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

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 225

[FNS–2013–0026]

RIN 0584–AD84

Simplified Cost Accounting and Other Actions To Reduce Paperwork in the Summer Food Service Program; Correction

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to the final rule entitled ''Simplified Cost Accounting and Other Actions to Reduce Paperwork in the Summer Food Service Program,'' published in the **Federal Register** on June 1, 2018. These corrections do not impose new program requirements.

DATES: This document is effective April 16, 2019. Compliance with the final rule began July 31, 2018.

FOR FURTHER INFORMATION CONTACT: Andrea Farmer, Branch Chief, Community Meals Branch, Policy and Program Development Division, Food and Nutrition Service, at (703) 305–2590.

SUPPLEMENTARY INFORMATION: The Food and Nutrition Service published a final rule on June 1, 2018, (83 FR 25349), to simplify and streamline Program administration in the Summer Food Service Program. This document makes a technical correction to 7 CFR 225.6(b)(7) in order to clarify requirements for submission and review of annual budgets. The correction clarifies for program operators and State agencies the flexibilities available in the budget submission process. This does not alter the requirements of the provision. Additionally, the June 2018 final rule inadvertently removed regulatory text providing State agencies the discretion to determine the amount of advanced payments provided to sponsors. This document corrects this oversight by adding the missing regulatory text for 7 CFR 225.9(c)(3). The authority for this provision is provided by Section 13 in the Richard B. Russell National School Lunch Act, 42 U.S.C. 1761(e)(2). Finally, this document corrects small typographical errors in 7 CFR 225.9(d) and 7 CFR 225.15(m). All other regulatory provisions in the June 2018 final rule remain unchanged.

Need for Correction

As published, the regulatory text in 7 CFR part 225 after the June 1, 2018 final rule is being misinterpreted by program operators and requires technical corrections in 7 CFR 225.6, 225.9, and 225.15.

List of Subjects in 7 CFR Part 225

Food assistance programs, Grant programs—health, Infants and children, Labeling, Reporting and recordkeeping requirements.

Accordingly, 7 CFR part 225 is corrected by making the following correcting amendments:

PART 225—SUMMER FOOD SERVICE PROGRAM

■ 1. The authority citation for 7 CFR part 225 continues to read as follows:

Authority: Secs. 9, 13 and 14, Richard B. Russell National School Lunch Act, as amended (42 U.S.C. 1758, 1761 and 1762a).

■ 2. In § 225.6, revise paragraph (b)(7) to read as follows:

§ 225.6 State agency responsibilities.

* * * * *

(b) * * *

(7) The State agency shall review each applicant's administrative budget as a part of the application approval process in order to assess the applicant's ability to operate in compliance with these regulations within its projected reimbursement. In approving the applicant's administrative budget, the State agency shall take into consideration the number of sites and children to be served, as well as any other relevant factors. A sponsor's administrative budget shall be subject to review for adjustments by the State agency if the sponsor's level of site participation or the number of meals served to children changes significantly. State agencies may exempt school food authorities applying to operate the SFSP from submitting a separate budget to the State agency, if the school food authority submits an annual budget for the National School Lunch Program and the submitted budget includes the operation of SFSP.

* * * * *

■ 3. In § 225.9:

■ a. Revise paragraph (c)(2);

■ b. Redesignate paragraphs (c)(3), (4), and (5) as paragraphs (c)(4), (5), and (6);

■ c. Add a new paragraph (c)(3); and

■ d. In the third sentence of paragraph (d)(5), remove the word ''served''.

The revision and addition read as follows:

§ 225.9 Program assistance to sponsors.

* * * * *

(c) * * *

(2) *Advance payment estimates.* When determining the amount of advance payments payable to the sponsor, the State agency shall make the best possible estimate based on the sponsor's request and any other available data. Under no circumstances may the amount of the advance payment exceed the amount estimated by the State agency to be needed by the sponsor to meet Program costs.

(3) *Limit.* The sum of the advance payments to a sponsor for any one month shall not exceed $40,000 unless the State agency determines that a larger payment is necessary for the effective operation of the Program and the sponsor demonstrates sufficient administrative and managerial capability to justify a larger payment.

* * * * *

§ 225.15 [Amended]

■ 4. In § 225.15(m)(6), remove the word ''no'' and add in its place the word ''nor''.

Dated: April 3, 2019.

Brandon Lipps,

Administrator, Food and Nutrition Service.

[FR Doc. 2019–07499 Filed 4–15–19; 8:45 am]

BILLING CODE 3410–30–P

FEDERAL RESERVE SYSTEM

12 CFR Part 267

[Docket No. R–1657; RIN 7100 AF–44]

Collection of Administrative Debts; Collection of Debts Arising From Enforcement and Other Regulatory Activity

AGENCY: Board of Governors of the Federal Reserve System (Board).

ACTION: Final rule.

SUMMARY: The Board is issuing new regulations to provide for the collection of debts owing to the United States arising out of the Board's operations or its enforcement and other regulatory activities.

DATES: The rule is effective April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Yonatan Gelblum, Senior Counsel (202) 452–2046, Legal Division, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551. For users of Telecommunication Device for Deaf (TDD) contact (202) 263–4869.

SUPPLEMENTARY INFORMATION:

I. Background

The Board is promulgating new regulations to implement the Debt Collection Improvement Act of 1996 (''DCIA''), Public Law 104–134, 110 Stat. 1321–358. The DCIA generally governs the federal government's debt collection activities. Although the DCIA does not apply directly to the Board, these regulations are adopted pursuant to the Board's authority under Section 10(4) and 11 of the Federal Reserve Act, 12 U.S.C. 244, 248(i), to adopt rules and regulations governing its operations. The Board is adopting these regulations in order to improve the effectiveness of its debt collection efforts, primarily by allowing it to refer debts for collection to the U.S. Department of the Treasury (''Treasury''). In accordance with the DCIA, Treasury and the U.S. Department of Justice jointly promulgated Federal Claims Collection Standards (''FCCS''), 31 CFR parts 900–904. Agencies may adopt the FCCS without change, or may prescribe agency regulations for collecting debts by administrative offset that are consistent with the FCCS. 31 U.S.C. 3716. The U.S. Department of the Treasury has issued additional regulations applicable to collection under the DCIA at 31 CFR part 285. This rule generally adopts these regulations and the FCCS by cross-reference, except for purposes of establishing the general scope of these regulations or in limited instances where these authorities expressly require the Board to issue its own regulations.

II. Description of the Final Rule

The regulations set forth the procedures the Board will follow in collecting debts owed to the United States to which part 267 applies. The regulations describe procedures with respect to referral of debts to Treasury or another agency for collection by administrative offset or other means, collection by administrative wage garnishment or salary offset, and the assessment of interest and other charges on debts.

Section 267.1—Purpose and scope. This part establishes procedures for collection of debts owed to the United States. It does not apply if another statute or regulation, or a rule, regulation, or policy adopted by the Board under authority granted to it by the Federal Reserve Act, governs or prohibits collection. For example, the Board has a debt collection policy that provides separate procedures for collecting debts from current employees. These regulations do not apply to the collection of any debts that the Board chooses to collect solely under its debt collection policy rather than these regulations. Thus, the Board is not creating any right to individuals to use the process offered under this regulation for any debt the Board chooses to collect solely under its debt collection policy. In collecting debts under this part, the Board will also follow the procedures set forth in 5 CFR part 550, subpart K, 31 CFR part 285, and the FCCS.

Section 267.2—Definitions. The definitions in this section are generally based on the FCCS, the DCIA, and related authorities. For purposes of this part, a debt or claim owed to the United States is defined as including a debt owed to the Board, including a debt or claim for repayment of Board-funded benefits administered through the Office of Employee Benefits of the Federal Reserve System, but does not include any debt the Board chooses to collect solely under its debt collection policy.

Section 267.3—Referral of debts for collection action, including offset. This section indicates which debts may be referred to the U.S. Department of the Treasury for collection, including by centralized offset and offset of tax refunds, and adopts procedural protections provided under the FCCS and DCIA prior to such referrals. The Board is not required to duplicate any prior notice or review opportunities already afforded to the debtor prior to referral. The Board may request that an agency other than the U.S. Department of the Treasury conduct non-centralized offset.

Section 267.4—Administrative wage garnishment. This section provides that the Board may collect debts from the wages of persons employed outside of the federal government through administrative wage garnishment. Before doing so, the debtor will be provided an opportunity for a hearing in accordance with the procedures described at 31 CFR 285.11(f).

Section 267.5—Salary offset. This section provides that the Board may collect debts from the wages of person employed at a federal agency (other than the Board) through offset of the person's federal agency salary. It adopts the basic requirements set forth under 5 CFR 550.1104 for the content of agency regulations governing salary offset. It also establishes detailed procedures for a hearing prior to salary offset.

Section 267.6—Interest, penalties, and administrative costs. This section follows the guidelines in the FCCS for charges on delinquent debts and, as required by the FCCS, clarifies when the Board will waive such charges during the pendency of any review.

III. Administrative Law Matters

Administrative Procedure Act

This rule is not subject to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 553, requiring notice, public participation, and deferred effective date, because it relates solely to agency procedure and practice. 5 U.S.C. 553(b).

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* applies only to rules for which an agency publishes a notice of proposed rulemaking. Because a notice of proposed rulemaking for this rule is unnecessary, the Regulatory Flexibility Act does not apply to this final rule.

Paperwork Reduction Act Analysis

There is no collection of information required by this final rule that would be subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

Plain Language

Section 722 of the Gramm-Leach-Bliley Act requires each federal banking agency to use plain language in all rules published after January 1, 2000. In light of this requirement, the Board believes this final rule is presented in a simple and straightforward manner and is consistent with this ''plain language'' directive.

Review by the Office of Personnel Management

Because the proposed rule provides for salary offset pursuant to 5 U.S.C. 5514, in accordance with that section and with 5 CFR 550.1105(a), the Board submitted the proposed rule to the Office of Personnel Management, which approved the rule.

List of Subjects in 12 CFR Part 267

Administrative practice and procedure, Claims, Collection, Government employees, Hearing procedures, Wages.

Authority and Issuance

■ For the reasons set forth in the preamble, the Board adds part 267 to Chapter II, in Title 12 of the Code of Federal Regulations to read as follows:

PART 267—PROCEDURES FOR DEBT COLLECTION

Sec.
267.1 Purpose and scope.
267.2 Definitions.
267.3 Referral of debts for collection action, including offset.
267.4 Administrative wage garnishment.
267.5 Salary offset.
267.6 Interest, penalties, and administrative costs.

Authority: 5 U.S.C. 5514; 12 U.S.C. 244, 248; 31 U.S.C. 3711, 3716, 3717, 3720A, 3720D.

§ 267.1 Purpose and scope.

This part establishes Board procedures for the collection of certain debts owed to the United States.

(a) Except as provided in paragraph (b) of this section, this part applies to collections by the Board from persons, organizations, or entities indebted to the United States.

(b) This part does not apply to any debts whose collection is exclusively provided for or prohibited by another statute or applicable regulation, or to any debt of a current Board employee or other debtor where the Board has chosen to proceed solely under its existing internal debt collection policy. This part does not in any way limit or affect the Board's authority under 12 U.S.C. 244 and 12 U.S.C. 248. Nothing in this part precludes the collection of debts through any other legally-available means, or precludes the Board from engaging in litigation as provided under 12 U.S.C. 248(p), 1818(i), or any other applicable law.

(c) When the Board determines to collect a debt using the procedures under these regulations, in addition to the procedures set forth in this part and subject to paragraph (b) of this section, the Board shall also follow, as applicable, the procedures set forth in 31 CFR part 285 and the Federal Claims Collection Standards (FCCS) (31 CFR chapter IX and parts 900 through 904) for the collection of debts owed to the United States.

(d) Nothing in this part precludes the compromise, suspension, or termination of collection actions, where appropriate, under standards implementing the Debt Collection Improvement Act (DCIA) (31 U.S.C. 3711 *et seq.*), the FCCS, or any other applicable law, including rules, regulations, and policies adopted by the Board pursuant to authority granted to it under the Federal Reserve Act.

(e) Nothing in this part shall create any right or benefit, substantive or procedural, enforceable at law or in equity by a party against the United States, its agencies, its officers, or any other person, nor shall the Board's failure to comply with any of the provisions of this part be available to any debtor as a defense. Nothing in this part shall permit a debtor to collaterally attack a final administrative decision rendered under any other applicable statute or regulation, or a judgment by a competent court.

§ 267.2 Definitions.

Except where the context clearly indicates otherwise, the following definitions shall apply to this part.

Administrative offset means withholding funds payable by the United States to, or held by the United States for, a person to satisfy a claim.

Agency incudes all executive departments and agencies or instrumentalities in the executive branch, and any other entity referenced in 5 U.S.C. 5514(a)(5)(B).

Board means the Board of Governors of the Federal Reserve System.

Centralized offset is an offset initiated by referral to the Secretary of the Treasury (including a debt collection center designated by the Department of the Treasury) by a creditor agency of a debt for purposes of collection under the Treasury's centralized offset program.

Debt or *claim* means an amount of money, funds, or property that has been determined by a Board official, in connection with the operational or regulatory activities of the Board, to be owed to the United States from any person, organization or entity (except another Federal entity), including any type of debt referenced in 31 U.S.C. 3701(b). For purposes of this part, a debt or claim owed to the Board, including a debt or claim for repayment of Board-funded benefits administered through the Office of Employee Benefits of the Federal Reserve System, is a debt owed to the United States. A debt does not include any amounts owed by a current Board employee that the Board chooses to collect solely under its debt collection policy.

Debtor means a person who owes a debt, and includes any individual, organization, or entity except another agency.

Delinquent, with respect to a debt or claim, shall have the meaning given to such term at 31 CFR 900.2(b).

Eligible, with respect to a debt or claim, means that referral of the debt or claim for collection is not precluded by any statute or regulation, or by any guidance issued by the U.S. Department of the Treasury.

Garnishment means the process of withholding amounts from the disposable pay of a person employed outside the Federal Government, and the paying of those amounts to a creditor in satisfaction of a withholding order.

Salary offset means an administrative offset to collect a debt under 5 U.S.C. 5514 by deduction(s) at one or more officially established pay intervals from the current pay account of a Federal employee without his or her consent.

§ 267.3 Referral of debts for collection action, including offset.

(a) *In general.* To the extent not inconsistent with any applicable law or with any rule, regulation, or policy adopted by the Board in the exercise of authority granted to it under the Federal Reserve Act, the Board will refer debts covered by this regulation and which are eligible debts over 120 days delinquent to which this part applies to the U.S. Department of the Treasury for appropriate debt collection action, including but not limited to centralized offset, and offset of tax refunds. The Board may also refer any eligible debt less than 120 days delinquent to the U.S. Department of the Treasury for appropriate collection action.

(b) *Proceedings prior to referral.* At least 60 days prior to referring a debt in accordance with paragraph (a) of this section, the Board will send the debtor the notice described in 31 CFR 901.3(b)(4)(ii)(A), and afford the debtor the procedural protections described in 31 CFR 901.3(b)(4)(ii)(B) and 31 U.S.C. 3720A(b). However, the Board is not required to duplicate any prior notice or review opportunities that it has already afforded the debtor prior to referral.

(c) *Non-centralized offset.* The Board may request an agency other than the U.S. Department of the Treasury to conduct non-centralized offset. Except in the situations described in 31 CFR 901.3(b)(4)(iii)(A)–(C), the Board will

follow the procedures described in paragraph (b) of this section prior to making such a request. When making the request, the Board will certify in writing to the paying agency that the debtor owes the past due, legally enforceable delinquent debt in the amount stated, and that the Board has fully complied with these regulations.

§ 267.4 Administrative wage garnishment.

The Board may collect debts, or refer debts for collection, from the wages of persons employed outside of the Federal Government by administrative wage garnishment in accordance with the requirements of 31 U.S.C. 3720D.

Prior to such garnishment, the debtor will be provided a hearing in accordance with the procedures described at 31 CFR 285.11(f).

§ 267.5 Salary offset.

(a) *Applicability.* (1) This section covers government-wide collection of a delinquent debt by administrative offset under 5 U.S.C. 5514 from salary payments of federal government employees other than current Board employees.

(2) This section does not apply where an employee consents to the recovery of a debt from his or her federal government salary.

(b) *Notice.* A Federal Government employee from whom the Board proposes to collect a debt under this section will be provided written notice from the Board at least 30 days before any deductions begin. Such notice will state:

(1) The Board's determination that a debt is owed, including the origin, nature, and amount of that debt;

(2) The Board's intention to collect the debt by means of deduction from the employee's disposable pay (as defined in 5 CFR 550.1103);

(3) The frequency and amount of the intended deduction (stated as a fixed dollar amount or as a percentage of pay), and the Board's intention to continue the deductions until the debt is paid in full or otherwise resolved;

(4) An explanation of the Board's policy concerning interest, penalties, and administrative costs, including a statement that such assessments must be made unless excused in accordance with the Federal Claims Collections Standards published in 31 CFR parts 900 through 904;

(5) The employee's right to inspect and copy Government records relating to the debt or, if the employee or his or her representative cannot personally inspect the records, to request and receive a copy of such records;

(6) If not previously provided, the opportunity (under terms agreeable to Board) to establish a schedule for the voluntary repayment of the debt or to enter into a written agreement to establish a schedule for repayment of the debt in lieu of offset;

(7) The employee's right to a hearing conducted by an official arranged by the Board if a petition is filed as prescribed by the Board;

(8) The method and time period for petitioning for a hearing, including the contact information of the official to whom such a petition should be sent;

(9) That the timely filing of a petition for a hearing will stay the commencement of collection proceedings;

(10) That a final decision on the hearing (if one is requested) will be issued at the earliest practical date, but not later than 60 days after the filing of the petition requesting the hearing unless the employee requests and the hearing official grants a delay in the proceedings;

(11) That any knowingly false or frivolous statements, representations, or evidence may subject the employee to:

(i) Disciplinary procedures appropriate under chapter 75 of title 5, United States Code, part 752 of title 5, Code of Federal Regulations, or any other applicable statutes or regulations;

(ii) Penalties under the False Claims Act, sections 3729 through 3731 of title 31, United States Code, or any other applicable statutory authority; or

(iii) Criminal penalties under sections 286, 287, 1001, and 1002 of title 18, United States Code or any other applicable statutory authority.

(12) Any other rights and remedies available to the employee under statutes or regulations governing the program for which the collection is being made; and

(13) Unless there are applicable contractual or statutory provisions to the contrary, that amounts paid on or deducted for the debt which are later waived or found not owed to the United States will be promptly refunded to the employee.

(c) *Petitions for hearing*—(1) *Time to petition.* A Federal Government employee from whom the Board proposes to collect a debt under this section may request a hearing concerning the existence or amount of the debt or the offset schedule established by the Board by sending a written petition addressed to the official designated in the notice described in paragraph (b) of this section on or before the fifteenth day following receipt of such notice. A hearing will be granted on a petition that is not filed within such period only if the petitioner shows that the delay was because of circumstances beyond his or her control or because of failure to receive notice of the time limit (unless otherwise aware of it). In all other cases of late or non-filing of such a petition, the employee will be deemed to have waived the right to a hearing and will be subject to salary offset under this section.

(2) *Contents of petition.* The petition must:

(i) Be signed by the employee;

(ii) State why the employee believes the Board's determination concerning the existence of amount of the debt is in error;

(iii) Fully identify and explain with reasonable specificity all the facts, evidence and witnesses, if any, which the employee believes support his or her position.

(iv) Specify, if the employee desires an oral hearing, why the matter cannot be resolved by a paper hearing, which is a determination based upon a review of a written record, for example, because the existence or amount of the debt depends on the hearing official's determination of the credibility of witnesses.

(d) *Form of hearings*—(1) *Hearing official.* A hearing under this section will be conducted by an administrative law judge or another individual not under the supervision or control of the Board.

(2) *Notice of hearing.* After the employee requests a hearing, the hearing official must issue a notice to the employee and the Board of the type of hearing that will occur. If an oral hearing will occur, the notice will state the date, time, and location of the hearing. If a paper hearing will occur, the employee and the Board will be notified and required to submit evidence and arguments in writing to the hearing official by the date specified in the notice, after which the record will be closed. The employee's failure to appear for an oral hearing or timely submit evidence and arguments as provided for in the notice will be deemed a waiver of the right to a hearing unless the hearing official determines that the failure was due to good cause shown.

(3) *Oral hearing.* An employee who requests an oral hearing under this section will be provided such a hearing if the hearing official determines that the matter cannot be resolved by review of documentary evidence alone because an issue of credibility or veracity is involved. Where an oral hearing is appropriate, the hearing need not take the form of an evidentiary hearing, as long as both the employee and the Board are afforded a reasonable opportunity to present their case. Oral

hearings may take the form of, but are not limited to:

(i) Informal meetings in which the employee and Board representative are given full opportunity to present evidence, witnesses, and argument;

(ii) Informal meetings in which the hearing official interviews the employee and Board representative; or

(iii) Formal written submissions with an opportunity for oral presentation.

(4) *Paper hearing.* If the hearing official determines that an oral hearing is not necessary, he or she will make the determination based upon a review of the formal written record, including any documentation submitted by the employee or the Board.

(5) *Record.* The hearing official shall maintain a summary record of any hearing conducted under this section.

(e) *Decision on hearing.* Unless the employee requests and the hearing official grants a delay in the proceedings, at the earliest practicable date, but in any event no later than 60 days after the filing of the petition requesting the hearing, the hearing official will issue a written decision to the employee. The decision will state the Board's position concerning the existence and amount of the debt, facts purporting to evidence the nature and origin of the alleged debt, the hearing official's analysis, findings and conclusions, in light of the hearing, as to the employee's and/or Board's grounds, the amount and validity of the debt as determined by the hearing official, and the repayment schedule, if not established by written agreement between the employee and the Board. If the hearing official determines that a debt may not be collected under this section, but the Board finds that the debt is still valid, the Board may still seek collection of the debt through other means, including but not limited to offset of other Federal payments.

(f) *Deductions under this section.* The method of collection under this section is salary offset from disposable pay (as defined in 5 CFR 550.1103), except as described in this paragraph. The size of installment deductions shall ordinarily bear a reasonable relationship to the size of the debt and the employee's ability to pay. However, the amount deducted for any period under this section may not exceed 15 percent of disposable pay, unless the employee has agreed in writing to the deduction of a greater amount or a higher deduction has been ordered by a court under section 124 of Public Law 97–276 (97 stat. 1195). Ordinarily, debts must be collected in one lump sum where possible. However, if the employee is financially unable to pay in one lump sum or the amount of the debt exceeds 15 percent of disposable pay (or other applicable limitation as provided in this paragraph) for an officially established pay interval, collection must be made in installments. Such installment deductions must be made over a period not greater than the anticipated period of active duty or employment, as the case may be, except as provided in paragraph (g) of this section.

(g) *Separating or separated employees.* If the employee retires or resigns or if his or her employment or period of active duty ends before collection of the debt is completed, offset may be performed under 31 U.S.C. 3716 from subsequent payments of any nature (*e.g.* final salary payment, lump-sum leave, etc.) due the employee from the paying agency as of the date of separation to the extent necessary to liquidate the debt. Such offset may also be performed where appropriate against later payments of any kind due the former employee from the United States if the debt cannot be liquidated by offset from any final payment due the former employee as of the date of separation. Nothing in this section shall affect any limitation on alienation of benefits administered by the Federal Reserve System's Office of Employee Benefits.

(h) *Non-waiver and refunds of payments.* An employee's involuntary payment of all or any portion of a debt being collected under 5 U.S.C. 5514 must not be construed as a waiver of any rights which the employee may have under 5 U.S.C. 5514 or any other provision of contract or law, unless there are statutory or contractual provisions to the contrary. Any amounts paid or deducted under this section will be promptly refunded when a debt is waived or otherwise found not owing to the United States (unless expressly prohibited by statute or regulation), or the employee's paying agency is directed by an administrative or judicial order to refund amounts deducted from his or her current pay. Refunds do not bear interest unless required or permitted by law or contract.

§ 267.6 Interest, penalties, and administrative costs.

Except with respect to debts referenced in 31 U.S.C. 3717(g), the Board will charge interest, costs, and a six percent penalty on debts covered by this regulation in accordance with 31 CFR 901.9. The Board will not impose interest charges on the portion of the debt that is paid within 30 days after the date on which interest began to accrue, nor impose penalty charges on the portion of the debt that is paid within 90 days after the date on which penalty began to accrue. The Board will not impose any charges during periods during which collection activity has been suspended pending any review provided for in this part if the reviewing official determines that collection of such charges is against equity and good conscience or is not in the best interest of the United States. The Board may, in its discretion, also waive interest, penalties, and cost charges for good cause shown by the debtor (for example, the debtor is unable to pay any significant portion of the debt within a reasonable period of time, or collection of these charges will jeopardize collection of the principal of the debt) or otherwise as authorized in 31 CFR 901.9(g) and 902.2.

By order of the Board of Governors of the Federal Reserve System, April 11, 2019.

Ann Misback,

Secretary of the Board.

[FR Doc. 2019–07537 Filed 4–15–19; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–491]

Schedules of Controlled Substances: Temporary Placement of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to schedule the synthetic cannabinoids (SC), ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-EDMB-PINACA); methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-MDMB-PICA); *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (trivial names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL)); 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 5F-CUMYL-PINACA; SGT-25); and (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl) methanone (trivial name: FUB-144), and their optical, positional, and geometric isomers, salts, and salts of isomers in

schedule I. This action is based on a finding by the Acting Administrator that the placement of these SCs in schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144.

DATES: This temporary scheduling order is effective April 16, 2019, until April 16, 2021. If this order is extended or made permanent, the DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Lynnette M. Wingert, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling [1] for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

[1] Though DEA has used the term ''final order'' with respect to temporary scheduling orders in the past, this document adheres to the statutory language of 21 U.S.C. 811(h), which refers to a ''temporary scheduling order.'' No substantive change is intended.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.[2] The Acting Administrator transmitted notice of his intent to place 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 in schedule I on a temporary basis to the Assistant Secretary for Health of HHS by letter dated August 24, 2018. The Assistant Secretary responded to this notice by letter dated September 6, 2018, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no active investigational new drug applications or approved new drug applications for 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 in schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 are not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 was published in the **Federal Register** on December 28, 2018. 83 FR 67166.

To find that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Available data and information for 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144, summarized below, indicate that these synthetic cannabinoids (SCs) have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's three-factor analysis and the Assistant Secretary's September 6, 2018 letter are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *www.regulations.gov.*

Synthetic Cannabinoids

The illicit use of SCs continues to cause severe adverse effects, overdoses and deaths in the United States. SCs are substances synthesized in laboratories that mimic the biological effects of delta-9-tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana. SCs were introduced to the designer drug market in several European countries as ''herbal incense'' before the initial encounter in the United States by U.S. Customs and Border Protection (CBP) in November 2008. Since 2009, misuse of SCs has escalated in the United States as evidenced by large numbers of law enforcement encounters of SCs applied onto plant material and in other designer drug products intended for human consumption. Recent hospital reports, scientific publications, and/or law enforcement reports demonstrate that 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, FUB-144 and their associated designer drug products are being abused for their psychoactive properties (*see* DEA 3-Factor Analysis). As with many generations of SCs encountered since 2009, the abuse of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-

[2] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

CUMYL-PINACA and FUB-144 is negatively impacting communities in the United States.

As noted by the DEA and CBP, SCs originate from foreign sources, such as China. Bulk powder substances are smuggled via common carrier into the United States and find their way to clandestine designer drug product manufacturing operations located in residential neighborhoods, garages, warehouses, and other similar destinations throughout the country. According to online discussion boards and law enforcement encounters, spraying or mixing the SCs with plant material provides a vehicle for the most common route of administration—smoking (using a pipe, a water pipe, or rolling the drug-laced plant material in cigarette papers).

5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 have no accepted medical use in the United States. Use of 5F-MDMB-PICA, 5F-EDMB-PINACA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 has been reported to result in adverse effects in humans in the United States (*see* DEA 3-Factor Analysis). In addition, there have been multiple law enforcement seizures of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 in the United States. Use of other SCs has resulted in signs of addiction and withdrawal. Based on the pharmacological similarities between 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 and other SCs, these five SCs are likely to produce signs of addiction and withdrawal similar to those produced by other SCs.

5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 are SCs that have pharmacological effects similar to the schedule I hallucinogen THC, and other temporarily and permanently controlled schedule I SCs. In addition, the misuse of 5F-CUMYL-PINACA, 5F-EDMB-PINACA and FUB-144 has been associated with multiple overdoses requiring emergency medical intervention (*see* DEA 3-Factor Analysis) while deaths have been reported that involved FUB-AKB48. With no approved medical use and limited safety or toxicological information, 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 have emerged in the designer drug market, and the abuse of these substances for their psychoactive properties is concerning.

Factor 4. History and Current Pattern of Abuse

SCs have been developed by researchers over the last 30 years as tools for investigating the endocannabinoid system (*e.g.,* determining CB1 and CB2 receptor activity). The first encounter of SCs intended for illicit use within the United States occurred in November 2008 by CBP. Since then, the popularity of SCs as product adulterants and objects of abuse has increased as evidenced by law enforcement seizures, public health information, and media reports.

Numerous SCs have been identified as product adulterants, and law enforcement has seized bulk amounts of these substances. As successive generations of SCs have been identified and controlled as schedule I substances, illicit distributors have developed new SC substances that vary only by slight modifications to their chemical structure while retaining pharmacological effects related to their abuse potential. These substances, and products laced with these substances, are marketed under the guise of ''herbal incense'' and promoted as a ''legal high'' with a disclaimer that they are ''not for human consumption.'' Thus, after section 1152 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112–144, placed cannabimimetic agents and 26 specific substances (15 of these are SCs) into schedule I, law enforcement documented the emergence of new SCs including UR-144, XLR11, AKB48, PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA. After these substances were temporarily scheduled (78 FR 28735, May 16, 2013; 79 FR 7577, February 10, 2014) other generations of SCs appeared and were temporarily controlled, including AB-CHMINACA, AB-PINACA, THJ-2201 (80 FR 5042, January 30, 2015), MAB-CHMINACA (81 FR 6171, February 5, 2016), 5F-ADB, 5F-AMB, 5F-ABK48, ADB-FUBINACA, MDMB-CHMICA, MDMB-FUBINACA (82 FR 17119, April 10, 2017), FUB-AMB (82 FR 51154, November 3, 2017) NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA (83 FR 31877, July 10, 2018).

FUB-AKB48 was first identified in seized drug evidence in October 2013, followed by FUB-144 (January 2014), 5F-MDMB-PICA (October 2016), 5F-EDMB-PINACA (October 2017) and 5F-CUMYL-PINACA (February 2018). Following their manufacture in China, SCs are often encountered in countries including New Zealand, Australia, and Russia before appearing throughout Europe, and eventually in the United States. 5F-CUMYL-PINACA was first reported in the German and Swiss illicit drug markets in 2015 but didn't show up in the United States until February 2018; 5F-EDMB-PINACA was reported in China in 2016 but didn't appear in the United States until October 2017; and 5F-MDMB-PICA was reported in Germany in August 2016 and November 2016 in Belgium, a few months before showing up in the United States. These data further support that based upon trends, SCs appear in the illicit drug markets of other countries including those in Europe, often before being trafficked in the United States. The misuse of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 has been associated with law enforcement seizures, overdoses requiring emergency medical intervention, or both (*see* DEA 3-Factor Analysis).

The powder form of SCs is typically dissolved in solvents (*e.g.,* acetone) before being applied to plant material, or dissolved in a propellant intended for use in electronic cigarette devices. In addition, 5F-EDMB-PINACA was identified as an adulterant on pieces of paper that were smuggled into a detention facility and later found partially burned (*see* DEA 3—Factor Analysis). Law enforcement personnel have encountered various application methods including buckets or cement mixers in which plant material and one or more SCs are mixed together, or in large areas where the plant material is spread out so that a dissolved SC mixture can be applied directly. Once mixed, the SC plant material is then allowed to dry before manufacturers package the product for distribution, ignoring any control mechanisms to prevent contamination or to ensure a uniform concentration of the substance in each package. Adverse health consequences may also occur from directly ingesting the drug during the manufacturing process. The failure to adhere to any manufacturing standards with regard to amounts, the substance(s) included, purity, or contamination may increase the risk of adverse events. However, it is important to note that adherence to manufacturing standards would not eliminate their potential to produce adverse effects because the toxicity and safety profile of these SCs have not been studied.

5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144, similar to other SCs, have been found in powder form or mixed with dried leaves or herbal blends are marketed under the guise of ''herbal

incense'' and promoted as ''legal high'' with disclaimer that they are ''not for human consumption.'' Presentations at emergency departments directly linked to the abuse of 5F-EDMB-PINACA and FUB-144 have included seizures, agitation, vomiting, tachycardia and elevated blood pressure (*see* DEA 3-Factor Analysis).

Factor 5. Scope, Duration and Significance of Abuse

SCs continue to be encountered in the illicit market despite scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances (*see* DEA 3-Factor Analysis). Novel substances continue to be encountered, differing only by small chemical structural modifications intended to avoid prosecution while maintaining the pharmacological effects. Law enforcement and health care professionals continue to report the abuse of these substances and their associated products.

As described by NIDA, many substances being encountered in the illicit market, specifically SCs, have been available for years but have reentered the marketplace due to a renewed popularity. The threat of serious injury to the individual and the imminent threat to public safety following the ingestion of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 and other SCs persist.

Full reports of information obtained through STARLiMS,[3] STRIDE,[4] and NFLIS [5] for the past five years may be found in the DEA 3-Factor Analysis. According to NFLIS, STARLiMS and STRIDE data, forensic laboratories have detected the following information about the SCs in question:

- 5F-EDMB-PINACA was identified in 366 different NFLIS reports from eight states, since 2017 [6] and 22 STRIDE/STARLiMS reports from two states, since 2017.
- 5F-MDMB-PICA was identified in 381 NFLIS reports from 22 states, since 2016 and 32 STRIDE/STARLiMS reports from seven states and the District of Columbia, since 2017.
- FUB-AKB48 was identified in 362 NFLIS reports from 21 states, since 2014 and 37 STRIDE/STARLiMS reports from eight states, since 2014.
- 5F-CUMYL-PINACA was identified in 54 NFLIS reports from three states, since 2018.
- FUB-144 was identified in 403 NFLIS reports from 27 states, since 2014 and 79 STARLiMS reports from 14 states plus Washington, DC, since 2014.

Factor 6. What, if Any, Risk There Is to the Public Health

Since first being identified in the United States in 2008, the ingestion of SCs continues to result in serious adverse effects. Details of these events involving 5F-CUMYL-PINACA, 5F-EDMB-PINACA, FUB-144, FUB-AKB48 and 5F-MDMB-PICA are summarized below.

1. In 2015, in London (United Kingdom), a 34-year-old male was hospitalized after ingesting a synthetic cannabinoid product. Toxicological analysis identified 5F-AKB48 and 5F-CUMYL-PINACA in biological samples.

2. In late November and early December 2015, in Jackson, Mississippi, five individuals presented at local emergency facilities following ingestion of a synthetic cannabinoid-containing product. Evidence collected from the individuals tested positive for THC, MAB-CHMINACA and FUB-144. Toxicological analysis of biological samples in all five patients identified THC, MAB-CHMINACA, and FUB-144.

3. In March 2017, in Chaves, New Mexico, a 14-year-old female was found in the bathroom of her home with seizure-like activity. Following transport to a local hospital by family members, she was pronounced dead approximately 20 minutes later. Toxicological analysis upon autopsy identified three SCs: FUB-AKB48, AB-CHMINACA, and ADB-CHMINACA (MAB-CHMINACA). The cause of death was determined to be toxic effects of synthetic cannabinoids (FUB-AKB48, AB-CHMINACA, and ADB-CHMINACA).

4. In January 2018, in Pittsburgh, Pennsylvania, 13 correctional facility workers were treated for overdose symptoms including diaphoresis, hypertension and tachycardia following ingestion of an airborne substance while conducting cell searches for contraband. In response to the overdose events, evidence retrieved from the searches tested positive for the synthetic cannabinoids 5F-ADB, 5F-EDMB-PINACA, and 4-CN-CUMYL-BUTINACA.

5. In March 2018, in Chicago, Illinois, a 22-year-old male expired at a local hospital. Toxicological analysis confirmed buprenorphine, brodifacoum, bromadiolone, FUB-AMB and FUB-AKB48 in biological samples of this decedent.

6. In April 2018, in Harrisburg, Pennsylvania, a 38-year-old male presented at a local hospital due to repeated nosebleeds, gastrointestinal bleeding with anemia and bruising on his arms. Toxicological analysis confirmed brodifacoum, FUB-AMB, and FUB-AKB48 in biological samples.

7. In April 2018, in Harrisburg, Pennsylvania, another patient presented at a local hospital due to significant bleeding and anemia requiring a transfusion. Toxicological analysis confirmed brodifacoum, FUB-AMB, and FUB-AKB48 in biological samples.

8. In June 2018, in Chicago, Illinois, a 25-year-old male expired at a local hospital. Toxicological analysis confirmed brodifacoum, bromadiolone, FUB-AMB and FUB-AKB48 in biological samples of this decedent.

9. In July 2018, in Washington, DC, in excess of 260 overdoses and four deaths were reported following use of a synthetic cannabinoid product. Analysis of drug evidence from the overdose event confirmed the presence of the synthetic cannabinoids FUB-AMB, EMB-FUBINACA and FUB-144.

10. In August 2018, in New Haven, Connecticut, in excess of 47 overdoses were reported following the use of a synthetic cannabinoid product. Analysis of drug evidence from the overdose event confirmed the presence of the synthetic cannabinoids 5F-ADB, FUB-AMB and 5F-MDMB-PICA.

11. In September 2018, law enforcement in Georgia seized multiple electronic cigarettes with various colored viscous liquids following the reports of overdoses. Laboratory analysis on the seized evidence determined the substance to be 5F-CUMYL-PINACA.

12. From September 10 to 16, 2018, in Washington, DC, at least 244 overdoses were reported following use of a synthetic cannabinoid product. Analysis of drug evidence from the overdose event confirmed the presence of the synthetic cannabinoids FUB-AMB and 5F-MDMB-PICA.

Because they share pharmacological similarities with schedule I substances (Δ^9-THC, JWH-018 and other temporarily and permanently controlled schedule I SCs), 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-

[3] STARLiMS is a laboratory information management system that systematically collects results from drug chemistry analyses conducted by DEA laboratories. On October 1, 2014, STARLiMS replaced System to Retrieve Information from Drug Evidence (STRIDE) as the DEA laboratory drug evidence data system of record.

[4] STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from the DEA, other federal agencies, and some local law enforcement agencies.

[5] The National Forensic Laboratory Information System (NFLIS) is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories in the United States.

[6] At the time of query, 2018 data were still reporting.

PINACA, and FUB-144 pose serious risks to an abuser. Tolerance to SCs may develop fairly rapidly with larger doses being required to achieve the desired effect. Acute and chronic abuse of SCs in general have been linked to adverse health effects including signs of addiction and withdrawal, numerous reports of emergency department admissions, and overall toxicity and deaths. Psychiatric case reports have been reported in the scientific literature detailing the SC abuse and associated psychoses. As abusers obtain these drugs through unknown sources, the identity and purity of these substances is uncertain and inconsistent, thus posing significant adverse health risks to users.

5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 are being encountered on the illicit drug market and have no accepted medical use in the United States. Regardless, these products continue to be easily available and abused by diverse populations.

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the continued uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 indicate that these SCs have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Acting Administrator, through a letter dated August 24, 2018, notified the Assistant Secretary of the DEA's intention to temporarily place 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 in schedule I. A notice of intent was subsequently published in the **Federal Register** on December 28, 2018. 83 FR 67166.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Acting Administrator considered available data and information, and herein sets forth the grounds for his determination that it is necessary to temporarily schedule ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-EDMB-PINACA); methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-MDMB-PICA); *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (trivial names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL)); 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 5F-CUMYL-PINACA; SGT-25); and (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (trivial name: FUB-144) in schedule I of the CSA to avoid an imminent hazard to the public safety.

Because the Acting Administrator hereby finds it necessary to temporarily place 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 in schedule I to avoid an imminent hazard to the public safety, this temporary order scheduling these substances is effective on the date of publication in the **Federal Register**, and is in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Permanent scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The permanent scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the permanent scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this temporary order, 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312, as of April 16, 2019. Any person who currently handles 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144, and is not registered with the DEA, must submit an application for registration and may not continue to handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 as of April 16, 2019, unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA on or after April 16, 2019 is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 must surrender all currently held quantities of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144.

3. *Security.* 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in

accordance with 21 CFR 1301.71–1301.93, as of April 16, 2019.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from April 16, 2019, to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 on the effective date of this order must take an inventory of all stocks of these substances on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, 1317 and § 1307.11. Current DEA registrants authorized to handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants who manufacture or distribute 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304 and 1312 as of April 16, 2019.

8. *Order Forms.* All DEA registrants who distribute 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of April 16, 2019.

9. *Importation and Exportation.* All importation and exportation of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of April 16, 2019.

10. *Quota.* Only DEA registered manufacturers may manufacture 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of April 16, 2019.

11. *Liability.* Any activity involving 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144 not authorized by, or in violation of the CSA, occurring as of April 16, 2019, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order (as distinct from a rule) and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, which are applicable to rulemaking, do not apply to this temporary scheduling order. The specific language chosen by Congress indicates an intention for the DEA to proceed through the issuance of an order instead of proceeding by rulemaking. Given that Congress specifically requires the Attorney General to follow rulemaking procedures for *other* kinds of scheduling actions, see section 201(a) of the CSA, 21 U.S.C. 811(a), it is noteworthy that, in section 201(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

In the alternative, even assuming that this action might be subject to 5 U.S.C. 553, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Further, the DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the CRA, ''any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines.'' 5 U.S.C. 808(2). It is in the public interest to schedule these substances immediately to avoid an imminent hazard to the public safety. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA's need to move quickly to place these substances in schedule I because they pose an imminent hazard to the public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order shall take effect immediately

upon its publication. The DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraphs (h)(37) through (41) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(37) ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (trivial name: 5F-EDMB-PINACA) 7036
(38) methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (trivial name: 5F-MDMB-PICA) 7041
(39) *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers (trivial names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL)) 7047
(40) 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers (trivial names: 5F-CUMYL-PINACA; SGT-25) 7083
(41) (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl) methanone, its optical, positional, and geometric isomers, salts and salts of isomers (trivial name: FUB-144) 7014

Dated: April 5, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–07460 Filed 4–15–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0955]

RIN 1625–AA09

Drawbridge Operation Regulations; Belle River, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: The Coast Guard is issuing a temporary deviation to the operating schedule that regulates the State Route 70 (SR 70), pontoon bridge across the Belle River mile 23.8, near Pierre Part, Assumption Parish, Louisiana. This temporary deviation is needed to collect and analyze information on vehicle traffic congestion on SR 70 created when the drawbridge opens to vessel traffic and the impact to the reasonable needs of navigation when the bridge closes to vessels during periods of high vehicle traffic. During this temporary deviation the drawbridge will remain closed to navigation.

DATES: This deviation is effective from 6 a.m. on May 17, 2019 to 6 a.m. on August 30, 2019. Comments and related material must be received by the Coast Guard on or before September 23, 2019.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0955 using Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Mr. Doug Blakemore, Eighth Coast Guard District Bridge Administrator; telephone (504) 671–2128, email *Douglas.A.Blakemore@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
LA DOTD Louisiana Department of Transportation and Development
SR State Route
§ Section
U.S.C. United States Code

II. Background, Purpose and Legal Basis

LA DOTD has requested to change the operating requirements for the SR 70 pontoon bridge across the Belle River mile 23.8, near Pierre Part, Assumption Parish, Louisiana. This bridge currently opens on signal, except that from 10 p.m. to 6 a.m. the draw shall open on signal if at least four hour notice is given according to 33 CFR 117.424.

LA DOTD requested changing this bridge operating schedule because vehicle traffic has become congested during June, July, and August. This waterway is heavily used by recreational vessels during the summer months.

LA DOTD conducted a field study that showed that about 80 cars were delayed approximately 15 minutes each time the bridge opened to vessel traffic and that the bridge sometimes opened as many as 4 times per hour. To alleviate this congestion LA DOTD has requested to open the bridge to vessel traffic on the hour from 6 a.m. to 10 p.m. each day.

This 105-day temporary deviation to the regulations will allow LA DOTD to collect additional vehicle traffic data to measure the impact of bridge closures on traffic congestion. It will also allow the Coast Guard to collect data on the impact of the proposed regulation change on vessels.

This bridge has a vertical clearance of zero feet in the closed to vessel traffic position and unlimited vertical clearance in the open to vessel traffic position. In June, July, and August 2017 the bridge opened for vessels 374 times. During this temporary deviation the bridge will operate as follows:

From 6 a.m. on June 1, 2019 through 6 p.m. on August 31, 2019 the draw of the SR 70 pontoon bridge across the Belle River mile 23.8, near Pierre Part, Assumption Parish, Louisiana shall open on signal on the hour from 6 a.m. to 10 p.m.; and that from 10 p.m. to 6 a.m. the draw shall open on signal if at least four hour notice is given. The bridge will open on signal for emergencies.

The Coast Guard will inform the users of this waterway through Local and Broadcast Notice to Mariners of the

change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

III. Public Participation and Request for Comments

Public participation is essential to effective rulemaking. The Coast Guard will consider all comments and material received during the comment period. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

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.

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).

Documents mentioned in this temporary rule change, 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 or a final rule is published.

Dated: April 10, 2019.

Douglas A. Blakemore,

Bridge Administrator, Eighth Coast Guard District.

[FR Doc. 2019–07519 Filed 4–15–19; 8:45 am]

BILLING CODE 9110–04–P

COMMISSION OF FINE ARTS

45 CFR Part 2105

Freedom of Information Act Regulations

AGENCY: Commission of Fine Arts.

ACTION: Interim final rule; request for comments.

SUMMARY: This rule replaces the Commission of Fine Arts (CFA) Freedom of Information Act (FOIA) regulations, last updated in 1986, with regulations that incorporate FOIA-related mandates since the last update, including the FOIA Improvement Act of 2016

DATES: This rule is effective June 1, 2019. Comments are due by May 20, 2019.

ADDRESSES: Please address comments concerning this interim rule to *foia@cfa.gov.*

FOR FURTHER INFORMATION CONTACT: Thomas Luebke, Secretary, (202) 504–2200.

SUPPLEMENTARY INFORMATION: As established by Congress in 1910, the Commission of Fine Arts (CFA) is a small independent advisory body made up of seven presidentially appointed ''well qualified judges of the arts'' whose primary role is architectural review of designs for buildings, parks, monuments and memorials erected by the Federal or District of Columbia governments in Washington, DC. In addition to architectural review, the Commission considers and advises on the designs for coins, medals, and U.S. memorials on foreign soil. The Commission also advises the District of Columbia government on private building projects within the Georgetown Historic District, the Rock Creek Park perimeter, and the Monumental Core area. The Commission advises Congress, the President, Federal agencies, and the District of Columbia government on the general subjects of design, historic preservation, and on orderly planning on matters within its jurisdiction.

