, including the achievement of effective coordination and maximum uniformity within the Department.

(i) *Referral to the Department of Justice.* If as a result of an investigation, compliance review, or other enforcement activity, OCR determines that a recipient or sub-recipient is not in compliance with the Federal health care conscience and associated anti-discrimination laws or this part, OCR may, in coordination with the relevant Department component make referrals to the Department of Justice for further enforcement in Federal court or otherwise.

(j) *Resolution of matters.* (1) If an investigation or compliance review reveals that no action is warranted, OCR will so inform the subject of the complaint or review and complainant, if any, in writing.

(2) If an investigation or compliance review indicates a failure to comply with Federal health care conscience and associated anti-discrimination laws or this part, OCR will so inform the relevant parties and the matter will be resolved by informal means whenever possible. Attempts to resolve matters informally shall not preclude OCR from simultaneously pursuing any action described in § 88.7(j)(3).

(3) If there appears to be a failure or threatened failure to comply with Federal health care conscience and associated anti-discrimination laws or this part, compliance with these laws and this part may be effected by the following actions, taken in coordination with the relevant Department component:

(i) Temporarily withholding cash payments, in whole or in part, pending correction of the deficiency;

(ii) Denying use of Federal financial assistance or other Federal funds from the Department, including any applicable matching credit, in whole or in part;

(iii) Wholly or partly suspending award activities;

(iv) Terminating Federal financial assistance or other Federal funds from the Department, in whole or in part;

(v) Withholding new Federal financial assistance or other Federal funds from the Department, in whole or in part, administered by or through the Secretary for which an application or approval is required, including renewal or continuation of existing programs or activities or authorization of new activities;

(vi) Referring the matter to the Attorney General for proceedings to enforce any rights of the United States, or obligations of the recipient or sub-recipient, created by Federal law; and

(vii) Taking any other remedies that may be legally available.

§ 88.8 Relationship to other laws.

Nothing in this part shall be construed to preempt any Federal, State, or local law that is equally or more

protective of religious freedom and moral convictions. Nothing in this part shall be construed to narrow the meaning or application of any State or Federal law protecting free exercise of religious beliefs or moral convictions.

§ 88.9 Rule of construction.

This part shall be construed in favor of a broad protection of free exercise of religious beliefs and moral convictions, to the maximum extent permitted by the terms of the Federal health care conscience and associated antidiscrimination statutes implemented by the Constitution.

§ 88.10 Severability.

Any provision of this part held to be invalid or unenforceable either by its terms or as applied to any person, entity, or circumstance shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be severable from this part, which shall remain in full force and effect to the maximum extent permitted by law. A severed provision shall not affect the remainder of this part or the application of the provision to other persons or entities not similarly situated or to other, dissimilar circumstances.

Appendix A to Part 88—Notice Concerning Federal Health Care Conscience and Associated Anti-Discrimination Protections

[Name of recipient, the Department, or Department component] complies with

Federal health care conscience and associated anti-discrimination laws and does not exclude, treat adversely, coerce, or otherwise discriminate against persons or entities on the basis of their religious beliefs or moral convictions. You have the right to decline to participate in, refer for, undergo, or pay for certain health care-related treatments, research, or services (such as abortion or assisted suicide, among others) which violate your conscience, religious beliefs, or moral convictions under Federal law.

If you believe that [Name of recipient, the Department, or Department component] has failed to accommodate your conscientious, religious, or moral objection, or has unlawfully discriminated against you on those grounds, you can file a conscience and religious freedom complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf> or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW, Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms and more information about Federal health care conscience and associated anti-discrimination laws are available at <http://www.hhs.gov/conscience>.

Dated: January 18, 2018.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2018-01226 Filed 1-19-18; 11:15 am]

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FEDERAL REGISTER

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Part III

The President

Memorandum of January 9, 2018—Delegation of Responsibilities Under the Frank R. Wolf International Religious Freedom Act of 2016

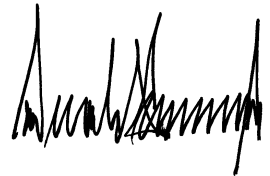
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Title 3—**The President****Delegation of Responsibilities Under the Frank R. Wolf International Religious Freedom Act of 2016****Memorandum for the Secretary of State**

By the authority vested in me by the Constitution and the laws of the United States of America, including section 301 of title 3 of the United States Code, I hereby delegate to the Secretary of State the functions and authorities vested in the President by section 301 of the Frank R. Wolf International Religious Freedom Act (Public Law 114–281) (the “Act”).

This memorandum’s reference to the Act shall be deemed to be a reference to the Act as amended from time to time.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, January 9, 2018

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