The Commission of Fine Arts routinely and promptly responds to requests from concerned citizens and interested parties to review a wide variety of agency documents. To this end, the staff regularly posts agendas for upcoming meetings and draft documents relevant to those meetings to the agency website (*https://www.cfa.gov/*). Agendas, meeting minutes, recommendation letters, and actions taken under the Shipstead-Luce and Old Georgetown Acts are posted on the website in a timely manner. In that same spirit of openness and transparency, the CFA strives to organize and fulfill Freedom of Information Act (FOIA) requests efficiently and expediently, within the perimeters of current legislation. Therefore, the CFA revises regulations to replace those published in 1986 and invites public commentary.

List of Subjects 45 CFR Part 2105

Administrative practice and procedure, Freedom of information.

■ For reasons stated in the preamble, the Commission of Fine Arts revises 45 CFR part 2105 to read as follows:

PART 2105—REQUIREMENTS FOR COMPLIANCE WITH THE FREEDOM OF INFORMATION ACT

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Authority: 5 U.S.C. 552, as amended by Public Law 110–175, 121 Stat. 2524 and Pub. L. 114–185, 130 Stat. 538.

Subpart A—Introduction

§ 2105.1 What should you know up front?

(a) This part contains the rules that the Agency follows in processing records under the Freedom of Information Act (FOIA), 5 U.S.C. 552.

(b) Definitions of terms used in this part are found at § 2105.68.

(c) This part should be read in conjunction with the text of the FOIA and the OMB Fee Guidelines.

(d) This part does not entitle any person to any service or to the disclosure of any record that is not required under the FOIA.

§ 2105.2 What kinds of records are not covered by the regulations in this part?

This part does not apply to records that fall under the law enforcement exclusions in 5 U.S.C. 552(c)(1)–(3). These exclusions may be used only in the limited circumstances delineated by the statute and require both prior approval from legal counsel and the recording of their use and approval process.

Subpart B—How To Make a Request

§ 2105.3 Where should you send a FOIA request?

(a) To make a request for Agency records, you must contact the Agency directly.

(b) Address requests to the FOIA Officer found in the Agency contacts at *https://www.cfa.gov/foia.*

§ 2105.4 How should you describe the records you seek?

(a) You must reasonably describe the records sought. A reasonable description contains sufficient detail to enable Agency personnel familiar with the subject matter of the request to locate the records with a reasonable amount of effort.

(b) You should include as much detail as possible about the specific records or types of records that you are seeking. This will assist the Agency in identifying the requested records (for example, time frames involved or specific personnel who may have the requested records). For example, whenever possible, identify:

(1) The date, title or name, author, recipient, and subject of any particular records you seek;

(2) The office that created the records you seek;

(3) The timeframe for which you are seeking records; and

(4) Any other information that will assist the Agency in locating the records.

(c) The Agency's FOIA Officer or Public Liaison can assist you in formulating or reformulating a request in an effort to better identify the records you seek.

(d) If the Agency determines that your request does not reasonably describe the records sought, the Agency will inform you what additional information you need to provide in order to reasonably describe the records that you seek so the requested records can be located with a reasonable amount of effort. The Agency will also notify you that it will not be able to comply with your request unless the additional information it has requested is received from you in writing within 20 workdays after the Agency has requested it and that you may appeal its determination. If you receive this type of notification, you may wish to discuss it with the Agency's designated FOIA contact or the FOIA Public Liaison (see § 2105.64). If the Agency does not receive your written response containing the additional information within 20 workdays after the Agency has requested it, the Agency will presume that you are no longer interested in the records and will close the file on the request.

§ 2105.5 How will fee information affect the processing of your request?

(a) Your request must explicitly state that you will pay all fees associated with processing the request, that you will pay fees up to a specified amount, and/or that you are seeking a fee waiver.

(b) If the Agency anticipates that the fees for processing the request will exceed the amount you have agreed to pay, or if you did not agree in writing to pay processing fees or request a fee waiver and the Agency anticipates the processing costs will exceed $50 (see § 2105.35(g)) or will exceed your entitlements (see § 2105.37), the Agency will notify you:

(1) Of the estimated processing fees;

(2) Of its need for either an advance payment (see § 2105.48) or your written assurance that you will pay the anticipated fees (or fees up to a specified amount); and

(3) That it will not be able to fully comply with your request unless you provide a fee waiver request and/or the requested written assurance or advance payment.

(c) If the Agency does not receive a written response from you within 20 workdays after requesting the information in paragraph (b) of this section, it will presume that you are no longer interested in the records and will close the file on the request.

(d) If you are seeking a fee waiver, your request must include a justification that addresses and meets the criteria in §§ 2105.43 and 2105.46. Failure to provide sufficient justification will result in a denial of the fee waiver request. If you are seeking a fee waiver, you may also indicate the amount you are willing to pay if the fee waiver is denied. This allows the Agency to process the request for records while it considers your fee waiver request. You may also inform the Agency of why you believe your request meets one or more of the criteria for a discretionary fee waiver under § 2105.54.

(e) The Agency will begin processing your request only after all issues regarding fees are resolved.

(f) If you are required to pay a fee and it is later determined on appeal that you were entitled to a full or partial fee waiver, you will receive an appropriate refund.

§ 2105.6 What information should you include about your fee category?

(a) A request should indicate your fee category (that is, whether you are a commercial-use requester, news media, educational or noncommercial scientific institution, or other requester as described in §§ 2105.36 and 2105.37).

(b) If you submit a FOIA request on behalf of another person or organization (for example, if you are an attorney submitting a request on behalf of a client), the Agency will determine the fee category by considering the underlying requester's identity and intended use of the information.

(c) If your fee category is unclear, the Agency may ask you for additional information (see § 2105.49).

§ 2105.7 Can you ask for records to be disclosed in a particular form or format?

(a) Generally, you may choose the form or format of disclosure for records requested. The Agency must provide the records in the requested form or format if the Agency can readily reproduce the record in that form or format. If the Agency cannot readily reproduce the record in that form or format, it must explain why it cannot.

(b) The Agency may charge you the direct costs involved in converting records to the requested format if the Agency does not normally maintain the records in that format (see § 2105.42).

§ 2105.8 What if your request seeks records about another person?

(a) When a request seeks records about another person, you may receive greater access by submitting proof that the person either:

(1) Consents to the release of the records to you (for example, a notarized authorization signed by that person); or

(2) Is deceased (for example, a copy of a death certificate or an obituary).

(b) The Agency can require you to supply additional information if necessary to verify that a particular person has consented to disclosure or is deceased.

§ 2105.9 May you ask for the processing of your request to be expedited?

You may ask for the processing of your request to be expedited. If you are seeking expedited processing, your request must include a justification that addresses and meets the criteria in § 2105.18 and includes the certification required at § 2105.18(b)(2). Failure to provide sufficient justification or the required certification will result in a denial of the expedited processing request.

§ 2105.10 What contact information should your request include?

A request should include your name and a way (such as a mailing or email address) for the Agency to send responsive records to you and/or to request additional information or clarification of your request. You may also wish to include a daytime telephone number (or the name and telephone number of an appropriate contact).

Subpart C—Processing Requests

§ 2105.11 What should you know about how the Agency processes requests?

(a) Except as described in § 2105.12, the Agency is responsible for responding to the request and for making a reasonable effort to search for responsive records.

(b) In determining which records are responsive to a request, the Agency will include only records in its possession and control on the date that it begins its search.

(c) The Agency will make reasonable efforts to search for the requested records. As part of its reasonable efforts, the Agency will search paper and/or electronic records (for example, emails), as appropriate. The Agency will not search for records in an electronic form or format if these efforts would significantly interfere with the operation of the Agency's automated information system.

(d) If the Agency receives a request for records in its possession that it did not create or that another Federal agency is substantially concerned with, it may undertake consultations and/or referrals as described in § 2105.12.

§ 2105.12 How do consultations and referrals work?

(a) Consultations and referrals generally occur outside the Agency.

(1) Paragraphs (b) through (e) of this section address consultations and referrals that occur outside the Agency when the Agency has responsive records.

(2) Paragraph (f) of this section addresses what happens when the Agency has no responsive records but believes responsive records may be in the possession of a Federal agency outside the Agency.

(b) If, while responding to a request, the Agency locates records that originated with another Federal agency, it usually will refer the request and any responsive records to that other agency for a release determination and direct response.

(c) If the Agency refers records to another agency, it will document the referral and maintain a copy of the records that it refers and notify you of the referral in writing, unless the notification will itself disclose a sensitive, exempt fact. When the Agency notifies you of the referral, it will tell you whether the referral was for part or all of your request and provide the name and contact information for the other agency. You may treat such a response as a denial of records and file an appeal, in accordance with the procedures in § 2105.57.

(d) If the Agency locates records that originated with another Federal agency while responding to a request, the Agency will make the release determination itself (after consulting with the originating agency) when:

(1) The record is of primary interest to the Agency (for example, a record may be of primary interest to the Agency if it was developed or prepared according to the Agency's regulations or directives, or in response to an Agency request);

(2) The Agency is in a better position than the originating agency to assess whether the record is exempt from disclosure;

(3) The originating agency is not subject to the FOIA; or

(4) It is more efficient or practical depending on the circumstances.

(e) If the Agency receives a request for records that another Federal agency has classified under any applicable Executive order concerning record classification, it must refer the request to that agency for response.

(f) If the Agency receives a request for records not in its possession, but that the Agency believes may be in the possession of a Federal agency outside the Agency, the Agency will return the request to you, may advise you to submit it directly to the other agency, will notify you that the Agency cannot comply with the request, and will close the request. If you believe this response was in error, you may file an appeal in accordance with the procedures in § 2105.57.

Subpart D—Timing of Responses to Requests

§ 2105.13 In what order are responses usually made?

The Agency ordinarily will respond to requests according to their order of receipt within their processing track.

§ 2105.14 What is multitrack processing and how does it affect your request?

(a) Processing tracks are used to distinguish simple requests from more complex ones on the basis of the estimated number of workdays needed to process the request.

(b) In determining the number of workdays needed to process the request, the Agency considers factors such as the number of pages involved in processing the request or the need for consultations.

(c) The basic processing tracks are designated as follows:

(1) *Simple:* Requests in this track will take between one to five workdays to process;

(2) *Normal:* Requests in this track will take between six to twenty workdays to process;

(3) *Complex:* Requests in this track will take between twenty-one workdays and sixty workdays to process; or

(4) *Exceptional/Voluminous:* Requests in this track involve very complex processing challenges, which may include a large number of potentially responsive records, and will take over sixty workdays to process.

(d) The Agency also has a specific processing track for requests that are granted expedited processing under the standards in § 2105.18. These requests will be processed as soon as practicable.

(e) The Agency must advise you of the track into which your request falls and, when appropriate, will offer you an opportunity to narrow your request so that it can be placed in a different processing track. If you request placement in a particular processing track but the Agency places you in a different processing track, the Agency will provide you with an explanation of why you were not placed in the processing track you requested.

(f) The use of multitrack processing does not alter the statutory deadline for an Agency to determine whether to comply with your FOIA request (see § 2105.15).

(g) You may inquire about the status of your request, including its estimated processing completion date, by contacting the FOIA Public Liaison, whose contact information may be found at *https://www.cfa.gov/foia.*

§ 2105.15 What is the basic time limit for responding to a request?

(a) Ordinarily, the Agency has 20 workdays (including the date of receipt) to determine whether to comply with a request, but unusual circumstances may allow the Agency to take longer than 20 workdays (see § 2105.17).

(b) A consultation or referral under § 2105.12 does not restart the statutory time limit for responding to a request.

§ 2105.16 When can the Agency suspend the basic time limit?

(a) The basic time limit in § 2105.15 may be temporarily suspended for the time it takes you to respond to one written communication from the Agency reasonably asking for clarifying information.

(b) The basic time limit in § 2105.15 may also repeatedly be temporarily suspended for the time it takes you to respond to written communications from the Agency that are necessary to clarify issues regarding fee assessment (see § 2105.49).

§ 2105.17 When may the Agency extend the basic time limit?

(a) The Agency may extend the basic time limit, if unusual circumstances exist, by notifying you in writing of:

(1) The unusual circumstances involved; and

(2) The date by which it expects to complete processing the request.

(b) If the processing time will extend beyond a total of 30 workdays, the Agency will:

(1) Give you an opportunity to limit the scope of the request or agree to an alternative time period for processing; and

(2) Make available its FOIA Public Liaison (see § 2105.64) to assist in resolving any disputes between you and the Agency, and notify you of your right to seek dispute resolution from the Office of Government Information Services (OGIS).

(c) If the Agency extends the time limit under this section and you do not receive a response in accordance with § 2105.15(a) in that time period, you may consider the request denied and file an appeal in accordance with the procedures in § 2105.57.

(d) Your refusal to reasonably modify the scope of a request or arrange an alternative time frame for processing a request after being given the opportunity to do so may be considered for litigation purposes as a factor when determining whether exceptional circumstances exist.

§ 2105.18 When will expedited processing be provided and how will it affect your request?

(a) The Agency will provide expedited processing upon request if you demonstrate to the satisfaction of the Agency that there is a compelling need for the records. The following circumstances demonstrate a compelling need:

(1) Where failure to expedite the request could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(2) Where there is an urgency to inform the public about an actual or alleged Federal Government activity and the request is made by a person primarily engaged in disseminating information.

(i) In most situations, a person primarily engaged in disseminating information will be a representative of the news media.

(ii) If you are not a full time member of the news media, to qualify for expedited processing here, you must establish that your main professional activity or occupation is information dissemination, although it need not be your sole occupation.

(iii) The requested information must be the type of information which has particular value that will be lost if not disseminated quickly; this ordinarily refers to a breaking news story of general public interest.

(iv) Information of historical interest only or information sought for litigation

or commercial activities would not qualify, nor would a news media deadline unrelated to breaking news.

(b) If you seek expedited processing, you must submit a statement that:

(1) Explains in detail how your request meets one or both of the criteria in paragraph (a) of this section; and

(2) Certifies that your explanation is true and correct to the best of your knowledge and belief.

(c) You may ask for expedited processing of your request by writing to the appropriate FOIA contact in the Agency that maintains the records requested any time before the Agency issues its final response to your request. When making a request for expedited processing of an administrative appeal, submit the request to the appropriate deciding official for FOIA appeals.

(d) The Agency must notify you of its decision to grant or deny expedited processing within 10 calendar days of receiving an expedited processing request.

(e) If expedited processing is granted, the request will be given priority, placed in the processing track for expedited requests, and be processed as soon as practicable.

(f) If expedited processing is denied, the Agency will:

(1) Inform you of the basis for the denial, including an explanation of why the expedited processing request does not meet the Agency's expedited processing criteria under this section; and

(2) Notify you of the right to appeal the decision on expedited processing in accordance with the procedures in subpart H of this part.

(g) If you appeal the Agency's expedited processing decision, that portion of your appeal (if it is properly formatted under § 2105.57) will be processed before appeals that do not challenge expedited processing decisions.

(h) If the Agency has not responded to the request for expedited processing within 10 calendar days, you may file an appeal (for nonresponse in accordance with § 2105.55(a)(8)).

Subpart E—Responses to Requests

§ 2105.19 How will the Agency respond to requests?

(a) When the Agency informs you of its decision to comply with a request by granting, partially granting, or denying the request, it will do so in writing and in accordance with the deadlines in subpart D of this part. The Agency's written response will include a statement about the services offered by its FOIA Public Liaison. The Agency's written response will also include a statement about the services offered by the Office of Government Information Services (OGIS).

(b) If the Agency determines that your request will take longer than 10 workdays to process, the Agency immediately will send you a written acknowledgment that includes the request's individualized tracking number and processing track (see § 2105.14(e)). The acknowledgement may also include a brief description of the subject of your request.

§ 2105.20 How will the Agency grant requests?

(a) Once the Agency makes a determination to grant a request in full or in part, it must notify you in writing.

(b) The notification will inform you of any fees charged under subpart G of this part.

(c) The Agency will release records (or portions of records) to you promptly upon payment of any applicable fees (or before then, at its discretion).

(d) If the records (or portions of records) are not included with the Agency's notification, the Agency will advise you how, when, and where the records will be released or made available.

§ 2105.21 When will the Agency deny a request or procedural benefits?

(a) The Agency denies a request when it makes a decision that:

(1) A requested record is exempt, in full or in part;

(2) The request does not reasonably describe the records sought;

(3) A requested record does not exist, cannot be located, or is not in the Agency's possession and/or control; or

(4) A requested record is not readily reproducible in the form or format you seek.

(b) The Agency denies a procedural benefit only, and not access to the underlying records, when it makes a decision that:

(1) A fee waiver, or another fee-related issue, will not be granted; or

(2) Expedited processing will not be provided.

(c) The Agency must consult with legal counsel before it denies a fee waiver request or withholds all or part of a requested record.

§ 2105.22 How will the Agency deny requests?

(a)The Agency must notify you in writing of any denial of your request.

(b) The denial notification must include:

(1) The name and title or position of the person responsible for the denial, along with an office phone number or email address;

(2) A statement of the reasons for the denial;

(3) A reference to any FOIA exemption applied by the Agency to withhold records in full or in part, along with a statement that the Agency reasonably foresees that disclosure would harm an interest protected by the applied exemption(s) or disclosure is prohibited by law;

(4) An estimate of the volume of any records withheld in full or in part (for example, by providing the number of pages or some other reasonable form of estimation), unless including an estimate would harm an interest protected by an exemption used to withhold the records and the Agency explains this harm to you;

(5) The name and title of legal counsel consulted (if the Agency is denying a fee waiver request or withholding all or part of a requested record); and

(6) A statement that the denial may be appealed under subpart H of this part and a description of the procedures in subpart H of this part.

§ 2105.23 What if the requested records contain both exempt and nonexempt material?

If responsive records contain both exempt and nonexempt material, the Agency will consult with legal counsel, as discussed in § 2105.21(c). After consultation, the Agency will partially grant and partially deny the request by:

(a) Segregating and releasing the nonexempt information, unless the nonexempt material is so intertwined with the exempt material that disclosure of it would leave only meaningless words and phrases;

(b) Indicating on the released portion of the record the amount of information deleted and the FOIA exemption under which the deletion was made, unless doing so would harm an interest protected by the FOIA exemption used to withhold the information; and

(c) If technically feasible, indicating the amount of information deleted and the FOIA exemption under which the deletion was made at the place in the record where the deletion was made.

Subpart F—Handling Confidential Information

§ 2105.24 May submitters of possibly confidential information designate information as confidential when making submissions?

(a) The Agency encourages, but does not require, submitters to designate confidential information in good faith (in other words, to identify specific information as information the

submitter considers protected from disclosure under Exemption 4 of the FOIA, found at 5 U.S.C. 552(b)(4)), at the time of submission or reasonably soon thereafter.

(b) The designations discussed in paragraph (a) of this section assist the Agency in identifying what information obtained from the submitter is possibly confidential and triggers the requirement for Agency-provided notifications under § 2105.25(a)(1).

§ 2105.25 When will the Agency notify a submitter of a request for their possibly confidential information?

(a) Except as outlined in § 2105.27, an Agency must promptly notify a submitter in writing when it receives a FOIA request if:

(1) The requested information has been designated by the submitter as confidential information under § 2105.24(a); or

(2) The requested information has not been designated as confidential information by the submitter under § 2105.24(a), but the Agency identifies it as possibly confidential information.

(b) If a voluminous number of submitters are involved, the Agency may publish a notice in a manner reasonably calculated to reach the attention of the submitters (for example, in newspapers or newsletters, the Agency's website, or the **Federal Register**) instead of providing a written notice to each submitter.

§ 2105.26 What information will the Agency include when it notifies a submitter of a request for their possibly confidential information?

A notice to a submitter must include:

(a) Either a copy of the request, the exact language of the request, or (for notices published under § 2105.25(b)) a general description of the request;

(b) Either a description of the possibly confidential information located in response to the request or a copy of the responsive records, or portions of records, containing the information;

(c) A description of the procedures for objecting to the release of the possibly confidential information under §§ 2105.28 and 2105.29;

(d) A time limit for responding to the Agency—no less than 10 workdays from receipt or publication of the notice (as set forth in § 2105.25(b))—to object to the release and to explain the basis for the objection;

(e) Notice that information contained in the submitter's objections may itself be subject to disclosure under the FOIA;

(f) Notice that the Agency, not the submitter, is responsible for deciding whether the information will be released or withheld;

(g) A request for the submitter's views on whether they still consider the information to be confidential if the submitter designated the material as confidential commercial or financial information 10 or more years before the request; and

(h) Notice that failing to respond within the time frame specified under paragraph (d) of this section will create a presumption that the submitter has no objection to the disclosure of the information in question.

(i) Except as outlined in § 2105.27, an Agency must promptly notify a submitter in writing when it receives a FOIA request if:

(1) The requested information has been designated by the submitter as confidential information under § 2105.24(a); or

(2) The requested information has not been designated as confidential information by the submitter under § 2105.24(a), but the Agency identifies it as possibly confidential information.

§ 2105.27 When will the Agency not notify a submitter of a request for their possibly confidential information?

The notice requirements of § 2105.26 will not apply if:

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

(b) Disclosure of the information is required by a statute other than the FOIA or by a regulation (other than this part) issued in accordance with the requirements of Executive Order 12600.

§ 2105.28 How and when may a submitter object to the disclosure of confidential information?

(a) If a submitter has any objections to the disclosure of confidential information, the submitter should provide a detailed written statement to the Agency that specifies all grounds for withholding the particular information under any FOIA exemption (see § 2105.29 for further discussion of Exemption 4 objection statements).

(b) A submitter who does not respond within the time period specified under § 2105.26(d) will be considered to have no objection to disclosure of the information. Responses received by the Agency after this time period will not be considered by the Agency unless the appropriate Agency FOIA contact determines, in his or her sole discretion, that good cause exists to accept the late response.

§ 2105.29 What must a submitter include in a detailed Exemption 4 objection statement?

(a) To rely on Exemption 4 as basis for nondisclosure, the submitter must explain why the information is confidential information. To do this, the submitter must give the Agency a detailed written statement. This statement must include a specific and detailed discussion of why the information is a trade secret or, if the information is not a trade secret, the following three categories must be addressed (unless the Agency informs the submitter that a response to one of the first two categories will not be necessary):

(1) Whether the submitter provided the information voluntarily and, if so, how disclosure will impair the Government's ability to obtain similar information in the future and/or how the information fits into a category of information that the submitter does not customarily release to the public;

(2) Whether the Government required the information to be submitted, and if so, how disclosure will impair the Government's ability to obtain similar information in the future and/or how substantial competitive or other business harm would likely result from disclosure; and

(3) A certification that the information is confidential, has not been disclosed to the public by the submitter, and is not routinely available to the public from other sources.

(b) If not already provided, the submitter must include a daytime telephone number, an email and mailing address, and a fax number (if available).

§ 2105.30 How will the Agency consider the submitter's objections?

(a) The Agency must carefully consider a submitter's objections and specific grounds for nondisclosure in deciding whether to disclose the requested information.

(b) The Agency, not the submitter, is responsible for deciding whether the information will be released or withheld.

§ 2105.31 What if the Agency determines it will disclose information over the submitter's objections?

If the Agency decides to disclose information over the objection of a submitter, the Agency must notify the submitter by certified mail or other traceable mail, return receipt requested. The notification must be sent to the submitter's last known address and must include:

(a) The specific reasons why the Agency determined that the submitter's disclosure objections do not support withholding the information;

(b) Copies of the records or information the Agency intends to release; and

(c) Notice that the Agency intends to release the records or information no less than 10 workdays after receipt of the notice by the submitter.

§ 2105.32 Will a submitter be notified of a FOIA lawsuit?

If you file a lawsuit seeking to compel the disclosure of confidential information, the Agency must promptly notify the submitter.

§ 2105.33 Will you receive notification of activities involving the submitter?

If any of the following occur, the Agency will notify you:

(a) The Agency provides the submitter with notice and an opportunity to object to disclosure;

(b) The Agency notifies the submitter of its intent to disclose the requested information; or

(c) A submitter files a lawsuit to prevent the disclosure of the information.

§ 2105.34 Can an Agency release information protected by Exemption 4?

If an Agency determines that the requested information is protected from release by Exemption 4 of the FOIA, the Agency has no discretion to release the information. Release of information protected from release by Exemption 4 is prohibited by the Trade Secrets Act, a criminal provision found at 18 U.S.C. 1905.

Subpart G—Fees

§ 2105.35 What general principles govern fees?

(a) The Agency will charge for processing requests under the FOIA in accordance with this subpart and with the OMB Fee Guidelines.

(b) The Agency may contact you for additional information to resolve fee issues.

(c) The Agency ordinarily will collect all applicable fees before sending copies of records to you.

(d) You may usually pay fees by check, certified check, or money order made payable to the ''Commission of Fine Arts.''

(1) Where appropriate, the Agency may require that your payment be made in the form of a certified check.

(e) The Agency should ensure that it conducts searches, review, and duplication in the most efficient and the least expensive manner so as to minimize costs for both you and the Agency.

(f) If the Agency does not comply with any of the FOIA's statutory time limits:

(1) Except as provided in paragraph (f)(2) of this section, the Agency cannot assess any search fees (or, if you are in the fee category of a representative of the news media or an educational and noncommercial scientific institution, duplication fees).

(2)(i) If the Agency has determined that unusual circumstances apply (as the term is defined in § 2105.68) and the Agency provided you a timely written notice to extend the basic time limit in accordance with § 2105.17, the noncompliance is excused for an additional 10 workdays.

(ii) If the Agency has determined that unusual circumstances apply and more than 5,000 pages are necessary to respond to the request, the noncompliance is excused if the Agency has provided you a timely written notice in accordance with § 2105.17 and has discussed with you via written mail, email, or telephone (or made not less than 3 good-faith attempts to do so) how you could effectively limit the scope of the request.

(iii) If a court has determined that exceptional circumstances exist (as that term is defined in § 2105.68), the noncompliance is excused for the length of time provided by the court order.

(g) If the fee for processing your request is less than $50, you will not be charged unless multiple requests are aggregated under § 2105.52 to an amount that is $50 or more.

(h) If you fail to pay any FOIA-related fee within 30 calendar days of the date of billing, the processing of any new or ongoing requests and/or appeals from you shall ordinarily be suspended.

(i) If you would like to reformulate your request so it will meet your needs at a lower cost, you may wish to seek assistance from the Agency's designated FOIA contact or its FOIA Public Liaison (see § 2105.64).

§ 2105.36 What are the requester fee categories?

(a) There are four categories of requesters for the purposes of determining fees—commercial-use, educational and noncommercial scientific institutions, representatives of news media, and all others.

(b) The Agency's decision to place you in a particular fee category will be made on a case-by-case basis based on your intended use of the information and, in most cases, your identity. If you do not submit sufficient information in your FOIA request for the Agency to determine your proper fee category, the Agency may ask you to provide additional information (see § 2105.49). If you request placement in a particular fee category but the Agency places you in a different fee category, the Agency will provide you with an explanation of why you were not placed in the fee category you requested (for example, if you were placed in the commercial use requester category rather than the category you requested, the Agency will describe how the records would further your commercial, trade, or profit interests).

(c) See § 2105.68 for the definitions of each of these fee categories.

§ 2105.37 How does your requester category affect the fees you are charged?

You will be charged as shown in the following table:

TABLE 1 TO § 2105.37

Requester category	Search fees	Review fees	Duplication fees
Commercial use requester	Yes	Yes	Yes.
Educational and noncommercial scientific institutions.	No	No	Yes (first 100 pages, or equivalent volume, free).
Representative of news media requester.	No	No	Yes (first 100 pages, or equivalent volume, free).
All other requesters	Yes (first two hours free)	No	Yes (first 100 pages, or equivalent volume, free).

§ 2105.38 How will fee amounts be determined?

(a) The Agency will charge the types of fees discussed in this subpart unless a waiver of fees is required under § 2105.37 or has been granted under § 2105.43 or § 2105.54.

(b) Because the types of fees discussed in this subpart already account for the overhead costs associated with a given

fee type, the Agency should not add any additional costs to those charges.

§ 2105.39 What search fees will you have to pay?

(a) The Agency will charge search fees for all requests, subject to the restrictions of §§ 2105.35(f), 2105.37, and 2105.38(a). The Agency may charge you for time spent searching even if it does not locate any responsive records or if it determines that the records are entirely exempt from disclosure.

(b) For each quarter hour spent by personnel searching for requested records, including electronic searches that do not require new programming, the fees will be the average hourly General Schedule (GS) base salary, plus the District of Columbia locality payment, plus 16 percent for benefits, of employees in the following three categories, as applicable:

(1) Clerical—Based on GS–6, Step 5, pay (all employees at GS–7 and below are classified as clerical for this purpose);

(2) Professional—Based on GS–11, Step 7, pay (all employees at GS–8 through GS–12 are classified as professional for this purpose); and

(3) Managerial—Based on GS–14, Step 2, pay (all employees at GS–13 and above are classified as managerial for this purpose).

(c) You can review the current fee schedule for the categories discussed above in paragraph (b) of this section at *https://www.cfa.gov/foia.*

(d) Some requests may require retrieval of records stored at a Federal records center operated by the National Archives and Records Administration. For these requests, the Agency will charge additional costs in accordance with the Transactional Billing Rate Schedule established by the National Archives and Records Administration.

§ 2105.40 What duplication fees will you have to pay?

(a) The Agency will charge duplication fees, subject to the restrictions of §§ 2105.35(f), 2105.37, and 2105.38(a).

(b) If photocopies or scans are supplied, the Agency will provide one copy per request at the cost determined by the table in appendix A to this part.

(c) For other forms of duplication, the Agency will charge the actual costs of producing the copy, including the time spent by personnel duplicating the requested records. For each quarter hour spent by personnel duplicating the requested records, the fees will be the same as those charged for a search under § 2105.39(b).

(d) If the Agency must scan paper records to accommodate your preference to receive records in an electronic format or print electronic records to accommodate your preference to receive records in a paper format, you will pay both the per page amount noted in appendix A to this part and the time spent by personnel scanning or printing the requested records. For each quarter hour spent by personnel scanning or printing the requested records, the fees will be the same as those charged for a search under § 2105.39(b).

§ 2105.41 What review fees will you have to pay?

(a) The Agency will charge review fees if you make a commercial-use request, subject to the restrictions of §§ 2105.35(f), 2105.37, and 2105.38(a).

(b) The Agency will assess review fees in connection with the initial review of the record (the review conducted by the Agency to determine whether an exemption applies to a particular record or portion of a record).

(c) The Agency will not charge for reviews at the administrative appeal stage of exemptions applied at the initial review stage. However, if the appellate authority determines that an exemption no longer applies, any costs associated with the Agency's re-review of the records to consider the use of other exemptions may be assessed as review fees.

(d) The Agency will charge review fees at the same rates as those charged for a search under § 2105.39(b).

(e) The Agency can charge review fees even if the record(s) reviewed ultimately is not disclosed.

§ 2105.42 What fees for other services will you have to pay?

(a) Although not required to provide special services, if the Agency chooses to do so as a matter of administrative discretion, it will charge you the direct costs of providing the service.

(b) Examples of these services include providing multiple copies of the same record, converting records that are not already maintained in a requested format to the requested format, obtaining research data under § 2105.67, sending records by means other than first class mail, and conducting a search that requires the creation of a new computer search program to locate the requested records.

(c) The Agency will notify you of these fees before they accrue and will obtain your written assurance of payment or an advance payment before proceeding. See §§ 2105.47 and 2105.48.

§ 2105.43 When will the Agency waive fees?

(a) The Agency will release records responsive to a request without charge (in other words, it will give you a full fee waiver) or at a reduced charge (in other words, it will give you a partial fee waiver, as discussed further in paragraph (b) of this section) if the Agency determines, based on all available information, that you have demonstrated (by addressing and meeting each of the criteria listed in § 2105.46) that disclosing the information is:

(1) In the public interest because it is likely to contribute significantly to public understanding of Government operations or activities, and

(2) Not primarily in your commercial interest.

(b) A partial fee waiver may be appropriate if some but not all of the requested records are likely to contribute significantly to public understanding of the operations and activities of the Government.

(c) When deciding whether to waive or reduce fees, the Agency will rely on the fee waiver justification submitted in your request letter. If the letter does not include sufficient justification, the Agency will deny the fee waiver request. The Agency may, at its discretion, request additional information from you (see § 2105.49).

(d) The burden is on you to justify entitlement to a fee waiver. Requests for fee waivers are decided on a case-by-case basis under the criteria discussed in paragraph (a) of this section and § 2105.46. If you have received a fee waiver in the past, that does not mean you are automatically entitled to a fee waiver for every request submitted.

(e) Discretionary fee waivers are addressed in § 2105.54.

(f) The Agency must not make value judgments about whether the information at issue is ''important'' enough to be made public; it is not the Agency's role to attempt to determine the level of public interest in requested information.

§ 2105.44 When may you ask the Agency for a fee waiver?

(a) You should request a fee waiver when your request is first submitted to the Agency (see § 2105.5).

(b) You may submit a fee waiver request at a later time if the Agency has not yet completed processing your request.

§ 2105.45 How will the Agency notify you if it denies your fee waiver request?

If the Agency denies your request for a fee waiver, it will notify you, in writing, of the following:

(a) The basis for the denial, including a full explanation of why the fee waiver request does not meet the Agency's fee waiver criteria in § 2105.46;

(b) The name and title or position of each person responsible for the denial;

(c) The name and title of legal counsel consulted;

(d) Your right to appeal the denial under subpart H of this part and a description of the requirements set forth therein, within 30 workdays from the date of the fee waiver denial letter; and

(e) Your anticipated fees, in accordance with § 2105.47.

§ 2105.46 How will the Agency evaluate your fee waiver request?

(a) In deciding whether your fee waiver request meets the requirements of § 2105.43(a)(1), the Agency will consider the criteria listed in paragraphs (a)(1) through (4) of this section. You must address and meet each of these criteria in order to demonstrate that you are entitled to a fee waiver.

(1) How the records concern the operations or activities of the Federal Government.

(2) How disclosure is likely to contribute to public understanding of those operations or activities, including:

(i) How the contents of the records are meaningfully informative;

(ii) The logical connection between the content of the records and the operations or activities;

(iii) How disclosure will contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to your individual understanding;

(iv) Your identity, vocation, qualifications, and expertise regarding the requested information and information that explains how you plan to disclose the information in a manner that will be informative to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to your individual understanding; and

(v) Your ability and intent to disseminate the information to a reasonably broad audience of persons interested in the subject (for example, how and to whom do you intend to disseminate the information). If we have categorized you as a representative of the news media under § 2105.36, we will presume you have this ability and intent.

(3) How disclosure is likely to significantly contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to your individual understanding, including:

(i) Whether the information being requested is new;

(ii) Whether the information would confirm or clarify data that has been released previously;

(iii) How disclosure will increase the level of public understanding of the operations or activities of the Agency that existed prior to disclosure; and

(iv) Whether the information is already publicly available. If the Government previously has published the information you are seeking or it is routinely available to the public in a library, reading room, through the internet, or as part of the administrative record for a particular issue, it is less likely that there will be a significant contribution from release.

(4) How the public's understanding of the subject in question will be enhanced to a significant extent by the disclosure.

(b) In deciding whether the fee waiver meets the requirements in § 2105.43(a)(2), the Agency will consider any commercial interest of yours that would be furthered by the requested disclosure.

(1) You are encouraged to provide explanatory information regarding this consideration.

(2) The Agency will not find that disclosing the requested information will be primarily in your commercial interest where the public interest is greater than any identified commercial interest in disclosure.

(3) If you do have a commercial interest that would be furthered by disclosure, explain how the public interest in disclosure would be greater than any commercial interest you or your organization may have in the documents.

(i) Your identity, vocation, and intended use of the requested records are all factors to be considered in determining whether disclosure would be primarily in your commercial interest.

(ii) If you are a representative of a news media organization seeking information as part of the news gathering process, we will presume that the public interest outweighs your commercial interest.

(iii) If you represent a business/corporation/association or you are an attorney representing such an organization, we will presume that your commercial interest outweighs the public interest unless you demonstrate otherwise.

§ 2105.47 When will you be notified of anticipated fees?

(a) The Agency will notify you under this section unless:

(1) The anticipated fee is less than $50 (see § 2105.35(g));

(2) You have been granted a full fee waiver; or

(3) You have previously agreed to pay all the fees associated with the request.

(b) If none of the exceptions in paragraph (a) of this section apply, the Agency will:

(1) Promptly notify you of the estimated costs for search, review, and/or duplication;

(2) Ask you to provide written assurance within 20 workdays that you will pay all fees or fees up to a designated amount;

(3) Notify you that it will not be able to comply with your FOIA request unless you provide the written assurance requested; and

(4) Give you an opportunity to reduce the fee by modifying the request.

(c) If the Agency does not receive your written response containing the additional information that resolves any fee issues, in accordance with paragraphs (b)(2) and/or (4) of this section, within 20 workdays after the Agency has requested it, the Agency will presume that you are no longer interested in the records and will close the file on the request.

(d) After the Agency begins processing a request, if it finds that the actual cost will exceed the amount you previously agreed to pay, the Agency will:

(1) Stop processing the request;

(2) Promptly notify you of the higher amount and ask you to provide written assurance of payment; and

(3) Notify you that it will not be able to fully comply with your FOIA request unless you provide the written assurance requested; and

(4) Give you an opportunity to reduce the fee by modifying the request.

(e) If you wish to modify your request in an effort to reduce fees, the Agency's FOIA Officer or Public Liaison can assist you.

§ 2105.48 When will the Agency require advance payment?

(a) The Agency will require advance payment before starting further work when it finds the estimated fee is over $250 and:

(1) You have never made a FOIA request to the Agency requiring the payment of fees; or

(2) You did not pay a previous FOIA fee within 30 calendar days of the date of billing.

(b) If the Agency believes that you did not pay a previous FOIA fee within 30 calendar days of the date of billing, the Agency will require you to either:

(1) Demonstrate you paid prior fee within 30 calendar days of the date of billing; or

(2) Pay any unpaid amount of the previous fee, plus any applicable interest penalties (see § 2105.51), and pay in advance the estimated fee for the new request.

(c) When the Agency notifies you that an advance payment is due under paragraph (a) of this section, it will give you an opportunity to reduce the fee by modifying the request.

(d) Your payment of the funds you owe the Agency for work it has already completed before records are sent to you is not an advance payment under paragraph (a) of this section.

(e) If the Agency requires advance payment, it will start further work only after receiving the advance payment. It will also notify you that it will not be able to comply with your FOIA request unless you provide the advance payment. Unless you pay the advance payment within 20 workdays after the date of the Agency's fee letter, the Agency will presume that you are no longer interested and will close the file on the request.

§ 2105.49 What if the Agency needs clarification about fee issues?

(a) If your FOIA request does not contain sufficient information for the Agency to determine your proper fee category or leaves another fee issue unclear, the Agency may ask you to provide additional clarification. If it does so, the Agency will notify you that it will not be able to comply with your FOIA request unless you provide the clarification requested.

(b) If the Agency asks you to provide clarification, the 20-workday statutory time limit for the Agency to respond to the request is temporarily suspended.

(1) If the Agency receives a written response within 20 workdays after the Agency has requested the additional clarification, the 20-workday statutory time limit for processing the request will resume (see § 2105.15).

(2) If you still have not provided sufficient information to resolve the fee issue, the Agency may ask you again to provide additional clarification and notify you that it will not be able to comply with your FOIA request unless you provide the additional information requested within 20 workdays after the Agency has requested the additional clarification.

(3) If the Agency asks you again for additional clarification, the statutory time limit for response will be temporarily suspended again and will resume again if the Agency receives a written response from you within 20 workdays after the Agency has requested the additional clarification.

(c) If the Agency asks for clarification about a fee issue and does not receive a written response from you within 20 workdays after the Agency has requested the additional clarification, it will presume that you are no longer interested and will close the file on the request.

§ 2105.50 How will you be billed?

If you are required to pay a fee associated with a FOIA request, the Agency will send a bill for collection.

§ 2105.51 How will the Agency collect fees owed?

(a) The Agency may charge interest on any unpaid bill starting on the 31st day following the billing date.

(b) The Agency will assess interest charges at the rate provided in 31 U.S.C. 3717 and interest will accrue from the billing date until the Agency receives payment.

(c) The Agency will follow the provisions of the Debt Collection Act of 1982 (Pub. L. 97–365, 96 Stat. 1749), as amended, and its administrative procedures, including the use of consumer reporting agencies, collection agencies, and offset to collect overdue amounts and interest.

(d) This section does not apply if you are a state, local, or tribal government.

§ 2105.52 When will the Agency combine or aggregate requests?

(a) The Agency may aggregate requests and charge accordingly when it reasonably believes that you, or a group of requesters acting in concert with you, are attempting to avoid fees by dividing a single request into a series of requests on a single subject or related subjects.

(1) The Agency may presume that multiple requests of this type made within a 30-day period have been made to avoid fees.

(2) The Agency may aggregate requests separated by a longer period only where there is a reasonable basis for determining that aggregation is warranted in view of all the circumstances involved.

(b) The Agency will not aggregate multiple requests involving unrelated matters.

§ 2105.53 What if other statutes require the Agency to charge fees?

(a) The fee schedule in appendix A to this part does not apply to fees charged under any statute that specifically requires the Agency to set and collect fees for particular types of records.

(b) If records otherwise responsive to a request are subject to a statutorily-based fee schedule, the Agency will inform you whom to contact to obtain the records.

§ 2105.54 May the Agency waive or reduce your fees at its discretion?

(a) The Agency may waive or reduce fees at its discretion if a request involves furnishing:

(1) A copy of a record that the Agency has reproduced for free distribution;

(2) One copy of a personal document (for example, a birth certificate) to a person who has been required to furnish it for retention by the Agency;

(3) One copy of the transcript of a hearing before a hearing officer in a grievance or similar proceeding to the employee for whom the hearing was held;

(4) Records to donors with respect to their gifts;

(5) Records to individuals or private nonprofit organizations having an official, voluntary, or cooperative relationship with the Agency if it will assist their work with the Agency;

(6) A reasonable number of records to members of the U.S. Congress; state, local, and foreign governments; public international organizations; or Indian tribes, when to do so is an appropriate courtesy, or when the recipient is carrying on a function related to an Agency function and the waiver will help accomplish the Agency's work;

(7) Records in conformance with generally established business custom (for example, furnishing personal reference data to prospective employers of current or former Agency employees); or

(8) One copy of a single record to assist you in obtaining financial benefits to which you may be entitled (for example, veterans or their dependents, employees with Government employee compensation claims).

(b) You cannot appeal the denial of a discretionary fee waiver or reduction.

Subpart H—Administrative Appeals

§ 2105.55 When may you file an appeal?

(a) You may file an appeal when:

(1) The Agency withholds records, or parts of records;

(2) The Agency informs you that your request has not adequately described the records sought;

(3) The Agency informs you that it does not possess or cannot locate responsive records and you have reason to believe this is incorrect or that the search was inadequate;

(4) The Agency did not address all aspects of the request for records;

(5) You believe there is a procedural deficiency (for example, fees are improperly calculated or you have been placed in the wrong fee category);

(6) The Agency denied your request for a fee waiver;

(7) The Agency did not make a decision within the time limits in § 2105.15 or, if applicable, § 2105.16; or

(8) The Agency denied, or was late in responding to, a request for expedited

processing filed under the procedures in § 2105.18.

(b) An appeal under paragraph (a)(8) of this section relates only to the request for expedited processing and does not constitute an appeal of the underlying request for records. Special procedures apply to requests for expedited processing of an appeal (see § 2105.61).

(c) Before filing an appeal, you may wish to communicate with the contact person listed in the FOIA response, the Agency's FOIA Officer, and/or the FOIA Public Liaison to see if the issue can be resolved informally. However, appeals must be received by the FOIA Appeals Officer within the time limits in § 2105.56 or they will not be processed.

§ 2105.56 How long do you have to file an appeal?

(a) Appeals covered by § 2105.55(a)(1) through (5) must be received by the FOIA Appeals Officer no later than 90 workdays from the date of the final response.

(b) Appeals covered by § 2105.55(a)(6) must be received by the FOIA Appeals Officer no later than 90 workdays from the date of the letter denying the fee waiver.

(c) Appeals covered by § 2105.55(a)(7) may be filed any time after the time limit for responding to the request has passed.

(d) Appeals covered by § 2105.55(a)(8) should be filed as soon as possible.

(e) Appeals arriving or delivered after 5 p.m. Eastern Time, Monday through Friday, will be deemed received on the next workday.

§ 2105.57 How do you file an appeal?

(a) You must submit the appeal in writing by mail, fax or email to the FOIA Appeals Officer (using the address available at *https://www.cfa.gov/foia/*). Your failure to send an appeal directly to the FOIA Appeals Officer may delay processing.

(b) The appeal must include:

(1) Copies of all correspondence between you and the Agency concerning the FOIA request, including the request and the Agency's response (if there is one); and

(2) An explanation of why you believe the Agency's response was in error.

(c) The appeal should include your name, mailing address, daytime telephone number (or the name and telephone number of an appropriate contact), email address, and fax number (if available) in case the Agency needs additional information or clarification.

(d) An appeal concerning a denial of expedited processing or a fee waiver denial should also demonstrate fully how the criteria in § 2105.18 or §§ 2105.43 and 2105.46 are met.

(e) All communications concerning an appeal should be clearly marked with the words: ''FREEDOM OF INFORMATION APPEAL.''

(f) The Agency will reject an appeal that does not attach all correspondence required by paragraph (b)(1) of this section, unless the FOIA Appeals Officer determines, in his or her sole discretion, that good cause exists to accept the defective appeal. The time limits for responding to an appeal will not begin to run until the correspondence is received.

§ 2105.58 Who makes decisions on appeals?

(a) The FOIA Appeals Officer is the deciding official for FOIA appeals.

(b) When necessary, the appropriate deciding official for FOIA appeals will consult other appropriate offices, including legal counsel, for denials of records and fee waivers.

(c) The deciding official for FOIA appeals normally will not make a decision on an appeal if the request becomes a matter of FOIA litigation.

§ 2105.59 How are decisions on appeals issued?

(a) A decision on an appeal must be made in writing.

(b) A decision that upholds the Agency's determination will notify you of the decision and your statutory right to file a lawsuit.

(c) A decision that overturns, remands, or modifies the Agency's determination will notify you of the decision. The Agency then must further process the request in accordance with the appeal determination.

§ 2105.60 When can you expect a decision on your appeal?

(a) The basic time limit for responding to an appeal is 20 workdays after receipt of an appeal meeting the requirements of § 2105.57.

(b) If the Agency is unable to reach a decision on your appeal within the given time limit for response, the appropriate deciding official for FOIA appeals will notify you of your statutory right to seek review in a United States District Court.

§ 2105.61 Can you receive expedited processing of appeals?

(a) To receive expedited processing of an appeal, you must demonstrate to the Agency's satisfaction that the appeal meets one of the criteria under § 2105.18 and include a statement that the need for expedited processing is true and correct to the best of your knowledge and belief.

(b) The appropriate deciding official for FOIA appeals will advise you whether the Agency will grant expedited processing within 10 calendar days of receiving the appeal.

(c) If the appropriate deciding official for FOIA appeals decides to grant expedited processing, he or she will give the appeal priority over other pending appeals and process it as soon as practicable.

§ 2105.62 Must you submit an appeal before seeking judicial review?

Before seeking review by a court of the Agency's adverse determination, you generally must first submit a timely administrative appeal.

Subpart I—General Information

§ 2105.63 Where are records made available?

Records that are required by the FOIA to be made proactively available for public inspection and copying are accessible on the Agency's website. They may also be available at the Agency's office location.

§ 2105.64 What are public liaisons?

(a) The Agency has a FOIA Officer or Public Liaison who can assist requesters who have concerns about the service they received when seeking records or who are seeking assistance under § 2105.3 or § 2105.35(i).

(b) FOIA Public Liaisons report to the Agency's Chief FOIA Officer and you can raise concerns to them about the service you have received.

(c) FOIA Public Liaisons are responsible for assisting in reducing delays, increasing transparency and understanding of the status of requests, and assisting in resolving disputes.

(d) A list of the Agency's FOIA Public Liaisons is available at *https://www.cfa.gov/foia*.

§ 2105.65 When will the Agency make records available without a FOIA request?

(a) Each Agency must:

(1) Determine which of its records must be made publicly available under the FOIA (for example, certain frequently requested records);

(2) Identify additional records of interest to the public that are appropriate for public disclosure; and

(3) Post those records in FOIA libraries.

(b) Because of these proactive disclosures, you are encouraged to review the Agency's FOIA libraries before filing a FOIA request. The material you seek may be immediately available electronically at no cost.

§ 2105.66 How will FOIA materials be preserved?

(a) Each Agency must preserve all correspondence pertaining to the

requests that it receives under subpart B of this part, as well as copies of all requested records, until disposition or destruction is authorized by the General Records Schedule 4.2 of the National Archives and Records Administration (NARA) or another NARA-approved records schedule.

(b) Materials that are identified as responsive to a FOIA request will not be disposed of or destroyed while the request or a related appeal or lawsuit is pending. This is true even if they would otherwise be authorized for disposition or destruction under the General Records Schedule 4.2 of NARA or another NARA-approved records schedule.

§ 2105.67 How will an Agency handle a request for federally-funded research data?

(a) If you request research data that were used by the Federal Government in developing certain kinds of agency actions, and the research data relate to published research findings produced under an award, in accordance with OMB Circular A–110:

(1) If the Agency was the awarding agency, it will request the research data from the recipient;

(2) The recipient must provide the research data within a reasonable time; and

(3) The Agency will review the research data to see if it can be released under the FOIA.

(b) If the Agency obtains the research data solely in response to your FOIA request, the Agency may charge you a reasonable fee equaling the full incremental cost of obtaining the research data.

(1) This fee should reflect costs incurred by the Agency, the recipient, and applicable subrecipients.

(2) This fee is in addition to any fees the Agency may assess under the FOIA.

(c) The Agency will forward a copy of the request to the recipient, who is responsible for searching for and reviewing the requested information in accordance with these FOIA regulations. The recipient will forward a copy of any responsive records that are located, along with any recommendations concerning the releasability of the data, and the total cost incurred in searching for, reviewing, and providing the data.

(d) The Agency will review and consider the recommendations of the recipient regarding the releasability of the requested research data. However, the Agency, not the recipient, is responsible for deciding whether the research data will be released or withheld.

§ 2105.68 What definitions apply to this part?

For the purposes of this part, the following definitions apply:

Agency means the Commission of Fine Arts.

Commercial interest means a commercial, trade, or profit interest as these terms are commonly understood. Your status as profitmaking or non-profitmaking is not the deciding factor in determining whether you have a commercial interest.

Commercial use means a use that furthers your commercial, trade or profit interests or that of the person on whose behalf the request is made.

Confidential information means trade secrets or commercial or financial information (that is privileged or confidential and obtained by the Agency from a person) that may be protected from disclosure under Exemption 4 of the FOIA.

Direct costs means those resources that the Agency expends in searching for and duplicating (and, in the case of commercial-use requests, reviewing) records to respond to a FOIA request. For example, direct costs include the salary of the employee performing the work (the basic rate of pay for the employee plus 16 percent of that rate to cover benefits) and the cost of operating duplicating machinery, such as photocopiers and scanners. Direct costs do not include overhead expenses such as the costs of space and of heating or lighting a facility.

Duplication means reproducing a copy of a record or of the information contained in it necessary to respond to a FOIA request. Copies can take the form of paper, audiovisual materials, or electronic records, among others.

Educational institution means any school that operates a program of scholarly research. In order to fall within this category, you must show that the request is authorized by and made under the auspices of, a qualifying institution and that the records are not sought for a commercial use, but rather are sought to further scholarly research.

Exceptional circumstances means a delay that does not result from a predictable workload of requests (unless the Agency demonstrates reasonable progress in reducing its backlog of pending requests).

Exempt means the record in question, or a portion thereof, is not subject to disclosure due to one or more of the FOIA's nine statutory exemptions, found at 5 U.S.C. 552(b)(1)–(9).

Exemption means one or more of the FOIA's nine statutory exemptions, found at 5 U.S.C. 552(b)(1)–(9).

Expedited processing means giving a FOIA request priority and processing it ahead of other requests pending in the Agency because you have shown a compelling need for the records.

Fee category means one of the four categories, discussed in §§ 2105.36 and 2105.37, that agencies place you in for the purpose of determining whether you will be charged fees for search, review, and duplication.

FOIA means the Freedom of Information Act, 5 U.S.C. 552, as amended.

FOIA libraries means a physical or electronic compilation of records required to be made available to the public for inspection and copying under 5 U.S.C. 552(a)(2). It also includes a physical or electronic compilation of records that the Agency, at its discretion, makes available to the public for inspection and copying.

Frequently requested records means records that have been released to any person in response to a FOIA request and that have been requested, or that the Agency anticipates will be requested, at least two more times under the FOIA.

Multitrack processing means placing simple requests, requiring relatively minimal review, in one processing track and more voluminous and complex requests in one or more other tracks. Requests in each track are ordinarily processed on a first-in/first-out basis.

Noncommercial scientific institution means an institution that is not operated for commerce, trade or profit, and that 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 be in this category, you 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 scientific research.

OMB Fee Guidelines means the Uniform Freedom of Information Fee Schedule and Guidelines published by the Office of Management and Budget on March 27, 1987.

Published means, for the purposes of § 2105.67 only, when:

(1) Research findings are published in a peer-reviewed scientific or technical journal; or

(2) A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

Recipient means, for the purposes of § 2105.67 only, an organization receiving financial assistance directly from Federal awarding agencies to carry out a project or program. The term

includes public and private institutions of higher education, public and private hospitals, and other quasi-public and private non-profit organizations. The term may include commercial organizations, foreign or international organizations (such as agencies of the United Nations) which are recipients, subrecipients, or contractors or subcontractors of recipients or subrecipients at the discretion of the Federal awarding agency. The term does not include Government-owned contractor-operated facilities or research centers providing continued support for mission-oriented, large-scale programs that are Government-owned or controlled, or are designated as federally-funded research and development centers.

Record means an agency record that is either created or obtained by an agency and is under agency possession and control at the time of the FOIA request, or is maintained by an entity under Government contract for the purposes of records management.

Representative of the news media means any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. The term news as used in this definition means information that is about current events or that would be of current interest to the public. Examples of news media entities are newspapers, television, websites, or radio stations broadcasting to the public at large, and publishers of periodicals (but only if such entities qualify as disseminators of news) who make their products available for purchase by or subscription by or free distribution to the general public. These examples are not all inclusive. As methods of news delivery evolve, alternative representatives of news media may come into being. A freelance journalist will qualify as a news-media entity if he or she can demonstrate a solid basis for expecting publication through that entity, whether or not the journalist is actually employed by that entity (for example, a publication contract would present a solid basis for such an expectation).

Research data means, for the purposes of § 2105.67 only, the recorded factual material commonly accepted in the historic and/or architectural communities as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. The term recorded as used in this definition excludes physical objects (*e.g.,* laboratory samples). Research data also do not include:

(1) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and

(2) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

Review means the examination of a record located in response to a request to determine whether any portion of it is exempt from disclosure. Review time includes processing any record for disclosure, such as doing all that is necessary to prepare the record for disclosure, including the process of redacting the record and marking the appropriate exemptions. Review time also includes time spent both obtaining and considering any formal objection to disclosure made by a confidential information submitter under subpart G of this part, but it excludes time spent resolving general legal or policy issues regarding the application of FOIA exemptions.

Search means the process of looking for and retrieving records responsive to a request. Search time includes page-by-page or line-by-line identification of information within records; and the reasonable efforts expended to locate and retrieve electronic records.

Submitter means any person or entity outside the Federal Government from whom the Agency obtains confidential information, directly or indirectly. The term includes, but is not limited to individuals, corporations, and state, local, tribal, and foreign governments.

Unusual circumstances means the need to search for and collect requested records from field facilities or other establishments that are separate from the office processing the request; the need to search for, collect, and examine a voluminous amount of separate and distinct records which are demanded in a single request; or the need for consultation, which shall be conducted with all practicable speed, with another agency, or among two or more components of the Agency, having a substantial interest in the determination of the request.

Workday means a regular Federal workday. It excludes Saturdays, Sundays, or Federal legal public holidays. Items arriving or delivered after 5 p.m. Eastern Time will be deemed received on the next workday.

You means a person requesting records, or filing an appeal, under the FOIA.

Appendix A to Part 2105—Fee Schedule

Types of records	Fee
(1) Physical records:	
Pages no larger than 8.5 x 14 inches, when reproduced by standard office copying machines or scanned into an electronic format.	$.15 per page ($.30 for double-sided copying).
Color copies of pages no larger than 8.5 x 11 inches	$.90 per page.
Pages larger than 8.5 x 14 inches	Direct cost to CFA.
Color copies of pages no larger than 11 x 17 inches	$1.50 per page.
Photographs and records requiring special handling (for example, because of age, size, or format).	Direct cost to CFA.
(2) Electronic records:	
Charges for services related to processing requests for electronic records	Direct cost to CFA.
Certification	
Each certificate of verification attached to authenticate copies of records	$.25.
(4) Postage:	
Charges that exceed the cost of first class postage, such as express mail or overnight delivery	Postage or delivery charge.
(5) Other Services:	
Cost of special services or materials, other than those provided for by this fee schedule, when requester is notified of such costs in advance and agrees to pay them.	Direct cost to CFA.

Dated: April 3, 2019.

Thomas Luebke,

Secretary.

[FR Doc. 2019–06919 Filed 4–15–19; 8:45 am]

BILLING CODE 6330–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 11

[Docket No. FWS–HQ–LE–2018–0117; FF09L00200–FX–LE18110900000]

RIN 1018–BD05

Civil Penalties; 2019 Inflation Adjustments for Civil Monetary Penalties

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service or we) is issuing this final rule, in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Inflation Adjustment Act) and Office of Management and Budget (OMB) guidance, to adjust for inflation the statutory civil monetary penalties that may be assessed for violations of Service-administered statutes and their implementing regulations. We are required to adjust civil monetary penalties annually for inflation according to a formula specified in the Inflation Adjustment Act. This rule replaces the previously issued amounts with the updated amounts after using the 2019 inflation adjustment multiplier provided in the OMB guidance.

DATES: This rule is effective April 16, 2019.

ADDRESSES: This rule may be found on the internet at *http://www.regulations.gov* in Docket No. FWS–HQ–LE–2018–0117. The previous rulemaking actions related to this rule and described below in **SUPPLEMENTARY INFORMATION** may be found at *http://www.regulations.gov* in Docket Nos. FWS–HQ–LE–2017–0097, FWS–HQ–LE–2017–0001, and FWS–HQ–LE–2016–0045.

FOR FURTHER INFORMATION CONTACT: Dan Coil, Special Agent in Charge, Branch of Investigations, U.S. Fish and Wildlife Service, Office of Law Enforcement, (703) 358–1949.

SUPPLEMENTARY INFORMATION:

Background

The regulations in title 50 of the Code of Federal Regulations at 50 CFR part 11 provide uniform rules and procedures for the assessment of civil penalties resulting from violations of certain laws and regulations enforced by the Service.

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (sec. 701 of Pub. L. 114–74) (Inflation Adjustment Act). The Inflation Adjustment Act requires Federal agencies to adjust the level of civil monetary penalties with an initial ''catch-up'' adjustment through rulemaking and then make subsequent annual adjustments for inflation. The purpose of these adjustments is to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statutes.

Under section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note, as amended by the Inflation Adjustment Act, Public Law 114–74, 129 Stat. 584 (2015), each Federal agency is required to issue regulations adjusting for inflation the statutory civil monetary penalties (civil penalties) that can be imposed under the laws administered by that agency. The Inflation Adjustment Act provided for an initial ''catch-up adjustment'' to take effect no later than August 1, 2016, followed by subsequent adjustments to be made no later than January 15 every year thereafter. This final rule adjusts the civil penalty amounts that may be imposed pursuant to each statutory provision beginning on the date specified above in **DATES**.

On June 28, 2016, the Service published in the **Federal Register** an interim rule that revised 50 CFR part 11 (81 FR 41862). We did not receive any comments on the interim rule during the public comment period provided. Therefore, the interim rule became effective on July 28, 2016, as specified in that rule. The Service subsequently published a final rule on December 23, 2016, adopting the interim rule as final (81 FR 94274). On February 12, 2018, the Service published a final rule updating the civil penalty amounts with the 2018 inflation multiplier (83 FR 5950). This final rule adjusts the civil monetary penalty amounts that were listed in the February 12, 2018, final rule and subsequently codified at 50 CFR 11.33 by using the 2019 inflation multiplier provided to all Federal agencies by OMB (see below).

OMB issued a memorandum, M–19–04, entitled ''Implementation of Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,'' which provides the cost-of-living adjustment multiplier for 2019: 1.02522. Therefore, we multiplied each penalty in the table published in the final rule on February 12, 2018 (83 FR 5950), by 1.02522 to obtain the 2019 annual adjustment. The new amounts are reflected in the table in the rule portion of this document and replace the current amounts in 50 CFR 11.33.

Required Determinations

In this final rule, we are affirming our required determinations made in the June 28, 2016, interim rule (81 FR 41862); for descriptions of our actions to ensure compliance with the following statutes and Executive Orders, see that rule:

National Environmental Policy Act (42 U.S.C. 4321 *et seq.*);

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

Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2));

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

Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*);

Executive Orders 12630, 12866, 12988, 13132, 13175, 13211, and 13563; and

Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs.

This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

Administrative Procedure Act

As stated above, under section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note, as amended by the Inflation Adjustment Act, Public Law 114–74, 129 Stat. 584 (2015), each Federal agency is required to issue regulations adjusting for inflation the statutory civil monetary penalties that can be imposed under the laws administered by that agency. The Inflation Adjustment Act provided for an initial ''catch-up adjustment'' to take effect no later than August 1, 2016, followed by subsequent adjustments to be made no later than January 15 every year thereafter. This final rule adjusts the civil penalty amounts that may be imposed pursuant to each statutory provision beginning on the effective date of this rule. To comply with the Inflation Adjustment Act, we are issuing these regulations as a final rule.

Section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule

without providing notice and an opportunity for prior public comment. The Service finds that providing for public comment before issuing this rule is unnecessary as this rulemaking is a nondiscretionary action. The Service is required to publish this rule in order to update the civil penalty amounts by the specified formula described above. The Service has no discretion to vary the amount of the adjustment to reflect any views or suggestions provided by commenters. Since this update to the February 12, 2018, final rule (83 FR 5950) is merely ministerial, we find that pre-publication notice and public comment with respect to the revisions set forth in this rule is unnecessary. The statutory deadline imposed by the Inflation Adjustment Act also gives us good cause under 5 U.S.C. 553(d) to make this rule effective upon publication.

List of Subjects in 50 CFR Part 11

Administrative practice and procedure, Exports, Fish, Imports, Penalties, Plants, Transportation, Wildlife.

Regulation Promulgation

For the reasons described above, we amend part 11, subchapter B of chapter I, title 50 of the Code of Federal Regulations as set forth below.

PART 11—CIVIL PROCEDURES

■ 1. The authority citation for part 11 continues to read as follows:

Authority: 16 U.S.C. 470aa–470mm, 470aaa–470aaa-11, 668–668d, 1361–1384, 1401–1407, 1531–1544, 3371–3378, 4201–4245, 4901–4916, 5201–5207, 5301–5306; 18 U.S.C. 42–43; 25 U.S.C. 3001–3013; and Sec. 107, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

■ 2. Revise the table in § 11.33 to read as follows:

§ 11.33 Adjustments to penalties.

* * * * *

Law	Citation	Type of Violation	Maximum civil monetary penalty
(a) African Elephant Conservation Act	16 U.S.C. 4224(b)	Any violation	$10,519
(b) Bald and Golden Eagle Protection Act.	16 U.S.C. 668(b)	Any violation	13,291
(c) Endangered Species Act of 1973	16 U.S.C. 1540(a)(1)	(1) Knowing violation of section 1538	52,596
		(2) Other knowing violation	25,246
		(3) Any other violation	1,329
(d) Lacey Act Amendments of 1981	16 U.S.C. 3373(a)	(1) Violations referred to in 16 U.S.C. 3373(a)(1).	26,582
		(2) Violations referred to in 16 U.S.C. 3373(a)(2).	664
(e) Marine Mammal Protection Act of 1972.	16 U.S.C. 1375	Any violation	26,582
(f) Recreational Hunting Safety Act of 1994.	16 U.S.C. 5202(b)	(1) Violation involving use of force or violence or threatened use of force or violence.	16,915
		(2) Any other violation	8,457
(g) Rhinoceros and Tiger Conservation Act of 1998.	16 U.S.C. 5305a(b)(2)	Any violation	18,504
(h) Wild Bird Conservation Act	16 U.S.C. 4912(a)(1)	(1) Violation of section 4910(a)(1), section 4910(a)(2), or any permit issued under section 4911.	44,585
		(2) Violation of section 4910(a)(3)	21,400
		(3) Any other violation	892

Dated: March 18, 2019.

Andrea Travnicek,

Principal Deputy Assistant Secretary, Fish and Wildlife and Parks, Exercising the Authority of the Assistant Secretary, Fish and Wildlife and Parks.

[FR Doc. 2019–07578 Filed 4–15–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 151211999–6343–02]

RIN 0648–XG971

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Witch Flounder Trimester Total Allowable Catch Area Closure for the Common Pool Fishery

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

ACTION: Temporary rule; area closure.

SUMMARY: This action closes the Witch Flounder Trimester Total Allowable Catch Area to Northeast multispecies common pool vessels fishing with trawl gear through April 30, 2019. The closure is required because the common pool fishery is projected to have caught over 90 percent of its Trimester 3 quota for witch flounder. This closure is intended to prevent an overage of the common pool's quota for this stock.

DATES: This action is effective April 12, 2019, through April 30, 2019.

FOR FURTHER INFORMATION CONTACT: Spencer Talmage, Fishery Management Specialist, (978) 281–9232.

SUPPLEMENTARY INFORMATION: Federal regulations at § 648.82(n)(2)(ii) require the Regional Administrator to close a common pool Trimester Total Allowable Catch (TAC) Area for a stock when 90 percent of the Trimester TAC

is projected to be caught. The closure applies to all common pool vessels fishing with gear capable of catching that stock, and remains in effect for the remainder of the trimester. During the closure, affected common pool vessels may not fish for, harvest, possess, or land regulated multispecies or ocean pout in or from the Trimester TAC Area for the stock.

The Trimester 3 TAC for witch flounder is 10,009 lb (4.5 mt). Catch data (including landings and discards) indicate that the common pool fishery caught 7,689 lb (3.5 mt) of witch flounder, or 77 percent of the Trimester 3 TAC, through March 26, 2019. Based on remaining quota and recent catch rates, we have projected that by April 2, 2019, the common pool achieved 90 percent of the Trimester 3 TAC.

Effective April 12, 2019, the Witch Flounder Trimester TAC Area is closed for the remainder of Trimester 3, through April 30, 2019. The Witch Flounder Trimester TAC Area consists of statistical areas 512, 513, 514, 515, 521, 522, and 525. During the closure, common pool vessels fishing with trawl gear may not fish for, harvest, possess, or land regulated multispecies or ocean pout in or from this area. The area reopens at the beginning of fishing year 2019 on May 1, 2019.

If a vessel declared its trip through the Vessel Monitoring System (VMS) or the interactive voice response system, and crossed the VMS demarcation line prior to April 12, 2019, it may complete its trip within the Witch Flounder Trimester TAC Area.

If the common pool fishery exceeds its annual sub-Allowable Catch Limit (sub-ACL) for a stock in the 2018 fishing year, the overage must be deducted from the common pool's sub-ACL for that stock for fishing year 2019. The fishing year 2018 sub-Allowable Catch Limit for witch flounder is 40,433 lb (18.3 mt). We estimate that the common pool has caught 38,112 lb (17.3 mt) so far in fishing year 2018.

Weekly quota monitoring reports for the common pool fishery are on our website at: *http://www.greateratlantic.fisheries.noaa.gov/ro/fso/MultiMonReports.htm.* We will continue to monitor common pool catch through vessel trip reports, dealer-reported landings, VMS catch reports, and other available information and, if necessary, will make additional adjustments to common pool management measures.

Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866. The Assistant Administrator for Fisheries, NOAA, finds good cause pursuant to 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3) to waive prior notice and the opportunity for public comment and the 30-day delayed effectiveness period because it would be impracticable and contrary to the public interest.

The regulations require the Regional Administrator to close a trimester TAC area to the common pool fishery when 90 percent of the Trimester TAC for a stock has been caught. Updated catch information through March 26, 2019, only recently became available indicating that the common pool fishery is projected to have caught 90 percent of its Trimester 3 TAC for witch flounder. The time necessary to provide for prior notice and comment, and a 30-day delay in effectiveness, would prevent the immediate closure of the Witch Flounder Trimester TAC Area. This would be contrary to the regulatory requirement and would increase the likelihood that the common pool fishery would exceed its annual quota of witch flounder. Any overage of the Trimester 1 or Trimester 2 TACs are deducted from the Trimester 3 TAC, and any overage of the annual quota would be deducted from common pool's quota for the next fishing year, to the detriment of this stock. This could undermine conservation and management objectives of the Northeast Multispecies Fishery Management Plan. Fishermen expect these closures to occur in a timely way to prevent overages and their payback requirements. Overages of the trimester or annual common pool quota could cause negative economic impacts to the common pool fishery as a result of overage paybacks deducted from a future trimester or fishing year.

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

Dated: April 10, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–07492 Filed 4–12–19; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 84, No. 73
Tuesday, April 16, 2019

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 966

[Doc. No. AMS–SC–18–0075; SC19–966–1 PR]

Tomatoes Grown in Florida; Modification of Handling Regulations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the Florida Tomato Committee (Committee) to change the handling regulations under the Marketing Order regulating the handling of tomatoes grown in Florida. This action would remove the standard weight requirements for tomato containers under the handling regulations.

DATES: Comments must be received by May 16, 2019.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or internet: *http://www.regulations.gov*. All comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov*. All comments submitted in response to this proposal will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Steven W. Kauffman, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (863)324–3375, Fax: (863) 291–8614, or Email: *Steven.Kauffman@usda.gov* or *Christian.Nissen@usda.gov*.

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@ams.usda.gov*.

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes an amendment to regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Agreement No. 125 and Order No. 966, as amended (7 CFR part 966), regulating the handling of tomatoes grown in Florida. Part 966 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of producers operating within the production area.

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 13563 and 13175. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this proposed rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB's Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This proposed rule invites comments on eliminating the standard weight certification requirement established under the Order for the 2019–20 and subsequent fiscal periods. This action would reduce time and costs associated with tomato inspection at handling facilities. The Committee unanimously approved this recommendation at public meetings held on August 24, 2018, and on September 6, 2018.

Section 966.52 of the Order provides authority to the Committee to establish pack and container requirements for tomatoes grown within the regulated area. This includes fixing the size, weight, capacity, dimensions, markings, or pack of the container which may be used in the packaging, transportation, sale, shipment, or other handling of tomatoes.

Section 966.323 sets forth the handling regulations for Florida tomatoes. Section 966.323(a)(3)(i) designates the container requirements for weight and that Section 51.1863 of the U.S. Tomato Standards (7 CFR 51.1863), which specifies the standard weight requirement, shall apply to all containers.

Section 966.60 requires Florida tomatoes to be inspected and certified by authorized representatives of the Federal or Federal-State Inspection Service (FSIS), or such other inspection service as the Secretary shall designate. The Florida Department of Agriculture and Consumer Services is an agency employing state workers who collaborate with the USDA to provide inspection services to areas not serviced by federal employees. FSIS currently certifies to standard weight as part of the inspection process.

The Committee met on August 24, 2018, and on September 6, 2018, to discuss current standard weight procedures and compliance with the standard weight certification requirements. Representatives from USDA's Specialty Crop Inspection Division (SCI) and from FSIS were present to participate in the discussion. These representatives informed Committee members that some handling facilities were not maintaining compliance with the standard weight certification requirements.

The current inspection sampling rate for standard weight certification is 36 containers sampled based on a lot size of 1600 containers. FSIS currently samples eight tomato containers from each lot for grade and size inspection, and these containers are also weighed as part of the sampling for standard weight. In order to comply with standard weight certification procedures, an additional 28 containers need to be weighed. To lower the inspection time and cost, many tomato handlers provide an employee to sample and weigh the additional 28 containers to reach the total 36 samples required for the standard weight certification of each lot.

The containers weighed must meet the prescribed inspection requirements in § 51.1863 for certification of the lot. Section 51.1863 specifies that when packages are marked to a net weight of 15 pounds or more, the net weight of the contents shall not be less than the designated net weight and shall not exceed the designated weight by more than 2 pounds. In order to allow for variations incident to proper sizing, not more than 15 percent, by count, of the packages in any lot may fail to meet the requirements for standard weight. Most of the tomatoes produced in the production area are packed in 25-pound containers.

In their discussion, Committee members stated the current sampling rate requires costly labor and is a time-consuming process that is difficult to maintain due to the handling volume in many operations. One industry member stated that the volume of lots inspected at some handling operations can total around 50 lots in a single 24-hour period. If 50 lots were inspected in one day this would equal a total of 1800 samples selected for recording the weight. The handler's employee would be responsible for pulling and weighing 1400 of these 25-pound samples to meet the standard weight requirement. Thus, high volume handlers may have to employ multiple people to perform the weight inspections.

The labor provided by the handler expedites the certification process and is lower than the cost of having FSIS inspectors weigh the additional cartons. However, standard weight certification is still expensive to maintain. One member stated that providing the necessary employees at their handling facility to properly administer the certification program cost an extra $80,000 a year above the fees charged by FSIS inspection.

The Committee asked if it might be possible to lower the sampling rate while maintaining the certification process as the container sampling size for standard weight is several times greater than the number of containers sampled by FSIS when certifying for grade and size. SCI stated that certification at a rate lower than 36 samples would require a study that could statistically support a new sampling rate. SCI indicated a study would possibly take a year to develop, implement, and to analyze the results. Committee members expressed concern over the time and cost of carrying out such a study, and that the best course of action may be to remove the requirement for standard weight inspection.

In discussing the value of the weight certification program, Committee members stated that receivers of Florida tomato shipments still perform weight inspections regardless of the required weight certification. Even with the standard weight certification, there are occasions when weight is an issue and the shipper often rectifies any discrepancies by making an adjustment to the shipment for the receiver. At both meetings, Committee members expressed that handling operations are spending thousands of dollars annually to meet the certification requirement without realizing a significant benefit from the program. Committee members stated that the expense of labor and inspection time for certification is difficult to justify since the handler already makes an adjustment for the receiver regardless of the certification.

Committee members also stated that tomato handlers outside the regulated area are not required to maintain standard weight certification. One member indicated that eliminating the standard weight requirement on Florida tomato handlers would allow the industry's inspection procedures to be more comparable to handlers outside the regulated area. Another commenter stated that most handlers are now using in-line scales to weigh each container and did not see the benefit of requiring standard weight certification.

Removing the standard weight requirement would allow handlers to avoid the time and labor costs associated with the certification process. The Committee believes there is no longer enough benefit to justify maintaining the standard weight certification, and unanimously recommended eliminating the standard weight requirements for the 2019–20 and subsequent fiscal periods.

Committee members agreed that maintaining the individual net weight requirements for containers is still a valuable component of the Order. The current net weight requirements state all tomatoes packed by a registered handler shall be packed in containers of 10, 20, and 25 pounds designated net weights. The net weight of the contents shall not be less than the designated net weight and shall not exceed the designated net weight by more than two pounds. This action would not modify that requirement.

With this action, FSIS would still sample the required containers to perform size and grade inspection along with recording the weights from each sample. FSIS could provide a record of the weights from the eight samples inspected for size and grade upon request. The Committee noted that the eight samples weighed by FSIS would provide an independent record to reference in addition to the in-line automated weighing systems used by many handlers. The Committee believes the eight samples weighed by FSIS in conjunction with the automated weighing systems would provide ample information regarding the container weights for each lot. Further, eliminating the standard weight requirement would not preclude the handler from requesting a standard weight inspection.

Section 8e of the Act (7 U.S.C. 608e–1) provides that when certain domestically produced commodities, including tomatoes, are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality, and maturity requirements. No corresponding change to the import regulations is required as this is a proposal to change the container requirements.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 75 producers of Florida tomatoes in the production area and 37 handlers subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,500,000 (13 CFR 121.201).

According to industry and Committee data, the average annual price for fresh Florida tomatoes during the 2017–18 season was approximately $12.56 per 25-pound container, and total fresh shipments were 25.9 million containers. Using the average price and shipment information, the number of handlers, and assuming a normal distribution, the majority of handlers have average annual receipts of more than $7,500,000, ($12.56 times 25.9 million containers equals $325,304,000 divided by 37 handlers equals $8,792,000 per handler).

In addition, based on production data, an estimated producer price of $6.00 per 25-pound container, the number of Florida tomato producers, and assuming a normal distribution, the average annual producer revenue is above $750,000 ($6.00 times 25.9 million containers equals $155,400,000 divided by 75 producers equals $2,072,000 per producer). Thus, the majority of handlers and producers of Florida tomatoes may be classified as large entities.

This proposed rule would eliminate the standard weight certification requirement under the Order. The Committee determined there is no longer sufficient benefit to justify the cost and time required for the standard weight certification. This proposed action would enable handlers to reduce inspection time and labor costs associated with the standard weight program. This rule would revise § 966.323. Authority for these changes is provided in § 966.52.

It is not anticipated that this action would impose additional costs on handlers or growers, regardless of size. The proposed changes are intended to reduce expenses incurred for labor and inspection time associated with the certification process for standard weight.

The current inspection sampling rate for standard weight certification based on a lot size of 1600 containers is 36 containers. FSIS currently samples eight tomato containers from each lot for grade and size inspection, and these containers are also weighed as part of the sampling for standard weight. In order to comply with standard weight certification procedures, an additional 28 containers need to be weighed. To lower the inspection time and cost, many tomato handlers provide an employee to sample and weigh the additional 28 containers to reach the total 36 samples required for the standard weight certification of each lot.

Total fresh shipments of Florida tomatoes for the 2017–18 season were 25.9 million 25-pound containers. This volume represents approximately 16,188 normal lots of tomatoes requiring inspection for standard weight. Using 2017–18 volume, this change would eliminate the requirement that inspection personnel or handler employees lift, weigh, and record approximately 453,265 25-pound containers during a similar season. This analysis illustrates the laborious nature involved in the standard weight inspection and certification process.

Avoiding the time and labor costs associated with standard weight certification would reduce expenses for the Florida tomato industry. This proposed action would reduce the labor required for the inspection process by thousands of hours every year, reducing the cost for handlers. The expense of labor for inspection can vary widely between handler employees and the FSIS. However, one Committee member stated that this action would save his handling operation $80,000 every year. This proposed action is expected to lower handler cost associated with the inspection process. The benefits of this rule are expected to be equally available to all Florida fresh tomato handlers, regardless of size.

The Committee considered an alternative to this proposed action. Prior to this recommendation, the Committee discussed lowering the sampling size for the standard weight certification program with the SCI. However, after further discussion on the inspection process and the time it could possibly take to review, the Committee determined the standard weight program no longer provided sufficient benefit to justify the cost and time required for certification. Therefore, the alternative was rejected.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178 Vegetable and Specialty Crops. No changes are necessary in those requirements as a result of this proposed action. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would not impose any additional reporting or recordkeeping requirements on either small or large Florida tomato handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this proposed rule.

The Committee's meetings were widely publicized throughout the Florida tomato industry, and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the August 24 and September 6, 2018, meetings were public meetings, and all entities, both large and small, were able to express their views on this issue. Interested persons are invited to submit comments on this proposed rule, including the regulatory and information collection impacts of this proposed action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 30-day comment period is provided to allow interested persons to respond to this proposal. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 966

Marketing agreements, Reporting and recordkeeping requirements, Tomatoes.

For the reasons set forth in the preamble, 7 CFR part 966 is proposed to be amended as follows:

PART 966—TOMATOES GROWN IN FLORIDA

■ 1. The authority citation for 7 CFR part 966 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Amend § 966.323 by revising paragraphs (a)(3)(i) and the last two sentences of paragraph (g) to read as follows:

§ 966.323 Handling Regulations.

* * * * *

(a) * * *

(3) * * *

(i) All tomatoes packed by a registered handler shall be packed in containers of 10, 20, and 25 pounds designated net weights. The net weight of the contents shall not be less than the designated net weight and shall not exceed the designated net weight by more than two pounds.

* * * * *

(g) * * * *U.S. tomato standards* means the revised United States Standards for Fresh Tomatoes (§§ 51.1855 through 51.1877) effective October 1, 1991, as amended, or variations thereof specified in this section, Provided that 51.1863 shall not apply to tomatoes covered by this part. Other terms in this section shall have the same meaning as when used in Marketing Agreement No. 125, as amended, and this part, and the U.S. tomato standards.

Dated: April 11, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–07530 Filed 4–15–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2019–0235; Notice No. 25–19–02–SC]

Special Conditions: Airbus Model A330 Series Airplanes; Seats With Inertia Locking Devices

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for Airbus Model A330 series airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is seats with inertia locking devices. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Send comments on or before May 16, 2019.

ADDRESSES: Send comments identified by Docket No. FAA–2019–0235 using any of the following methods:

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

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket website, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478).

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

FOR FURTHER INFORMATION CONTACT: Shannon Lennon, Cabin and Airframe Safety Section, AIR–675, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3209; email *shannon.lennon@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On February 13, 2019, Airbus applied for a change to Type Certificate No. A46NM for seats with inertia locking devices in Model A330 series airplanes. The Model A330 series airplane is a twin-engine, transport-category airplane with a maximum takeoff weight of 533,518 pounds and seating for 440 passengers.

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Airbus must show that the Model A330 series airplanes, as changed, continue to meet the applicable provisions of the regulations listed in Type Certificate No. A46NM, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for Airbus Model A330 series airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, Airbus Model A330 series airplanes must comply with the fuel-vent and exhaust-emission requirements

of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

Airbus Model A330 series airplanes will incorporate the following novel or unusual design features:

Seats with inertia locking devices (ILD).

Discussion

Airbus has proposed to install, in Model A330 series airplanes, Thompson Aero Seating Ltd. passenger seats that can be translated in the fore and aft direction by an electrically powered motor (actuator) that is attached to the seat primary structure. Under typical service-loading conditions, the motor internal brake is able to translate the seat and hold the seat in the translated position. However, under the inertial loads of emergency-landing loading conditions specified in 14 CFR 25.562, the motor internal brake may not be able to maintain the seat in the required position. The ILD is an ''active'' device intended to control seat movement (*i.e.,* a system that mechanically deploys during an impact event) to lock the gears of the motor assembly in place. The ILD mechanism is activated by the higher inertial load factors that could occur during an emergency landing event. Each seat place incorporates two ILDs; one on either side of the seat pan. Only one ILD is required to hold an occupied seat in position during worst-case dynamic loading specified in § 25.562.

The ILD will self-activate only in the event of a predetermined airplane loading condition such as that occurring during crash or emergency landing, and will prevent excessive seat forward translation. A minimum level of protection must be provided if the seat-locking device does not deploy.

The normal means of satisfying the structural and occupant protection requirements of § 25.562 result in a non-quantified, but nominally predictable, progressive structural deformation or reduction of injury severity for impact conditions less than the maximum specified by the rule. A seat using ILD technology, however, may involve a step change in protection for impacts below and above that at which the ILD activates and deploys to retain the seat pan in place. This could result in structural deformation or occupant injury output being higher at an intermediate impact condition than that resulting from the maximum impact condition. It is acceptable for such step-change characteristics to exist, provided the resulting output does not exceed the maximum allowable criteria at any condition at which the ILD does or does not deploy, up to the maximum severity pulse specified by the requirements.

The ideal triangular maximum severity pulse is defined in Advisory Circular (AC) 25.561–1B. For the evaluation and testing of less-severe pulses for purposes of assessing the effectiveness of the ILD deployment setting, a similar triangular pulse should be used with acceleration, rise time, and velocity change scaled accordingly. The magnitude of the required pulse should not deviate below the ideal pulse by more than 0.5g until 1.33 t_1 is reached, where t_1 represents the time interval between 0 and t_1 on the referenced pulse shape as shown in AC 25.561–1B. This is an acceptable method of compliance to the test requirements of the special conditions.

Proposed conditions 1 through 5 address ensuring that the ILD activates when intended in order to provide the necessary protection of occupants. This includes protection of a range of occupants under various accident conditions. Proposed conditions 6 through 10 address maintenance and reliability of the ILD, including any outside influences on the mechanism, to ensure it functions as intended.

The proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to Airbus Model A330 series airplanes. Should Airbus apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only one novel or unusual design feature on one model series of airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, 44704.

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Airbus Model A330 series airplanes.

In addition to the requirements of § 25.562, passenger seats incorporating inertia locking device (ILD)s must meet the following:

1. Level of Protection Provided by ILD—It must be demonstrated by test that the seats and attachments, when subject to the emergency-landing dynamic conditions specified in § 25.562, and with one ILD not deployed, do not experience structural failure that could result in:

a. Separation of the seat from the airplane floor.

b. Separation of any part of the seat that could form a hazard to the seat occupant or any other airplane occupant.

c. Failure of the occupant restraint or any other condition that could result in the occupant separating from the seat.

2. Protection Provided Below and Above the ILD Actuation Condition—If step-change effects on occupant protection exist for impacts below and above that at which the ILD deploys, tests must be performed to demonstrate that the occupant is shown to be protected at any condition at which the ILD does or does not deploy, up to the maximum severity pulse specified by § 25.562. Test conditions must take into account any necessary tolerances for deployment.

3. Protection Over a Range of Crash Pulse Vectors—The ILD must be shown to function as intended for all test vectors specified in § 25.562.

4. Protection During Secondary Impacts—The ILD activation setting must be demonstrated to maximize the probability of the protection being available when needed, considering a secondary impact that is above the severity at which the device is intended to deploy up to the impact loading required by § 25.562.

5. Protection of Occupants other than 50th Percentile—Protection of occupants for a range of stature from a two-year-old child to a ninety-five percentile male must be shown.

6. Inadvertent Operation—It must be shown that any inadvertent operation of the ILD does not affect the performance of the device during a subsequent emergency landing.

7. Installation Protection—It must be shown that the ILD installation is protected from contamination and interference from foreign objects.

8. Reliability—The performance of the ILD must not be altered by the effects of wear, manufacturing tolerances, aging/drying of lubricants, and corrosion.

9. Maintenance and Functional Checks—The design, installation and operation of the ILD must be such that it is possible to functionally check the device in place. Additionally, a functional check method and a maintenance check interval must be included in the seat installer's instructions for continued airworthiness (ICA) document.

10. Release Function—If a means exists to release an inadvertently activated ILD, the release means must not introduce additional hidden failures that would prevent the ILD from functioning properly.

Issued in Des Moines, Washington, on April 10, 2019.

Paul Siegmund,

Acting Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2019–07516 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 147

[Docket No.: FAA–2015–3901; Notice No. 19–02]

RIN 2120–AK48

Aviation Maintenance Technician Schools

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

ACTION: Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: On October 2, 2015, the FAA published in the **Federal Register** a notice of proposed rulemaking proposing to amend the regulations governing the curriculum and operations of FAA-certificated Aviation Maintenance Technician Schools. Commenters suggested expanding the scope of that proposal to allow competency-based training and satellite training locations and to eliminate the national passing norms specified in the quality of instruction requirements. After analyzing the comments, the FAA agrees with expanding the scope of the proposal. The FAA is proposing to allow the option of competency-based training and satellite training locations. Additionally, the FAA is proposing to amend the quality of instruction requirements by replacing the national passing norms with a standard pass rate.

DATES: Send comments on or before June 17, 2019.

ADDRESSES: Send comments identified by docket number FAA–2015–3901 using any of the following methods:

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

Privacy: 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.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20591, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact Robert W. Warren, Aircraft Maintenance Division, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267 1711; email *Robert.W.Warren@faa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

This rulemaking is promulgated under the authority described in Title 49, Subtitle VII, Part A, Subpart I, Chapter 401, Section 40113 (prescribing general authority of the Administrator of the FAA, with respect to aviation safety duties and powers, to prescribe regulations); and Subpart III, Chapter 447, Sections 44701 (general authority of the Administrator to prescribe regulations and minimum standards in the interest of safety for inspecting, servicing, and overhauling aircraft, engines, propellers, and appliances, including for other practices, methods, and procedures necessary for safety in air commerce); 44702 (authority of the Administrator to issue air agency certificates); 44707 (authority of the Administrator to examine and rate air agencies, including civilian schools giving instruction in repairing, altering, and maintaining aircraft, aircraft engines, propellers, and appliances, on the adequacy of instruction, the suitability and airworthiness of equipment, and the competency of instructors); and 44709 (authority of the Administrator to amend, modify, suspend, and revoke air agency and other FAA-issued certificates).

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I. Executive Summary

On October 2, 2015, the FAA published a NPRM titled ''Aviation Maintenance Technician Schools'' (80 FR 59674) proposing to amend 14 CFR part 147 (part 147), which contains the curriculum and operating requirements for Aviation Maintenance Technician Schools (AMTS). The FAA received over 300 comments in response to the NPRM. Among these comments were requests to the FAA to allow competency-based training (CBT) and satellite training locations. The FAA also received comments on the quality of instruction requirements, including the suggestion to remove the national passing norms.

Since any changes to the regulations covering these three topics would be beyond the scope of what was proposed in the NPRM, the FAA is publishing this SNPRM to provide notice of the proposed changes and the opportunity for comments on these new proposals.

In this SNPRM, The FAA proposes to allow AMTSs to deliver their approved curriculums using a CBT program. The FAA also proposes to allow satellite training locations for these schools, which could expand the capacity to recruit and educate future aircraft mechanics. Lastly, the FAA proposes to replace the current national passing norm requirements with a standard pass rate that would apply to all AMTSs.

CBT and satellite training locations would be voluntary provisions. Therefore, the FAA assumes the utilization of these flexibilities would produce benefits net of costs because AMTSs will only adopt these changes if they believe they will be cost beneficial. The FAA estimates that the overall cost saving of the requirement to replace the national passing norms with a standard pass rate would be minimal. Therefore, the expected outcome of this proposed rule will be a minimal impact.

Providing flexibility to AMTSs to use CBT may produce cost savings and generate benefits. For instance, CBT would allow AMTSs to pre-screen applicants for competencies they possess at the time of application, and provide relief to those applicants for the corresponding curriculum elements. CBT may also allow the AMTS to focus on the competencies for which their students require more remedial attention, providing a more individualized and higher-quality training for its students. At this time, the FAA does not have data to quantitatively assess whether the relief provided by the pre-assessment of student competencies would outweigh the costs associated with the additional care and attention provided to students who require remedial attention. Nevertheless, the FAA believes that CBT would allow AMTSs to concentrate resources on where they will provide the most benefits.

The FAA acknowledges that there would be some startup costs incurred for some schools to transition over to CBT. However, the FAA believes that because this SNPRM provides CBT as an additional flexibility, rather than a requirement, it can safely presume that any utilization of CBT would provide benefits or cost savings that exceed the costs. Similarly, the FAA acknowledges that AMTSs would incur costs to set up satellite locations, but the FAA presumes that AMTSs would only incur those costs if there were sufficient demand to recover them.

The FAA estimates that the overall cost saving of the requirement to replace the national passing norms with a standard pass rate would be minimal.

II. Background

A. Summary of NPRM

As previously stated, on October 2, 2015, the FAA published an NPRM titled ''Aviation Maintenance Technician Schools.'' [1] In the NPRM, the FAA proposed to amend the regulations governing the curriculum and operations of FAA-certificated AMTSs. The proposed rule would modernize and reorganize the required curriculum subjects found in the appendices of the current regulations. The FAA also proposed to remove the course content items from the appendices and relocate them to each school's operations specifications.[2] This change would enable easier and more timely amendments to course content when necessary. Additionally, the FAA proposed to revise the curriculum requirements to include an option for schools to use a credit hour curriculum as an alternative to an instructional hour curriculum.

The FAA proposed these changes because the existing curriculums in some areas are outdated, do not meet current industry needs, and can be changed only through notice and comment rulemaking. These amendments would better enable students to receive current foundational training that meets the demanding and dynamic needs of the aviation industry.

Additionally, with respect to the quality of instruction requirements, the FAA proposed to retain the current national passing norms, which require a named proportion of each school's graduates who apply within 60 days after graduation to pass the FAA written knowledge test during a specified period of time. The proportion of graduates who must pass the written knowledge test varies depending on the number of students who graduated from the school.

The proposals in the NPRM remain unchanged. However, given the length of time that has passed since the close of the NPRM's comment period, the FAA will accept any new or updated comments on the provisions in the NPRM. To avoid delay in issuing a final rule, the FAA requests that commenters refrain from resubmitting prior comments that are unchanged as those comments are already in the docket and will be addressed in the final rule.

B. Summary of Comments on NPRM

The FAA received 324 comments in response to the NPRM. Commenters included industry organizations, individuals, instructors, and management of AMTSs. This section summarizes only the comments that relate to the three topics proposed in this SNPRM. All other comments will be disposed of in the final rule.

Several commenters asked the FAA to allow schools to provide some form of CBT in lieu of training based on a set number of curriculum hours. These commenters included 15 industry organizations (*see* Table: Industry Organization Commenters) and 9 individuals. Commenters explained that allowing a CBT curriculum would create flexibility and allow students to progress as they demonstrate mastery of subject matter. All but one individual supported CBT without hesitation. One individual commented that he is opposed to CBT if there is no test period or study to validate the effectiveness of the new method of training.

TABLE—INDUSTRY ORGANIZATION COMMENTERS

Aviation Technician Education Council.
Aeronautical Repair Station Association.
Aerospace Maintenance Council.
Aircraft Electronics Association.
Aircraft Mechanic Fraternal Association.
Aircraft Owners and Pilots Association.
Airlines for America.
Aviation Suppliers Association.

[1] 80 FR 59677.

[2] Part 147 contains general curriculum subjects (appendix B), airframe curriculum subjects (appendix C), and powerplant curriculum subjects (appendix D). Each of these appendices contains subject headings, tasks within those subject headings, and the levels of proficiency to be demonstrated for each task. In the NPRM, the FAA proposed to revise and retain the subject headings but remove the remaining course content (*i.e.,* the tasks and proficiency levels) and place them in the AMTS' operations specifications.

TABLE—INDUSTRY ORGANIZATION COMMENTERS—Continued

Helicopter Association International.
Modification and Replacement Parts Association.
National Air Carrier Association.
National Air Transportation Association.
Regional Airline Association.
STEM Education Coalition.
University Aviation Association.

One commenter asked the FAA to allow schools to conduct training at satellite locations away from the schools' primary location, such as at high schools.

Several commenters commented on the quality of instruction requirements. One commenter recommended the FAA remove the quality of instruction requirements entirely. The commenter explained that requiring passing norms is unnecessary and creates additional surveillance burdens on the FAA without an increase in safety. Several commenters expressed concern with the FAA's proposal to add a requirement that stated the failure to maintain the quality of instruction may be the basis for suspending or revoking the school's certificate.

These comments are discussed in more detail in section III of this preamble, ''Discussion of SNPRM.''

C. General Overview of SNPRM

The commenters' requests to allow CBT and satellite training locations and to eliminate the passing norms were beyond the scope of the NPRM. After considering the comments and the potential benefits to industry, the FAA has decided to expand the scope of the rulemaking by issuing an SNPRM. This SNPRM contains three new proposals. First, the FAA proposes to allow AMTSs to deliver their approved curriculums using CBT programs. The FAA proposes to add a new section, § 147.22, that would prescribe the requirements for a CBT program. Second, the FAA proposes new § 147.14 to allow satellite training locations for AMTSs, such as at high schools, which could expand the capacity to recruit and educate future aircraft mechanics. Lastly, the FAA proposes to amend the quality of instruction requirements in § 147.37 by removing the national passing norm requirements and replacing them with a standard pass rate. These proposals are discussed in more detail in the following section.

III. Discussion of SNPRM

A. Competency-Based Training (CBT)

In the NPRM, the FAA proposed to revise § 147.21(b) to allow schools to use a credit hour curriculum instead of a traditional instructional hour curriculum. In the context of this proposal, the NPRM mentioned the term ''competency-based training.'' [3]

One commenter explained that a CBT curriculum would be based on knowledge and skill requirements rather than hour requirements. Another commenter asserted that the FAA confused credit hours with competency. The FAA received several comments asking for a competency-based standard free of defined schedules and hour requirements. Many commenters suggested that CBT would allow industry to transition away from classroom ''seat'' time in favor of a structure that creates flexibility and would allow students to progress as they demonstrated mastery of the specific subject matter, regardless of time, place, or pace of learning. Another commenter explained that competency-based instruction would allow instructors to meet each student's learning needs and styles.

After analyzing these comments, the FAA recognized that its use of the term ''competency-based training'' in the context of a credit hour curriculum was inconsistent with the concept of competency-based education. The International Civil Aviation Organization (ICAO) defines ''competency-based training and assessment'' as training and assessment that are characterized by a performance orientation, emphasis on standards of performance and their measurement, and the development of training to the specified performance standards.[4] Upon review of the comments on the NPRM, the FAA has decided to expand the proposal to include an option for schools to use a CBT curriculum.

In this SNPRM, the FAA proposes to add a new § 147.22, which would contain the requirements for a CBT program. Additionally, because proposed § 147.21(b) would require each school's approved curriculum to offer a prescriptive number of instruction hours or credit hours for the rating sought, the FAA is proposing to include an exception in proposed § 147.21(b) for CBT programs that satisfy the requirements of proposed § 147.22. Section 147.22 would add CBT as an option for certificated AMTSs. Under the proposed regulatory framework, the FAA would allow an AMTS to offer a CBT program in addition to either an instructional hour program or a credit hour program. Alternatively, an AMTS would have the option to provide only CBT under proposed § 147.22. However, based on proposed § 147.21(b), if a school chooses not to offer CBT, that school must offer either instruction hours or credit hours.

Under proposed § 147.22, a certificated AMTS could develop and use a CBT curriculum, provided the school obtains FAA-approval of its CBT program through an operations specification. An AMTS may develop a general, airframe, and/or powerplant CBT curriculum, or a combined airframe and powerplant curriculum, as applicable to the school's ratings. In addition, the proposal would allow an AMTS to develop individualized curriculums for students based on pre-training assessments. A CBT program would encompass an AMTS's CBT curriculum(s). In addition, proposed § 147.22 would require a CBT program to include the following elements: Structure and content, training, competency assessments, students with prior training and experience, instructor qualification, data collection and analysis process, and recordkeeping. These proposed requirements are addressed in more detail in the following discussions.

1. Structure and Content

CBT is a method of instruction that defines a set of competencies and that trains and assesses each student to achieve those competencies. A competency is a combination of skills, knowledge, and observable behaviors required to perform a task to the prescribed standard.[5] The FAA proposes to allow certificated AMTSs to develop a CBT program for FAA-approval.

Under proposed § 147.22, to obtain FAA approval, the CBT curriculum would be required to cover the subjects prescribed in appendices B, C, and/or D, the course content items and teaching levels included under those subject headings, and the applicable competencies for each of those items. The FAA would give schools the flexibility to define the competencies in their CBT curriculums. However, the schools would be required to define the competencies based on the course content items and associated teaching levels, which the FAA proposed to include in the schools' operations specifications.[6] The FAA believes the

[3] 80 FR 59677.

[4] ICAO Doc 9868, Procedures for Air Navigation Services, Training, 2d Edition (2016).

[5] ICAO defines competency as ''[a] combination of skills, knowledge, and attitudes required to perform a task to the prescribed standard.'' Doc 9868, Procedures for Air Navigation Services, Training, 2nd ed. (Oct. 11, 2016).

[6] 59674 FR at 59676.

course content items and associated teaching levels convey the minimum standards necessary to qualify students to meet the requirements for a mechanic certificate, which are specified in part 65, subpart D. Accordingly, proposed § 147.22(b)(2) would allow a certificated AMTS to define in its CBT curriculum the competencies, to include knowledge, skills, and observable behaviors, that apply to each course content item and associated teaching level. The school would then train and assess its students to the competencies defined in its curriculum.

Additionally, the FAA believes that a certificated AMTS should have the flexibility to develop course content items that are not prescribed by the FAA, and add those course content items, which must be approved, to the operations specification. The FAA therefore proposes § 147.22(b)(3) to allow schools to develop additional course content items in its approved curriculum. Additional course content items would be listed in Table II of the appropriate operations specification. For each additional course content item the school develops, the FAA proposes to require the school to define the applicable competencies, to include the knowledge, skills, and observable behaviors to which the student would be trained and assessed.

2. Training, Competency Assessments, and Remedial Training

Under a CBT program, rather than focusing on the number of instructional hours received in a classroom, schools would be focused on training students to achieve the competencies, which include knowledge, skills, and observable behaviors, that are necessary to perform as a certificated mechanic. A CBT curriculum would allow schools to train students in a more individualized manner based on the students' knowledge and skill levels. Students would advance in the areas they demonstrate competency and would receive additional training in the areas they are deficient. This competency-based structure would enable students to advance at their own pace while placing emphasis on demonstrated proficiency rather than the instruction time.

A CBT curriculum would train a student to achieve the applicable competencies, assess whether the student can demonstrate the applicable competencies, and conduct remedial training in areas in which the student has failed to demonstrate the applicable competencies. Therefore, the FAA is proposing training requirements in § 147.22(c), assessment requirements in § 147.22(d), and remedial training requirements in § 147.22(e).

Proposed § 147.22(c)(1) would require the AMTS to train each student to achieve the competencies defined in its curriculum. The FAA proposes to allow a CBT curriculum to consist of a variety of teaching methods that are not based on hours of instruction or credit hours. For example, these teaching methods may include, but are not limited to, lectures, distance learning, and practical projects in the shop or laboratory. Additionally, the FAA proposes to allow a CBT curriculum to offer group instruction, one-on-one instruction, or any combination thereof. However, the AMTS would still be required to comply with instructor to student ratios in § 147.23 and instruction equipment requirements in § 147.17(c). The FAA believes this flexibility would allow schools to tailor their teaching methods to their students.

While the FAA intends to give schools the necessary flexibility in developing their CBT curriculums, these curriculums are still required to be approved by the FAA. Therefore, under proposed § 147.22(c)(2), the FAA proposes to require the school to describe, for each course content item, various elements of its CBT curriculum. In addition to defining the applicable competencies for each course content item, the school would be required to describe which teaching methods it intends to use for each course content item, including any classroom, distance learning, and laboratory or shop requirements. The school would also be required to describe which portions of the curriculum would be given in a group setting and which would be given one-on-one. The FAA also believes a school should be required to define its order of instruction in its CBT curriculum. The order of instruction is necessary because under a CBT program a student should not advance to a related course content item or subject area until the student has demonstrated mastery of the current subject matter. A related course content item or subject area is one for which the school has defined a prerequisite or precursor for subsequent learning. Furthermore, while a school would have the flexibility to determine when a test or assessment should be conducted under a CBT program, the FAA proposes to require each school to describe the schedule of tests and assessments for each course content item. The school would also be required to describe the objective testing and grading criteria it would use in conducting any tests or assessments.

Proposed § 147.22(d) would include the requirements for competency assessments. The FAA believes that competency assessments are a key element in a CBT program because they measure the effectiveness of the training, the student's comprehension of the material, and the student's knowledge and skill level in the course content item being assessed. Each school must determine the scoring guide(s) that would be used to conduct each competency assessment. By assessing whether a student has achieved the competencies defined in the CBT curriculum, the school would determine whether the student needs additional training in a certain area.

Under proposed § 147.22(d), each school conducting a CBT program would be required to assess whether its students can demonstrate the applicable competencies for each course content item. The FAA proposes to allow the school to determine when and how it would assess its students; however, these details must be described in its CBT program. Additionally, the school must develop a series of assessments that, in their totality, assess each course content item; determine whether the student can demonstrate all applicable competencies; and are consistent with the required teaching levels specified in the operations specification.

In accordance with § 147.22(d)(4), a school may find a student competent when the student can demonstrate each applicable competency, with respect to the course content item being assessed, at a minimum of 70 percent. A generally accepted academic standard for passing is a minimum of 70 percent. This is the current standard used by the FAA to determine adequate knowledge and skill for airmen. Certificated AMTSs would have the discretion to use a standard that exceeds 70 percent, provided the standard is defined in the school's approved CBT program.

Under proposed § 147.22(d)(5), the FAA would allow issuance of a graduation certificate or certificate of completion when the student can demonstrate successful completion of each competency outlined in the student's curriculum. The school would still be required to comply with § 147.35 (as proposed in the NPRM). Thus, the school would be required to provide a graduation certificate or certificate of completion to every student it graduates. The certificate would be required to show the date of graduation, the approved curriculum, and an official of the school would be required to authenticate it. The FAA seeks comment on whether the graduation certificate

should also include the school's name and air agency certificate number.

Because the objective of CBT is to train each student to achieve the applicable competencies, to include knowledge, skill, and observable behaviors, the FAA proposes to require remedial training in any course content item for which the student has failed to demonstrate competency during the required assessment. The FAA proposes requirements governing remedial training in § 147.22(e). At the conclusion of a competency assessment, the school would determine whether remedial training is necessary in accordance with proposed § 147.22(e). If a student fails to demonstrate competency of a course content item in accordance with the standard specified in proposed § 147.22(d)(4), the school would be required to provide additional training and reassessment in areas of deficiency until the student can demonstrate the knowledge, skills, and observable behaviors that reflect the competencies at a minimum of 70 percent. The FAA emphasizes that a student would not be allowed to advance to a subsequent related course content item or subject area until that student has achieved the competencies in the subject area in which they were found deficient.

3. Students With Prior Training or Experience

The FAA received several comments regarding how a CBT program would benefit an individual with prior training or experience. One commenter explained how qualified mechanics from other fields are currently required to sit through redundant training to meet the prescribed number of hours under the traditional instruction hour curriculum. The FAA sees some minor redundancies in training when comparing, for example, an aircraft mechanic to an automobile mechanic. However, these redundancies are limited in scope. Because aviation maintenance practices and procedures are governed by a specific and unique regulatory framework, it is essential that students with maintenance experience in other fields receive comprehensive and complete training within AMTS curriculums. The FAA proposes to require a pre-training assessment for students that are seeking credit for prior training or experience in aviation maintenance, such as in a certain subject area or specific course content items. Persons with non-aviation related mechanical experience or training would not be eligible for pre-training assessments. Individuals must receive specific training relating to aircraft and aircraft safety because of the hazards, risks, and responsibilities associated with aviation maintenance. Students with non-aviation experience or training still stand to benefit from a CBT program, progressing at their own pace rather than attending class for the required number of instructional hours.

Proposed § 147.22(f)(1) would allow a school to conduct a pre-training assessment of the student's initial competencies. Because a student with prior training or experience should be trained and assessed to the same standard as the other students, the FAA proposes to require the pre-training assessment to meet the competency assessment requirements of § 147.22(d)(1), as applicable to the course content item being assessed. If during a pre-training assessment, the student fails to demonstrate each applicable competency, with respect to the course content item being assessed, at a minimum of 70 percent, the school may not credit the student with competency in the course content item(s). At the completion of a pre-training assessment, the student would receive an individualized curriculum that would include only those subject areas and/or course content items where competency was not demonstrated. After the curriculum is determined for the individual, the student should receive training, competency assessments, and remedial training (if applicable) in the same form and manner as the other students.

Proposed § 147.22(f) is intended to allow individuals with prior training or experience to advance quickly through certain subject areas or course content items, provided they can demonstrate that they have already achieved the applicable competencies.

4. Instructors

The FAA believes that transitioning to the proposed CBT program from a traditional curriculum based on instructional hours would affect the way instructors teach and assess their students. Currently, instructors teach their students to achieve knowledge and skill for each course content item. CBT adds the dynamic of observable behaviors as applicable to a particular course content item and the competencies associated with it. Under the proposed CBT program, the instructors' emphasis would be on training and assessing students based on their knowledge, skills, and observable behaviors with respect to each course content item. Instructors must know and understand the competencies that are applicable to each course content item and the associated observable behaviors that the student must demonstrate.

For the reasons stated above, the FAA believes it would be necessary to require the schools to train their instructors on the school's CBT program, including delivery methods and assessment techniques. Additionally, the FAA believes schools should evaluate the instructors' competencies to ensure the instructors are qualified to provide CBT training and assessments. Therefore, proposed § 147.22(g) would require a CBT program to describe how the school will train and evaluate its instructors.

Furthermore, the FAA recognizes the concerns from one commenter regarding the instructor-to-student ratio in a CBT curriculum. The commenter explained how a CBT curriculum would require a lesser ratio of students to instructor in order to accommodate students progressing at different rates. The commenter further stated that, with practical application projects, a CBT program may require one-on-one instruction.

As proposed in § 147.22(c)(1), a CBT program may include group instruction, individualized instruction, or any combination thereof. For any group instruction offered under a CBT program, the FAA proposes to require schools to describe the instructor-to-student ratios that would apply, including the ratio that would apply in the laboratory or shop. The FAA is also proposing to require the CBT program to meet the requirements of proposed § 147.23, which would require at least 1 instructor for each 25 students in the shop or laboratory. The FAA believes these proposed requirements would provide schools with enough flexibility to define their own instructor to student ratio, while giving the FAA the ability to review and approve such ratios. The FAA seeks comments regarding the instructor-to-student ratios in a CBT program. Specifically, the FAA seeks comments regarding whether the FAA should impose more prescriptive requirements in proposed § 147.22 in terms of how many students should be allowed per instructor under a CBT program, taking account for the various methods of training that the instructor may provide.

5. Data Collection, Analysis and Recordkeeping

The proposal to allow CBT would introduce an entirely new method of training in the aviation maintenance industry. While the FAA believes CBT training would have several benefits in the field, as previously discussed, requirements would be necessary to ensure the program is accomplishing its

objectives. As one commenter pointed out, if the FAA allows CBT, it should be verified as effective to ensure it achieves the goal of enabling graduates to perform the duties of a FAA certificated mechanic. The primary objective of a CBT program, to prepare student mechanics for FAA certification, is the same as for the instruction hour or credit hour programs. However, a secondary objective is to better prepare student mechanics for the workplace by teaching course content items and how they relate to a competency and its observable behaviors. The FAA has concluded that a student educated in this CBT program would have a better foundation and contribute more rapidly in their future workplace.

Under proposed § 147.22(h), the FAA proposes to require each school conducting a CBT program to establish and maintain a data collection and analysis process on its students and instructors that would enable the school and the FAA to determine whether the CBT program is accomplishing its objectives. The FAA believes this proposal would benefit both the school and the FAA because it would enable the school and the FAA to identify any deficiencies in the program and adjust the CBT curriculum or instruction accordingly. This proposal would foster a better understanding of CBT curriculums and assist the FAA in its oversight of approved CBT programs.

In connection with the data collection and analysis process, the FAA proposes to require the school to maintain records reflecting the outputs of the process for a minimum of 2 years. The records would include, at a minimum, the data collected by the process, the results of the analysis, and the plans for corrective actions that were taken as a result of the analysis process. The intent is to identify deficiencies within the CBT program, and to verify that action is being taken to correct those deficiencies. Maintaining the records for 2 years is consistent with existing AMTS recordkeeping requirements and provides sufficient data for trend analysis.

Furthermore, the FAA believes that additional recordkeeping requirements would be necessary under a CBT program to ensure that each student's progression through the CBT curriculum is clearly documented. Under a CBT program, a school would have more flexibility in developing a curriculum and students would receive competency assessments rather than traditional tests. These competency assessments would assess whether the student may progress to subsequent course content items. The FAA notes that competency assessments are a new concept in the regulations and are not encompassed by the recordkeeping requirements of proposed § 147.33. Therefore, the FAA proposes, in § 147.22(i), to require each certificated AMTS conducting an approved CBT curriculum to establish and maintain for each student enrolled records that show the student's progression through his or her individual curriculum, including documentation of any pre-training assessments and competency assessments. The FAA believes this proposed recordkeeping requirement would ensure that the proper records verifying the student's completion of the curriculum, or portions thereof, would be retained. The FAA notes that the AMTS would also be required to meet the record requirements of § 147.33. The FAA may find that changes are needed to a CBT program to ensure its effectiveness. Under performance of an AMTS is usually observed by an FAA inspector during on-site surveillance or through the test results of recently graduated students. The *8080–08 School Norms* vs. *National Passing Norms Report*[7] published quarterly is a useful tool for the school and the inspector to identify subject areas needing improvement. An AMTS is expected to maintain compliance with the standard in § 147.37. If the FAA observes that the CBT program is not producing the desired results the certificate holder will be notified and must make the necessary corrections. The FAA would revise Advisory Circular (AC) 147–3, which provides guidance to comply with the proposed rules.[8]

B. Satellite Training Locations

In the NPRM, the FAA did not propose to permit satellite training locations for AMTSs. However, the Aviation Technician Education Council (ATEC) suggested a revision to proposed § 147.13 to permit a school to conduct operations outside of its primary location, such as at high schools. ATEC recommended language that would allow a school to make educational programs more readily available through partnerships with secondary education institutions. ATEC noted that several programs currently exist that help recruit future technicians before they graduate from high school, and its suggested change would ensure that all schools have the same, consistent opportunity to expand programs to local high school students.

The FAA agrees with ATEC's comment and therefore, proposes to add a new section, § 147.14, to facilitate satellite training locations for AMTSs. A satellite training location would be a training location away from the school's primary location. Under the proposal, an AMTS could add one or more satellite training locations. A satellite training location may be either dependent, which means it would not hold its own AMTS certificate under part 147, or independent. An independent satellite training location would hold its own AMTS certificate and be held responsible for complying with the requirements of part 147.

To conduct operations at a satellite training location, a certificated AMTS would be required to apply to the FAA at least 60 days before the training would commence. The application would be required to include the following: A description of the proposed curriculum; a list of the facilities, including their physical addresses, and the materials and equipment to be used; a list of the instructors to be used, including the kind of certificate and ratings held by each, and their certificate numbers; and the maximum number of students to be enrolled at any one time.[9]

Both dependent and independent satellite training locations would be approved through a new operations specification, which would be issued to the parent AMTS (the certificate holder), provided the satellite training location meets the applicable requirements of part 147. The parent AMTS OpSpec would list all of the parent's authorized satellite training locations. For each satellite training location, the operations specifications would list the person responsible for operations conducted at the location. For dependent satellite training locations, the operations specifications would also list the curriculum, or portion thereof, that the satellite is authorized to teach. The FAA notes that the parent AMTS operations specifications would not list the curriculum that the independent satellite training location would be authorized to teach because an independent satellite training location would have its own part 147 certificate and thus its own operations specifications outlining its approved curriculum. This approved curriculum, however, is expected to mirror that of the parent AMTS curriculum. The

[7] Quality of instruction results are published quarterly in the *8080–08 School Norms* vs. *National Passing Norms Report*. These reports provide AMTS students testing results for the specific subject areas in which they are tested.

[8] *See* Docket No. FAA–2015–3901.

[9] These requirements are contained in § 147.5(a)(1) through (5), as proposed in the NPRM.

parent AMTS must develop adequate procedures describing satellite operations acceptable to the FAA, and make them available to each satellite location. For example, procedures would be necessary to address the sharing of equipment, tools, and personnel.

Both types of satellite training locations must use the curriculum and procedures of the parent AMTS. The independent satellite training locations, however, may implement differences in the curriculum and procedures, provided those differences are documented and accepted or approved by the FAA, as applicable. Satellite training locations may also share tools, equipment, and instructors with the parent AMTS and with other satellites of the parent AMTS.[10] The proposed requirements that would apply to both dependent and independent satellite training locations are contained in § 147.14(a).

The first kind of satellite is a dependent satellite training location. The dependent satellite training location would be managed by the parent AMTS and would operate under the part 147 certificate issued to the parent AMTS. Therefore, the parent AMTS would be responsible for ensuring the dependent satellite training location maintains compliance with all part 147 requirements. Under this proposed structure, a dependent satellite (*e.g.,* a trade school, a high school, or other training location) [11] would for example, offer some of the courses in the AMTSs' General Curriculum. The satellite training location would be issued a unique designator code to identify its satellite status. The proposed requirements for dependent satellite training locations are contained in § 147.14(b). The FAA proposes to include a provision in § 147.14(b)(3) that would subject dependent satellite training locations to FAA inspection of facilities to determine compliance with part 147.[12]

The second kind of satellite is an independent satellite training location. As previously mentioned, an independent satellite training location would operate under its own part 147 certificate and would be responsible for ensuring its own compliance with the applicable requirements of part 147. A currently certificated AMTS may choose to be an independent satellite training location in order to have its training program under the control of a parent AMTS certificate holder. This proposed structure may be beneficial because it would allow a certificated AMTS to serve as a satellite training location without having to surrender its current part 147 certificate. Additionally, an independent satellite training location may find value in using a parent AMTS training program and in sharing facilities, equipment, and personnel with the parent AMTS and its other satellite locations. An AMTS that wants to become an independent satellite must use the curriculum and procedures of the parent AMTS. An independent satellite training location would already hold an air agency certificate and certificate number. Its 4-letter designator would be used to identify its satellite status. As with all certificated AMTSs, the independent satellite would be issued applicable operations specifications. Because a satellite training location must use the curriculum and procedures of the parent AMTS, and the curriculum is a function of the ratings, an independent satellite location may not hold a rating that the parent AMTS does not hold. An independent satellite training location would not be eligible to have a satellite training location of its own.

The FAA appreciates that if an AMTS is able to have a satellite training location, it could expand its capacity to educate future airframe and powerplant (A&P) mechanics, especially if offered as part of a high school program. The expansion of student mechanic training would benefit industry by helping to mitigate A&P mechanic shortages. Expanding the geographic base by allowing satellite locations may also reduce commuting times for some students.

The FAA would revise AC 147–3 to include guidance on satellite operations.[13]

C. Quality of Instruction

In the NPRM, the FAA proposed to move the quality of instruction requirements from § 147.38(a) to § 147.37. Additionally, the FAA proposed to revise the quality of instruction requirements by adding proposed § 147.37(b), which would have stated that the failure of a school to maintain the quality of instruction specified in § 147.37(a) may be the basis for suspending or revoking that school's certificate.

Several commenters objected to the language in proposed § 147.37(b). One commenter stated ''the ability of the FAA to suspend or revoke without due process in this manner should not be available.'' Another commenter pointed out that the NPRM preamble did not address the new language in proposed § 147.37(b) and that it should be removed.

Though the FAA did not discuss proposed paragraph § 147.37(b) in the NPRM preamble, the proposed language would not have created a new burden or imposition on industry. Currently, if a certificated AMTS fails to meet the quality of instruction requirements in § 147.38(a), the inspector would discuss the expectations and requirements for compliance. The AMTS is then given the opportunity to correct the deficiencies by developing a corrective action plan, and implementing that plan, to achieve compliance. However, if an AMTS refuses to correct the non-compliance or fails to achieve compliance over time, the FAA may suspend or revoke the schools' AMTS certificate.[14] In light of the comments, however, the FAA recognizes that proposed § 147.37(b) was focused more on revocation and suspension of a certificate, rather than on corrective action. In an effort to be more consistent with the FAA's compliance and enforcement policy,[15] the FAA emphasizes that the failure of a school to maintain the quality of instruction requirements may be the basis for compliance action. However, the FAA has concluded that it is unnecessary to include this language in the regulation. Persons should know that any failure to comply with the regulations of 14 CFR may be the basis for a compliance action. The FAA is therefore withdrawing § 147.37(b) (as proposed in the NPRM). As a result, § 147.37(a) (as proposed in the NPRM) is now proposed § 147.37.

ATEC recommended deleting the quality of instruction requirements entirely with the justification ''the schools have specific accreditation and DOE requirements, not to mention ''customer'' demands that necessitate high quality programs. Having passing norms dictated in regulation only creates additional surveillance burdens on FAA without an increase in safety.''

[10] Instructors must be listed on either the parent AMTS OpSpec, or an independent satellite's OpSpec.

[11] The FAA notes that the examples listed could become independent satellites if they chose to pursue part 147 certification. This list of examples is not all-inclusive.

[12] The FAA notes that it is unnecessary to include a similar requirement for independent satellite training locations because an independent satellite training location would be operating under its own part 147 certificate and would be subject to FAA inspection.

[13] *See* Docket No. FAA–2015–3901.

[14] An aviation maintenance technician school certificate or rating is effective until it is surrendered, suspended, or revoked. 14 CFR 147.7. *See* FAA Order 2150.3, FAA Compliance and Enforcement Program (Feb. 2, 2017).

[15] FAA Order 2150.3, FAA Compliance and Enforcement Program (Feb. 2, 2017).

Because the FAA certificates and maintains oversight of AMTSs, the FAA needs to ensure that the quality of instruction received by the students is reflected positively in their FAA written knowledge tests. After a critical analysis of proposed § 147.37,[16] the FAA acknowledges that requiring an AMTS to meet a norm based on relative peer performance is not particularly relevant. Comparing one school's graduates to another school's graduates does not effectively measure either school's quality of instruction. The FAA believes a better measure of success would be to set a uniform standard for all AMTSs. The FAA would evaluate a school's quality of instruction by determining whether the school's graduates achieved the standard rather than comparing schools against one another. A generally accepted academic standard for passing is a minimum of 70 percent. This is the current standard used by the FAA to determine whether an airman has demonstrated adequate knowledge on an FAA written exam. Therefore, the FAA proposes to simplify § 147.37 to require each AMTS to ensure that, in the prior 24 calendar months, it provided instruction of sufficient quality that at least 70 percent of its graduates passed [17] on the first attempt each written knowledge test leading to a certificate or rating. The Airman Testing Branch will continue to receive FAA written exam test results from the Airmen Knowledge Testing Centers and compile quarterly reports.[18] The FAA will use the quarterly reports to ensure the quality of instruction required by § 147.37. The proposal does not impose any reporting requirements on an AMTS or its graduates.

D. Miscellaneous Amendment

The FAA is also proposing a clarifying amendment to § 147.17(a)(2). Currently, § 147.17(a)(2) requires an applicant for a mechanic school certificate and rating, or for an additional rating, to have ''at least one aircraft of a type currently certificated by FAA for private or commercial operation.'' As explained in AC 147–3B,[19] certification in this context refers to FAA type certification.[20] However, it has been brought to the FAA's attention that this language, which dates back to the 1950's,[21] could be interpreted otherwise. For example, a person could interpret ''an aircraft of a type currently certificated by the FAA'' as referring to any aircraft certificated by the FAA for private or commercial operation, such as an amateur-built aircraft. The FAA believes that AC 147–3B, which states that § 147.17(a)(2) requires an AMTS to provide a type-certificated aircraft for student instruction,[22] reflects the FAA's original intent. Therefore, the FAA is proposing to revise § 147.17(a)(2) to require each certificated AMTS to provide and maintain at least one aircraft type-certificated by the FAA.

IV. Regulatory Notices and Analyses

A. Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (RFA) (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing United States (U.S.) standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995; current value is $155 million). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this proposed rule.

In conducting these analyses, the FAA has determined that this proposed rule: (1) Has benefits that justify its costs, (2) is not an economically ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, (3) is not ''significant'' as defined in DOT's Regulatory Policies and Procedures; (4) would not have a significant economic impact on small entities; (5) would not create unnecessary obstacles to the foreign commerce of the U.S.; and (6) would not impose an unfunded mandate on state, local, or tribal governments, or on the private sector by exceeding the threshold identified above. These analyses are summarized below.

Affected Population

In the NPRM, the FAA estimated 162 part 147 AMTSs would be affected by the proposed rule. In this SNPRM, the FAA estimates the same affected AMTSs have the option of either implementing competency-based training and/or to set up satellite training locations.

Additional Flexibilities

This SNPRM provides additional flexibilities to the NPRM published October 2, 2015, provisions proposed in the NPRM not discussed here are unchanged from the NPRM. More specifically, the SNPRM would expand the scope of that proposal to allow CBT and satellite training locations, which are voluntary provisions, and it would also eliminate the national passing norms specified in the quality of instruction requirements.

Voluntary Provisions

Under a CBT program, rather than focusing on the number of instructional hours received in a classroom, AMTSs would be focused on training students to achieve the competencies, which include knowledge, skills, and observable behaviors, that are necessary to perform as a certificated mechanic. A CBT curriculum would allow schools to train students in a more individualized manner based on the students' knowledge and skill level. Students would advance in the areas they demonstrate competency in and would receive additional training in the areas in which they are found deficient. This competency-based structure would enable students to advance at their own pace while placing emphasis on demonstrated proficiency rather than the instruction time.

The FAA recognizes that if an AMTS is able to have a satellite training location, then it could expand its capacity to educate future A&P mechanics, especially if offered with a

[16] The quality of instruction requirements are currently found in § 147.38(a). In the NPRM, the FAA proposed to relocate these requirements to § 147.37.

[17] Under 14 CFR 65.17(b), the minimum passing grade for each test is 70 percent.

[18] *https://www.faa.gov/data_research/aviation_data_statistics/test_statistics/*.

[19] AC 147–3B, ''Certification and Operation of Aviation Maintenance Technician Schools,'' (June 5, 2015).

[20] AC 147–3B, Section 2–10, Page 13.

[21] Part 53 Mechanic School Certificates, Rules, Policies, and Interpretations of CAA, 18 FR 4281 (July 23, 1953). Section 53.25(b) required ''at least one modern-type aircraft complete with powerplant, propeller, instruments, radio (two-way), landing lights, flares, and other items of equipment and accessories on which a mechanic might be required to work and with which he should be familiar.'' *Id.* at 4283. In § 53.25–1, the CAA interpreted a modern-type aircraft as meaning ''an airplane of a type currently certificated by CAA for private or commercial operation.'' *Id.*

[22] AC 147–3B, Section 3–14, Page 21.

high school program. The expansion of student mechanic training would benefit industry by expanding educational opportunities, which would mitigate A&P mechanic shortages. Additionally, if a school has the option of providing some of its training through satellite training locations, then its geographic base can expand, along with the opportunity to partner with high schools in order to expand the recruiting age envelope. Expanding the geographic base by allowing satellite locations may also reduce commuting times for some students.

Providing flexibility to AMTSs to use CBT may produce cost savings and generate benefits. For instance, CBT would allow AMTSs to pre-screen applicants for competencies they possess at the time of application, and provide relief to those applicants for the corresponding curriculum elements. CBT may also allow the AMTS to focus on the competencies for which their students' require more remedial attention, providing a more individualized and higher-quality training for its students. At this time, the FAA does not have data to quantitatively assess whether the relief provided by the pre-assessment of student competencies would outweigh the costs associated with the additional care and attention provided to students who require remedial attention. Nevertheless, the FAA believes that CBT would allow AMTSs to concentrate resources on where they will provide the most benefits.

The FAA acknowledges that there would be some startup costs incurred for some schools to transition over to CBT. However, the FAA believes that because this SNPRM provides CBT as an additional flexibility, rather than a requirement, it can safely presume that any utilization of CBT would provide benefits or cost savings that exceed the costs. Similarly, the FAA acknowledges that AMTSs would incur costs to set up satellite locations, but the FAA presumes that AMTSs would only incur those costs if there were sufficient demand to recover them.

CBT and satellite training locations are voluntary provisions. Therefore, the FAA assumes the utilization of these flexibilities would produce benefits net of costs.

Quality of Instruction

The FAA proposal to eliminate the national passing norms specified in the quality of instruction requirements would result in the elimination of some national data from the 8080–08 report.[23] The FAA estimates this would provide minor cost savings associated with reduced paperwork for the FAA as estimated in the Paperwork Reduction Act section.

Cumulative Impacts

The total estimated cost savings of the NPRM over the analysis period would be about $6.8 million in 2016 dollars.[24] This stream of cost savings has a present value of $3.4 million when discounted at seven percent. The total estimated cost savings of the SNPRM over the analysis period would be minimal. The following table presents the cumulative cost savings over 10 years for the NPRM and SNPRM.

Cost Savings Over 10 years of NPRM and SNPRM (in 2016 Dollars)		
	NPRM	
	Present Value at 7%	Annualized at 7%
Changes to the curriculum hours	$6,567,198	$935,038
Exemptions	$159,608	$22,725
Curriculum Revisions	-$3,300,950	-$469,989
Total	$3,425,856	$487,774
	SNPRM	
	Present Value at 7%	Annualized at 7%
Competency-based training	Optional	Optional
Satellite training locations	Optional	Optional
Quality of instruction	Minimal	Minimal
Total	Minimal	Minimal

Therefore, the cumulative impact of this SNPRM will be minimal, and a regulatory evaluation was not prepared. The FAA requests comments with supporting justification about the FAA determination of minimal impact.

B. Regulatory Flexibility Determination

The RFA establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation.'' To achieve that principle, the RFA requires agencies to solicit and consider flexible regulatory proposals

[23] As a result of this change the National Applicants and the National Norm columns would be eliminated from the 8080–08 report.

[24] U.S. DOT/FAA—Regulatory Evaluation—Aviation Maintenance Technician Schools—NPRM 14 CFR parts 147, *https://www.regulations.gov/searchResults?rpp=25&po=0&s=2015-3901-0093&fp=true&ns=true.*

and to explain the rationale for their actions. The RFA covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

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

The FAA identified a total of 19 AMTSs with less than 1,500 employees which are classified as small entities. The FAA believes that this SNPRM would not have a significant economic impact on these small AMTSs because any costs they would voluntarily incur would be small and offset by cost savings.

If an agency determines that a rulemaking will not result in a significant economic impact on a substantial number of small entities, the head of the agency may so certify under section 605(b) of the Regulatory Flexibility Act. Therefore, as provided in section 605(b), based on the previous analysis the head of the FAA certifies that this rulemaking will not result in a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the U.S., so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this proposed rule and determined that the objective would only affect domestic firms therefore would not create unnecessary obstacles to the foreign commerce of the United States.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $155 million in lieu of $100 million. This proposed rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

On April 3, 2018, the FAA published a notice proposing to amend the OMB supporting statement for information collection, OMB Control Number: 2120–0040, which would update the information collection to account for recordkeeping burdens in part 147 that were not previously accounted for. As part of the part 147 proposed rulemaking, the FAA has identified provisions in the NPRM and SNPRM with Paperwork Reduction Act (PRA) implications that, if finalized as proposed, will require the FAA to make additional amendments to information collection OMB Control Number: 2120–0040. The FAA notes that the part 147 NPRM, which published on October 2, 2015,[25] did not discuss the proposed provisions that would require changes to the information collection burden. Therefore, this document discusses both the NPRM and SNPRM provisions that would have PRA implications.

The Safety Standards, Aircraft Maintenance Division has determined that three primary positions at an AMTS will be performing the information and record collection activities. They are the school's Director, at a salary of $56/hour, an Instructor, at a salary of $28/hour, and an Administrative Assistant, at a salary of $23/hour.[26] A fringe benefit factor of $1.17[27] was applied to the relevant median salary.

The NPRM proposed to remove current §§ 147.36, 147.37, and 147.38 because they are unnecessary in light of the corresponding initial certification requirements, which are continuing and ongoing. Therefore, the information collections currently required by §§ 147.36, 147.37, and 147.38 would now be associated with §§ 147.23, 147.13, and 147.21 respectively. No additional information collection burden has been identified.

The FAA introduced operation specifications for part 147 by Notice N 8900.278 on November 21, 2014. Certificated part 147 schools were required to have their OpSpecs authorized by July 21, 2015. Originally, there were 14 OpSpecs, but A012 Affiliated Designated Mechanic Examiners (DME) has since been archived. The pending 2018 revision of OMB information collection control #2120–0040 accounts for the 13 OpSpec paragraphs currently required at initial certification.

PART 147 OPERATIONS SPECIFICATIONS

Part 147 OpSpecs	Operations Specifications (OpSpecs) title
A001	Issuance and Applicability (Mandatory).
A002	Definitions and Abbreviations (Mandatory).
A003	Aviation Maintenance Technician School Ratings (Mandatory).
A004	Summary of Special Authorizations and Limitations (Mandatory).
A005	Exemptions (Optional).
A006	Management Personnel (Mandatory).
A007	Designated Persons (Mandatory).

[25] 80 FR 59674.

[26] Wage rates for these positions came from the Department of Labor, Bureau of Labor Statistics, May 2016 NAICS 481000—Air Transportation codes for the AMTS Director, #11–3131, AMTS Instructor #25–0000, and AMTS Administrative Assistant #43–6014.

[27] Volpe Memorandum, Estimating Total Cost of Compensation based on Wage Rate or Salaries, Jan. 30, 2014.

PART 147 OPERATIONS SPECIFICATIONS—Continued

Part 147 OpSpecs	Operations Specifications (OpSpecs) title
A008**	Satellite Training Locations (Optional).
A012	Affiliated DMEs (Archived).
A013	Instructors (Mandatory).
A015*	Facilities, equipment, and materials (Mandatory).
A025	Recordkeeping System (Mandatory).
A026	Authorizations/Limitations (Optional).
B002	Required Minimum Curriculum for General (Part 147 Appendix B) (Mandatory).
B003	Required Minimum Curriculum for Airframe (Part 147 Appendix C) (Mandatory).
B004	Required Minimum Curriculum for Powerplant (Part 147 Appendix D) (Mandatory).
B005**	Competency-based training (Optional).

* = proposed by NPRM, ** = proposed by SNPRM.

The FAA proposed in the NPRM a new section, § 147.9 Operations Specifications, that would provide, among other things, each AMTS's operations specifications contain its complete curriculum, the course content items, and teaching levels required under each of the subjects specified in the part 147 appendices. The NPRM would require an additional mandatory OpSpec paragraph A015 to list the facilities, equipment and materials used by the AMTS. The NPRM also has a proposed requirement that would amend OpSpec A013, Instructors, due to the proposed changes to § 147.23 for schools that provide specially qualified instructors who are not FAA certificated mechanics to teach general, airframe, powerplant, or specialized subjects.

Furthermore, the SNPRM proposes to add two additional OpSpecs: An optional OpSpec A008 for satellite training locations as covered in proposed § 147.14, and an optional OpSpec B005 for the competency-based training curriculum, proposed by § 147.22. The estimated annual changes reflects the estimated number of new part 147 applicants but does not include AMTSs seeking to make changes as a result of this rulemaking.

The FAA estimates the additional annual information collection burden for proposed § 147.9, which accounts for the OpSpec changes proposed in both the NPRM and SNPRM, would be 48 hours with an estimated annual cost of $2,688.

§ 147.9 Provision	Basis	Estimated annual changes	Director @ $56/hour		Instructor @ $28/hour		Administrative @ $23/hour		Estimated annual cost
			Estimated hours per change	Estimated annual hours	Estimated hours per change	Estimated annual hours	Estimated hours per change	Estimated annual hours	
Preparation of OpSpec A008: AMTS Satellite Training Locations.	Initial Certification	5	2	10					$560
Preparation of OpSpec A015: Facilities Equipment and Materials.	Initial Certification	5	2	10					560
Preparation of OpSpec B005: Competency-Based Training (CBT) Program.	Initial Certification	5	4	20					1,120
§ 147.9 estimated annual initial certification reporting burden.				40		0		0	2,240
Amendment of OpSpec A008: AMTS Satellite Training Locations.	On Occasion	6	.25	1.5					84
Amendment of OpSpec A013: Instructors.	On Occasion	20	.25	5					280
Amendment of OpSpec A015: Facilities Equipment and Materials.	On Occasion	2	.25	.5					28
Amendment of OpSpec B005: Competency-Based Training (CBT) Program.	On Occasion	4	.25	1					56
§ 147.9 estimated annual post certification reporting burden.				8		0		0	448

§ 147.9 Provision	Basis	Estimated annual changes	Director @ $56/hour		Instructor @ $28/hour		Administrative @ $23/hour		Estimated annual cost
			Estimated hours per change	Estimated annual hours	Estimated hours per change	Estimated annual hours	Estimated hours per change	Estimated annual hours	
§ 147.9 estimated total annual reporting burden.	.....	.....	.....	48	.....	0	.....	0	2,688

The SNPRM proposes new § 147.14, which would provide an option to allow a certificated AMTS to have or operate as a satellite training location. Under the proposal, an AMTS could add one or more satellite training locations. A satellite training location may be either dependent, which means it would not hold its own AMTS certificate under part 147, or independent. An independent satellite training location would hold its own AMTS certificate and be held responsible for complying with the requirements of part 147. The proposal would require any satellite training location(s) to be authorized by OpSpec A008. The parent AMTS would be required to make application to have a satellite training location. The FAA estimates the additional annual information collection burden for proposed § 147.14 would be 374 hours with an estimated annual cost of $20,086.

§ 147.14 Provision	Basis	Estimated annual changes	Director @ $56/hour		Instructor @ $28/hour		Administrative @ $23/hour		Estimated annual cost
			Estimated hours per change	Estimated annual hours	Estimated hours per change	Estimated annual hours	Estimated hours per change	Estimated annual hours	
Apply for additional training location.	Initial Certification	5	60	300	.....	.....	4	20	$17,260
Changes to additional training locations.	On occasion	6	8	48	.....	.....	1	6	2,826
§ 147.14 estimated total annual reporting burden.	.....	.....	.....	348	.....	0	.....	26	20,086

The SNPRM proposes in new § 147.22 an option to allow AMTSs to deliver their approved curriculums using a CBT curriculum. The CBT curriculum must be FAA approved and authorized using OpSpec B005. A CBT program would require initial development and amendment on occasion by the AMTS. Ongoing CBT requirements would include:

- Pre-training assessment for persons with previous aviation training or experience. Proposed § 147.22(f)
- Record-keeping for CBT training and assessment of AMTS instructors. Proposed § 147.22(g)
- Establish and maintain a data collection and analysis process on its students and instructors that would enable the school and the FAA to determine whether the CBT program is accomplishing its objectives. Proposed § 147.22(h)
- A certificated AMTS conducting an approved CBT curriculum must establish and maintain, for each student enrolled, records that show the student's progression through his or her individual curriculum, including documentation of any pre-training assessments and competency assessments. Proposed § 147.22(i)

The FAA estimates the additional annual information collection burden for proposed § 147.22 would be 1,315 hours with an estimated annual cost of $63,315.

§ 147.22 Provision	Basis	Estimated annual changes	Director @ $56/hour		Instructor @ $28/hour		Administrative @ $23/hour		Estimated annual cost
			Estimated hours per change	Estimated annual hours	Estimated hours per change	Estimated annual hours	Estimated hours per change	Estimated annual hours	
Create CBT Program	Initial Certification	5	80	400	.....	.....	.....	.....	$22,400
Revise CBT Program	On Occasion	4	10	40	.....	.....	.....	.....	2,240
Records of Instructor Training and Assessment.	Ongoing	35	5	175	.....	.....	1	35	10,605
CBT Data Collection and Analysis.	Ongoing	35	10	350	2	70	1	35	22,365
CBT Student assessment, enrollment and progress records.	Ongoing	35	.....	.....	5	175	1	35	5,705
§ 147.22 estimated total annual reporting burden.	.....	.....	.....	965	.....	245	.....	105	63,315

The NPRM proposed to modify § 147.23 so that each school would be required to maintain and keep in its operations specifications an up-to-date list of the names and qualifications of all its instructors. The FAA estimates the additional annual information collection burden for proposed § 147.23 is 30 hours with an estimated annual cost of $1,350.

§ 147.23 Provision	Basis	Estimated annual changes	Director @ $56/hour		Instructor @ $28/hour		Administrative @ $23/hour		Estimated annual cost
			Estimated hours per change	Estimated annual hours	Estimated hours per change	Estimated annual hours	Estimated hours per change	Estimated annual hours	
Maintain a list of the names and qualifications of all AMTS instructors.	Ongoing	40	.5	20			.25	10	1,350
§ 147.23 estimated total annual reporting burden.				20		0		10	1,350

The NPRM proposed § 147.31(f) to permit a student who had successfully completed the general curriculum to take the general written knowledge test even if the student had not met the experience requirements of 14 CFR 65.77. The school would be required to prepare and issue a Certificate of Completion to identify students who are eligible to take the written general knowledge test. An official of the school would be required to authenticate the certificate.

Also proposed in the NPRM was § 147.31(g) that would provide an option for an AMTS to offer some of their approved curriculum using distance learning instruction. The approval for a distance learning program would be authorized by OpSpec A026. This OpSpec was not counted as a NPRM or SNPRM affected change since it was available prior to the publication of the NPRM.

The FAA estimates the additional annual information collection burden for proposed § 147.31 would be 5,011 hours with an estimated annual cost of $199,153.

§ 147.31 Provision	Basis	Estimated annual changes	Director @ $56/hour		Instructor @ $28/hour		Administrative @ $23/hour		Estimated annual cost
			Estimated hours per change	Estimated annual hours	Estimated hours per change	Estimated annual hours	Estimated hours per change	Estimated annual hours	
Prepare Certificate of Completion for student eligible to take written general knowledge test.	Ongoing	9,800	.25	2,450			.25	2,450	$193,550
Develop and Create a distance learning program and submit for FAA approval.	Initial	1	60	60	10	10	2	2	3,686
Amend Distance Learning Program.	On Occasion	3	10	30	2	6	1	3	1,917
§ 147.31 estimated total annual reporting burden.				2,540		16		2,455	199,153

The cumulative estimated annual information collection burden for the NPRM and SNPRM, if adopted as proposed, would be 6,778 hours with an estimated cost of $286,592.

Cumulative estimated burden of new and revised sections of NPRM & SNPRM	Director @ $56/hour	Instructor @ $28/hour	Administrative @ $23/hour	Estimated annual cost
	Estimated annual hours	Estimated annual hours	Estimated annual hours	
§ 147.9 Operations Specifications	48			$2,688
§ 147.14 Satellite Training Locations	348		26	20,086
§ 147.22 Competency-Based Training	965	245	105	63,315
§ 147.23 Instructor Requirements	20		10	1,350
§ 147.31 Attendance and enrollment, test, and credit for prior instruction or experience	2,540	16	2,455	199,153
Estimated annual reporting burden of new rule	3,921	261	2,596	286,592

Paperwork Impact to the Federal Government

The FAA proposal to eliminate the national passing norms specified in the quality of instruction requirements would result in the elimination of some national data from the 8080–08 report.[28] The FAA estimates that the FAA would save about 3 hours per quarter from the elimination of the aforementioned data. FAA statisticians who produce this report are at an FV H level, averaging an hourly wage rate of $37.13.[29] The fringe benefit for the government is 36 percent; [30] thus the fully-loaded wage rate is $50.50. The FAA estimates 12 fewer annual hours and annual cost saving of $606 for provision § 147.31.

§ 147.31 Provision	FAA Statistician @$50.50/hour	Estimated annual cost savings
	Estimated annual hours	
Eliminate the national passing norms specified in the quality of instruction requirements	12	$606

The FAA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the FAA, including whether the information will have practical utility;

(2) Evaluate the accuracy of the FAA's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of collecting information on those who are to respond, including by using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Individuals and organizations may send comments on the information collection requirement to the address listed in the **ADDRESSES** section at the beginning of this preamble by June 17, 2019. Comments also should be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Desk Officer for FAA, New Executive Building, Room 10202, 725 17th Street NW, Washington, DC 20053.

F. International Compatibility and Cooperation

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

G. Environmental Analysis

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6 of FAA Order 1050.1F and involves no extraordinary circumstances.

V. Executive Order Determinations

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

This proposed rule is expected to be an Executive Order 13771 deregulatory action. Details on the flexibilities and potential cost savings of the NPRM rule can be found in the NPRM Regulatory Evaluation.

B. Executive Order 13132, Federalism

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

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

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

VI. Additional Information

A. Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The agency also invites comments relating to the economic, environmental, and 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.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The agency may change this proposal in light of the comments it receives.

Proprietary or Confidential Business Information: Commenters should not file proprietary or confidential business information in the docket. Such information must be sent or delivered directly to the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document, and marked as proprietary or confidential. If submitting information on a disk or CD ROM, mark the outside of the disk or CD ROM, and

[28] As a result of this change the National Applicants and the National Norm columns would be eliminated from the 8080–08 report.

[29] Mid-range salary of 2017 FV–H level divided by 2,080 hours. Accessed on December 5, 2017 from *https://my.faa.gov/employee_services/pay_perf/pay.html.html#plansTables.*

[30] Memorandum ''Update to Civilian Position Full Fringe Benefit Cost Factor, Federal Pay Raise Assumptions, and Inflation Factors used in OMB Circular No. A–76, 'Performance of Commercial Activities,' '' 3/11/2008, page 2.

identify electronically within the disk or CD ROM the specific information that is proprietary or confidential.

Under 14 CFR 11.35(b), if the FAA is aware of proprietary information filed with a comment, the agency does not place it in the docket. It is held in a separate file to which the public does not have access, and the FAA places a note in the docket that it has received it. If the FAA receives a request to examine or copy this information, it treats it as any other request under the Freedom of Information Act (5 U.S.C. 552). The FAA processes such a request under DOT procedures found in 49 CFR part 7.

B. Availability of Rulemaking Documents

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

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

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

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

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Commenters must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this proposed rule, including economic analyses and technical reports, may be accessed from the internet through the Federal eRulemaking Portal referenced in item (1) above.

List of Subjects in 14 CFR Part 147

Aircraft, Airmen, Educational facilities, Reporting and recordkeeping requirements, Schools.

The Proposed Amendment

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

PART 147—AVIATION MAINTENANCE TECHNICIAN SCHOOLS

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44707–44709.

■ 2. Add § 147.14 to read as follows:

§ 147.14 Satellite training locations.

(a) Except as specified in paragraph (c)(5) of this section, the holder of an aviation maintenance technician school certificate may, with FAA approval, conduct training at either a dependent satellite training location in accordance with paragraph (b) of this section, or at an independent satellite training location in accordance with paragraph (c) of this section, provided the following requirements are met—

(1) The parent aviation maintenance technician school must make an application for a satellite training location in a form and manner prescribed by the FAA at least 60 days prior to the intended start date of training. The application must include the scheduled training start date and the content specified in § 147.5(a)(1) through (4) of this part;

(2) The parent aviation maintenance technician school's operations specifications must include the name and physical address of the satellite training location and the person with responsibility for operations at the satellite training location;

(3) The parent aviation maintenance technician school must develop adequate procedures describing satellite operations acceptable to the FAA, and make them available to each satellite location;

(4) The satellite training location must use the curriculum and procedures of the parent aviation maintenance technician school, and the curriculum must meet the applicable requirements of this part;

(5) The satellite training location may share personnel and equipment from the parent aviation maintenance technician school and from each of the satellite training location(s), unless the FAA indicates otherwise; and

(6) The facilities, equipment, and personnel of the satellite training location must meet the applicable requirements of this part.

(b) *Dependent satellite training location.* Except as specified in paragraph (c)(5) of this section, the holder of an aviation maintenance technician school certificate may conduct training in accordance with its FAA-approved curriculum at a satellite training location away from the school's primary location, provided the following requirements are met—

(1) The certificate holder's operations specifications must include the course curriculum to be offered at the dependent satellite training location;

(2) The certificate holder must ensure the dependent satellite training location complies with the applicable requirements of this part; and

(3) The dependent satellite training location must allow the FAA to inspect its facility to determine compliance with this part.

(c) *Independent satellite training locations.* A certificated aviation maintenance technician school may serve as an independent satellite training location of another certificated school, provided the independent satellite training location operates under its own certificate issued by the FAA. An independent satellite training location—

(1) Must operate using the curriculum and procedures of the parent aviation maintenance technician school, except for any documented differences that have been accepted or approved by the FAA as applicable;

(2) May not hold a rating not held by the parent aviation maintenance technician school;

(3) Must meet the requirements for each rating it holds;

(4) Must ensure compliance with the applicable requirements of this part independent of the parent aviation maintenance technician school; and

(5) May not conduct training at another satellite training location.

■ 3. Amend § 147.17 by revising paragraph (a)(2) to read as follows:

§ 147.17 Instructional equipment requirements.

(a) * * *

(1) * * *

(2) At least one aircraft type-certificated by the FAA with powerplant, propeller, instruments, navigation and communications equipment, landing lights, and other equipment and accessories on which a maintenance technician might be required to work and with which the technician should be familiar.

* * * * *

■ 4. Amend § 147.21 by revising the introductory text of paragraph (b) to read as follows:

§ 147.21 General curriculum requirements.

* * * * *

(b) Except as provided in § 147.22 of this part, the curriculum required by paragraph (a) of this section must offer at least the number of instructional hours or credit hours for the rating sought as set forth in paragraph (b)(1) or (b)(2) of this section as follows:

* * * * *

■ 5. Add § 147.22 to read as follows:

§ 147.22 Competency-based training curriculum.

(a) *General.* The FAA-approved curriculum required by § 147.21(a) may include competency-based training. A certificated aviation maintenance technician school may use a

competency-based training curriculum provided the school obtains FAA approval of its competency-based training program through an operations specification and has shown the requirements of this section are met. Except for the hour requirements of § 147.21(b), all other requirements of this part apply to a competency-based training program.

(b) *Structure and content.* (1) The competency-based training curriculum must cover the subjects prescribed in appendixes B, C, or D, as appropriate to the course being approved, the course content items and teaching levels included under those subject area headings in the school's operations specifications, and the applicable competencies for each of those items.

(2) Each competency-based training curriculum must define the competencies, to include knowledge, skills, and observable behaviors, that apply to each course content item and associated teaching level, which are prescribed in the school's operations specification. The students will be trained and assessed to the competencies defined in the curriculum.

(3) The certificated aviation maintenance technician school may develop additional course content items in its curriculum for FAA approval. For each additional course content item, the certificated aviation maintenance technician school must define the applicable competencies, to include the knowledge, skills, and observable behaviors, that the student will be trained and assessed to.

(c) *Training.* (1) The certificated aviation maintenance technician school must train each student to achieve the applicable competencies, with respect to each course content item as defined in the competency-based training curriculum. A competency-based training program may be defined to include—

(i) A variety of teaching methods; and

(ii) Group instruction, individualized instruction, or any combination thereof.

(2) For each course content item, the certificated aviation maintenance technician school must describe the following:

(i) Theory requirements in classroom or by distance learning;

(ii) Laboratory or shop requirements, including a description of the practical projects to be completed;

(iii) The order of instruction;

(iv) Whether the instruction will be individualized or given in a group;

(v) The applicable competencies, to include knowledge, skills, and observable behaviors;

(vi) Objective testing and grading criteria; and

(vii) Schedule of required tests and assessments that shows the sequence of examinations for each subject in the curriculum.

(d) *Competency assessments.* (1) The competency-based training curriculum must describe how and when the school will assess whether the student can demonstrate the applicable competencies (knowledge, skills, and observable behaviors) for each course content item. The assessments must—

(i) Assess each course content item;

(ii) Determine whether the student can demonstrate all applicable competencies (the knowledge, skills, and observable behaviors); and

(iii) Be consistent with the required teaching levels specified in the operations specification.

(2) The competency-based training curriculum must describe what each competency assessment will consist of, including proportions of theory to be tested, a list of tests or assessments to be given, and a description of practical projects to be completed.

(3) For each competency assessment described in the competency based training curriculum, the school must develop a scoring guide that its instructors will use to conduct the assessment.

(4) The school may find a student competent when the student can demonstrate each applicable competency, with respect to the course content item being assessed, at a minimum of 70 percent.

(5) A graduation certificate or certificate of completion will be issued only when the student competency, as defined in paragraph (d)(4) of this section, can be shown for each competency outlined in the student's individual curriculum. The certificate must meet the requirements of § 147.35.

(e) *Remedial training.* For a student who fails to demonstrate competency of a course content item in accordance with paragraph (d)(4) of this section—

(1) The school must provide additional training and reassessment in areas of deficiency until the student can demonstrate the knowledge, skills, and observable behaviors that reflect the competencies at a minimum of 70 percent; and

(2) Where order of instruction requirements are specified in an approved competency-based training program, the student may not progress to a subsequent related course content item or subject area until the student has demonstrated competency in the subject matter in which they were found deficient.

(f) *Students with prior aviation maintenance training or experience.*

(1) Pre-training assessment. For students that have prior aviation maintenance training or experience in a subject area, the school may conduct a pre-training assessment of the student's initial competencies. The assessment must meet the requirements specified in paragraph (d)(1) of this section, as applicable to the subject areas and/or course content item(s) being assessed. The school must describe how it will assess the student's knowledge, skills and observable behaviors, including for each course content item:

(i) The proportions of theory to be tested;

(ii) A list of tests or assessments to be given; and

(iii) A description of the practical projects to be completed.

(2) Individualized Training. The result of the pre-training assessment is the student's individual curriculum. The individual's curriculum must include the subject areas and course content items for which the student did not demonstrate competency. For each subject area and course content item, the certificated aviation maintenance technician school must satisfy paragraph (c)(2) of this section.

(3) Competency Assessments and Remedial Training. The school must conduct competency assessments that satisfy the requirements of paragraph (d) of this section. If the student fails to demonstrate competency in a course content item or subject area in accordance with paragraph (d)(4) of this section, the school must satisfy the remedial training requirements of paragraph (e) of this section.

(g) *Instructors.* (1) The competency-based training program must describe the following—

(i) How the school's method ensures that instructors used to deliver competency-based training curriculum material are trained on the school's competency-based training program requirements, including delivery methods and assessment techniques; and

(ii) How the school will evaluate the instructors' competencies to ensure they are qualified to provide competency-based training and assessments.

(2) The competency-based training program must meet the requirements of § 147.23 and describe the instructor to student ratios that will apply to group instruction in the laboratory or shop.

(h) *Data collection and analysis process.* The certificated aviation maintenance technician school must establish and maintain a data collection and analysis process on its students and

instructors that will enable the school and the FAA to determine whether the competency-based training program is accomplishing its objectives. The school must maintain records of outputs of the data collection and analysis process. Such records must be retained for a minimum of 2 years.

(i) *Recordkeeping requirements.* In addition to meeting the record requirements specified in § 147.33, each certificated aviation maintenance technician school conducting an approved competency-based training curriculum must establish and maintain for each student enrolled records that show the student's progression through the student's individual curriculum, including documentation of any pre-training assessments and competency assessments.

(j) *Revisions.* Whenever the FAA finds that revisions are necessary for the continued adequacy of a competency-based training program that has been granted FAA approval, the certificate holder shall, after notification, make any changes in the program that are found necessary by the FAA.

■ 6. Revise § 147.37 to read as follows:

§ 147.37 Quality of instruction.

On a quarterly basis, each certificated aviation maintenance technician school must have provided instruction of a sufficient quality that, in the prior 24 calendar months, at least 70 percent of its graduates passed on the first attempt within 60 days of graduation each written knowledge test leading to a certificate or rating. As set forth in § 65.17 of this chapter, the minimum passing grade is 70 percent.

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), 44703, and 44707 in Washington, DC, on March 22, 2019.

Robert C. Carty,

Deputy Executive Director, Flight Standards Office.

[FR Doc. 2019–06399 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 55

[EPA–R03–OAR–2011–0140; FRL–9991–70–Region 3]

Outer Continental Shelf Air Regulations; Consistency Update for Virginia

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule; consistency update.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to update a portion of the Outer Continental Shelf (OCS) Air Regulations. Requirements applying to OCS sources located within 25 miles of states' seaward boundaries must be updated periodically to remain consistent with the requirements of the corresponding onshore area (COA), as mandated by section 328(a)(1) of the Clean Air Act (CAA). The portion of the OCS air regulations that is being updated pertains to the requirements for OCS sources for which Virginia is the designated COA. The Commonwealth of Virginia's requirements discussed in this document are proposed to be incorporated by reference into the Code of Federal Regulations and listed in the appendix to the OCS air regulations.

DATES: Written comments must be received on or before May 16, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2011–0140 at *http://www.regulations.gov,* or via email to *maldonado.zelma@epa.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Mrs. Amy Johansen, Office of Permits and State Programs (3AP10), Air Protection Division, U.S. Environmental Protection Agency, Region 3, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2156. Mrs. Johansen can also be reached via electronic mail at *johansen.amy@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On September 4, 1992, EPA promulgated 40 CFR part 55,[1] which established requirements to control air pollution from OCS sources in order to attain and maintain federal and state ambient air quality standards and to comply with the provisions of part C of title I of the CAA. The regulations at 40 CFR part 55 apply to all OCS sources except those located in the Gulf of Mexico west of 87.5 degrees longitude. *See* 40 CFR 55.3(a). Section 328 of the CAA requires that for such sources located within 25 miles of a state's seaward boundary, the requirements shall be the same as would be applicable if the sources were located in the COA. Because the OCS requirements are based on onshore requirements, and onshore requirements may change, section 328(a)(1) requires that EPA update the OCS requirements as necessary to maintain consistency with onshore requirements.

Pursuant to 40 CFR 55.12, consistency reviews will occur (1) at least annually; (2) upon receipt of a Notice of Intent (NOI) under 40 CFR 55.4; or (3) when a state or local agency submits a rule to EPA to be considered for incorporation by reference in 40 CFR part 55. This proposed action is being taken in response to the submittal of a NOI, received on January 28, 2019, by Dominion Energy Virginia, for the proposed installation of a 12-megawatt offshore wind technology testing facility located approximately 24 nautical miles east of the City of Virginia Beach, Virginia.[2] Public comments received in writing within 30 days of publication of this document will be considered by EPA before publishing a final rule.

Section 328(a) of the CAA requires that EPA establish requirements to control air pollution from OCS sources located within 25 miles of States' seaward boundaries that are the same as onshore requirements. To comply with this statutory mandate, EPA must incorporate applicable onshore rules into 40 CFR part 55 as they exist

[1] The reader may refer to the Notice of Proposed Rulemaking, December 5, 1991 (56 FR 63774), and the preamble to the final rule promulgated September 4, 1992 (57 FR 40792) for further background and information on the OCS regulations.

[2] The EPA Region III Office was directly impacted by Congress' failure to appropriate funds during the 2018–19 federal government shutdown and resulting furlough of many federal employees, including Region III personnel. As a result, although the NOI from Dominion Energy Virginia was signed on December 21, 2018, it was not received and date-stamped by EPA Region III until January 28, 2019, when the Region III office returned to operation.

onshore. This limits EPA's flexibility in deciding which requirements will be incorporated into 40 CFR part 55 and prevents EPA from making substantive changes to the requirements it incorporates. As a result, EPA may be incorporating rules into 40 CFR part 55 that do not conform to all of EPA's state implementation plan (SIP) guidance or certain requirements of the CAA. Consistency updates may result in the inclusion of state or local rules or regulations into 40 CFR part 55, even though the same rules may ultimately be disapproved for inclusion as part of the SIP. Inclusion in the OCS rule does not imply that a rule meets the requirements of the CAA for SIP approval, nor does it imply that the rule will be approved by EPA for inclusion in the SIP.

II. EPA Analysis

EPA reviewed Virginia's rules for inclusion in 40 CFR part 55 to ensure that they are rationally related to the attainment or maintenance of federal or state ambient air quality standards and compliance with part C of title I of the CAA, that they are not designed expressly to prevent exploration and development of the OCS, and that they are potentially applicable to OCS sources. *See* 40 CFR 55.1. EPA has also evaluated the rules to ensure they are not arbitrary or capricious. *See* 40 CFR 55.12(e). In addition, EPA has excluded administrative or procedural rules, and requirements that regulate toxics which are not related to the attainment and maintenance of federal and state ambient air quality standards.[3]

EPA is soliciting public comments on the issues discussed in this document or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the federal rulemaking procedure by submitting written comments to the EPA Regional Office listed in the **ADDRESSES** section of this **Federal Register**.

III. Proposed Action

EPA is proposing to incorporate the rules potentially applicable to sources for which the Commonwealth of Virginia will be the COA. The rules that EPA proposes to incorporate are applicable provisions of the Virginia Administrative Code (VAC). The rules EPA proposes to incorporate are listed in detail at the end of the document. The intended effect of proposing approval of the OCS requirements for the Virginia Department of Environmental Quality (VADEQ) is to regulate emissions from OCS sources in accordance with the requirements for onshore sources.

IV. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference the applicable provisions of the Virginia Administrative Code set forth below. EPA has made, and will continue to make, these materials available through *www.regulations.gov* and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to establish requirements to control air pollution from OCS sources located within 25 miles of states' seaward boundaries that are the same as onshore air pollution control requirements. To comply with this statutory mandate, the EPA must incorporate applicable onshore rules into 40 CFR part 55 as they exist onshore. *See* 42 U.S.C. 7627(a)(1); 40 CFR 55.12. Thus, in promulgating OCS consistency updates, EPA's role is to maintain consistency between OCS regulations and the regulations of onshore areas, provided that they meet the criteria of the CAA. Accordingly, this action simply updates the existing OCS requirements to make them consistent with requirements onshore, without the exercise of any policy direction by EPA. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not 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
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

This proposed rule incorporating by reference sections of the Virginia Administrative Code, does not apply on any Indian reservation land as defined in 18 U.S.C. 1151 or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, this rule incorporating by reference sections of the Virginia Administrative Code 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).

Under the provisions of the Paperwork Reduction Act, 44 U.S.C 3501 *et seq.,* an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in 40 CFR part 55 and, by extension, this update to the rules, and has assigned OMB control number 2060–0249. OMB approved the EPA Information Collection Request (ICR) No. 1601.08 on September 18, 2017.[4] The current approval expires September 30, 2020. The annual public reporting and recordkeeping burden for collection of information under 40 CFR part 55 is

[3] Each COA which has been delegated the authority to implement and enforce 40 CFR part 55 will use its administrative and procedural rules as onshore. However, in those instances where EPA has not delegated authority to implement and enforce 40 CFR part 55, EPA will use its own administrative and procedural requirements to implement the substantive requirements. *See* 40 CFR 55.14(c)(4).

[4] OMB's approval of the ICR can be viewed at *www.reginfo.gov.*

estimated to average 643 hours per response, using the definition of burden provided in 44 U.S.C. 3502(2).

EPA is proposing to incorporate the rules potentially applicable to sources for which the Commonwealth of Virginia will be the COA. The rules that EPA proposes to incorporate are applicable provisions of the Virginia Administrative Code.

List of Subjects in 40 CFR Part 55

Environmental protection, Administrative practice and procedure, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Outer continental shelf, Ozone, Particulate matter, Permits, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: March 26, 2019.

Cosmo Servidio,

Regional Administrator, Region III.

Part 55 of Chapter I, title 40 of the Code of Federal Regulations is proposed to be amended as follows:

PART 55—OUTER CONTINENTAL SHELF AIR REGULATIONS

■ 1. The authority citation for part 55 continues to read as follows:

Authority: Section 328 of the Clean Air Act (42 U.S.C. 7401 *et seq.*) as amended by Public Law 101–549.

■ 2. Section 55.14 is amended by revising paragraphs (e)(22)(i)(A) to read as follows:

§ 55.14 Requirements that apply to OCS sources located within 25 miles of States' seaward boundaries, by State.

* * * * *

(e) * * *

(22) * * *

(i) * * *

(A) Commonwealth of Virginia Requirements Applicable to OCS Sources, February 20, 2019.

* * * * *

■ 3. Appendix A to part 55 is amended by revising paragraph (a)(1) under the heading ''Virginia'' to read as follows:

Appendix A to Part 55—Listing of State and Local Requirements Incorporated by Reference Into Part 55, by State

* * * * *

Virginia

(a) * * *

(1) The following Commonwealth of Virginia requirements are applicable to OCS Sources, February 20, 2019, Commonwealth of Virginia—Virginia Department of Environmental Quality.

The following sections of Virginia Regulations for the Control and Abatement of Air Pollution Control (VAC), Title 9, Agency 5:

Chapter 10—General Definitions

(Effective 05/19/2017)
9VAC5–10–10. General.
9VAC5–10–20. Terms defined.
9VAC5–10–30. Abbreviations.

Chapter 20—General Provisions

(Effective 02/19/2018)

Part I—Administrative

9VAC5–20–10. Applicability.
9VAC5–20–21. Documents incorporated by reference.
9VAC5–20–50. Variances.
9VAC5–20–70. Circumvention.
9VAC5–20–80. Relationship of state regulations to federal regulations.
9VAC5–20–121. Air quality program policies and procedures.

Part II—Air Quality Programs

9VAC5–20–160. Registration.
9VAC5–20–170. Control programs.
9VAC5–20–180. Facility and control equipment maintenance or malfunction.
9VAC5–20–200. Air quality control regions.
9VAC5–20–203. Maintenance areas.
9VAC5–20–204. Nonattainment areas.
9VAC5–20–205. Prevention of significant deterioration areas.
9VAC5–20–206. Volatile organic compound and nitrogen oxides emission control areas.
9VAC5–20–220. Shutdown of a stationary source.
9VAC5–20–230. Certification of documents.

Chapter 30—Ambient Air Quality Standards

(Effective 05/15/2017)
9VAC5–30–10. General.
9VAC5–30–15. Reference conditions.
9VAC5–30–30. Sulfur oxides (sulfur dioxide).
9VAC5–30–40. Carbon monoxide.
9VAC5–30–50. Ozone (1-hour).
9VAC5–30–55. Ozone (8-hour, 0.08 ppm).
9VAC5–30–56. Ozone (8-hour, 0.075 ppm).
9VAC5–30–57. Ozone (8-hour, 0.070 ppm).
9VAC5–30–60. Particulate matter (PM_{10}).
9VAC5–30–65. Particulate matter ($PM_{2.5}$).
9VAC5–30–66. Particulate matter ($PM_{2.5}$).
9VAC5–30–67. Particulate matter ($PM_{2.5}$).
9VAC5–30–70. Oxides of nitrogen with nitrogen dioxide as the indicator.
9VAC5–30–80. Lead.

Chapter 40—Existing Stationary Sources

Part I—Special Provisions

(Effective 12/12/2007)
9VAC5–40–10. Applicability.
9VAC5–40–20. Compliance.
9VAC5–40–21. Compliance schedules.
9VAC5–40–22. Interpretation of emission standards based on process weight-rate tables.
9VAC5–40–30. Emission testing.
9VAC5–40–40. Monitoring.
9VAC5–40–41. Emission monitoring procedures for existing sources.
9VAC5–40–50. Notification, records and reporting.

Part II—Emission Standards

Article 1—Visible Emissions and Fugitive Dust/Emissions

(Effective 02/01/2003)
9VAC5–40–60. Applicability and designation of affected facility.
9VAC5–40–70. Definitions.
9VAC5–40–80. Standard for visible emissions.
9VAC5–40–90. Standard for fugitive dust/emissions.
9VAC5–40–100. Monitoring.
9VAC5–40–110. Test methods and procedures.
9VAC5–40–120. Waivers.

Article 4—General Process Operations

(Effective 12/15/2006)
9VAC5–40–240. Applicability and designation of affected facility.
9VAC5–40–250. Definitions.
9VAC5–40–260. Standard for particulate matter (AQCR 1–6).
9VAC5–40–270. Standard for particulate matter (AQCR 7).
9VAC5–40–280. Standard for sulfur dioxide.
9VAC5–40–290. Standard for hydrogen sulfide.
9VAC5–40–320. Standard for visible emissions.
9VAC5–40–330. Standard for fugitive dust/emissions.
9VAC5–40–350. Standard for toxic pollutants.
9VAC5–40–360. Compliance.
9VAC5–40–370. Test methods and procedures.
9VAC5–40–380. Monitoring.
9VAC5–40–390. Notification, records and reporting.
9VAC5–40–400. Registration.
9VAC5–40–410. Facility and control equipment maintenance or malfunction.
9VAC5–40–420. Permits.

Article 7—Incinerators

(Effective 01/01/1985)
9VAC5–40–730. Applicability and designation of affected facility.
9VAC5–40–740. Definitions.
9VAC5–40–750. Standard for particulate matter.
9VAC5–40–760. Standard for visible emissions.
9VAC5–40–770. Standard for fugitive dust/emissions.
9VAC5–40–790. Standard for toxic pollutants.
9VAC5–40–800. Prohibition of flue-fed incinerators.
9VAC5–40–810. Compliance.
9VAC5–40–820. Test methods and procedures.
9VAC5–40–830. Monitoring.
9VAC5–40–840. Notification, records and reporting.
9VAC5–40–850. Registration.
9VAC5–40–860. Facility and control equipment maintenance or malfunction.
9VAC5–40–870. Permits.

Article 8—Fuel Burning Equipment

(Effective 01/01/2002)
9VAC5–40–880. Applicability and designation of affected facility.
9VAC5–40–890. Definitions.

9VAC5–40–900. Standard for particulate matter.
9VAC5–40–910. Emission allocation system.
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(Effective 08/13/2015)

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(Effective 07/15/2015)

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Part IV—Local Ordinances

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Chapter 151—Transportation Conformity

(Effective 11/16/2016)

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(Effective 05/15/2017)

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 216 and 300

[Docket No. 171227999–9220–02]

RIN 0648–BH48

International Fisheries; Pacific Tuna Fisheries; Procedures for the Active and Inactive Vessel Register

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS is proposing regulations under the Tuna Conventions Act of 1950 (TCA), as amended, to implement International Maritime Organization (IMO) requirements in Inter-American Tropical Tuna Commission (IATTC) Resolution C–18–06 (*Resolution (Amended) on a Regional Vessel Register*) and amendments to existing regulations related to the IATTC Regional Vessel Register (Vessel Register) for purse seine vessels fishing in the eastern Pacific Ocean (EPO). The proposed rule would expand the IMO number requirements to include certain categories of smaller U.S. vessels fishing for tuna and tuna-like species in the EPO. The proposed rule would also modify regulations associated with the Vessel Register and prohibition and incidental catch provisions. These revisions would provide more clarity and make U.S. regulations more consistent with the IATTC management framework, while allowing controlled operational flexibility for the U.S. industry.

DATES: Comments on the proposed rule and supporting documents must be submitted in writing by May 16, 2019.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2018–0030, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0030,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Daniel Studt, NMFS West Coast Region Long Beach Office, 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802. Include the identifier ''NOAA–NMFS–2018–0030'' in the comments.

Instructions: Comments must be submitted by one of the above methods to ensure they are received, documented, and considered by NMFS. 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. 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, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of the draft Regulatory Impact Review and other supporting documents are available via the Federal eRulemaking Portal: *http://www.regulations.gov,* docket NOAA–NMFS–2018–0030, or by contacting Daniel Studt, NMFS West Coast Region, 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802, or emailing *WCR.HMS@noaa.gov*.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information

requirements contained in this proposed rule may be submitted to the NMFS West Coast Region Long Beach Office at the address listed above, by email to *OIRA_Submission@omb.eop.gov,* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Daniel Studt, NMFS, West Coast Region, 562–980–4073.

SUPPLEMENTARY INFORMATION:

Background on the IATTC

The United States is a member of the IATTC, which was established under the 1949 Convention for the Establishment of an Inter-American Tropical Tuna Commission. In 2003, the IATTC adopted the Antigua Convention, which was negotiated to strengthen and replace the 1949 Convention establishing the IATTC. The Antigua Convention entered into force in 2010. The United States acceded to the Antigua Convention on February 24, 2016. The full text of the Antigua Convention is available at: *https://www.iattc.org/PDFFiles2/Antigua_Convention_Jun_2003.pdf*.

The IATTC consists of 21 member nations and five cooperating non-member nations (collectively termed CPCs). The IATTC facilitates scientific research, conservation, and management of tuna and tuna-like species in the IATTC Convention Area (Convention Area), defined as waters of the EPO within the area bounded by the west coast of the Americas and by 50° N latitude, 150° W longitude, and 50° S latitude. The IATTC maintains a scientific research and fishery monitoring program and regularly assesses the status of tuna, shark, and billfish stocks in the EPO to determine appropriate catch limits and other measures to promote sustainable fisheries and prevent the overexploitation of these stocks.

International Obligations of the United States Under the Antigua Convention

As a Party to the Antigua Convention and a member of the IATTC, the United States is legally bound to implement certain decisions of the IATTC. The TCA (16 U.S.C. 951 *et seq.*), as amended on November 5, 2015, by Title II of Public Law 114–81, directs the Secretary of Commerce, in consultation with the Secretary of State and, with respect to enforcement measures, the Secretary of the Department of Homeland Security, to promulgate such regulations as may be necessary to carry out the United States' international obligations under the Antigua Convention, including recommendations and decisions adopted by the IATTC. The Secretary of Commerce's authority to promulgate such regulations has been delegated to NMFS.

IATTC Resolution on IMO Numbers

An International Maritime Organization (IMO) number is a unique vessel identifier that is permanently associated with the vessel hull, even if the vessel name or ownership changes or if the vessel is reflagged to another nation. For those reasons, there is a wide recognition that IMOs can be useful in helping combat illegal, unreported, and unregulated (IUU) fishing. The IMO, on December 6, 2017, approved amendments to the IMO Ship Identification Number Scheme (IMO Resolution A.1117(30)) expanding fishing vessels' eligibility for IMO numbers. Prior to the amendments, only vessels 100 gross tonnage or above were eligible. The amendment extends eligibility to motorized inboard fishing vessels of less than 100 gross tons GT that are at least 12 meters in length overall and that are authorized to operate outside waters under the national jurisdiction of the flag State.

The IATTC adopted IMO numbering requirements at its 87th meeting in July 2014. Resolution C–14–01 (*Resolution (amended) on a Regional Vessel Register*) required an IMO number or Lloyd's Register number for fishing vessels of at least 100 GT or 100 GRT authorized to fish in the Convention Area. A ''Lloyd's Register number,'' or ''LR number,'' has the same meaning as an IMO number except that an LR number refers to the number issued for a vessel not required to have an IMO number under IMO agreements. The administrator of the IMO ship identification number scheme issues both types of numbers using the same numbering scheme. CPCs are required to provide the IATTC Director IMO numbers for vessels authorized to fish in the Convention Area. NMFS implemented the IMO numbering requirements under Resolution C–14–01 for vessels equal to or greater than 100 GT or 100 GRT in a final rule, effective February 13, 2016 (81 FR 1878).

The IATTC adopted at its 93rd meeting in August 2018 Resolution C–18–06 (*Resolution (amended) on a Regional Vessel Register*), which amended Resolution C–14–01. Resolution C–18–06 expands the IMO number requirement from all fishing vessels of at least 100 GRT or 100 GT to also include all inboard motorized fishing vessels (except for recreational fishing vessels) of 12 meters or greater in overall length (LOA) or registered length, provided that these vessels are authorized to fish for tuna or tuna-like species on the high seas in the Convention Area. Resolution C–18–06 is available at *http://www.iattc.org/ResolutionsActiveENG.htm.*

Previous IATTC Decisions Regarding Capacity in the Purse Seine Fishery

In June 2002, at its 69th meeting, the IATTC adopted Resolution C–02–03 (*Resolution on the Capacity of the Tuna Fleet Operating in the Eastern Pacific Ocean*) to limit fleet capacity to a level that would ensure sustainable tuna fisheries in the region. Resolution C–02–03 established a total capacity limit of 158,000 cubic meters for all vessels authorized by the IATTC to fish for tuna species in the EPO. Each CPC was allocated a vessel capacity limit based on historical fishing levels in the EPO.

When Resolution C–02–03 was adopted, the United States was allocated a total of 39,228 cubic meters of capacity in the purse seine fishery. The Resolution also allowed up to 32 U.S. purse seine vessels operating under an alternative international fisheries management regime (*e.g.,* the South Pacific Tuna Treaty) to make a single trip in the EPO, not to exceed 90 days in length without counting towards the U.S. available fleet capacity. Due to removal and additions of vessels from the Vessel Register, the IATTC currently allows the United States up to 31,866 cubic meters of carrying capacity for its EPO purse seine fleet, as well as the additional 32 vessel trips.

The United States promulgated regulations for Vessel Register requirements, including specific regulations for management of the list of active purse seine vessels. NMFS published a final rule in the **Federal Register** (76 FR 283; January 4, 2011) that required that all purse seine vessels, regardless of size, be on the Vessel Register and categorized as ''active'' in order to be authorized to fish for tuna in the Convention Area. The final rule also exempted small purse seine vessels (*i.e.,* vessel with 362.8 metric tons carrying capacity or less) from frivolous request provisions for active status at 50 CFR 300.22(b)(4)(ii), based on the difficulty of anticipating whether unassociated schools of tuna would come within their range off the U.S. West Coast during a given year. Vessels that do not utilize their active status to a certain extent are considered to have made a frivolous request for that year and become lower in the prioritization of requests for active status for the following year. Following that final rule, further input from stakeholders and further consideration of the U.S.-specific regulations

implementing Vessel Register requirements, NMFS sought additional public input on the measures.

Advance Notice of Proposed Rulemaking

NMFS published an Advance Notice of Proposed Rulemaking (ANPR) on March 29, 2018 (83 FR 13466), requesting public comments on the administrative processes to improve the management of capacity limits associated with the Vessel Register. The capacity of U.S. purse seine vessels has approached the U.S. capacity limit in recent years, resulting in the inability to add vessels to the Vessel Register. In addition, requests to be added to the Vessel Register have exceeded the available IATTC-allotted capacity limit for the U.S. Uncertainty and an increase in the cost of fishing in other areas (*e.g.,* the western central Pacific Ocean under the South Pacific Tuna Treaty) has led to an increase in the number of large purse seine vessels (*i.e.,* greater than 362.8 metric tons (mt) carrying capacity) seeking fishing access in the Convention Area. Furthermore, since 2014, there has been increased interest in tuna from small purse seine vessels based on the U.S. West Coast. NMFS anticipates that these trends are likely to continue.

NMFS received comments with suggestions for management measures from three stakeholders representing both small and large U.S. tuna purse seine vessels that fish in the EPO. Stakeholders submitted comments related to the fleet capacity limit, inactive status, small purse seine vessel requirements, vessel replacement process, and more. In developing this proposed rule, NMFS examined these comments for their validity under current IATTC resolutions and evaluated the likelihood of the perceived benefits to the U.S. EPO tuna purse seine fleet. The resulting actions in this proposed rule are described below.

Actions in This Proposed Rule

IMO Numbers

Per Resolution C–18–06, the proposed rule would require that the owner of a fishing vessel of the United States engaging in fishing activities for tuna or tuna-like species in the Convention Area, and for which a high seas fishing permit under 50 CFR 300.333 is required, shall ensure that an IMO number has been issued for the vessel if the vessel's total internal volume is less than 100 GRT or less than 100 GT but equal to or greater than 12 meters in overall length. Vessel measurements will be based on the vessel's Certificate of Documentation issued under 46 CFR part 67, or State documentation. Currently, IMO numbers are issued on behalf of the IMO by IHS Markit, formerly known as IHS Maritime, at no cost to the vessel (*https://imonumbers.lrfairplay.com/*). The current instructions for requesting an exemption at 50 CFR 300.22(b)(3)(iv) would also apply to the vessels subject to this proposed IMO number requirement.

Purse Seine Well Volume Capacity Correction

The proposed rule would make a technical correction to the vessel capacity limit for the U.S. tuna purse seine fishery operating in the EPO so that the limit would be consistent with the amount authorized by the IATTC. This would add 91 cubic meters to the current U.S. fleet capacity limit of 31,775 cubic meters, and bring the limit to 31,866 cubic meters. These additional 91 cubic meters of capacity resulted from an IATTC revision of our historical capacity calculation.

Inactive Vessels on the Vessel Register

The proposed rule would also update the regulatory text to clarify that vessels listed as inactive or sunk on the Vessel Register count towards the United States' 31,866 cubic meter fleet-wide capacity limit. This is the long-standing practice by the IATTC. Current regulations at 50 CFR 300.22(b)(4) exclude such vessels from the allocation of available capacity, due to an administrative error.

Additionally, the proposed rule would set a time limit of two consecutive calendar years for vessels holding inactive or sunk status, after which a request by such a vessel to be listed on the Vessel Register would be subject to the prioritization hierarchy of request under the current 50 CFR 300.22(b)(4)(i)(C). Therefore, the active status requests for the following year received between August 1 and November 30 would be prioritized in the following order: Currently active, currently inactive, first-come first served, and, lastly, those who made a frivolous request or were listed as inactive or sunk for more than two consecutive calendar years. NMFS considers this proposed revision to be consistent with the intent of the existing inactive status provision at 50 CFR 300.22(b)(4)(iii) (*i.e.,* to allow for vessel replacement or repair while not paying a full active vessel assessment fee), while also preventing an indefinite hold on capacity. NMFS believes that two years is a sufficient length of time for a vessel to be repaired or to be replaced, based upon our understanding of the amount of time necessary to find a shipyard for repairs and for repairs to be completed, or the amount of time for a replacement vessel to be purchased and delivered. NMFS welcomes public comment on the appropriate such length of time.

The proposed rule would also allow for a vessel owner or managing owner of a purse seine vessel that has sunk but is listed as active on the Vessel Register to request the vessel be listed as sunk and categorized as inactive on the Vessel Register within 30 days of its sinking. Currently, regulations provide that sunken vessels are immediately removed from the Vessel Register. Under the proposed rule, if a request is not made to list the vessel as sunk within 30 days of its sinking, then the vessel may be removed from the Vessel Register by the NMFS West Coast Regional Administrator.

Frivolous Request Requirements for Small Purse Seiner Vessels

The proposed rule would also treat as frivolous any request by a small coastal purse seine vessel for active status if that vessel did not make at least one landing of tuna caught in the Convention Area in the calendar year prior to the request through November 15 of the year in which the request is made (*i.e.,* a request made in 2019 to fish in 2020 would require one landing of tuna between January 1, 2018, and November 15, 2019). If a small purse seine vessel has not landed tuna caught in the Convention Area within the year before the request was made and through November 15th of the year the request was made, and requests active status on the Vessel Register for the following year (*i.e.,* the third consecutive year of requesting active status), the request would be considered frivolous and subject to the prioritization hierarchy of request under 50 CFR 300.22(b)(4)(i)(C).

While there is difficulty in anticipating whether schools of tuna would come within range of the small purse seine vessels off the U.S. West Coast during a given year, NMFS is proposing changes to regulations in this proposed rule to help ensure the inclusion on the Vessel Register of vessels that are actively fishing and landing tuna. Since 2011, small purse seine vessels that harvested tuna for more than one year landed tuna every 1.75 years on average. Thus, the proposed rule expands on the intent of the existing frivolous request provision, 50 CFR 300.22(b)(4)(ii), by also including small purse seine vessels, while recognizing the variability in

harvesting tuna in coastal waters by such vessels. The proposed frivolous request provision for small purse seine vessels would allow considerations of *force majeure* or other extraordinary circumstances that may have prevented a vessel from making a landing during the two year time period. Extraordinary circumstances may include lack of tuna availability or other unique situations as determined by the Regional Administrator.

Frivolous Request for Large Purse Seine Vessels

Based on a comment received on the ANPR, NMFS considered revising the existing frivolous request provision for large purse seine vessels (requiring that large purse seine vessels must catch 20 percent of their tuna in the EPO during the year in which the request was made at 50 CFR 300.22(b)(4)(ii)) in order to allow for an activity requirement based on time spent fishing in the EPO. Such an activity requirement would be in addition to the existing requirement for a 20 percent catch composition, and would be applied in the event a vessel was not able to meet this percentage requirement, and despite reasonably attempting to do so. NMFS declined to further revise the existing frivolous request provision for large purse seine vessels in this manner, as NMFS believes an existing exemption to the frivolous request provision already addresses this type of situation. Specifically, the regulatory text at 50 CFR 300.22(b)(4)(ii)(B)(*1*) allows the NMFS West Coast Regional Administrator to determine whether *force majeure* or other extraordinary circumstances apply to a particular request for active status.

Aging Fleet Provision

NMFS agrees with a comment received on the ANPR that U.S. purse seine vessels are aging and that there is currently no process to replace them without risk of losing the aging vessel's status on the Vessel Register. Thus, the proposed rule would include a new ''aging fleet'' provision in 50 CFR 300.22(b) to allow for purse seine vessel owners to replace a purse seine vessel on the Vessel Register with a new or different purse seine vessel, of equal or lesser carrying capacity, without losing the vessel's status on the Vessel Register. The proposed rule would give the vessel owner a period of two years for replacing the existing vessel with a new vessel or a different used vessel.

The replacement process under the aging fleet provision would begin with the vessel owner submitting a request to the NMFS West Coast Regional Administrator to remove their vessel from the Vessel Register. When a vessel is removed from the Vessel Register, the NMFS West Coast Regional Administrator is currently required to send a notification to the fleet regarding available capacity under 50 CFR 300.22(b)(7)(iii). The proposed rule would include an exception to this notification requirement when a vessel has been removed under the proposed aging fleet provision. Under the proposed aging fleet provision, NMFS would reserve the capacity on the Vessel Register for a period of up to two years and the vessel owner must complete the replacement process within the two-year period in order to resume utilization of the capacity being held by NMFS. Vessel owners would be authorized to use this provision only once for a particular purse seine vessel, to prevent situations where a vessel is passed back and forth between owners who have no intention of using the capacity and whose actions prevent others from utilizing that capacity. The proposed rule also would modify the existing provision on the prioritization of requests to be listed on the Vessel Register so that vessel owners using the proposed aging fleet provision will have first priority to active status, provided that the aging fleet provision replacement process is completed within the two-year period.

Revisions to Regulations on Bycatch

In June 2006, at its 74th meeting, the IATTC revised Resolution C–04–05 (*Consolidated Resolution on Bycatch (Rev 2)*). The resolution addressed reduction of the incidental mortality of juvenile tuna and release of non-target species, and called for various sea turtle protection measures. NMFS implemented Resolution C–04–05 at 50 CFR 300.24 (Prohibitions) and at 50 CFR 300.27 (Incidental Catch and Tuna Retention Requirements). However, NMFS now believes that certain provisions are more restrictive for the U.S. industry than what is required by the resolution, and, therefore, has proposed the revisions discussed below.

NMFS is proposing to revise the regulatory text at 50 CFR 300.24(f) and (g) and 300.27(b) to be more consistent with Resolution C–04–05. For example, in 50 CFR 300.24(f) and 300.27(b), the proposed rule would amend the release requirements so that they would no longer apply to tuna-like species. Exempting tuna-like species from the release requirement would allow purse seine vessels to retain tuna-like species, such as the Pacific bonito and black skipjack that were historically targeted, while remaining consistent with the goal of the Resolution to conserve non-target species. The prohibition on landing non-tuna species would be removed from 50 CFR 300.24(g) to allow for the landing of tuna-like species. Purse seine vessels would still be prohibited from landing non-tuna species, as prohibited in the existing language of 50 CFR 300.24(g), other than tuna-like species, because the prohibition on failing to release any non-tuna species would continue to be found in 50 CFR 300.24(g) and 50 CFR 300.27(b). The continued requirement to release fish other than tuna, tuna-like species, and those retained for consumption on board the vessel, is necessary to comply with the Resolution and to promote the conservation of such species. Allowing for the retention and landing of tuna-like species may help offset operational costs, provide flexibility in operations, and allow the utilization of a resource that would have otherwise been discarded.

Advance Notice of Vessel Departure

For purposes of facilitating use of the EPO tuna fleet capacity, the requirement for a 5-day advance notice of vessel departure in order to allow for placement of an observer under § 216.24(b)(8)(iv) would be amended. A supplemental notification would require that a vessel owner or managing owner request placement of a cross-endorsed observer, pursuant to the Memorandum of Cooperation (MOC) between the IATTC and the Western and Central Pacific Fisheries Commission (WCPFC), if the vessel also intends to fish in the WCPFC Convention Area under 50 CFR part 300, subpart O during the same fishing trip. This MOC facilitates observer placement onboard vessels that fish in the areas of both conventions during the same trip.

Vessel Assessment Fees, Notifications to NMFS, and Other Housekeeping Revisions

The proposed rule would amend existing regulatory text to clarify that vessel owners must coordinate with NMFS to pay the vessel assessment fee directly to the IATTC, and not to NMFS, as currently stated in 50 CFR, sections 300.22(b)(4)(i), 300.22(b)(4)(iii), 216.24(b)(6)(iii) and 216.24(b)(8). As established by the IATTC and implemented in existing regulations, the vessel assessment fee supports the placement of observers on individual tuna purse seine vessels and maintenance of the observer program. Additional changes would be made to the regulatory text, as described below, for clarification purposes at 50 CFR,

sections 300.21, 300.22(b)(1), 300.22(b)(4), and 300.22(b)(7).

The proposed rule would amend notification requirements to facilitate requests for active and inactive status on the Vessel Register. A business email address would be required to assist in communications between NMFS and vessel owners. NMFS would not specify which notification method to use in sending requests for active status or requests under the aging fleet provision to the NMFS West Coast Regional Administrator. Written notification requirements not calling for payment of the vessel assessment fee or not relating to permit applications would be directed to the Highly Migratory Species (HMS) Branch of the NMFS West Coast Region to facilitate communication. The HMS Branch definition in 50 CFR 300.21 would be amended to include the branch email address, *wcr.hms@noaa.gov*.

The proposed rule would amend text in 50 CFR 300.22(b)(7) to clarify that the capacity of inactive vessels is counted towards the U.S. capacity limit, for reasons explained above. Text in 50 CFR 300.22(b)(1) would also be amended to clarify that the vessel capacity of a purse seine vessel that is permitted and authorized under an alternative international tuna purse seine fisheries management regime in the Pacific Ocean and authorized to exercise an option to fish with purse seine gear to target tuna in the Convention Area is not counted towards the U.S. capacity limit. The proposed rule would further clarify that any vessel exercising this single trip exception must follow the procedures, where applicable, as described in 50 CFR 300.22(b)(4).

The proposed rule would also remove the phrase ''Eastern Pacific Fisheries'' in the subheadings of current sections 50 CFR 300.22 and 50 CFR 300.23, because 50 CFR part 300, subpart C, is specific to eastern Pacific tuna fisheries.

The proposed rule would also reorganize, and make changes to, the existing text at 50 CFR 300.22(b)(4) and 50 CFR 300.22(b)(7) to implement changes to the purse seine Vessel Register listing and procedures for replacing purse seine vessels removed from the Vessel Register, as described above.

Classification

The NMFS Assistant Administrator has determined that this proposed rule is consistent with the Tuna Conventions Act and other applicable laws, subject to further consideration after public comment.

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

This proposed rule contains collection-of-information requirements subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) under control number 0648–0387. A request for revision to account for the additional information and updated notification requirements that would be required pursuant to this rule is under OMB review. Public reporting burden for obtaining an IMO number, for making an IMO exemption request, for making a sunk status request, and for making an aging fleet provision request, are each estimated to average 30 minutes per response. This includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Public reporting burden for requesting utilization of a cross-endorsed observer is estimated to add two minutes to the vessel departure notification requirement, which is estimated to average 10 minutes per response.

NMFS is seeking public comment regarding: 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; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Comments on these or any other aspects of the collection of information should be sent to the NMFS West Coast Region Long Beach Office at the addresses above, by email to *OIRA_Submission@omb.eop.gov,* or by fax to (202) 395–5806.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number. All currently approved NOAA collections of information may be viewed at: *http://www.cio.noaa.gov/services_programs/prasubs.html.*

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605(b), 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 rationale for the certification is provided in the following paragraphs.

As described previously in the **SUPPLEMENTARY INFORMATION** section, the proposed regulations would implement IATTC Resolution C–18–06, which would establish IMO number requirements, and amend regulations governing the management of purse seine well capacity and bycatch in the Convention Area.

The SBA defines a ''small business'' (or ''small entity'') as one with annual revenue that meets or is below an established size standard. On December 29, 2015, NMFS issued a final rule establishing a small business size standard of $11 million in annual gross receipts for all businesses primarily engaged in the commercial fishing industry (NAICS 11411), for Regulatory Flexibility Act (RFA) compliance purposes only (80 FR 81194, December 29, 2015; 50 CFR 200.2). The $11 million standard became effective on July 1, 2016, and is to be used in place of the U.S. SBA current standards of $20.5 million, $5.5 million, and $7.5 million for the finfish (NAICS 114111), shellfish (NAICS 114112), and other marine fishing (NAICS 114119) sectors of the U.S. commercial fishing industry in all NMFS rules subject to the RFA. The new standard results in fewer commercial finfish businesses being considered small.

NMFS prepared analyses for this regulatory action in light of the NMFS size standard for the commercial fishing industry. All of the entities directly regulated by this regulatory action are commercial finfish fishing businesses. Using the NMFS size standards, NMFS found that the action on purse seine Vessel Register and incidental catch applies to large and small businesses and the action on the IMO number applies to only small businesses.

There are two components to the U.S. tuna purse seine fishery in the EPO: (1) Large purse seine vessels with a carrying capacity of more than 362.8 mt, typically based in the western and central Pacific Ocean (WCPO) and also in Ecuador; and (2) small purse seine vessels based on the U.S. West Coast. In addition to the U.S. purse seine fishery, U.S. tuna longline, troll, and bait boat fisheries exist on the high seas in the EPO.

As of March 2019, there are 18 U.S. large purse seine vessels on the Vessel Register, listed as either active or inactive. The number of large purse seine vessels on the Vessel Register has

increased substantially in the past five years. This was due in part to uncertainty regarding fishing access pursuant to the Treaty on Fisheries between the Governments of Certain Pacific Island States and the Government of the United States of America (the South Pacific Tuna Treaty). Negotiations for an amended South Pacific Tuna Treaty were concluded in 2016. In 2018, sixteen large purse seine vessels went on 38 fishing trips during which some part of the fishing activity occurred in the EPO. Large purse seine vessels land most of the yellowfin, skipjack, and bigeye tuna catch in the EPO. Ex-vessel price information for large purse seine vessels that fished exclusively in the EPO in 2018 is not available to NMFS, because these vessels did not land on the U.S. West Coast, and the cannery receipts are not available through the IATTC. However, estimates for ex-vessel price information for large purse seine vessels based in the WCPO that fish in both the EPO and WCPO may be used as a proxy for U.S. large purse seine vessels. The number of these U.S. purse seine vessels is approximated by the number with Western and Central Pacific Fisheries Commission (WCPFC) Area Endorsements, which are the NMFS-issued authorizations required to fish commercially for tuna and tuna-like species on the high seas in the WCPFC Convention Area. As of March 2019, the number of purse seine vessels with WCPFC Area Endorsements was 33. Neither gross receipts nor ex-vessel price information specific to individual fishing vessels fishing in the WCPO and EPO are available to NMFS, so NMFS applied indicative regional cannery prices of the WCPO—as approximations of ex-vessel prices—to annual catches of individual vessels to estimate their annual receipts. Indicative regional cannery prices are available through 2014 (developed by the Pacific Islands Forum Fisheries Agency; available at *https://www.ffa.int/node/425*). NMFS estimated vessels' annual receipts during 2012 through 2014. Using this approach, NMFS estimates that among the affected vessels, the range in annual average receipts per vessel in 2012 through 2014 was $3 million to $20 million and the median was about $13 million.

Based on the limited financial information available about the affected fishing fleets, and using individual vessels as proxies for individual businesses, NMFS believes that about half of the large vessels in the purse seine fleet are small entities as defined by the RFA. These vessels are independently owned and operated, not dominant in their fields of operation, and have annual receipts of no more than $11 million. Within the purse seine fleet, analysis of average revenue by vessel for the three years of 2014–2016 reveals that average fleet revenue was about $10.2 million, and the three-year annual averages were less than the $11 million threshold for 22 vessels in the fleet.

As of March 2019, there are 14 U.S. small purse seine vessels on the Vessel Register. Between 2016 and 2018, there were 10 U.S. small purse seine vessels fishing in the EPO for HMS. The average ex-vessel revenue of HMS since 2016 by those vessels was approximately $482,000. Based on the financial information about the affected fishing fleets, and using individual vessels as proxies for individual businesses, NMFS believes that all of the vessels in the small purse seine fleet are small entities as defined by the RFA. They are independently owned and operated, not dominant in their fields of operation, and have annual receipts of no more than $11 million.

The proposed action would require approximately 155 additional vessels fishing for tuna on the high seas in the EPO, including longline, troll, and bait boat vessels, to obtain an IMO number or request an exemption. The average revenue of vessels from the affected fleet landing on the West Coast for the three years of 2015–2017 was approximately $188,000. Using individual vessels as proxies for individual business, NMFS believes that all of these affected vessels are small entities as defined by the RFA. Complying with the IMO number requirement in this proposed action requires no out-of-pocket expenses because applications are free. The 30 minutes estimated to apply for an IMO number would not result in a significant opportunity cost to the fisherman considering it is a one-time occurrence for the life of the vessel hull. The rule is not expected to change fishery operations. Accordingly, the impact of this rule on the affected vessel owners' and operators' income is not expected to be significant.

The proposed regulation would provide a technical correction to the current regulatory fleet capacity to that which is authorized under the IATTC. The action would increase the available capacity to the U.S. purse seine fleet by 91 cubic meters, from 31,755 cubic meters to 31,866 cubic meters. This would allow for increased fishing capacity and thus, economic benefits.

The proposed amendments providing administrative changes to the regulations to facilitate notification requirements and processes for replacing and adding purse seine vessels to the Vessel Register are not likely to change fishery operations or have any economic impacts.

An aging fleet provision would create a process to allow purse seine vessel owners to replace aging vessels currently on the Vessel Register without losing the ability to have the replacement vessel be placed on the active Vessel Register. This is not likely to change the fishing practices of vessels. The revision could result in an economic benefit to vessel owners by allowing for the replacement of a vessel without the added risk of losing their vessel's active status on the Vessel Register and, with it, their access to fish and income. Because NMFS cannot predict the level of use or fleet activity, the quantitative benefit cannot be estimated.

The proposed rule would also treat as frivolous any request by a small coastal purse seine vessel for active status if that vessels did not make at least one landing of tuna caught in the Convention Area in the calendar year prior to the request through November 15 of the year in which the request is made (*i.e.,* a request made in 2019 to fish in 2020, would require one landing of tuna between January 1, 2018 and November 15, 2019). If a small purse seine vessel has not landed tuna caught in the Convention Area within the year before the request was made and through November 15th of the year the request was made, and requests active status on the Vessel Register for the following year (*i.e.,* the third consecutive year of requesting active status), the request would be considered frivolous and subject to the hierarchy of request under 50 CFR 300.22(b)(4)(i)(C). The almost two-year time frame for making a landing of tuna accounts for flexibility in availability of fish in the variable coastal environment. A frivolous request provision for large purse seine vessels already exists; this amendment would align with the intent of the frivolous request provision while attempting to fairly apply the provision to purse seine vessels of all sizes. Since 2011, the average number of days between tuna-related fishing trips by small purse seine vessels averaged just over one year, and vessels which fished for more than one year fished for tuna approximately every 1.75 years. As of September 2018, approximately 8 vessels have not met the requirement for landings over the past two calendar years. Because these vessels are participating in, and have access to, other fisheries, this action is not likely to change fleet behavior and is not likely

to have a significant economic impact on small purse seine vessels.

The proposed regulations would limit vessels to holding inactive and sunk status for a period of two consecutive years, after which their request for inclusion on the Vessel Register would be considered as a frivolous request in the prioritization of requests. In keeping with the intent of the frivolous request provisions, the action would limit vessels from indefinitely holding capacity from vessels requesting to actively fish in the EPO, while still allowing an appropriate amount of time for inactive and sunk vessels to be repaired or replaced. One vessel has been listed as inactive on the Vessel Register since 2015, occupying 1,523 cubic meters of fishing capacity. Allowing active vessels to replace inactive and sunk vessels that are holding capacity would open capacity for use by vessels requesting to actively fish. This would allow additional vessels to benefit economically through utilization of the capacity, though it is not necessarily known that unutilized capacity would be filled.

The provision in this proposed rule to supplement the vessel departure notification requirement with a statement requesting the use of a cross-endorsed observer, pursuant to an MOC between the IATTC and WCPFC, is not expected to impact fisheries operations. The request would facilitate coordination among the vessels, NMFS, and the IATTC for placement of observers, and may provide an economic benefit by reducing delays in vessel operations.

The provision in this proposed rule to revise current provisions on prohibitions and non-target incidental catch are not likely to substantially change fishery operations nor substantially increase economic impacts. Between 1995 and 2004, the year Resolution C–04–05 was adopted, the average annual landings of Pacific bonito and black skipjack, which are two important non-tuna species, was 138 mt by large purse seiners and 246 mt by small purse seine vessels.

This proposed rule is not expected to have a significant economic impact on a substantial number of small entities. The entities for which this proposed rule would apply are considered large businesses and small businesses; however, disproportional economic effects are not expected between small and large businesses.

The proposed actions are not expected to substantially change the typical fishing practices of affected vessels, or to significantly affect income of U.S. vessels, and therefore will not have a significant economic impact on a substantial number of small entities. As a result, an Initial Regulatory Flexibility Analysis is not required and was not prepared for this proposed rule.

List of Subjects in 50 CFR Parts 216 and 300

Fish, Fisheries, Fishing, Fishing vessels, Reporting and recordkeeping requirements.

Dated: April 9, 2019.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, 50 CFR parts 216 and 300 are proposed to be amended as follows:

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 216 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.,* unless otherwise noted.

■ 2. In § 216.24, revise paragraphs (b)(4), (b)(6)(iii)(A) through (D), (b)(6)(iii)(F), and (b)(8)(iv)(A) to read as follows:

§ 216.24 Taking and related acts in commercial fishing operations including tuna purse seine vessels in the eastern tropical Pacific Ocean.

* * * * *

(b) * * *

(4) *Application for vessel permit.* ETP tuna purse seine vessel permit application forms and instructions for their completion are available from NMFS. To apply for an ETP vessel permit, a vessel owner or managing owner must complete, sign, and submit the appropriate form via fax to (562) 980–4047, for prioritization purposes as described under § 300.22(b)(4)(v) of this title, allowing at least 15 days for processing. To request that a vessel in excess of 400 st (362.8 mt) carrying capacity be categorized as active on the Vessel Register under § 300.22(b)(4)(ii) of this title in the following calendar year, the owner or managing owner must submit the vessel permit application via fax, payment of the vessel permit application fee, and payment of the vessel assessment fee no later than September 15 for vessels for which a DML is requested for the following year, and no later than November 30 for vessels for which a DML is not requested for the following year.

* * * * *

(6) * * *

(iii) * * *

(A) The owner or managing owner of a purse seine vessel for which a DML has been requested must submit the vessel assessment fee to the IATTC, no later than September 15 of the year prior to the calendar year for which the DML is requested. Payment of the vessel assessment fee must be consistent with the fee for active status on the Vessel Register under § 300.22(b)(4) of this title.

(B) The owner or managing owner of a purse seine vessel for which active or inactive status on the Vessel Register, as defined in § 300.21 of this title, has been requested, but for which a DML has not been requested, must submit payment of the vessel assessment fee to the IATTC, no later than November 30 of the year prior to the calendar year in which the vessel will be listed on the Vessel Register. Payment of the vessel assessment fee is required only if the vessel is listed as active and is required to carry an observer, or if the vessel is listed as inactive and exceeds 400 st (362.8 mt) in carrying capacity. Payment of the vessel assessment fee must be consistent with the vessel's status, either active or inactive, on the Vessel Register in § 300.22(b)(4) of this title.

(C) The owner or managing owner of a purse seine vessel that is permitted and authorized under an alternative international tuna purse seine fisheries management regime in the Pacific Ocean must submit the vessel assessment fee to the IATTC, prior to obtaining an observer and entering the ETP to fish. Consistent with § 300.22(b)(1) of this title, this class of purse seine vessels is not required to be listed on the Vessel Register under § 300.22(b)(4) of this title in order to purse seine for tuna in the ETP during a single fishing trip per calendar year of 90 days or less. Payment of the vessel assessment fee must be consistent with the fee for active status on the Vessel Register under § 300.22(b)(4)(ii) of this title.

(D) The owner or managing owner of a purse seine vessel listed as inactive on the Vessel Register at the beginning of the calendar year and who requests active status on the Vessel Register under § 300.22(b)(4) of this title during the year, must pay the vessel assessment fee associated with active status, less the vessel assessment fee associated with inactive status that was already paid, before NMFS will request the IATTC Director change the status of the vessel from inactive to active. Payment of the vessel assessment fee is required only if the vessel is required to carry an observer.

* * * * *

(F) Payments will be subject to a 10 percent surcharge if received under paragraph (b)(6)(iii)(E) of this section for vessels that were listed as active on the Vessel Register in the calendar year prior to the year for which active status was requested; or if received after the dates specified in paragraphs (b)(6)(iii)(A) or (b)(6)(iii)(B) of this section for vessels for which active status is requested if the vessel was listed as active during the year the request was made. Payments will not be subject to a 10 percent surcharge if received under paragraph (b)(6)(iii)(C) or (b)(6)(iii)(D) of this section, or if received under paragraph (b)(6)(iii)(E) of this section for vessels that were not listed as active on the Vessel Register in the calendar year prior to the year for which active status was requested. Payments will also not be subject to a 10 percent surcharge if received after the date specified in paragraph (b)(6)(iii)(B) of this section for vessels for which inactive status is requested, or for vessels for which active status is requested if the vessel was not listed as active during the year the request was made. Payment of all vessel assessment fees described in this section must be made to the IATTC.

* * * * *

(8) * * *

(iv) * * *

(A) The vessel permit holder of each permitted vessel must notify the Administrator, West Coast Region, or the IATTC contact designated by the Administrator, West Coast Region, at least 5 days in advance of the vessel's departure on a fishing trip to allow for observer placement on every trip. If the vessel permit holder would like to use an IATTC and Western and Central Pacific Fisheries Commission (WCPFC) cross-endorsed observer when fishing in the IATTC Convention Area, the notification must also include a request for the placement of a cross-endorsed observer pursuant to the Memorandum of Cooperation between the IATTC and WCPFC.

* * * * *

PART 300—INTERNATIONAL FISHERIES REGULATIONS

Subpart C—Eastern Pacific Tuna Fisheries

■ 1. The authority citation for part 300, subpart C, continues to read as follows:

Authority: 16 U.S.C. 951 *et seq.*

■ 2. In § 300.21, revise the definitions for ''Highly Migratory Species (HMS) Branch'' and ''Tuna'' to read as follows:

§ 300.21 Definitions.

* * * * *

Highly Migratory Species (HMS) Branch means the Chief of the HMS Branch of the Sustainable Fisheries Division, National Marine Fisheries Service West Coast Region, Suite 4200, 501 W. Ocean Blvd., Long Beach, CA 90802, and *wcr.hms@noaa.gov.*

* * * * *

Tuna means any fish of the genus Thunnus and the species *Katsuwonus pelamis.*

* * * * *

■ 3. In § 300.22, revise the heading and paragraphs (b)(1), (b)(2), (b)(3)(iii) through (v), (b)(4), (b)(5), (b)(7), and (b)(8), and add paragraph (b)(9) to read as follows:

§ 300.22 Recordkeeping and reporting requirements.

* * * * *

(b) * * *

(1) *Exception.* Once per year, a vessel that is permitted and authorized under an alternative international tuna purse seine fisheries management regime in the Pacific Ocean may exercise an option to fish with purse seine gear to target tuna in the Convention Area without the vessel's capacity counted towards the cumulative carrying capacity described under paragraph (b)(4)(i)(A) of this section. This exception is for a single fishing trip that does not exceed 90 days in duration. At any time during the calendar year, a vessel exercising this exception shall follow the procedures, where applicable, described in paragraphs (b)(4) of this section. No more than 32 of such trips are allowed each calendar year. After the commencement of the 32nd such trip, the Regional Administrator shall announce, in the **Federal Register** and by other appropriate means, that no more such trips are allowed for the remainder of the calendar year. Under § 216.24(b)(6)(iii)(C) of this title, vessel assessment fees must be paid for vessels exercising this option.

(2) *Requirements for inclusion of purse seine vessels on the Vessel Register.* The tuna purse seine portion of the Vessel Register shall include, consistent with resolutions of the IATTC, only vessels that fished in the Convention Area prior to June 28, 2002. Inclusion on the tuna purse seine portion of the Vessel Register is valid through December 31 of each year. New tuna purse seine vessels may be added to the Vessel Register at any time to replace those previously removed by the Regional Administrator, provided that the total capacity of the replacement vessel or vessels does not exceed that of the tuna purse seine vessel or vessels being replaced.

(3) * * *

(iii) *Requirements for IMO numbers.* The owner of a fishing vessel of the United States used for commercial fishing for tuna and tuna-like species in the IATTC Convention Area shall ensure that an IMO number has been issued for the vessel if the vessel's Certificate of Documentation issued under 46 CFR part 67 indicates that the vessel's total internal volume is 100 gross register tons or greater or 100 gross tonnage or greater. In addition, the owner of a fishing vessel of the United States engaging in fishing activities for tuna or tuna-like species in the IATTC Convention Area, and for which a high seas fishing permit under § 300.333 is required, shall ensure that an IMO number has been issued for the vessel if the vessel's total internal volume is less than 100 gross register tons or less than 100 gross tonnage, but equal to or greater than 12 meters in overall length, as indicated in the vessel's Certificate of Documentation issued under 46 CFR part 67 or State documentation. A vessel owner may request that an IMO number be issued for a vessel by following the instructions given by the administrator of the IMO ship identification number scheme; those instructions are currently available on the website of IHS Markit, *https://imonumbers.lrfairplay.com/.*

(iv) *Request for exemption.* In the event that a fishing vessel owner, after following the instructions given by the designated manager of the IMO ship identification number scheme, is unable to ensure that an IMO number is issued for the fishing vessel, the fishing vessel owner may request an exemption from the requirement from the Regional Administrator. The request must be sent by mail to NMFS HMS Branch, West Coast Region, 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802, or by email to *wcr.hms@noaa.gov,* and must include the vessel's name, the vessel's official number, a description of the steps taken to request an IMO number, and a description of any responses from the administrator of the IMO ship identification number scheme.

(v) *Exemption process.* Upon receipt of a request for an exemption under paragraph (b)(3)(iv) of this section, the Regional Administrator will, to the extent he or she determines appropriate, assist the fishing vessel owner in requesting an IMO number. If the Regional Administrator determines that the fishing vessel owner has followed all appropriate procedures and yet is unable to obtain an IMO number for the fishing vessel, he or she will issue an

exemption from the requirements of paragraph (b)(3)(iii) of this section for the vessel and its owner and notify the owner of the exemption. The Regional Administrator may limit the duration of the exemption. The Regional Administrator may rescind an exemption at any time. If an exemption is rescinded, the fishing vessel owner must comply with the requirements of paragraph (b)(3)(iii) of this section within 30 days of being notified of the rescission. If the ownership of a fishing vessel changes, an exemption issued to the former fishing vessel owner becomes void.

(4) *Purse seine Vessel Register listing.* For a tuna purse seine vessel to be listed on the Vessel Register and to be categorized as either ''active'' or ''inactive'' in the following calendar year, the vessel owner or managing owner must submit to the Regional Administrator the required permit applications, written notifications, and fees as described under § 216.24(b) of this title and under paragraphs (b)(4)(ii) and (b)(4)(iii) of this section as well as payment of the vessel assessment fee, where applicable, to the IATTC.

(i) *Restrictions.* The following restrictions apply:

(A) The cumulative carrying capacity of all tuna purse seine vessels on the Vessel Register may not exceed 31,866 cubic meters in a given year; and

(B) A purse seine vessel in excess of 400 st (362.8 mt) carrying capacity may not be added to active status on the Vessel Register unless the captain of the vessel has obtained a valid operator permit under § 216.24(b)(2) of this title.

(ii) *Active status.* As early as August 1 of each year, vessel owners or managing owners may request that a purse seine vessel qualified to be listed on the Vessel Register under paragraph (b)(2) of this section be categorized as active for the following calendar year. To request a purse seine vessel in excess of 400 st (362.8 mt) carrying capacity be listed on the Vessel Register and be categorized as active, the vessel owner or managing owner must submit to the Regional Administrator the vessel permit application and payment of the permit application fee and submit to the IATTC payment of the vessel assessment fee.

(A) To request a purse seine vessel of 400 st (362.8 mt) carrying capacity or less be listed on the Vessel Register and be categorized as active, the vessel owner or managing owner must submit to the HMS Branch written notification including, but not limited to, a vessel photograph, the vessel information as described under paragraph (b)(3) of this section, and the owner or managing owner's signature, business email address, and business telephone and fax numbers. If a purse seine vessel of 400 st (362.8 mt) carrying capacity or less is required by the Agreement on the IDCP to carry an observer, the vessel owner or managing owner must also submit payment of the vessel assessment fee to the IATTC.

(B) The Regional Administrator must receive the vessel permit application or written notification and payment of the permit application fee and payment confirmation of the vessel assessment fee no later than September 15 for vessels for which a DML was requested for the following year and no later than November 30 for vessels for which a DML was not requested for the following year. Submission of the vessel permit application or written notification and payment of the vessel assessment fee and permit application fee will be interpreted by the Regional Administrator as a request for a vessel to be categorized as active.

(iii) *Inactive status.* (A) From August 1 through November 30 of each year, vessel owners or managing owners may request that purse seine vessels qualified to be listed on the Vessel Register under paragraph (b)(2) of this section be categorized as inactive for the following calendar year. To request a purse seine vessel in excess of 400 st (362.8 mt) carrying capacity be listed on the Vessel Register and categorized as inactive for the following calendar year, the vessel owner or managing owner must submit to the IATTC payment of the associated vessel assessment fee. Payment of the vessel assessment fee consistent with inactive status will be interpreted by the Regional Administrator as a request for the vessel to be categorized as inactive.

(B) To request a tuna purse seine vessel of 400 st (362.8 mt) carrying capacity or less be listed on the Vessel Register and categorized as inactive for the following calendar year, the vessel owner or managing owner must submit to the HMS Branch a written notification including, but not limited to, the vessel name and registration number and the vessel owner or managing owner's name, signature, business address, business email address, and business telephone and fax numbers. Payment of the vessel assessment fee is not required for vessels of 400 st (362.8 mt) carrying capacity or less to be categorized as inactive.

(C) At any time during the year, a vessel owner or managing owner may request that a tuna purse seine vessel qualified to be listed on the Vessel Register under paragraph (b)(2) of this section be categorized as inactive for the remainder of the calendar year, provided the cumulative carrying capacity described in (b)(4)(i)(A) of this section is not exceeded. To request a purse seine vessel in excess of 400 st (362.8 mt) carrying capacity be listed on the Vessel Register and categorized as inactive for the remainder of the calendar year, the vessel owner or managing owner must submit to the IATTC payment of the associated vessel assessment fee. To request a tuna purse seine vessel of 400 st (362.8 mt) carrying capacity or less be listed on the Vessel Register and categorized as inactive for the remainder of the calendar year, the vessel owner or managing owner must submit to the HMS Branch written notification as described in (b)(4)(iii)(A). Payment of the vessel assessment fee is not required for such vessels.

(D) The vessel owner or managing owner of a purse seine vessel listed as active on the Vessel Register that has sunk may request the vessel be listed as sunk and categorized as inactive on the Vessel Register. To request the vessel be listed as sunk and categorized as inactive on the Vessel Register, the vessel owner or managing owner must submit to the HMS Branch written notification within 30 days of the vessel's sinking. Written notification shall include, but is not limited to, the vessel name, date of sinking, registration number, the vessel owner or managing owner's name, signature, business address, business email address, and business telephone and fax numbers. For subsequent calendar years, vessel assessment fee payment shall be made as described in paragraph (b)(4)(iii) of this section.

(E) A vessel listed as inactive or sunk on the Vessel Register for more than two consecutive calendar years after [*effective date of final rule publication*] requesting active status will be prioritized according to the hierarchy under paragraph (b)(4)(v) of this section. A vessel listed as inactive or sunk on the Vessel Register for more than two consecutive calendar years after *[effective date of final rule publication*] will be removed from the Vessel Register as described in paragraph (b)(5)(ix) of this section.

(iv) *Frivolous requests.* (A) Except as described under paragraph (b)(4)(iv)(B) of this section, requests for active status under paragraph (b)(4)(ii) of this section will be considered frivolous if, for a vessel categorized as active on the Vessel Register in a given calendar year:

(*1*) Less than 20 percent of the vessel's total landings, by weight, in that same year is comprised of tuna harvested by purse seine in the Convention Area; or

(*2*) The vessel did not fish for tuna at all in the Convention Area in that same year.

(B) Exceptions. Requests described under paragraph (b)(4)(iv)(A) of this section will not be considered frivolous requests if:

(*1*) The vessel's catch pattern fell within the criteria described in paragraph (b)(4)(iv)(A) of this section as a result of force majeure or other extraordinary circumstances as determined by the Regional Administrator; or

(*2*) The vessel's carrying capacity is 400 st (362.8 mt) or less and there was at least one documented landing of tuna caught by the vessel in the Convention Area in the calendar year prior to the year in which the request is made and through November 15 of the year of the request, unless the vessel was not able to make a landing as a result of force majeure or other extraordinary circumstances as determined by the Regional Administrator.

(*3*) The vessel was listed as inactive before [*effective date of final rule publication*] and has not been listed as inactive for more than two consecutive calendar years since [*effective date of final rule publication*].

(v) *Listing hierarchy.* Requests for active status and inactive status will be prioritized according to the following hierarchy:

(A) Requests received for replacement vessels of those removed from the Vessel Register under the request described in (b)(9) of this section;

(B) Requests received for vessels that were categorized as active in the previous year, unless the request was determined to be frivolous by the Regional Administrator under paragraph (b)(4)(ii) of this section;

(C) Requests received for vessels that were categorized as inactive under paragraph (b)(4)(iii) of this section in the previous year, unless that vessel has been listed as inactive or sunk under paragraph (b)(4)(iii) for more than two consecutive calendar years after [*effective date of final rule publication*];

(D) Requests for vessels not described in paragraphs (b)(4)(v)(A) through (C) of this section will be prioritized on a first-come, first-served basis according to the date and time of receipt, provided that the associated vessel assessment fee is paid by the applicable deadline described in § 216.24(b)(6)(iii) of this title; and

(E) Requests received from owners or managing owners of vessels that were determined by the Regional Administrator to have made a frivolous request for active status under paragraph (b)(4)(iv) of this section or that have been listed as inactive or sunk as described in paragraph (b)(4)(iii) of this section for more than two consecutive calendar years after [*effective date of final rule publication*].

(5) *Removal from the Vessel Register.* A vessel may be removed from the Vessel Register by the Regional Administrator:

(i) If the vessel has sunk, and the vessel owner or managing owner has not submitted written notification as described in paragraph (b)(4)(iii)(C) of this section;

(ii) Upon written request by the vessel's owner or managing owner;

(iii) Following a final agency action on a permit sanction for a violation; and

(iv) For failure to pay a penalty or for default on a penalty payment agreement resulting from a final agency action for a violation.

(v) If the U.S. Maritime Administration or the U.S. Coast Guard notifies NMFS that:

(A) The owner has submitted an application for transfer of the vessel to foreign registry and flag; or

(B) The documentation for the vessel will be or has been deleted for any reason.

(vi) If the vessel does not have a valid state registration or U.S. Coast Guard certificate of documentation;

(vii) For tuna purse seine vessels, upon receipt of written notification from the owner or managing owner of the intent to transfer the vessel to foreign registry and flag, as described in paragraph (b)(8) of this section; or

(viii) For tuna purse seine vessels, if the request for active status on the Vessel Register has been determined to be a frivolous request; or

(ix) If the vessel has been listed as inactive or sunk on the Vessel Register for more than two consecutive calendar years after [*effective date of final rule publication*].

(6) * * *

(7) *Procedures for replacing purse seine vessels removed from the Vessel Register.* (i) A purse seine vessel that was previously listed on the Vessel Register, but not included for a given year or years, may be added back to the Vessel Register and categorized as inactive at any time during the year, provided the cumulative carrying capacity described in (b)(4)(i)(A) of this section is not exceeded. The owner or managing owner of a purse seine vessel of more than 400 st (362.8 mt) carrying capacity must pay the vessel assessment fee associated with inactive status. The owner or managing owner of a purse seine vessel of 400 st (362.8 mt) carrying capacity or less must submit written notification as described in paragraph (b)(4)(iii) of this section.

(ii) A purse seine vessel may be added to the Vessel Register and categorized as active in order to replace a vessel or vessels removed from active status under paragraph (b)(5) of this section, provided the total carrying capacity described in (b)(4)(i)(A) of this section is not exceeded and the owner submits a complete request under paragraph (b)(7)(iv) or (b)(7)(v) of this section.

(iii) *Notification of available capacity.* (A) After a purse seine vessel categorized as active or inactive is removed from the Vessel Register, the Regional Administrator will notify owners or managing owners of vessels eligible for, but not included on, the Vessel Register that replacement capacity is available on the active or inactive list of the Vessel Register.

(B) Exception. When a purse seine vessel categorized as active or inactive on the Vessel Register has been removed from the Vessel Register under the procedures described in (b)(9) of this section, the Regional Administrator will not make available the capacity of the vessel removed from the Vessel Register, and will reserve that capacity for a replacement vessel for a period of two years. The replacement vessel will be eligible to be listed as active on the Vessel Register if it has a carrying capacity equal to or less than the vessel being replaced.

(iv) Vessel owners or managing owners may request a purse seine vessel of 400 st (362.8 mt) carrying capacity or less be categorized as active to replace a vessel or vessels removed from the Vessel Register by submitting to the HMS Branch written notification as described in paragraph (b)(4)(ii) of this section and, only if the vessel is required by the Agreement on the IDCP to carry an observer, payment of the vessel assessment fee to the IATTC within 10 business days after submission of the written notification. The replacement vessel will be eligible to be categorized as active on the Vessel Register if it has a carrying capacity equal to or less than the vessel or vessels being replaced. Payments received will be subject to a 10 percent surcharge for vessels that were listed as active on the Vessel Register in the previous calendar year, but not listed as inactive at the beginning of the calendar year for which active status was requested.

(v) Vessel owners or managing owners may request a purse seine vessel in excess of 400 st (362.8 mt) carrying capacity be categorized as active to replace a vessel or vessels removed from the Vessel Register by submitting to the

Regional Administrator the vessel permit application as described under § 216.24(b) of this title and payment of the vessel assessment fee to the IATTC and payment of the permit application fee to the Regional Administrator within 10 business days after submission of the vessel permit application for the replacement vessel. The replacement vessel will be eligible to be categorized as active on the Vessel Register if it has a carrying capacity equal to or less than the vessel or vessels being replaced, and the captain of the replacement vessel possesses an operator permit under § 216.24(b) of this title. Payments received will be subject to a 10 percent surcharge for vessels that were listed as active on the Vessel Register in the previous calendar year, but not listed as inactive at the beginning of the calendar year for which active status was requested.

(vi) The Regional Administrator will forward requests to replace vessels removed from the Vessel Register within 15 days of receiving each request.

(8) The owner or managing owner of a purse seine vessel listed on the Vessel Register must provide written notification to the Regional Administrator prior to submitting an application for transfer of the vessel to foreign registry and flag. Written notification must be submitted to the Regional Administrator at least 10 business days prior to submission of the application for transfer. The written notification must include the vessel name and registration number; the expected date that the application for transfer will be submitted; and the vessel owner or managing owner's name and signature. Vessels that require approval by the U.S. Maritime Administration prior to transfer of the vessel to foreign registry and flag will not be subject to the notification requirement described in this paragraph.

(9) *Aging fleet provision.* (i) The vessel owner or managing owner of a purse seine vessel listed as active or inactive on the Vessel Register may request to replace the current vessel with a new or used vessel without losing the vessel's placement in the hierarchy of requests for active status as described in paragraph (b)(4)(v) of this section. The replacement vessel will be eligible to be listed as active on the Vessel Register if it has a carrying capacity equal to or less than the vessel being replaced. This provision may be used only once per vessel by the vessel owner or managing owner.

(ii) A request made under this provision may include a request to remove the vessel from the Vessel Register. The Regional Administrator will ensure the capacity for the replacement vessel is available for up to 2 years from the date of notification described in paragraph (b)(9)(iv) of this section.

(iii) To request a vessel be replaced under this provision, the vessel owner or managing owner must submit to the HMS Branch written notification including, but not limited to, the vessel name and registration number, the vessel owner or managing owner's name, signature, business address, business email address, and business telephone and fax numbers, and the expected month and year the replacement vessel will be ready to fish in the Convention Area.

(iv) Within 30 days of receiving each request described in (b)(9)(i) of this section, the Regional Administrator shall notify the vessel owner or managing owner in writing whether the request has been accepted or denied, and the reasons therefore.

■ 4. In § 300.23, revise the section heading to read as follows:

§ 300.23 Persons and vessels exempted.

■ 5. In § 300.24, revise paragraph (f) and remove and reserve paragraph (g) to read as follows:

§ 300.24 Prohibitions.

* * * * *

(f) When using purse seine gear to fish for tuna in the Convention Area, fail to release any fish species (excluding mobulid rays, tuna, tuna-like species, and those being retained for consumption aboard the vessel) as soon as practicable after being identified on board the vessel during the brailing operation as required in § 300.27(b).

* * * * *

■ 6. In § 300.27, revise paragraph (b) to read as follows:

§ 300.27 Incidental catch and tuna retention requirements.

* * * * *

(b) *Release requirements for fish species on purse seine vessels.* All purse seine vessels must release, as soon as practicable after being identified on board the vessel during the brailing operation, all billfish, rays (not including mobulid rays, which are subject to paragraph (i) of this section), dorado (*Coryphaena hippurus*), and other fish species except tuna, tuna-like species and those being retained for consumption aboard the vessel. Sharks caught in the IATTC Convention Area and that are not retained for consumption aboard the vessel must be released according to the requirements in paragraph (k) of this section. Tuna caught in the IATTC Convention Area are subject to the retention requirements in paragraph (a) of this section.

* * * * *

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 181015951–9259–01]

RIN 0648–BI53

Fisheries of the Exclusive Economic Zone off Alaska; Halibut Deck Sorting Monitoring Requirements for Trawl Catcher/Processors Operating in Non-Pollock Groundfish Fisheries off Alaska

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes regulations to implement catch handling and monitoring requirements to allow Pacific halibut (halibut) bycatch to be sorted on the deck of trawl catcher/processors and motherships participating in the non-pollock groundfish fisheries off Alaska. Halibut bycatch is required to be discarded and returned to the sea with a minimum of injury in the directed groundfish fisheries in the Bering Sea and Aleutian Islands (BSAI) and Gulf of Alaska (GOA) management areas. This action includes additional minor regulatory changes that will improve consistency and clarity of existing regulations, remove unnecessary and outdated regulations, and update cross references to reflect these proposed regulations. This action is intended to promote the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the Fishery Management Plan (FMP) for Groundfish of the GOA (GOA FMP), the FMP for Groundfish of the BSAI Management Area (BSAI FMP), and other applicable law.

DATES: Submit comments on or before May 16, 2019.

ADDRESSES: You may submit comments, identified by NOAA–NMFS–2018–0122, by any of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to

www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0122, click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

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 Regulatory Impact Review (referred to as the ''Analysis'') and the Categorical Exclusion prepared for this proposed rule may be obtained from *http://www.regulations.gov* or from the NMFS Alaska Region website at *http://alaskafisheries.noaa.gov.*

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to NMFS at the above address; by email to *OIRA_Submission@omb.eop.gov;* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Joseph Krieger, 907–586–7228 or *joseph.krieger@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Authority for Action

NMFS manages the groundfish fisheries in the exclusive economic zone under the GOA FMP and under the BSAI FMP. The North Pacific Fishery Management Council (Council) prepared these FMPs under the authority of the Magnuson-Stevens Act, 16 U.S.C. 1801 *et seq.* Regulations governing U.S. fisheries and implementing the FMPs groundfish of the GOA and BSAI appear at 50 CFR parts 600 and 679.

II. Background

Pacific halibut (*Hippoglossus stenolepis*) is fully utilized in Alaska as a target species in subsistence, personal use, recreational (sport), and commercial halibut fisheries. Halibut has significant social, cultural, and economic importance to fishery participants and fishing communities throughout the geographical range of the resource. Halibut is also incidentally taken as bycatch in groundfish fisheries. The Magnuson-Stevens Act defines bycatch as ''fish which are harvested in a fishery, but which are not sold or kept for personal use, and includes economic discards and regulatory discards. The term does not include fish released alive under a recreational catch and release fishery management program.'' 16 U.S.C 1802 3(2).

The International Pacific Halibut Commission (IPHC) and NMFS manage halibut fisheries through regulations established under the authority of the Northern Pacific Halibut Act of 1982 (Halibut Act) (16 U.S.C. 773–773k). The IPHC adopts regulations governing the target fishery for halibut under the Convention between the United States and Canada for the Preservation of the Halibut Fishery of the North Pacific Ocean and Bering Sea (Convention), signed at Ottawa, Ontario, on March 2, 1953, as amended by a Protocol Amending the Convention (signed at Washington, DC, on March 29, 1979). For the United States, regulations governing the fishery for Pacific halibut developed by the IPHC are subject to acceptance by the Secretary of State with concurrence from the Secretary of Commerce. After acceptance by the Secretary of State and the Secretary of Commerce, NMFS publishes the IPHC regulations in the **Federal Register** as annual management measures pursuant to 50 CFR 300.62. The final rule implementing IPHC regulations for 2019 published on March 14, 2019 (84 FR 9243).

Section 773c(c) of the Halibut Act also provides the Council with authority to develop regulations that are in addition to, and not in conflict with, approved IPHC regulations. The Council has exercised this authority in the development of Federal regulations for the halibut fishery such as (1) subsistence halibut fishery management measures, codified at § 300.65; (2) the limited access program for charter vessels in the guided sport fishery, codified at § 300.67; and (3) the Individual Fishing Quota (IFQ) Program for the commercial halibut and sablefish fisheries, codified at 50 CFR part 679, under the authority of section 773c(c) of the Halibut Act and section 303(b) of the Magnuson-Stevens Act.

NMFS has implemented regulations that limit the amount of halibut bycatch in the directed groundfish fisheries in the BSAI and GOA. Regulations establish specific limits on the amount of halibut bycatch, PSC limits, in specific groundfish fisheries in the BSAI and GOA. These PSC limits are based on the amount of halibut discard mortality estimated under specific monitoring procedures. NMFS has implemented halibut PSC limits consistent with the requirements of the Magnuson-Stevens Act to minimize bycatch to the extent practicable while achieving, on a continuing basis, optimum yield from the groundfish fisheries.

In recent years, catch limits for the commercial halibut fishery in the BSAI and GOA have declined in response to changing halibut stock conditions. Most recently, NMFS implemented Amendment 111 to the BSAI FMP (81 FR 24714, April 27, 2016), and Amendment 95 to the GOA FMP (79 FR 9625, February 20, 2014), to further reduce PSC limits for Pacific halibut in the BSAI and GOA groundfish fisheries.

NFMS proposes regulations to implement catch handling and monitoring requirements to allow halibut bycatch to be sorted on the deck of trawl catcher/processors (CPs) and motherships when operating in the non-pollock groundfish fisheries off Alaska. The monitoring requirements included in this action have been developed and tested on vessels participating in the non-pollock groundfish fisheries. The harvest of non-pollock groundfish fisheries may be limited by existing halibut PSC limits and participating vessels are operationally different than vessels participating in pollock fisheries. As such, the scope of this action is limited to vessels participating in the non-pollock groundfish fisheries. This proposed rule would not modify existing halibut PSC limits, but it would allow halibut to be discarded faster than current monitoring requirements allow which could reduce halibut discard mortality. Reducing halibut discard mortality could maximize prosecution of the directed non-pollock groundfish fisheries that otherwise might be constrained by restrictive halibut PSC limits, and may also benefit vessels participating in the directed halibut fishery by returning more live halibut to the water.

This proposed rule would allow three categories of CPs and motherships to participate in deck sorting in the non-pollock groundfish fisheries. This proposed rule would allow deck sorting for: (1) Vessels operating in the non-pollock groundfish fisheries in the BSAI and GOA under the Amendment 80 Program (72 FR 52667, September 14, 2007), also referred to as the Amendment 80 sector, (2) vessels harvesting non-pollock groundfish in

the BSAI under the Western Alaska Community Development Quota Program (CDQ Program, also referred to as the CDQ Sector), and (3) CPs and motherships harvesting non-pollock groundfish in the BSAI trawl limited access sector (TLAS). The term ''mothership'' is defined in regulation at § 679.2, and it includes vessels that receive catch from other vessels. See section 3 of the Analysis for a detailed description of the affected fisheries. The following sections provide descriptions of (1) the affected fisheries and halibut PSC management; (2) current monitoring requirements; (3) the need for this action; and (4) the proposed rule.

III. The Affected Fisheries and Halibut PSC Management

This action would be applicable to CPs and motherships using trawl gear in the non-pollock groundfish fisheries off Alaska. This includes vessels participating in the Amendment 80 sector, BSAI TLAS, and the CDQ Sector. Existing monitoring requirements such as observer coverage, video monitoring systems, and other requirements for the affected vessels are described at §§ 679.28, 679.32, 679.51, 679.63, 679.84, and 679.93. The following section describes the affected fisheries and halibut PSC management.

A. The Affected Fisheries

1. Amendment 80 Sector

The BSAI non-pollock groundfish fishery has been prosecuted mostly by a fleet of trawl CPs. These CPs are managed under the Amendment 80 Program. The Amendment 80 Program is a catch share program that allocates several BSAI non-pollock trawl species among fishing sectors, and facilitates the formation of harvesting cooperatives in the non-American Fisheries Act (AFA) trawl CP sector. The AFA is a limited access program for Bering Sea pollock implemented by statute in 1998 (Pub. L. 105–277, 16 U.S.C. 1851 statutory note).

The Amendment 80 sector is composed of 28 CPs with history of harvesting non-pollock groundfish in the BSAI. Species allocated to the Amendment 80 sector include: Aleutian Islands Pacific ocean perch, BSAI Atka mackerel, BSAI flathead sole, BSAI Pacific cod, BSAI rock sole, and BSAI yellowfin sole. In addition, the Amendment 80 cooperatives and vessels receive allocations of Pacific halibut and crab PSC limits for use while fishing in the BSAI to constrain bycatch, or unintended take, of these species while harvesting groundfish. Amendment 80 allocates the six target species and five prohibited species in the BSAI to the CP sector and allows qualified vessels to form cooperatives. These voluntary harvest cooperatives coordinate use of the target allocations, incidental catch allowances, and prohibited species allocations among active member vessels. Detailed information on the Amendment 80 Program is available in the final rule implementing the program (72 FR 52667, September 14, 2007), and at the Alaska Region website: (*https://alaskafisheries.noaa.gov/fisheries/amendment-80*).

Some Amendment 80 vessels also participate in the Central GOA Rockfish Program (Rockfish Program). This rule proposes that these vessels would be able to deck sort halibut PSC while participating in the Rockfish Program. The Rockfish Program is a limited access privilege program established under section 303A of the Magnuson-Stevens Act (76 FR 81248, December 27, 2011). As described later in this preamble, some of the provisions in this proposed rule would also affect monitoring provisions applicable to CPs participating in the Rockfish Program. Detailed information on the Rockfish Program is available in the final rule implementing the program (76 FR 81248, December 27, 2011), and at the Alaska Region website: (*https://alaskafisheries.noaa.gov/fisheries/central-goa-rockfish-program*).

2. BSAI TLAS (Trawl Limited Access Sector)

When the Amendment 80 Program was implemented, it allocated specific amounts of non-pollock Amendment 80 species, including PSC species, to non-Amendment 80 vessels that that comprise the BSAI TLAS. The BSAI TLAS includes AFA CPs, AFA catcher vessels (CVs), and other non-AFA CVs. The BSAI TLAS comprises all the trawl vessels in the BSAI except the Amendment 80 CPs. The BSAI TLAS fishery provides harvesting opportunities of some Amendment 80 species by non-Amendment 80 vessels.

Each year, NMFS allocates an amount of each Amendment 80 target species available for harvest, called the initial allowable catch, and crab and halibut PSC to the Amendment 80 sector and the BSAI TLAS sector, with the TLAS allocations representing a small proportion of overall allocation of Amendment 80 species. NMFS apportions the BSAI TLAS sector's PSC limit into PSC allowances among the following trawl fishery categories: (1) Yellowfin sole fishery, (2) rock sole/ flathead sole/ ''other flatfish'' fishery, (3) Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish fishery, (4) rockfish fishery, (5) Pacific cod fishery, and (6) pollock/Atka mackerel/''other species'' fishery, which includes the midwater pollock fishery.

Under this proposed rule, AFA vessels would not be eligible to participate in halibut deck sorting when operating in pollock fisheries. However, vessels participating in the BSAI TLAS fishery—which may include AFA vessels—may choose to participate in halibut deck sorting when operating in non-pollock fisheries in the BSAI TLAS. Detailed information on the BSAI TLAS is available in the final rule implementing the Amendment 80 Program (72 FR 52667, September 14, 2007), and at the Alaska Region website: (*https://alaskafisheries.noaa.gov/fisheries/amendment-80*).

3. The CDQ Sector

The CDQ sector includes all trawl and non-trawl vessels that harvest groundfish under the CDQ Program. The CDQ Program consists of six different non-profit managing organizations (CDQ groups) representing different geographical regions in Alaska. The CDQ Program receives annual allocations of TAC for a variety of commercially valuable species in the BSAI groundfish, crab, and halibut fisheries, which are then allocated among the CDQ groups. The halibut PSC limit is divided among the six CDQ groups by established percentages (71 FR 51804, August 31, 2006). Each CDQ group receives an apportionment of this halibut PSC limit as halibut prohibited species quota (PSQ), which is a specific amount of halibut that vessels fishing for that CDQ group may use in a year. The CDQ group manages the use of its halibut PSQ apportionment. The CDQ group has the responsibility to ensure that the vessels fishing its CDQ groundfish allocation do not use halibut PSQ in excess of the amount of the CDQ group's halibut PSQ. This limit is enforced at § 679.7(d)(3), which prohibits a CDQ group from exceeding its apportionment of halibut PSQ. Detailed information on the CDQ Program is at the Alaska Region website: (*https://alaskafisheries.noaa.gov/fisheries/cdq*).

B. Halibut PSC Management

Table 2b to 50 CFR part 679 and § 679.2 define halibut caught incidentally to directed fishing for groundfish as PSC. Halibut PSC in the directed groundfish fisheries of the GOA and BSAI are regulated under § 679.21. These regulations require that all vessels minimize catch of prohibited species and that all vessels discard PSC with a minimum of injury after allowing for

sampling by an observer. NMFS established requirements to discard halibut caught with trawl gear in 1977 (42 FR 9297, February 15, 1977). These requirements are intended to minimize the incidental catch of halibut in the trawl fisheries, as well as minimize the mortality of discarded halibut. NMFS requirements are also consistent with long-standing regulations adopted by the IPHC that prohibit the retention of halibut by trawl (see 2018 Annual Management Measures found at: *https://iphc.int/uploads/pdf/regs/iphc-2018-regs.pdf*).

Although participants in the non-pollock groundfish fisheries are under an obligation to avoid halibut, all halibut cannot be avoided. The groundfish fisheries cannot be prosecuted without some amount of halibut PSC because groundfish and halibut occur in the same areas at the same times and because no fishing gear or technique has been developed that can avoid all halibut PSC. NMFS manages halibut PSC in the BSAI groundfish fisheries by (1) establishing halibut PSC limits for trawl and non-trawl fisheries; (2) apportioning those halibut PSC limits among groundfish sectors, fishery categories, and seasons; and (3) managing groundfish fisheries to prevent halibut PSC use from exceeding the established limits.

While halibut is taken as bycatch by vessels using all types of gear (trawl, hook-and-line, pot, and jig), halibut bycatch in the BSAI primarily occurs in the groundfish fisheries using hook-and-line and trawl gear. Though halibut bycatch occurs in both the GOA and the BSAI, the greatest portion by weight of halibut bycatch occurs in the BSAI.

To monitor halibut PSC limits and apportionments, the Regional Administrator uses observer data on halibut incidental catch rates, halibut discard mortality rates (DMRs), and estimates of groundfish catch to project when a fishery's halibut PSC limit or seasonal apportionment is reached. Halibut incidental catch rates (weight of halibut caught per weight of groundfish total catch) are based on estimates derived from observer data of halibut incidental catch in the groundfish fisheries. DMRs are estimates of the proportion of incidentally caught halibut that will not survive after being returned to the sea with values ranging from 0% (all halibut survived) to 100% (no halibut survived). DMRs are calculated annually on a fleet-wide basis using methodology developed by NMFS, the IPHC, and in consultation with the Council. DMRs are published in harvest specification tables in the **Federal Register**. For a given haul, the appropriate DMR is applied based on gear, sector, and year. The cumulative halibut mortality that accrues to a particular halibut PSC limit is the product of a DMR multiplied by the estimated halibut PSC. See section 1.3.2 of the Analysis for additional detail about the DMR estimation process.

To minimize halibut mortality, NMFS requires that all halibut must be returned to the sea as soon as possible after they have been sampled by observers. However, current regulations require observers onboard trawl CPs and motherships to complete data collection duties in the factory of the vessel after the unsorted catch has been weighed on a motion compensated at-sea flow scale (flow scale). Halibut mortality increases with increased handling and time out of water (see section 1.3.5 of the Analysis for additional detail). In the non-pollock groundfish fisheries most of the halibut are typically out of the water for long periods of time, such as 3 to 4 hours in some cases, and are usually dead or in poor viability condition at the time of discard after weighing and sorting in the factory. This results in high halibut DMRs for the non-pollock groundfish fishery, which in turn, results in high halibut PSC mortality estimates.

Current Monitoring Requirements

NMFS uses observer data to provide reliable estimates of allocated species in catch share and reliable estimates of total catch and bycatch in non-catch share fisheries. Since 1999 with the implementation of the CDQ Program, closely followed by the implementation of AFA Program in 2002, NMFS has consistently imposed additional monitoring requirements on vessels participating in groundfish catch share programs. These monitoring requirements are necessary because of the unique incentives to misreport catch that are created by the act of assigning quota and therefore accountability to individual entities (cooperatives or vessels). Vessels affected by this action participate in catch share and non-catch share fisheries including Amendment 80 Program, BSAI TLAS, and the groundfish CDQ fisheries. Observer information is used in the NMFS Catch Accounting System to monitor catch of target and bycatch species on a daily basis. Current monitoring requirements for CPs and motherships participating in the non-pollock groundfish fisheries off Alaska vary, depending upon the specific fishery in which the vessel is participating. Each catch share program includes monitoring requirements designed to ensure that observer data produce reliable catch and bycatch estimates of allocated species. Catch monitoring regulations applicable to vessels participating in the non-pollock groundfish directed fisheries are found at §§ 679.28, 679.32, 679.51, 679.63, 679.84, and 679.93, and are summarized in the following sections of this preamble.

A. Monitoring and Enforcement Tools

1. Observer Coverage

Observers have sampled catch in the Alaska Federal groundfish fisheries since the early 1990s and have routinely collected lengths, weights, and viability metrics of the sampled catch. Amendment 80 CPs, CPs acting as motherships, and CPs managed under the Rockfish Program are required to carry two observers, one of which must have a lead level 2 endorsement for a CP using trawl gear or mothership. The current workload restriction defined at 679.51(a)(2)(iii) state that an observer's workload may not exceed 12 consecutive hours in a 24-hour period. If vessel operations require an observer to work more than 12 consecutive hours to complete sampling and data entry duties, additional observers are required. Motherships and CPs fishing in the BSAI TLAS must also meet these same observer coverage requirements. However, CPs that choose to opt out of the Rockfish Program and Amendment 80 CPs fishing under sideboards in the GOA are required to carry only one observer. This observer follows a random sampling table to determine which hauls to sample.

2. Observer Access to Catch

Before catch is sorted or discarded on any trawl vessel, at-sea observers must collect data necessary to estimate halibut and groundfish catch amounts. Regulations in 50 CFR part 679 are designed to ensure that observer data result in reliable estimates of halibut and groundfish catch, and that potential bias is minimized. For example, NMFS requires fishing vessels to make all catch available for sampling by an observer; prohibits vessel crew from tampering with observer samples; prohibits vessel crew from removing halibut from a codend, bin, or conveyance system prior to being observed and counted by an at-sea observer; and prohibits fish (including halibut) from remaining on deck unless an observer is present.

Current halibut discard requirements state that an observer must first have access to sample the catch prior to sorting and discard. The specific point of discard and catch handling procedures may vary depending on each vessel's deck configuration. However,

since the implementation of monitoring requirements for the Amendment 80 Program and the Rockfish Program, vessels are generally allowed only one operational line for the mechanized movement of fish from the flow scale used to weigh catch and the location where the observer collects species composition samples.

Observers sample the species composition of catch and NMFS estimates the ratio of halibut to groundfish from each haul sampled and applies it to the official total catch of groundfish for each sampled haul. NMFS applies a consistent process to determine which halibut catch rates apply to which hauls based on vessel type, whether sampled hauls occurred on the same vessel, processing sector, nearness in time, trip target, gear type, FMP area, reporting area, special areas, management program, and observer sampling method. These factors are applied to algorithms to give a rate of incidentally caught halibut to every haul. This rate is then applied to the official total catch of each haul. Once the estimated halibut catch for every haul is calculated, DMRs are applied to calculate the amount of halibut PSC mortality accrued. See sections 1.3.2 and 4.1 of the Analysis for more detail on DMR estimation and observer coverage requirements.

3. Pre-Cruise Meeting

Vessel owners and operators of Amendment 80 CPs are required to notify the North Pacific Observer Program (Observer Program) at least 24 hours prior to departure on a trip with an observer who has not deployed on that vessel in the last 12 months. This allows the Observer Program to schedule a pre-cruise meeting between the observer and vessel operator or manager and adequately prepare the observer(s) to successfully collect the high quality data necessary for fisheries management.

Pre-cruise meetings provide an opportunity for vessel crew and observers to discuss sampling and vessel operations prior to embarking on a trip. Pre-cruise meetings can help improve data quality, reduce conflicts between observers and vessel crew, and can assist vessel operators and managers to comply with observer related regulations.

B. Equipment Requirements

1. Motion Compensated At-Sea Flow Scale and Observer Sampling Station

Flow scales are required to be used in the Amendment 80 and CDQ Program fisheries, and on motherships and CPs in the BSAI TLAS fishery. Typically, flow scales are installed in the vessel's fish processing area, below the deck. Flow scales allow all catch to be weighed. Because observer samples are extrapolated to the entire haul, catch from each haul is weighed separately on the scale. To facilitate separate weighing, catch from each haul cannot be mixed with other hauls.

Vessels are also required to provide an observer sampling station where an observer can work safely and effectively. Stations must meet specifications for size and location and must be equipped with a motion-compensated platform scale, a table, adequate lighting, floor grating, and running water. Additionally, the observer sampling station must have room to store at least ten observer sampling baskets. These vessels must also have only one operational line for the mechanized movement of catch to ensure that the observer has access to the entire catch to collect species composition samples.

Vessels subject to Amendment 80 sideboards in the GOA as specified at 679.92(b), as well as those vessels that opt out of the Rockfish Program, are not required to use a flow scale or have an observer sampling station. These vessels are prohibited from mixing hauls (combine the catch of two or more individual hauls) and must only have one operational line for the mechanized movement of catch. This is to ensure that observer data collected is appropriately attributed to each haul. However, most vessels subject to the sideboards in the GOA do continue to use the flow scale and make the observer sampling station available for use by the observer.

2. Video Monitoring

All CPs and motherships required to use a flow scale must have a video monitoring system that shows all areas where catch moves across the flow scale, any access point to the scale that may be adjusted by vessel crew, and the scale display and fault light. These vessels are also required to have a video monitor available to NMFS observer.

CPs and motherships participating in Amendment 80 fisheries may choose video monitoring of the inside of fish bins as one method of ensuring that catch is not selectively sorted inside the bins prior to observer sampling. This video is used to ensure that fish, including halibut, are not pre-sorted from the catch prior to observer sampling. These vessels are required to have a video monitor available at the observer sampling station.

AFA CPs and motherships that participate in the BSAI TLAS are required to have video monitoring of all areas where salmon are sorted from the catch, of all crew actions in these areas, and provide a view of the salmon storage container. The video is used to ensure that all salmon are available to the observer to conduct a census of salmon at the end of each haul. These vessels are also required to have a monitor available in the observer sampling station. System specifications for video monitoring requirements are detailed at § 679.28(e).

IV. Need for This Action

Amendment 111 to the BSAI FMP, published on April 27, 2016 (81 FR 24714), reduced halibut PSC limits in the BSAI groundfish fisheries in four groundfish sectors: The Amendment 80 sector; the BSAI TLAS (all non-Amendment 80 trawl fishery participants); the non-trawl sector (primarily hook-and-line CPs); and the CDQ Program. The purpose of Amendment 111 was to decrease BSAI halibut PSC to the extent practicable by the BSAI groundfish fisheries while continually achieving optimum yield from the BSAI groundfish fisheries. Although halibut bycatch is not believed to have significant impact on halibut stock status since most incidentally caught halibut from the BSAI Groundfish fisheries are relatively small (under 26 inches), the loss of many small individuals does impact the future number of larger halibut (over 26 inches) that are available to the directed halibut fishery (80 FR 71649, November 16, 2015).

Similarly, Amendment 95 to the GOA FMP, published on March 24, 2014 (79 FR 9625), reduced halibut PSC limits in the GOA groundfish fisheries in three sectors: The hook-and-line CP sector, the hook-and-line catcher vessel (CV) sector, and the trawl sector. The purpose of Amendment 95 was to minimize halibut bycatch in the GOA in the extent practicable, while at the same time achieving optimum yield from the GOA groundfish fishery.

By reducing halibut PSC, the final rules for Amendment 111 and Amendment 95 aimed to increase harvest opportunities for the directed halibut fisheries. However, these reductions increased the potential for the halibut PSC limit to constrain the harvest of allocated species in groundfish fisheries, thereby potentially reducing the overall economic benefit of the fisheries if the directed fisheries would be closed prior to harvesting all the allocated species.

Under current monitoring requirements for most vessels participating in the non-pollock

groundfish fisheries, all halibut must be weighed along with the rest of the unsorted catch and made available for sampling by an observer prior to discard. This means that all halibut enter the fish bin and are weighed in the factory prior to observer data collection and discard, resulting in high DMRs. For several years, experiments conducted through Exempted Fishing Permits (EFPs) have tested procedures to reduce halibut discard mortality by sorting, collecting observer data, and discarding halibut from the deck of trawl CPs and motherships. The data collected during EFP fishing showed that the practice of deck sorting reduces halibut discard mortality. Results from these EFPs suggest that substantial amounts of halibut can be returned to the water and provide for additional harvest opportunity for the directed halibut fisheries. See section 1.3.5 of the Analysis for additional detail on halibut deck sorting EFPs.

In order to accurately account for halibut sorted on deck during EFP fishing, additional catch handling and monitoring requirements were necessary to ensure that an observer has access to all halibut sorted on deck as well as all other catch in the factory for the collection of data and sampling. These requirements were necessary to ensure that observer data resulted in reliable estimates of catch and bycatch as well as mitigated safety risks due to additional time spent on deck.

NMFS also considered the costs and benefits of not implementing formal halibut deck sorting regulations. Under this alternative measure, current fisheries management and operation would remain unchanged. Halibut deck sorting could still be permitted under an EFP, provided that participating vessels adhered to the additional monitoring requirements required under the EFP. However, the purpose of an EFP is not to provide long-term management solutions. Rather, EFPs are meant to be short-term and to facilitate exploration of innovative or novel practices that may benefit fishery management practice. Deck sorting EFP renewals and annual reauthorizations are not guaranteed and it is unlikely that the deck sorting EFP could continue indefinitely. In addition, participation in the halibut deck sorting and monitoring activities outlined in this proposed regulation is voluntary, allowing industry the flexibility to assess economic conditions and to conduct halibut deck sorting when the benefits of reduced mortality provide valuable fishing opportunity that outweigh the operational cost of halibut deck sorting.

V. The Proposed Rule

This proposed rule would implement catch handling and monitoring requirements to allow halibut PSC to be sorted on the deck of trawl CPs and motherships participating in the non-pollock groundfish fisheries off Alaska. NMFS and EFP participants worked together to develop the monitoring and enforcement requirements required during EFP fishing and included in this proposed rule. These requirements build upon existing monitoring and enforcement requirements (described in the Current Monitoring Requirements section of this proposed rule), and are designed to allow halibut to be returned to the sea more quickly while also ensuring that observer data continue to result in reliable estimates of halibut incidental catch rate and viability. This proposed rule draws on the lessons learned from halibut deck sorting EFP activities to develop monitoring requirements and observer sampling protocols for halibut deck sorting (See sections 2.2 and 4.1 of the Analysis for additional detail). Participation in halibut deck sorting would be voluntary. However, any vessel choosing to participate in halibut deck sorting would be required to comply with all applicable monitoring requirements.

This proposed rule would add subpart K, § 679.120—Halibut Deck Sorting, to part 679 to specify halibut deck sorting catch handling and monitoring requirements. Additionally, existing catch handling and monitoring regulations would be modified as necessary to be consistent with the catch handling and monitoring requirements included in this proposed rule. The catch handling and monitoring requirement included in this proposed rule were developed and tested under halibut deck sorting EFPs since 2009 (see section 1.3.5 of the Analysis for additional detail). In addition to the primary action, this would also make changes to observer sampling station inspection requirements in Federal groundfish fisheries and minor changes to bin monitoring requirements in the Amendment 80 fleet. The proposed rule would also make minor changes in terminology, reorganize regulatory text, and make other technical changes.

A. Halibut Deck Sorting

This proposed rule would define the term ''Halibut Deck Sorting'' at § 679.2. The term ''Halibut Deck Sorting'' is used to specify the activity of separating or removing halibut from the catch on deck, prior to fish entering the fish bin.

1. Monitoring and Enforcement Tools

a. Observer Coverage

This proposed rule would specify observer coverage requirements for vessels participating in halibut deck sorting at § 679.51(a)(2)(vi)(F). Vessels would be required to carry on board at least two observers at all times when participating in halibut deck sorting. One of these observers must be endorsed as a lead level 2 observer and additional observers would be required if an observer's workload restriction would otherwise preclude sampling as required. Although this level of observer coverage is already a requirement for most vessels participating in the non-pollock groundfish fisheries, this proposed rule would require all vessels choosing to participate in halibut deck sorting to maintain this level of observer coverage. This requirement is necessary to ensure at least one experienced observer is deployed on a vessel when halibut deck sorting due to added difficulty and increase in observer duties associated with halibut deck sorting.

b. Observer Access to Catch

This proposed rule would establish prohibitions specific to halibut deck sorting at § 679.7(e). These regulations would specify that when a vessel participates in halibut deck sorting, fish must not be spilled from the codend, halibut must not be sorted, discarded, or weighed on a NMFS-approved scale unless an observer is present on deck and the vessel is in compliance with the requirements of § 679.120, which describe the vessel, crew, and catch handling and monitoring requirements for participation in halibut deck sorting. In addition, § 679.7(e) would prohibit catch from being weighed on flow scales when the observer is monitoring halibut deck sorting, unless three or more observers are present on the vessel and at least two observers are on duty. In these circumstances, one observer would monitor deck-sorting while another observer would monitor the flow scale in the factory. These regulations are necessary to ensure that an observer has access to all catch to complete data collection duties on deck and in the factory as specified in the Observer Sampling Manual.

c. Pre-Cruise Meeting

Vessel owners and operators who choose to halibut deck sort would be required to notify the Observer Program to schedule a pre-cruise meeting when they have an observer onboard who has not previously been onboard within the last 12 months. This meeting must

minimally include the vessel operator or manager and any observer(s) assigned to the vessel. The pre-cruise meeting is intended to familiarize the observer(s) with key vessel crew, discuss vessel operations, and talk through sample locations, as well as to get answers to sampling questions from NFMS staff before the vessel gets under way. In addition, the pre-cruise meeting would provide an opportunity to discuss any issues with Deck Safety Plans (described below) and the vessel crew's reasonable assistance necessary to allow an observer to sample halibut prior to departing on a trip.

d. Deck Safety Plan

This proposed rule would add requirements at § 679.120(d) to establish a Deck Safety Plan. Vessel owners and operators would be required to develop an approved Deck Safety Plan prior to participating in halibut deck sorting. This Deck Safety Plan would be approved annually by NMFS. If the vessel owner or operator wished change an existing Deck Safety Plan, the vessel owner or operator would be required to be submit proposed changes in writing and any changes would have to be approved by NMFS. Mandatory components of this Deck Safety Plan would include: A description of safe routes for the observer to access and/or leave the deck sampling station during gear retrieval and movement; description of hazardous areas and potentially hazardous conditions on deck the observer should be aware of; a list of personal protective equipment that must be worn by the observer while on deck; and a description of communication procedures to inform the observer when it is safe to access the deck, in order to ensure that the observer remains safe while working on the deck.

Vessel owners and operators would also be required to provide observers with a copy of the NMFS-approved Deck Safety Plan and conduct a deck sorting safety meeting prior to embarking on a trip when any one of the following—observer, vessel operator, or key crew member that will be responsible for providing notification or reasonable assistance during halibut deck sorting—boards the vessel. All elements of the vessel's Deck Safety Plan would be reviewed with the observer during this meeting.

If NMFS disapproves a Deck Safety Plan, the vessel owner and operator may resubmit a revised Deck Safety Plan or file an administrative appeal as set forth under the administrative appeals procedures set out at 15 CFR part 906.

e. Vessel Operator Requirements

Proposed regulations at § 679.120 would require vessel operators to notify the observer on duty at least 15 minutes prior to bringing fish on board that halibut deck sorting will occur. From the time the vessel operator notifies the observer that halibut deck sorting will occur until the codend from that haul is opened on deck, the vessel operator may choose not to engage in halibut deck sorting. In this way, the vessel operator can choose in real time if weather or vessel conditions are suitable to engage in halibut deck sorting on a particular haul. Halibut could only be sorted on deck if an observer is present, and all halibut would be required to be transported to the observer deck sampling station via a single pathway. The single pathway from which catch is conveyed to the observer will ensure that the observer has access to all halibut removed from the catch during deck sorting activities. Catch in the factory would not be weighed during halibut deck sorting activities unless, as explained above, an additional observer is available to complete data collection duties in the factory. Vessels would be required to devise and use a visual signal to communicate to the crew when catch may not be weighed during deck sorting activities.

Each vessel's Observer Sampling Station Inspection Report would indicate the time limit for halibut deck sorting activities. The time limit may be vessel specific and would be based on factors including, but not limited to, deck space and configuration, and the best available halibut viability information. For example, a total of 30 minutes could be established for halibut deck sorting activities, which may reflect the amount of time when halibut viability is maximized. This time would begin when the codend is opened and conclude once the time limit is reached. This time limit would not exceed the time indicated on the Observer Sampling Station Inspection Report. After the time limit for halibut deck sorting is reached, all halibut not sampled by the observer on deck must be transferred to the live tank(s) and passed over the flow scale in the factory. In the future, the time limit may change in order to account for changes in vessel configuration, sampling technologies, and as new information on halibut viability becomes available. Observer Sampling Station Inspection Reports would be issued annually by NMFS.

This proposed rule would add § 679.51(e)(1)(viii)(G) to require vessel operators to provide reasonable assistance to observers during halibut deck sorting. When halibut deck sorting, vessel operators and crewmen would be required to provide halibut sorted on the deck to the observer (upon request by the observer), in order to facilitate timely sampling by the observer and reduce delays in onboard factory processing of fish.

2. Equipment Requirements

a. Motion Compensated At-Sea Flow Scale and Observer Sampling Station

This proposed rule would modify existing catch weighing and data sources requirements at §§ 679.32(c)(3)(i)(C)(4), 679.63(a), 679.84(c)(1), and 679.93(c)(1) to add catch weighing requirements for CPs and motherships participating in halibut deck sorting in the Amendment 80 sector, BSAI TLAS, CDQ sector, and the Rockfish Program fisheries. These modifications would remove the requirement for halibut sorted on deck to be weighed on a NMFS-approved flow scale prior to discard. Because deck-sorted halibut are discarded from the deck and are not moved to the factory, there is no opportunity for weighing on a flow scale. Thus, under these circumstances, this requirement is unnecessary.

This proposed rule would modify regulations specifying methods used for CDQ catch estimation on CPs and motherships using trawl gear at § 679.32(c)(3)(ii)(C) to accurately describe catch accounting data sources including when halibut deck sorting occurs during groundfish CDQ fishing.

This proposed rule would modify § 679.28(d)(9) to outline and define requirements for an observer deck sampling station that must be onboard motherships and CPs participating in halibut deck sorting described at § 679.120. The observer deck sampling station would be located on deck and would be required in addition to the observer sampling station in the factory. The observer deck sampling station must meet the same specifications and requirements as the observer sampling station, with the exception that the proposed rule would require vessels participating in halibut deck sorting to have only a single pathway for halibut to be conveyed to an observer at an observer deck sampling station, as well as, a single point of discard after each work table that is visible to the observer collecting the data on discarded halibut.

b. Video Monitoring

This proposed rule would add video monitoring requirements specific for vessels operating in halibut deck sorting at § 679.28(l). Vessels would be required

to record and retain video for the entire trip where halibut deck sorting may occur for no less than 120 days after the date the video is recorded unless otherwise notified by NMFS. Vessels would also be required to maintain full video coverage of all areas where halibut may be sorted from the catch and/or discarded on deck. The number of required cameras will vary depending on vessel configuration. These additional video monitoring requirements are needed to ensure that all halibut collected from an individual haul can be tracked and accounted for once on the vessel.

B. Additional Regulatory Changes

This proposed rule would modify regulations at § 679.28(i)(1) to remove a monitoring provision known as Option 2—line of sight option for bin monitoring standards. This monitoring option facilitated an observer's view of fish holding bins, but is no longer used in this fishery, thus making this regulation unnecessary.

This proposed rule would modify regulations at §§ 679.28(d)(10) and 679.28(i)(5) to remove an unnecessary restriction on the duration of an observer sampling station and bin monitoring inspection and associated reports. NMFS proposes that it is not necessary to restrict the inspection to within 12 months of the date of the last inspection. Removing the requirement that restricts the validity of these inspection reports to 12 months from the date of the inspection would allow additional flexibility for the Observer Program to determine the exact length of the approval and potentially synchronize sampling station and bin monitoring inspections with other applicable equipment inspection requirements. This change could reduce the need for vessels to schedule multiple in-person inspections at different times of the year, thereby potentially reducing costs of complying with regulations.

This proposed rule would also make a number of regulatory edits to improve clarity, consistency and to remove unnecessary or out of date regulations. These modifications would have no impact on vessel operations. Paragraph § 679.28(b)(5)(v) would be removed since it describes calibration and log requirement regulations for printed reports from the fault log that were applicable to 2015 only. This proposed rule would add the word ''views'' when describing display requirements for cameras at §§ 679.28(e)(1)(vii) and (e)(1)(viii)(A), and would also update the website address for the NMFS Alaska Region in paragraph § 679.28(e)(2).

VI. Classification

Pursuant to section 305(d) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the BSAI and GOA FMPs, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration of comments received during the public comment period.

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

Regulatory Impact Review (RIR)

An RIR was prepared to assess the costs and benefits of available regulatory alternatives. A copy of this analysis is available from NMFS (see **ADDRESSES**). NMFS is recommending the regulatory revisions in this proposed rule based on those measures that maximize net benefits to the Nation. Specific aspects of the economic analysis related to the impact of this proposed rule on small entities are discussed below in the Initial Regulatory Flexibility Analysis section.

Initial Regulatory Flexibility Analysis (IRFA)

This IRFA was prepared for this proposed rule, as required by section 603 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 603), to describe the economic impact this proposed rule, if adopted, would have on small entities. An IRFA describes why this action is being proposed; the objectives and legal basis for the proposed rule; the number of small entities to which the proposed rule would apply; any projected reporting, recordkeeping, or other compliance requirements of the proposed rule; any overlapping, duplicative, or conflicting Federal rules; and any significant alternatives to the proposed rule that would accomplish the stated objectives, consistent with applicable statutes, and that would minimize any significant adverse economic impacts of the proposed rule on small entities. Descriptions of this proposed rule, its purpose, and the legal basis are contained earlier in this preamble and are not repeated here.

Number and Description of Small Entities Regulated by This Proposed Rule

This proposed rule would directly regulate the owners and operators of trawl CPs and motherships when operating in the non-pollock groundfish fisheries in the BSAI or GOA who voluntarily choose to sort halibut PSC on deck. In addition, the proposed rule would directly regulate the owners and operators of CPs and motherships subject to requirements for bin monitoring and observer sampling stations.

In 2017, the most recent complete year of data, there were 37 fishing vessels that participated in the groundfish fisheries in the BSAI or GOA and have sufficient deck configurations to participate in halibut deck sorting. Of these, 35 are CPs that participated in either the pollock or non-pollock groundfish fisheries, or in both, and two are AFA motherships. All of these vessels would be eligible to deck sort halibut as proposed under this proposed rule if they operated as a CP or mothership in a non-pollock groundfish fishery in the future. Eight of the 35 CPs also operated as motherships at some time during 2017 and two of the AFA motherships operated in the pollock fishery but not in non-pollock groundfish fisheries in 2017. One AFA mothership did not operate in 2017 but did operate in 2016 and plans to operate in 2019. Thus, these 38 vessels, and their operators, are entities that are potentially directly regulated by this proposed rule.

In addition to these 38 vessels that are presently operating or planning to operate in the BSAI or GOA groundfish fisheries, there are four AFA permitted CPs, and one Amendment 80 permitted CP that are not presently operating in the groundfish fisheries off Alaska; however, they could possibly be used in the future. Therefore, these five vessels also are entities potentially directly regulated by this proposed rule. Any of these 40 CPs (35 presently operating, five not operating) and three AFA motherships could choose to participate in halibut deck sorting under this proposed rule if they met all of the permitting requirements for the non-pollock groundfish fisheries and the catch monitoring and handling requirements for deck sorting.

One additional CP has been identified as being eligible to participate in halibut deck sorting. This CP is somewhat unique in several ways. First, it is Amendment 80 eligible but is not currently participating in the Amendment 80 Program. Secondly, due to limited holding capacity, this vessel pre-sorts all catch on deck prior to processing. This is in contrast to the practice of other CPs that hold fish in a bin below deck before delivery to the factory where sorting will then occur. This means that all halibut are presently deck sorted and discarded and do not enter the factory. In addition, this CP

has very limited deck space within which to accommodate the deck sorting equipment required by this action and such modifications may not be possible. Therefore, due to its configuration and operational practices, it is unlikely that this CP will choose to deck sort halibut PSC. Therefore, this vessel is not considered as a directly regulated entity under this proposed rule.

Three questions must be considered in classifying CPs and motherships to determine if they are small entities under the RFA. First, are the individual vessels independently owned and operated and not dominant in their field of operation, or are these vessels affiliated with any other business entities worldwide? Second, which industry classification is appropriate to use for the CPs that conduct both fish harvesting and fish processing and for the three motherships that process groundfish, but do not conduct any fishing activities themselves? Third, which income or employment threshold should be applied to identify the small entities among the universe of directly regulated entities in each of these entity categories?

The thresholds applied to determine if an entity or group of entities are ''small'' under the RFA depend on the industry classification for the entity or entities. Businesses classified as primarily engaged in commercial fishing are considered small entities if they have combined annual gross receipts not in excess of $11.0 million for all affiliated operations worldwide (81 FR 4469; January 26, 2016). Businesses classified as primarily engaged in fish processing are considered small entities if they employ 750 or fewer persons on a full-time, part-time, temporary, or other basis, at all affiliated operations worldwide.

CPs engage in both fish harvesting and fish processing activities. The eight CPs that operate as motherships during some part of the year operate primarily as CPs throughout the year, so they will be considered CPs for purposes of classification under this IRFA. Since at least 1993, NMFS Alaska Region has considered CPs to be predominantly engaged in fish harvesting rather than fish processing. Under this classification, the threshold of $11.0 million in annual gross receipts is the appropriate threshold to apply to identify any CPs that are small entities. Because the AFA motherships only process groundfish and do not conduct any fishing activities themselves, they are classified as fish processors, and the threshold of 750 employees is the appropriate threshold to apply to identify any motherships that are small entities under the RFA.

Analysis of fish harvesting revenue at the ex-vessel level for each of the 35 potentially directly regulated CPs that made landings in 2017 reveals that several individual vessels did not exceed the $11.0 million threshold. However, a review of ownership affiliations, and resulting aggregate revenue, reveals that the combined revenue of all co-owned CPs in each of the 10 fishing corporations that own these CPs exceeded the $11.0 threshold and are, thus, considered large entities for RFA purposes.

Additionally, four of the five permitted CPs that are not presently participating in the affected fisheries but are permitted to do so are affiliated through ownership with other CPs that are presently operating in the groundfish fisheries off Alaska. These corporations are a subset of the 10 corporations having ownership of the 35 participating CPs and have been determined to be large entities based on aggregate revenue. The one remaining permitted CP that is not presently participating has not maintained required Federal vessel documentation since 2004 and the owner corporation is inactive according to Washington State corporate records.

One directly regulated CP has annual gross ex-vessel revenue below the $11.0 million threshold. Thus, based on revenue analysis of the individual CPs, combined with ownership affiliation analysis, all but one of the 40 potentially directly regulated CP entities operating in the affected fishery are large entities for RFA purposes.

As noted above, three AFA motherships also could potentially deck sort halibut if they participated as a mothership in a non-pollock groundfish fishery in the BSAI or GOA. Motherships that only process groundfish are classified as fish processors and the threshold of 750 employees is the appropriate threshold to apply to identify if any of these motherships are small entities. NMFS does not have any information that establishes whether any of the three motherships are affiliated through ownership with other business entities worldwide, so they are considered as individual entities for this analysis. In addition, NMFS does not have access to firm level employment data for these mothership firms; however, given the size of the motherships it is unlikely that firm level employment exceeds the 750 employee threshold. Therefore, NMFS has determined that these three motherships also are small entities for RFA purposes.

Although one CP potentially directly regulated by this action is a small entity under the RFA, its participation in the formal deck sorting program is doubtful given current operations and constraints. However, if this CP did choose to sort halibut PSC on deck in the future, they would do so voluntarily and only if the benefits of accounting for reduced halibut mortality outweigh the costs of compliance with program requirements. This statement is also true for the three motherships that are potentially directly regulated small entities by this action. Thus, any impact on the one CP or the three motherships would not be a significant adverse economic impact.

The proposed rule also would directly regulate the owners and operators of CPs and motherships subject to requirements for bin monitoring and observer sampling stations. Revisions to the bin monitoring regulations to remove Option 2 (the line of sight option) would affect some of the same CPs that are potentially directly regulated by the halibut deck sorting action. This element of the proposed rule would not affect the one CP that is a small entity because unsorted fish are not held below deck in bins on this vessel. As described above, none of the potentially directly regulated CPs that use fish bins subject to the bin monitoring requirements are small entities. In addition, none of these vessels have used Option 2 since 2011, and then only in conjunction with other still available options. Therefore, removing Option 2 would not impose any additional costs or restrictions or create any impacts that would be considered significant adverse economic impacts on small entities.

Revisions to the timing of the observer sampling station and bin monitoring inspection reports would affect any CP using trawl, hook-and-line, or pot gear and any mothership subject to these regulations. Some of these CPs may be small entities. However, the proposed revisions increase flexibility for the time between inspections, so do not impose any additional costs or constraints on the vessel owners or operatives. The added flexibility constitutes a slight relaxation of regulations. Therefore, although this element of the proposed rule may affect some small entities, it would not impose any adverse economic impacts.

Although NMFS identified only one small entity CP and potentially three small entity motherships that could be directly regulated by the deck sorting elements of this proposed rule, NMFS believes that it is very unlikely that this action would impose a significant

adverse impact. However, NMFS has prepared this IRFA, which provides potentially affected small entities an opportunity to provide comments on this IRFA. NMFS will evaluate any comments received on the IRFA and may consider certifying under section 605 of the RFA (5 U.S.C. 605) that this action will not have a significant economic impact on a substantial number of small entities prior to publication of the final rule.

Recordkeeping, Reporting, and Other Compliance Requirements

This proposed rule would implement additional reporting, recordkeeping, and other compliance requirements for the owners and operators of trawl CPs and motherships who choose to sort halibut PSC on deck when operating in the non-pollock groundfish fisheries off Alaska. As noted earlier in the preamble to this proposed rule, these requirements include an observer deck sampling station, video monitoring, an approved Deck Safety Plan, prior approval by NMFS of the plan, a meeting onboard the vessel to review the plan, observer coverage and experience requirements, and other catch handling and monitoring requirements. In addition, the vessel owner or operator must notify the Observer Program by phone at least 24 hours prior to departure when a vessel will carry an observer who has not deployed on that vessel in the past 12 months, and participate in a pre-cruise meeting if NMFS requests such a meeting. Vessel operators also must notify the observer at least 15 minutes prior to fish being brought on board during trips when the vessel participates in halibut deck sorting activities.

No specific recordkeeping, reporting, or other compliance requirements are associated with the revisions to requirements for bin monitoring and observer sampling stations. These revisions would remove an option for providing observers visual access to the fish bins and provide additional flexibility for the timing of annual bin and observer sampling station inspections and reports. These revisions would not change the existing requirements for requesting bin and sampling station inspections and the equipment, operational, and documentation requirements associated with these inspection programs.

No small entity is subject to reporting requirements that are in addition to or different from the requirements that apply to all directly regulated entities. No unique professional skills are needed for the vessel operators to comply with any of the reporting and recordkeeping requirements associated with this proposed rule.

Description of Significant Alternatives That Minimize Adverse Impacts on Small Entities

No significant alternatives were identified that would accomplish the stated objectives for implementing a halibut deck sorting program via regulation, are consistent with applicable statutes, and that would minimize costs to potentially affected small entities more than the proposed rule. NMFS considered two alternatives for action in this proposed rule. Alternative 1 is the no action alternative. This alternative would continue to allow halibut deck sorting under an EFP; however, EFPs are not intended to continue indefinitely. Thus, under the no action alternative halibut deck sorting that is currently occurring under the EFP may not be an option in the future. The uncertainty of the EFP makes Alternative 1 potentially costly to vessels that would opt to continue halibut deck sorting, but would not be allowed to if the EFP was discontinued.

Alternative 2, along with Options 1 and 2, provide the greatest economic benefits. The primary economic benefit of this proposed rule is to reduce halibut mortality and allow program participants greater potential to harvest all allocations of target species at all levels of future halibut abundance and PSC limits. NMFS's administrative burden of managing the EFP process will also be reduced as will industry management and implementation costs that are presently born by the EFP applicants and the EFP manager. The economic effects on fishery participants that are affected by this proposed action are considered to be beneficial. Participants will enter the program voluntarily and only if the benefits of accounting for reduced halibut mortality outweigh the costs of compliance with program requirements.

Collection-of-Information Requirements

This proposed rule contains collection-of-information requirements subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). These requirements have been submitted to OMB for approval under Control Number 0648–0318 (North Pacific Observer Program) and Control Number 0648–0330 (Alaska Region, Scale and Catch Weighing Requirements). The public reporting burden for the collection-of-information requirements in this proposed rule includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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OMB Control No. 0648–0318

Vessel owners or operators of trawl CPs and motherships who choose to sort halibut PSC on deck must have a NMFS-approved Deck Safety Plan prior to participating in halibut deck sorting. When this action takes effect, 24 vessels will have participated in halibut deck sorting with a fully developed Deck Safety Plan. NMFS estimates approximately one new vessel annually in this program. Public reporting burden for the development of a new Deck Safety Plan during the first (initial) year a vessel participates in halibut deck sorting is estimated to average 12 hours. After the first year, the public reporting burden for a respondent to modify or renew an existing Deck Safety Plan is estimated to be one hour.

For vessel owners or operators of trawl CPs and motherships who choose to sort halibut PSC on deck, the public reporting burden per response to notify the Observer Program by phone is estimated to be five minutes, the burden to notify the observer is estimated at two minutes, and appeal of a disapproved Deck Safety Plan is estimated at 4 hours.

OMB Control No. 0648–0330

When this action takes effect, 24 vessels will have participated in halibut deck sorting with installed deck video monitoring systems and observer deck sampling stations in compliance with regulations. NMFS estimates approximately one new vessel annually in this program. Vessel owners or operators of trawl CPs and motherships who choose to sort halibut PSC on deck must install an observer sampling station on deck for use by the observer when deck sorting halibut. Public reporting burden for the installation of the observer deck sampling station

during the first (initial) year a vessel participates is halibut deck sorting is estimated to average 12 hours. After the first year, annual maintenance of observer sampling stations both in the factory and on deck would be expected to be minimal and would likely be done with other factory modifications initiated by the vessel to improve processing efficiency. Annual public reporting burden after the first year is estimated at one minute.

In addition, these vessels must install a deck sorting video monitoring system on deck. Public reporting burden for the installation of the video monitoring system is estimated to average 12 hours. After the first year, annual maintenance of the video monitoring system, including routine inspection and time required to call out for any needed repair, is estimated at one minute.

Public reporting burden for the Inspection Request for Observer Sampling Station, At-sea Scales, Video Monitoring Deck Sampling Station, and Deck Video Monitoring is estimated at 8 minutes.

Public comment is sought regarding (1) whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the burden estimate; (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, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to NMFS Alaska Region (see **ADDRESSES**), and to OIRA by email to *OIRA_Submission@omb.eop.gov* or by fax to 202–395–5806.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number. All currently approved NOAA collections of information may be viewed at *http://www.cio.noaa.gov/services_programs/prasubs.html.*

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Pacific halibut, Recordkeeping and reporting requirements.

Dated: April 5, 2019.

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 679 is proposed to be amended as follows:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

■ 1. The authority citation for 50 CFR part 679 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.;* 1801 *et seq.;* 3631 *et seq.;* Pub. L. 108–447; Pub. L. 111–281.

■ 2. In § 679.2, add the definition for ''Halibut Deck Sorting'' in alphabetical order to read as follows:

§ 679.2 Definitions.

* * * * *

Halibut Deck Sorting means the authorized sorting of halibut on deck pursuant to § 679.120.

* * * * *

■ 3. In § 679.7:

■ a. Amend paragraph (d)(4)(i)(B) by removing § 679.28(d)(8) and adding in its place § 679.28(d)(10);

■ b. Revise paragraph (e) to read as follows:

§ 679.7 Prohibitions.

* * * * *

(e) *Halibut Deck Sorting.* (1) Conduct halibut deck sorting without notifying the observer at least 15 minutes prior to bringing fish onboard as described in § 679.120(e)(2).

(2) For any haul for which the notification at § 679.120(e)(2) is provided, allow fish to be spilled from the codend without an observer being present to monitor halibut deck sorting.

(3) Sort halibut from the catch prior to weighing except in compliance with requirements at § 679.120.

(4) Sort halibut on deck without an observer present to monitor halibut deck sorting.

(5) Discard halibut sorted on deck prior to the observer's completion of data collection for each halibut.

(6) Sort or discard any species other than halibut during halibut deck sorting.

(7) Conduct halibut deck sorting past the time limit set by NMFS in the vessel's Observer Sampling Station Inspection Report.

(8) Conduct halibut deck sorting without complying with the observer deck sampling station requirements at § 679.28(d)(9).

(9) Fail to have an approved Deck Safety Plan before conducting halibut deck sorting.

(10) Fail to notify the Observer Program for purposes of the pre-cruise meeting when required by § 679.120(c).

(11) Weigh catch on a NMFS-approved scale that complies with the requirements at § 679.28(b) when halibut deck sorting unless three or more observers are present on the vessel and an observer has been notified and is available to complete data collection duties in the factory.

(12) Sort halibut without a video monitoring system meeting requirements at § 679.28(l).

(13) Fail to comply with any other requirement or restriction specified in this part or violate any provision of this part.

* * * * *

■ 4. In § 679.28,

■ a. Remove paragraph (b)(5)(v);

■ b. Redesignate paragraph (d)(9) as (d)(10);

■ c. Add new paragraph (d)(9);

■ d. Revise newly redesignated paragraph (d)(10) introductory text and (d)(10)(iii);

■ e. In newly redesignated paragraph (d)(10)(i) remove *http://alaskafisheries.noaa.gov* and add in its place *https://alaskafisheries.noaa.gov;*

■ f. Revise paragraphs (e)(1)(vii), (e)(1)(viii)(A);

■ g. In paragraph (e)(2) remove *http://alaskafisheries.noaa.gov* and add in its place *https://alaskafisheries.noaa.gov;*

■ h. Revise paragraph (i)(1) introductory text;

■ i. Redesignate paragraph (i)(1)(iii) as (i)(1)(ii) and revise newly redesignated paragraph (i)(1)(ii);

■ j. Revise paragraphs (i)(2) and (i)(5);

■ k. In paragraph (i)(3) remove *http://alaskafisheries.noaa.gov* and add in its place *https://alaskafisheries.noaa.gov;* and

■ l. Add paragraph (l).

The revisions and additions to read as follows:

§ 679.28 Equipment and operational requirements.

* * * * *

(d) * * *

(9) *Observer deck sampling station.* Motherships and catcher/processors subject to § 679.120 must be equipped with a deck sampling station that meets the following requirements:

(i) *Accessibility.* All equipment required for an observer deck sampling station must be available to the observer at all times when halibut deck sorting.

(ii) *Location.* The observer deck sampling station must be located adjacent to the point of discard.

(iii) *Work space.* The observer must be able to stand upright in front of the table.

(iv) *Table*—(A) *Size.* The observer deck sampling station must include a table at least 0.6 m deep, 1.2 m wide, and 0.9 m high, and no more than 1.1 m high. The entire surface area of the table must be available for use by the observer. The table must be secured to the deck when halibut deck sorting. The table must be constructed to prevent fish from sliding off.

(B) *Length measuring device.* The table must have a NMFS-approved length measuring device secured to the surface of the table.

(v) *Single pathway.* There must be a single pathway for halibut to be conveyed to the observer deck sampling station. All halibut sorted on deck must pass over the observer table. There must be a single point of discard after the observer deck sampling station visible to the observer. Halibut too large to be lifted to the table may be measured on deck.

(10) *Inspection of the observer sampling station.* Each observer sampling station must be inspected and approved by NMFS prior to its use for the first time and then once each year within 12 months of the most recent inspection with the following exceptions: If the observer sampling station is moved or if the space or equipment available to the observer is reduced or removed when use of the observer sampling station is required, the Observer Sampling Station Inspection Report issued under this section is no longer valid, and the observer sampling station must be reinspected and approved by NMFS. Inspection of the observer sampling station is in addition to inspection of the at-sea scales by an authorized scale inspector required at paragraph (b)(2) of this section.

* * * * *

(iii) *Observer Sampling Station Inspection Report.* An Observer Sampling Station Inspection Report will be issued by NMFS to the vessel owner if the observer sampling station meets the requirements in this paragraph (d). The vessel owner must maintain a current Observer Sampling Station Inspection Report on board the vessel at all times when the vessel is required to provide an observer sampling station approved for use under this paragraph (d). The Observer Sampling Station Inspection Report must be made available to the observer, NMFS personnel, or to an authorized officer upon request.

(A) *Deck Sorting.* An Observer Sampling Station Inspection Report issued to the owner of a vessel participating in halibut deck sorting as described at § 679.120 will indicate the time limit for halibut deck sorting activities. Considerations used by NMFS to determine the time limit for halibut deck sorting include, but are not limited to, deck space and configuration,, and best available halibut viability information.

(B) [Reserved].

* * * * *

(i) * * *

(1) *Bin monitoring standards.* The vessel owner or operator must comply with the requirements specified in paragraph (i)(1)(i) of this section unless the vessel owner or operator has requested, and NMFS has approved, the video monitoring option described at paragraph (i)(1)(ii) of this section.

* * * * *

(ii) *Option 2—Video monitoring system option.* A vessel owner and operator must provide and maintain a NMFS-approved video monitoring system as specified in paragraph (e) of this section. Additionally, the vessel owner and operator must ensure that the system:

(A) Records and retains all video for all periods when fish are inside the bin; and

(B) Provides sufficient resolution and field of view to see crew activities from any location within the tank where crew could be located.

(2) *Who must have a bin monitoring option inspection?* A vessel owner or operator choosing to operate under the video option (option 2) in paragraph (i)(1)(ii) of this section must receive an annual bin monitoring option inspection.

* * * * *

(5) *Bin monitoring option inspection report.* A bin monitoring option inspection report will be issued to the vessel owner if the bin monitoring option meets the requirements of paragraph (i)(1)(ii) of this section. The vessel owner must maintain a current bin option inspection report on board the vessel at all times the vessel is required to provide an approved bin monitoring option under this paragraph (i)(5). The bin monitoring option inspection report must be made available to the observer, NMFS personnel, or to an authorized officer upon request.

* * * * *

(l) *Video monitoring for halibut deck sorting.* The owner and operator of a mothership or catcher/processor subject to § 679.120 must provide and maintain a video monitoring system approved under paragraph (e) of this section when the vessel is halibut deck sorting. Additionally, the system must—

(1) Record and retain video for an entire trip when halibut deck sorting may occur; and

(2) Provide sufficient resolution and field of view to monitor all areas on deck where halibut may be sorted from the catch and discarded, and all crew actions in these areas.

■ 5. In § 679.32, revise paragraphs (c)(3)(i)(C)(*4*) and (c)(3)(ii)(C) to read as follows:

§ 679.32 Groundfish and halibut CDQ catch monitoring.

* * * * *

(c) * * *

(3) * * *

(i) * * *

(C) * * *

(*4*) The operator of a mothership taking deliveries of unsorted codends from catcher vessels must weigh all catch, except halibut sorted on deck by vessels participating in halibut deck sorting described at § 679.120, on a scale that complies with the requirements of § 679.28(b). Catch must not be sorted before it is weighed, unless a provision for doing so is approved by NMFS for the vessel. Each CDQ haul must be sampled by an observer for species composition and the vessel operator must allow observers to use any scale approved by NMFS to weigh partial CDQ haul samples.

* * * * *

(ii) * * *

(C) *Catcher/processors and motherships using trawl gear.* The weight and numbers of CDQ and PSQ species will be determined by applying the observer's sampling data to the total weight of the CDQ haul.

* * * * *

■ 6. In § 679.51, add paragraphs (a)(2)(vi)(F) and (e)(1)(viii)(G) to read as follows:

§ 679.51 Observer and Electronic Monitoring System requirements for vessels and plants.

(a) * * *

(2) * * *

(vi) * * *

(F) *Halibut deck sorting.* Vessels subject to § 679.120 must have at least two observers aboard at all times when halibut deck sorting may occur; one observer must be endorsed as a lead level 2 observer. More than two observers are required if the observer workload restriction would otherwise preclude sampling as required.

* * * * *

(e) * * *

(1) * * *

(viii) * * *

(G) During halibut deck sorting, providing halibut to the observer on deck.

* * * * *

■ 7. In § 679.63, revise paragraph (a)(1) to read as follows:

§ 679.63 Catch weighing requirements for vessels and processors.

(a) * * *

(1) *Catch weighing.* All groundfish landed by listed AFA catcher/processors or received by AFA motherships must be weighed on a NMFS-certified scale and made available for sampling by a NMFS certified observer. The owner and operator of a listed AFA catcher/processor or an AFA mothership must ensure that the vessel is in compliance with the scale requirements described at § 679.28(b), that each groundfish haul is weighed separately, and that no sorting of catch, except halibut sorted on deck by vessels participating in the halibut deck sorting described at § 679.120, takes place prior to weighing.

* * * * *

■ 8. In § 679.84, revise paragraph (c)(1) to read as follows;

§ 679.84 Rockfish Program recordkeeping, permits, monitoring, and catch accounting.

* * * * *

(c) * * *

(1) *Catch weighing.* All catch, except halibut sorted on deck by vessels participating in the halibut deck sorting described at § 679.120, is weighed on a NMFS-approved scale in compliance with the scale requirements at § 679.28(b). Each haul must be weighed separately and all catch must be made available for sampling by an observer.

* * * * *

■ 9. In § 679.93, revise paragraph (c)(1) to read as follows:

§ 679.93 Amendment 80 Program recordkeeping, permits, monitoring, and catch accounting.

* * * * *

(c) * * *

(1) *Catch weighing.* All catch, except halibut sorted on deck by vessels participating in halibut deck sorting described at § 679.120, are weighed on a NMFS-approved scale in compliance with the scale requirements at § 679.28(b). Each haul must be weighed separately, all catch must be made available for sampling by a NMFS-certified observer, and no sorting of catch, except halibut sorted on deck by vessels participating in halibut deck sorting described at § 679.120, may take place prior to weighing.

* * * * *

■ 10. Add subpart K, consisting of §§ 679.120 and 679.121 to read as follows:

Subpart K—Halibut Deck Sorting

Sec.
679.120 Halibut Deck Sorting
679.121 [Reserved]

§ 679.120 Halibut Deck Sorting.

(a) *Applicability.* The owner and operator of a mothership or catcher/processor using trawl gear in the non-pollock groundfish fisheries in the Gulf of Alaska and the Bering Sea and Aleutian Islands Management Area must comply with the requirements of this section when halibut deck sorting as defined at § 679.2.

(b) *Catch monitoring requirements.* (1) *Catch weighing.* When halibut deck sorting, all catch, except halibut sorted on deck, must be weighed on a NMFS-approved scale in compliance with the scale requirements at § 679.28(b). Each haul must be weighed separately, all catch must be made available for sampling by a NMFS-certified observer, and no sorting of catch, except halibut sorted on deck, may take place prior to weighing. When halibut deck sorting, no fish may be weighed on a NMFS-approved scale used to weigh catch at sea unless two observers are available to complete data collection duties, one on deck and one in the factory. A visual signal, specified in paragraph (e)(8) of this section, must be used to indicate when catch may not be weighed.

(2) *Observer sampling station.* An observer sampling station meeting the requirements at § 679.28(d) must be available at all times.

(3) *Observer coverage requirements.* Comply with the observer coverage requirements at § 679.51(a)(2).

(4) *Sample storage.* Provide a storage space sufficient to accommodate a minimum of 10 observer sampling baskets. This space must be within or adjacent to the observer sampling station.

(5) *Vessel crew in tanks or bins.* Comply with the bin monitoring standards at § 679.28(i)(1).

(6) *Observer deck sampling station.* An observer deck sampling station meeting the requirements at § 679.28(d)(9) must be available at all times.

(7) *Video monitoring.* Comply with the video monitoring standards specified at § 679.28(l).

(c) *Pre-cruise meeting.* Notify the Observer Program by phone at 1 (907) 581–2060 (Dutch Harbor, AK) or 1 (907) 481–1770 (Kodiak, AK) at least 24 hours prior to departure when the vessel will be carrying an observer who has not previously been deployed on that vessel within the last 12 months. Subsequent to the vessel's departure notification, but prior to departure, NMFS may contact the vessel to arrange for a pre-cruise meeting. The pre-cruise meeting must minimally include the vessel operator or manager and any observers assigned to the vessel.

(d) *Deck Safety Plan.* Submit and have an approved Deck Safety Plan prior to participating in halibut deck sorting. The owner and operator must comply with all the requirements described in the NMFS-approved Deck Safety Plan.

(1) *Deck Safety Plan requirements.* A Deck Safety Plan must:

(i) Describe the route for observers to safely access and leave the deck sampling station and specify locations where observers may shelter during gear retrieval and movement.

(ii) Describe hazardous areas and potentially hazardous conditions that could be encountered on deck.

(iii) Describe communication procedures to inform the observer when it is safe to access the deck. These procedures must identify who will tell the observer it is safe to access the deck, how that communication will happen, and how they will communicate with the observer if a new safety hazard arises while on deck.

(iv) List personal protective equipment that must be worn by the observer while on deck.

(v) List all personnel the observer may contact to report safety issues, including safety hazards identified by the observer that are not covered by the Deck Safety Plan, deviations from the Deck Safety Plan, and any conditions that would require the suspension of halibut deck sorting.

(vi) Provide procedures to ensure the observer's safety while working in the deck sampling station.

(vii) Include a scale drawing showing the deck sampling station, the routes to access and exit the deck sampling station, emergency muster location, and safety hazards that could be encountered on deck.

(2) *Approval.* NMFS will approve a Deck Safety Plan if it meets the requirements specified in paragraph (d)(1) of this section. The vessel must be inspected by NMFS prior to approval of the Deck Safety Plan to ensure that the vessel conforms to the elements addressed in the Deck Safety Plan. NMFS will normally complete its review of the Deck Safety Plan within 14 working days of receiving a complete Deck Safety Plan and conducting a Deck Safety Plan inspection. If NMFS disapproves a Deck Safety Plan, the vessel owner and operator may resubmit

a revised Deck Safety Plan or file an administrative appeal as set forth under the administrative appeals procedures set out at 15 CFR part 906.

(3) *Deck Safety Plan inspection.* The vessel owner and operator must submit a complete Deck Safety Plan to NMFS by fax (206–526–4066) or email (*station.inspections@noaa.gov*) at least 10 working days in advance of the requested date of inspection.

(4) *Location.* Deck Safety Plan inspections will be conducted on vessels tied up at docks in Kodiak, Alaska, Dutch Harbor, Alaska, and in the Puget Sound area of Washington State.

(5) *Changes to the Deck Safety Plan.* The vessel owner and operator may propose a change to the Deck Safety Plan by submitting a Deck Safety Plan addendum to NMFS. NMFS may require a Deck Safety Plan inspection described at paragraph (d)(3) of this section before approving the addendum.

(e) *Vessel operator responsibilities.* The operator of a vessel subject to this section must comply with the following:

(1) *Deck sorting safety meeting.* Provide the observer with a copy of the NMFS-approved Deck Safety Plan and make available all other applicable inspection reports described at § 679.28. The deck sorting safety meeting must be conducted prior to departing port and must include the observer, vessel operator, and key crew member who will be responsible for providing notification or reasonable assistance during halibut deck sorting. All elements of the vessel's Deck Safety Plan must be reviewed with the observer during this meeting.

(2) *Observer notification.* Before halibut deck sorting, notify the observer at least 15 minutes prior to bringing fish on board.

(3) *Observer present.* Conduct halibut deck sorting only when an observer is present in the deck sampling station.

(4) *Time limit.* Conduct halibut deck sorting only within the time limit indicated on the Observer Sampling Station Inspection Report. The time limit begins when the codend is opened on deck. When the time limit is reached, all halibut deck sorting must stop.

(5) *Single sorting pathway.* Convey all halibut sorted on deck to the observer deck sampling station via a single pathway.

(6) *Careful handling.* Handle all halibut sorted on deck with a minimum of injury.

(7) *Sorting pace.* Do not pressure or rush the observer to move halibut through the sampling process faster than the observer can handle.

(8) *Visual signal.* Use a visual signal to indicate to vessel crew when catch may not to be weighed on a NMFS-approved scale specified in paragraph (b)(1) of this section. The visual signal must be on the conveyor belt adjacent to the flow scale and visible in the view of a camera required at § 679.28(b)(8).

§ 679.121 [Reserved].

[FR Doc. 2019–07179 Filed 4–15–19; 8:45 am]

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Notices

Federal Register
Vol. 84, No. 73
Tuesday, April 16, 2019

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–23–2019]

Foreign-Trade Zone (FTZ) 38—Mount Pleasant, South Carolina; Notification of Proposed Production Activity; Electrolux Home Products, Inc. (Appliances), Anderson, South Carolina

The South Carolina State Ports Authority, grantee of FTZ 38, submitted a notification of proposed production activity to the FTZ Board on behalf of Electrolux Home Products, Inc. (Electrolux), located in Anderson, South Carolina. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on March 28, 2019.

Electrolux's facility is located within Subzone 38N. The facility is used for the production of refrigerators and freezers. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials/components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Electrolux from customs duty payments on the foreign-status materials/components used in export production (estimated 12 percent of production). On its domestic sales, for the foreign-status materials/components noted below, Electrolux would be able to choose the duty rates during customs entry procedures that apply to all refrigerators-less than 900 liters side by side, chest freezers-less than 800 liters, and upright freezers-less than 900 liters for residential use (duty-free). Electrolux would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The materials/components sourced from abroad include: Cyclopentane blowing agent—polyurethane foam; catalyst polycat insulation; surfactant insulation; compressor oil; polyol; isocycanate insulation; ice maker tubes and water lines; diffuser tops; plug-rubber suction tubes made of neoprene; glass shelves; glass crispers; crisper covers, freezer shelves made of clear flat tempered glass; stainless steel reversible, right hand refrigerator and freezer doors; steel, stainless steel, and serrated steel screws with zinc finish; steel screws with black phosphate; cold rolled steel screws, pan heavy duty steel screws, gray steel screws, hex heavy duty screws with zinc finish; rivets made of carbon steel; aluminum tape; label nameplates made of acrylonitrile butadiene styrene (ABS) with adhesive; label nameplates made of aluminum, stainless steel, and chrome with spaces made of ABS and adhesives; compressors and compressors with grommets; sub-assembly compressors and grommets; top mount refrigerators for residential use; side by side refrigerators less than 900 liters for residential use; chest freezers less than 800 liters for residential use; upright freezers less than 900 liters for residential use; high efficiency and standard condensers made of steel wire tubes—one coat baked enamel or black epoxy powder finish; stainless steel door handles; ice maker kits; stainless steel handle kits; ice makers; freezer door stops; air diverters, large ice bucket containers, ice maker covers, and duct cross-overs made of high impact polystyrene; half width deli drawers made of crystal polystyrene; suction tube connectors with copper tubing; User Interface Carriers; housings for ice-maker doors made of acetyl; fan front direct current evaporators; frames and trims of crispers; outer panels for door of freezers and fresh food compartments made of cold-rolled sheet steel; housings made of ABS for control boxes; housings made of high impact polystyrene for user interfaces; ice maker brackets, tube drain ferrule tops made of high impact polystyrene; outer door panels; cross-over ducts made of high impact polystyrene; roller adjustable subassemblies; tapping plates for upper hinges made of steel; right hand and left hand fresh food cantilever shelf supports made of cold-rolled sheet steel; fresh food door stops; bracket center hinges made of coiled steel and hot rolled steel; handle kits; control box light shields made of transparent polycarbonate; ring locks made of cold rolled steel; lower hinge brackets; right-hand and left-hand sub-assemblies and roller assemblies; Z-pan assemblies; sub-assemblies of ice makers; dryers; refrigerator door stops; evaporator shelves; right hand lower hinge brackets; rear cover panels; rear panel mechanical controls; pan-crispers made of crystal polystyrene; housing control boxes made of high impact polystyrene; knob-controls e-star made of ABS adhesive; deli-pans made of crystal polystyrene; right-hand and left-hand pan-crispers; flange inner endcaps made with high impact polystyrene; hidden right and left hand door stops; panel bottoms; right-hand and left-hand bottom reinforcements made of galvanized steel; endcap pocket doors and hidden doors made of ABS; front bottom plates made of galvanized steel; bottom harness housings made of ABS; humidity control housing assemblies comprised of membrane automatic humidity controls, inferior frame humidity controls, and superior frame humidity control silkscreens; evaporator assemblies with components, including evaporator coils, defrost heaters, expanded polystyrene caps right and left hand, heat shields left hand and aluminum straps; housings for ice-maker connector covers made of ABS; center hinges and washer assemblies, including hinge pins, and washers; upper hinge brackets made of hot rolled steel; right hand lower hinge brackets; spacer hinges made of polyethylene; block-light switches made of high impact polystyrene; fresh food cantilever shelf supports and foldable shelves made of cold rolled steel; humidity control dampers made of high impact polystyrene; LED housings made of ABS and high impact polystyrene; snow flake anchors made of high impact polystyrene; high efficiency blower motors; condenser fan motors; blower motors; run capacitors; compressor controllers; starters—positive temperature coefficient; starter-time starting devices; light sockets; sliding user interfaces; main boards; LED light bulbs; wire harnesses for freezer lights, freezers, machine compartments, short mechanical controls, main, fresh food, and main board housings; harnesses and labels; sub-assembly control boxes and

assemblies including box controls, light bulbs, light sockets, cold controls, light switches, cold control knobs, timer defrost/adaptive defrost controls, screws (#6–9 20 x 7/16), diffuser bottoms, diffuser tops, wire harnesses, plastic tubes, and foil tapes; sub-assemblies—electronic control boxes and components, including housing controls, knob controls, potentiometer boards, ERF 1500 boards, light switches, light sockets, light bulbs, temperature sensors, housing covers, housing gaskets, diffuser expanded polystyrene housings, heat shields, wire harnesses and labels; sub-assemblies—electronic control boxes and mechanical components, including box controls, diffuser bottoms, diffuser tops, seals, aluminum tapes, wire sleeves, cold controls, timer defrosts, light switches, knob controls, screws (# 6–20 x 7/16), light bulbs, light bulb sockets and wire harnesses; and, defrost timers (duty rate ranges from duty-free to 8.6%). The request indicates that suction tube connectors with copper tubing is subject to antidumping/countervailing duty (AD/CVD) orders if imported from certain countries. The FTZ Board's regulations (15 CFR 400.14(e)) require that merchandise subject to AD/CVD orders, or items which would be otherwise subject to suspension of liquidation under AD/CVD procedures if they entered U.S. customs territory, be admitted to the zone in privileged foreign status (19 CFR 146.41). The request also indicates that certain materials/components are subject to special duties under Section 232 of the Trade Expansion Act of 1962 (Section 232) and Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 232 and Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is May 28, 2019.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Christopher Wedderburn at *Chris.Wedderburn@trade.gov* or (202) 482–1963.

Dated: April 10, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–07546 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–23–2019]

Approval of Subzone Status; WPG Americas Inc., Southaven, Mississippi

On February 19, 2019, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Northern Mississippi FTZ, Inc., grantee of FTZ 262, requesting subzone status subject to the existing activation limit of FTZ 262, on behalf of WPG Americas Inc., in Southaven, Mississippi.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (84 FR 6129, February 26, 2019). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR Sec. 400.36(f)), the application to establish Subzone 262D was approved on April 10, 2019, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 262's 680-acre activation limit.

Dated: April 10, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–07547 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–72–2018]

Foreign-Trade Zone (FTZ) 122—Corpus Christi, Texas; Authorization of Production Activity; Gulf Coast Growth Ventures LLC (Ethylene, Polyethylene and Monoethylene Glycol and Related Co-Products), San Patricio County, Texas

On November 1, 2018, the Port of Corpus Christi Authority, grantee of FTZ 122, submitted a notification of proposed production activity to the FTZ Board on behalf of Gulf Coast Growth Ventures LLC, within Subzone 122W, in San Patricio County, Texas.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (83 FR 57718, November 16, 2018). On April 10, 2019, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: April 10, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–07545 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–122–865, C–201–851, C–570–103]

Certain Fabricated Structural Steel From Canada, Mexico, and the People's Republic of China: Postponement of Preliminary Determinations in the Countervailing Duty Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Whitley Herndon (202) 482–6274 or David Crespo (202) 482–3693 (Canada); Thomas Martin at (202) 482–3936 or Trisha Tran at (202) 482–4852 (Mexico); or Darla Brown at (202) 482–1791 (People's Republic of China (China)), AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On February 25, 2019, the Department of Commerce (Commerce) initiated countervailing duty (CVD) investigations of imports of certain fabricated structural steel from Canada, China, and Mexico.[1] Currently, the preliminary determinations are due no later than May 1, 2019.

Postponement of Preliminary Determinations

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary

[1] *See Certain Fabricated Structural Steel From Canada, Mexico, and the People's Republic of China: Initiation of Countervailing Duty Investigations,* 84 FR 7339 (March 4, 2019) (*Initiation Notice*).

determination in a CVD investigation within 65 days after the date on which Commerce initiated the investigation. However, if the petitioner makes a timely request for postponement, section 703(c)(1)(A) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On April 5, 2019, the petitioner [2] submitted a timely request that Commerce postpone the preliminary determinations in these CVD investigations.[3] The petitioner stated that it requests postponement of the preliminary determinations because Commerce recently issued questionnaires and additional time is required for Commerce to receive and analyze the questionnaire responses.[4] Furthermore, the petitioner stated that additional time will permit it to review and comment on the submitted data.[5]

In accordance with 19 CFR 351.205(e), the petitioner has stated the reasons for requesting postponement of the preliminary determinations, and Commerce finds no compelling reason to deny the request. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determinations to no later than 130 days after the date on which these investigations were initiated, *i.e.,* July 5, 2019. Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determinations of these investigations will continue to be 75 days after the date of the preliminary determinations.

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: April 10, 2019.

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. 2019–07539 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–810]

Stainless Steel Bar From India: Preliminary Results of Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that the producers/exporters subject to this review made sales of stainless steel bar (SS Bar) from India at less than normal value during the period of review (POR) February 1, 2017, through January 31, 2018. Interested parties are invited to comment on these preliminary results.

DATES: Applicable April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Mark Kennedy or Hermes Pinilla, 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) 482–7883 or (202) 482–3477, respectively.

SUPPLEMENTARY INFORMATION:

Background

This review covers four producers/exporter of the subject merchandise, Venus Wire Industries Pvt. Ltd., and its affiliates Hindustan Inox, Precision Metals and Sieves Manufacturers (India) Pvt. Ltd. (collectively, the Venus Group),[1] Jindal Stainless Hisar Ltd. (Jindal), Jindal Stainless Limited, and Laxcon Steels Limited.

Scope of the Order

The merchandise subject to the order is SS Bar. Imports of the product are currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7222.11.00, 7222.19.00, 7222.20.00, 7222.30.00. While the HTSUS subheadings are provided for convenience and customs purposes, the written description is dispositive. A full description of the scope of the order is contained in the Preliminary Decision Memorandum.[2]

Preliminary Determination of No Reviewable Entries

Based on our review of the U.S. Customs and Border Protection (CBP) data, we found no evidence of reviewable entries made by Jindal Stainless Limited during the POR.[3] However, Jindal Stainless Limited did not file a letter on the record stating whether or not it had shipments during the POR. It is Commerce's long-standing practice to rely on both a company's timely filed no-shipment letter and CBP data corroborating such company's no-shipment claim to determine that the company made no shipments during the POR.[4] Consistent with this practice, we find that it is not appropriate to rescind the review with respect to Jindal Stainless Limited. Rather, we will complete the review with respect to Jindal Stainless Limited and issue appropriate instructions to CBP based on the final results.[5]

Methodology

Commerce is conducting this review in accordance with section 751(a)(2) of the Tariff Act of 1930, as amended (the Act). Export prices were calculated in accordance with section 772 of the Act.

[1] Commerce has previously determined that Venus Wire Industries Pvt. Ltd., and its affiliates Hindustan Inox, Precision Metals and Sieves Manufacturers (India) Pvt. Ltd. constitute a single entity. *See Stainless Steel Bar From India: Preliminary Results of Changed Circumstances Review and Intent To Reinstate Certain Companies in the Antidumping Duty Order,* 82 FR 48483 (October 18, 2017) and accompanying Preliminary Decision Memorandum at 3–5, unchanged in *Final Results of Changed Circumstances Review and Reinstatement of Certain Companies in the Antidumping Duty Order,* 83 FR 17529 (April 20, 2018). We have received no information on the record of this review to dispute that finding.

[2] The petitioner is the Full Member Subgroup of the American Institute of Steel Construction, LLC.

[3] *See* the petitioner's Letter titled, ''Certain Fabricated Structural Steel From Canada, Mexico, and the People's Republic of China: Request to Postpone Determination,'' dated April 5, 2019.

[4] *Id.*

[5] *Id.*

[2] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Stainless Steel Bar from India: 2017–2018,'' dated concurrently with, and hereby adopted by this notice (Preliminary Decision Memorandum).

[3] *See* Memorandum to the File, ''Antidumping Duty Administrative Review on Stainless Steel Bar from India: Release of Customs and Border Protection Data,'' dated May 1, 2018. *See* also Memorandum, ''Re: Selection of respondents for Individual Examination,'' dated June 22, 2018.

[4] *See Certain Cut-to-Length Carbon-Quality Steel Plate Products from the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2012–2013,* 79 FR 54264 (September 11, 2014), and accompanying Issues and Decisions Memorandum at Comment 5.

[5] *See, e.g., Wooden Bedroom Furniture from the People's Republic of China: Final Results and Final Rescission, In Part, of Administrative Review and Final Results of New Shipper Review; 2013,* 80 FR 34619 (June 17, 2015).

Normal value was calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is made available to the public *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and to all parties in Commerce's Central Records Unit, located at room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be found at *http://enforcement.trade.gov/frn/index.html.* A list of topics discussed in the Preliminary Decision Memorandum is attached at the Appendix to this notice.

Preliminary Results of Administrative Review

We preliminarily determine that the following weighted-average dumping margins exist for the respondents for the period February 1, 2017, through January 31, 2018:

Producer/exporter	Weighted-average dumping margin (percent)
Venus Group	77.49
Jindal Stainless (Hisar) Limited	95.21
Laxcon Steels Limited	77.49

Disclosure and Public Comment

With respect to the Venus Group, we intend to disclose the calculations performed for these preliminary results to the parties within five days after public announcement of the preliminary results in accordance with 19 CFR 351.224(b). Because we preliminarily determined an antidumping margin for Jindal in these preliminary results, based on the application of adverse facts available, in accordance with section 776 of the Act, there are no calculations to disclose.

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[6] Parties who submit case briefs or rebuttal briefs in this proceeding 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.[7]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically *via* ACCESS. An electronically filed document must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[8] Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs.

Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act, and 19 CFR 351.213(h)(1) and (2).

Assessment Rates

Upon issuance of the final results in this administrative review, Commerce shall determine and CBP shall assess antidumping duties on all appropriate entries covered by this POR. If the preliminary results are unchanged for the final results, we will instruct CBP to apply the *ad valorem* assessment rates listed above to all entries of subject merchandise during the POR which were exported by the companies named above.

For entries of subject merchandise during the POR produced by the Venus Group for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

We intend to issue liquidation instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of this review for all shipments of SS Bar from India entered, or withdrawn from warehouse, for consumption on or after the date of publication as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for companies subject to this review will be the rates established in the final results of the review; (2) for merchandise exported by producers 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 recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the producer is, the cash deposit rate will be the rate established for the most recent period for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 12.45 percent, the all-others rate established in the less-than-fair-value investigation.[9] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Commerce is issuing and publishing these results in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.221(b)(4).

Dated: April 9, 2019.

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

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Cost of Production Analysis for the Venus Group
V. Application of Facts Otherwise Available and Adverse Inferences
A. Application of AFA to the Venus Group
B. Application of AFA to JSHL
C. Selection of AFA Rate
VI. Rate for Respondent Not Selected for Individual Examination
VII. Discussion of the Methodology
(1) Comparisons to Normal Value
A. Determination of Comparison Method

[6] *See* 19 CFR 351.309(d).

[7] *See* 19 CFR 351.309(c)(2) and (d)(2).

[8] *See* 19 CFR 351.310(c).

[9] *See Notice of Final Determination of Sales at Less Than Fair Value: Stainless Steel Bar from India,* 59 FR 66915, 66921 (December 28, 1994).

B. Results of the Differential Pricing Analysis
VIII. Date of Sale
IX. Product Comparisons
X. Export Price and Constructed Export Price
XI. 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 Cost of Production
2. Test of Comparison Market Sales Prices
3. Results of the COP Test
E. Calculation of Normal Value Based on Comparison Market Prices
XII. Currency Conversion
XIII. Recommendation

[FR Doc. 2019–07560 Filed 4–15–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–910]

Circular Welded Carbon Quality Steel Pipe From the People's Republic of China: Final Results of the Expedited Second Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) finds that revocation of the antidumping duty order on circular welded carbon quality steel pipe (CWP) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of dumping, at the level indicated in the ''Final Results of Sunset Review'' section of this notice, *infra.*

DATES: Applicable April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Jonathan Hill or Howard Smith, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3518 or (202) 482–5193, respectively.

Background

On July 22, 2008, Commerce published in the **Federal Register** the antidumping duty order on CWP from China.[1] On November 1, 2018, Commerce published the notice of initiation of this sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] From November 15, 2018, through November 16, 2018, pursuant to 19 CFR 351.218(d)(1), Commerce received timely and complete notices of intent to participate in the sunset review from Zekelman Industries (Zekelman), Bull Moose Tube Company (Bull), EXLTUBE (EXL), TMK IPSCO (TMK), Wheatland Tube (Wheatland), Independence Tube Corporation (Independence), and Southland Tube Incorporated (Southland) (collectively domestic interested parties) in which the domestic interested parties claimed interested party status, as domestic producers of CWP, under section 771(9)(C) of the Act.[3] This notice was filed within the time period specified in 19 CFR 351.218(d)(1)(i).[4] On November 29, 2018, pursuant to 19 CFR 351.218(d)(3)(i), domestic interested parties filed a timely and adequate substantive response.[5] Commerce did not receive a substantive response from any respondent interested party. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the *Order.*

Scope of the Order

The merchandise subject to the *Order* is certain welded carbon quality steel pipes and tubes, of circular cross-section, and with an outside diameter of 0.372 inches (9.45 mm) or more, but not more than 16 inches (406.4 mm), whether or not stenciled, regardless of wall thickness, surface finish (*e.g.,* black, galvanized, or painted), end finish (*e.g.,* plain end, beveled end, grooved, threaded, or threaded and coupled), or industry specification (*e.g.,* ASTM, proprietary, or other), generally known as standard pipe and structural pipe (they may also be referred to as circular, structural, or mechanical tubing).

The pipe products that are the subject of the *Order* are currently classifiable in HTSUS statistical reporting numbers 7306.30.10.00, 7306.30.50.25, 7306.30.50.32, 7306.30.50.40, 7306.30.50.55, 7306.30.50.85, 7306.30.50.90, 7306.50.10.00, 7306.50.50.50, 7306.50.50.70, 7306.19.10.10, 7306.19.10.50, 7306.19.51.10, and 7306.19.51.50. However, the product description, and not the Harmonized Tariff Schedule of the United States (''HTSUS'') classification, is dispositive of whether merchandise imported into the United States falls within the scope of the *Order.*[6]

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, specifically the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail if the *Order* were to be revoked, is provided in the accompanying Issues and Decision Memorandum, which is hereby adopted by this notice.[7] The Issues and Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://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 Issues and Decision Memorandum can be accessed at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Sunset Review

Pursuant to sections 751(c)(1), 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would likely lead to continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail would be weighted-average dumping margins up to 85.55 percent.

Notification Regarding Administrative Protective Orders

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective orders is hereby requested. Failure to comply

[1] *See Notice of Antidumping Duty Order: Circular Welded Carbon Quality Steel Pipe from the People's Republic of China,* 73 FR 42547 (July 22, 2008) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Review,* 83 FR 54915 (November 1, 2018).

[3] *See* Zekelman's Letter of Intent dated November 16, 2018; *see also* Bull, EXL, and TMK's Letter of Intent dated November 16, 2018, *see also* Wheatland, Independence, and Southland's Letter of Intent dated November 16, 2018.

[4] *Id.*

[5] *See* domestic interested parties Substantive Response dated November 29, 2018 (Substantive Response).

[6] For a complete description of the scope of the *Order,* see Commerce's Issues and Decision Memorandum for the Expedited Second Sunset Review of the Antidumping Duty Order on Circular Welded Carbon Quality Steel Pipe from the People's Republic of China (Issues and Decision Memorandum), dated concurrently with this notice.

[7] *Id.*

with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing the results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: April 10, 2019.

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. 2019–07543 Filed 4–15–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–011]

Certain Crystalline Silicon Photovoltaic Products From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review, and Rescission of Review in Part; 2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that producers and/or exporters subject to this administrative review received countervailable subsidies during the period of review (POR), January 1, 2017, through December 31, 2017. Interested parties are invited to comment on these preliminary results.

DATES: Applicable April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Gene H. Calvert, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3586.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the initiation of this administrative review on April 16, 2018.[1] This review covers three producers/exporters: Risen Energy Co., Ltd.; Shenzhen Sungold Solar Co., Ltd.; and Sol-Lite Manufacturing Co., Ltd. Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019.[2] As a result, the revised deadline for these preliminary results was extended to March 10, 2019.[3] On March 8, 2019, we extended the deadline for these preliminary results by 30 days to April 9, 2019.[4]

Scope of the Order

The merchandise covered by this order are modules, laminates and/or panels consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including building integrated materials. For purposes of this order, subject merchandise includes modules, laminates and/or panels assembled in the China consisting of crystalline silicon photovoltaic cells produced in a customs territory other than China. For a complete description of the scope of this administrative review, *see* the Preliminary Decision Memorandum.[5]

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, Commerce preliminarily finds that there is a subsidy (*i.e.,* a financial contribution from an authority that gives rise to a benefit to the recipient) and that the subsidy is specific.[6] Commerce notes that, in making these findings, we relied on total facts available and, because we find that the mandatory respondents did not act to the best of their ability to respond to Commerce's request for information, Commerce drew an adverse inference in selecting from the facts otherwise available.[7] For further information, *see* ''Use of Facts Otherwise Available and Application of Adverse Inferences,'' in the accompanying Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is provided at Appendix I to this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://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/index.html.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation of the requested review. This review was initiated on April 16, 2018. On July 16, 2018, Shenzhen Letsolar Technology Co., Ltd. (Letsolar) timely withdrew its request for review of its own entries.[8] As no other party requested an administrative review of Letsolar, we are rescinding this review with respect to Letsolar, in accordance with 19 CFR 351.213(d)(1).

Further, we received timely filed certifications of no shipments from Shanghai JA Solar Technology Co., Ltd. and Hefei JA Solar Technology Co., Ltd. (collectively, JA Solar).[9] To confirm JA Solar's statement, we issued a no-shipment inquiry to U.S. Customs and Border Protection (CBP) with respect to

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 16298 (April 16, 2018).

[2] *See* Memorandum to the Record from 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, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. As a result, all deadlines in this segment of the proceeding have been extended by 40 days.

[3] The March 10, 2019 deadline was a Sunday. As a result, this deadline fell to the next business day. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, as Amended,* 70 FR 24533 (May 10, 2005).

[4] *See* Memorandum, ''Administrative Review of the Countervailing Duty Order on Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China, Second Extension of Deadline for Preliminary Results,'' dated March 8, 2019. We note that this 30-day extension is from the March 10, 2019 deadline, which was a non-business day. Accordingly, the revised deadline for these preliminary results is April 9, 2019.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results in the Countervailing Duty Administrative Review of Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China; 2017,'' dated concurrently with and hereby adopted by this notice (Preliminary Decision Memorandum).

[6] *See* section 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[7] *See* sections 776(a) and (b) of the Act.

[8] *See* Letter from Letsolar, ''Letsolar Withdrawal of Review Request for Administrative Review of the Countervailing Duty Order on Crystalline Silicon Photovoltaic Products from the People's Republic of China,'' dated July 16, 2018.

[9] *See* Letter from JA Solar, ''Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China: No Shipment Certification of Shanghai JA Solar Technology Co., Ltd. and Hefei JA Solar Technology Co., Ltd.,'' dated May 16, 2018.

imports of subject merchandise from JA Solar during the POR.[10] On April 4, 2019, CBP responded to our no-shipment inquiry regarding JA Solar stating that it found no shipments of solar products from China that were produced and/or exported by JA Solar during the POR.[11] As there is no evidence on the record that JA Solar made entries of subject merchandise into the United States during the POR, we are rescinding this review with respect to JA Solar, in accordance with 19 CFR 351.213(d)(3).

Preliminary Rate for Non-Selected Companies Under Review

The statute and Commerce's regulations do not directly address the establishment of rates to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation. Section 705(c)(5)(A)(ii) of the Act provides that, if the countervailable subsidy rates established for all individually-examined exporters/producers are *de minimis* or based entirely on adverse facts available under section 776 of the Act, Commerce may use any reasonable method to establish a subsidy rate for exporters/producers that were not individually-examined, including averaging the weighted-average countervailable subsidy rates determined for the individually-examined exporters and producers.

In this review, the countervailable subsidy rates calculated for the three mandatory respondents are based entirely on facts available pursuant to section 776 of the Act. Accordingly, we are using ''any reasonable method'' to establish the subsidy rate for the non-selected companies under review. We find that it is reasonable to rely on the rates established for the mandatory respondents as the rate for the non-selected companies under review, particularly because there is no other information on the record that can be used to determine the rate for the non-selected companies. This method is consistent with our past practice.[12] A list of these non-selected companies can be found at Appendix II of this notice.

Preliminary Results of Review

We preliminarily determine the net countervailable subsidy rates for the period January 1, 2017, through December 31, 2017, are as follows:

Company	Subsidy rate (percent)
Risen Energy Co., Ltd	94.83
Shenzhen Sungold Solar Co., Ltd	94.83
Sol-Lite Manufacturing Co., Ltd	94.83
Non-Selected Companies Under Review[13]	94.83

Assessment and Cash Deposit Requirement

In accordance with 19 CFR 351.221(b)(4)(i), we assigned a subsidy rate for each producer/exporter subject to this administrative review. Upon issuance of the final results, Commerce shall determine, and CBP shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue instructions to CBP 15 days after the publication of the final results of this review. For companies for which this review is rescinded, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2017, through December 31, 2017, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions directly to CBP 15 days after publication of this notice.

Pursuant to section 751(a)(2)(C) of the Act, Commerce also intends to instruct CBP to collect cash deposits of estimated countervailing duties, in the amounts shown above for each of the respective companies shown above, on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption, on or after the date of publication of the final results of review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most-recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

Because Commerce had reached its conclusions on the basis of adverse facts available, the calculations performed in connection with these preliminary results are based on public information and are described in the Preliminary Decision Memorandum. Interested parties may submit case and rebuttal briefs, as well as request a hearing.[14] For a schedule of the deadlines for filing case briefs, rebuttal briefs, and for requesting a hearing, *see* the Preliminary Decision Memorandum.

Notification to Interested Parties

Commerce is issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: April 8, 2019.

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—List of Topics Discussed in the Preliminary Decision Memorandum

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V. Application of the Countervailing Duty Law to Imports From China
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Application of Total Adverse Facts Available
Calculation of the AFA Rates for the Mandatory Respondents
Corroboration of AFA Rates
VII. Subsidy Rate for Non-Selected Companies Under Review
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IX. Conclusion
Appendix I—AFA Rate Calculation
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[10] *See* CBP Message No. 9093304, dated April 3, 2019.

[11] *See* Memorandum, ''No shipment inquiry with respect to the companies below during the period 01/01/2017 through 12/31/2017,'' dated April 4, 2019.

[12] *See, e.g. Circular Welded Carbon-Quality Steel Pipe from Pakistan: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Countervailing Duty Determination with Final Antidumping Duty Determination,* 81 FR 20619 (April 8, 2016), unchanged in *Circular Welded Carbon-Quality Steel Pipe from Pakistan: Final Affirmative Countervailing Duty Determination,* 81 FR 75045 (October 28, 2016) (assigning the sole mandatory respondent's rate, which was based on adverse facts available, as the all-others rate), and *Circular Welded Carbon-Quality Steel Pipe from India: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Countervailing Duty Determination with Final Antidumping Duty Determination,* 77 FR 19192 (March 30, 2012), unchanged in *Circular Welded Carbon-Quality Steel Pipe from India: Final Affirmative Countervailing Duty Determination,* 77 FR 64468 (October 22, 2012) (assigning the average of the mandatory respondents' rates, which were based solely on adverse facts available, as the all-others rate).

[13] *See* Appendix II.

[14] *See* 19 CFR 351.309(c)–(d), and 19 CFR 351.310(c); *see also* 19 CFR 351.303 (for general filing requirements).

Appendix II—Non-Selected Companies Under Review

1. Changzhou Trina Solar Energy Co., Ltd.
2. Chint Solar (Zhejiang) Co., Ltd.
3. Hefei JA Solar Technology Co., Ltd.
4. Ri Shen Products (SZ) Ltd.
5. Shanghai JA Solar Technology Co., Ltd.
6. Sunny Apex Development Limited
7. Trina Solar (Changzhou) Science & Technology Co., Ltd.

[FR Doc. 2019–07540 Filed 4–15–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–967]

Aluminum Extrusions From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Rescission of Review, in Part; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that producers and/or exporters subject to this administrative review made sales of subject merchandise at less than normal value during the period of review (POR), May 1, 2017, through April 30, 2018. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Heather Lui or Mark Flessner, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0016 or (202) 482–6312, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 12, 2018, Commerce published the notice of initiation of the administrative review of the AD order on aluminum extrusions from China [1] for the POR covering 243 companies.[2] All requests for administrative review were timely withdrawn with regard to 217 companies (listed in Appendix II to this notice), leaving 26 companies subject to the administrative review.[3] On December 3, 2018, we selected Cosco (J.M.) Aluminum Co., Ltd. (Cosco) as the sole producer or exporter eligible for individual examination as a mandatory respondent in this administrative review.[4] For a complete description of the events that followed the initiation of this administrative review, *see* the Preliminary Decision Memorandum.[5]

The Preliminary Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's AD 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 on the internet at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content. A list of topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice.

Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019.[6] If the new deadline falls on a non-business day, in accordance with Commerce's practice, the deadline will become the next business day. On March 11, 2019, we extended the deadline for the preliminary results by 30 days.[7] The revised deadline for the preliminary results of this review is now April 11, 2019.

Scope of the Order

The merchandise covered by the *Order* is aluminum extrusions which are shapes and forms, produced by an extrusion process, made from aluminum alloys having metallic elements corresponding to the alloy series designations published by The Aluminum Association commencing with the numbers 1, 3, and 6 (or proprietary equivalents or other certifying body equivalents).[8]

Imports of the subject merchandise are provided for under the following categories of the Harmonized Tariff Schedule of the United States (HTSUS): 8541.90.00.00, 8708.10.30.50, 8708.99.68.90, 6603.90.8100, 7616.99.51, 8479.89.94, 8481.90.9060, 8481.90.9085, 9031.90.9195, 8424.90.9080, 9405.99.4020, 9031.90.90.95, 7616.10.90.90, 7609.00.00, 7610.10.00, 7610.90.00, 7615.10.30, 7615.10.71, 7615.10.91, 7615.19.10, 7615.19.30, 7615.19.50, 7615.19.70, 7615.19.90, 7615.20.00, 7616.99.10, 7616.99.50, 8479.89.98, 8479.90.94, 8513.90.20, 9403.10.00, 9403.20.00, 7604.21.00.00, 7604.29.10.00, 7604.29.30.10, 7604.29.30.50, 7604.29.50.30, 7604.29.50.60, 7608.20.00.30, 7608.20.00.90, 8302.10.30.00, 8302.10.60.30, 8302.10.60.60, 8302.10.60.90, 8302.20.00.00, 8302.30.30.10, 8302.30.30.60, 8302.41.30.00, 8302.41.60.15, 8302.41.60.45, 8302.41.60.50, 8302.41.60.80, 8302.42.30.10, 8302.42.30.15, 8302.42.30.65, 8302.49.60.35, 8302.49.60.45, 8302.49.60.55, 8302.49.60.85, 8302.50.00.00, 8302.60.90.00, 8305.10.00.50, 8306.30.00.00, 8414.59.60.90, 8415.90.80.45, 8418.99.80.05, 8418.99.80.50, 8418.99.80.60, 8419.90.10.00, 8422.90.06.40, 8473.30.20.00, 8473.30.51.00, 8479.90.85.00, 8486.90.00.00, 8487.90.00.80,

[1] *See Aluminum Extrusions from the People's Republic of China: Antidumping Duty Order,* 76 FR 30650 (May 26, 2011) (the *Order*).

[2] *See* Petitioner/Endura Letter re: Aluminum Extrusions from the People's Republic of China: Request for Administrative Review, dated May 31, 2018 (Petitioner/Endura's Request for Review); *see also* Columbia Letter re: Aluminum Extrusions from the People's Republic of China: Request for Administrative Review, dated May 31, 2018; *Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 32270, 32274–32277 (July 12, 2018) (*Initiation Notice*), corrected by *Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 39688, 39690, n.9 (August 10, 2018) (correcting the *Initiation Notice* with respect to Asia Alum Group and Atlas Integrated Manufacturing Ltd.) (*Initiation Notice Correction*).

[3] *See* Petitioner/Endura Letter re: Aluminum Extrusions from the People's Republic of China: Withdrawal of Request for Administrative Review, dated October 4, 2017. *See also* Columbia Letter re: Aluminum Extrusions from China, dated October 10, 2018. A request for an administrative review therefore remains in place for 26 companies.

[4] *See* Memorandum, ''Aluminum Extrusions from the People's Republic of China, 2017–2018 Administrative Review: Memorandum for Identification of Mandatory Respondent,'' dated December 3, 2018.

[5] *See* Memorandum, ''Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review: Aluminum Extrusions from the People's Republic of China; 2017–2018,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See* Memorandum to the Record from 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, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[7] *See* Memorandum, ''Aluminium Extrusions from the People's Republic of China: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated March 11, 2019.

[8] *See* Preliminary Decision Memorandum for a complete description of the scope of the *Order.*

8503.00.95.20, 8508.70.00.00, 8515.90.20.00, 8516.90.50.00, 8516.90.80.50, 8517.70.00.00, 8529.90.73.00, 8529.90.97.60, 8536.90.80.85, 8538.10.00.00, 8543.90.88.80, 8708.29.50.60, 8708.80.65.90, 8803.30.00.60, 9013.90.50.00, 9013.90.90.00, 9401.90.50.81, 9403.90.10.40, 9403.90.10.50, 9403.90.10.85, 9403.90.25.40, 9403.90.25.80, 9403.90.40.05, 9403.90.40.10, 9403.90.40.60, 9403.90.50.05, 9403.90.50.10, 9403.90.50.80, 9403.90.60.05, 9403.90.60.10, 9403.90.60.80, 9403.90.70.05, 9403.90.70.10, 9403.90.70.80, 9403.90.80.10, 9403.90.80.15, 9403.90.80.20, 9403.90.80.41, 9403.90.80.51, 9403.90.80.61, 9506.11.40.80, 9506.51.40.00, 9506.51.60.00, 9506.59.40.40, 9506.70.20.90, 9506.91.00.10, 9506.91.00.20, 9506.91.00.30, 9506.99.05.10, 9506.99.05.20, 9506.99.05.30, 9506.99.15.00, 9506.99.20.00, 9506.99.25.80, 9506.99.28.00, 9506.99.55.00, 9506.99.60.80, 9507.30.20.00, 9507.30.40.00, 9507.30.60.00, 9507.90.60.00, and 9603.90.80.50.

The subject merchandise entered as parts of other aluminum products may be classifiable under the following additional Chapter 76 subheadings: 7610.10, 7610.90, 7615.19, 7615.20, and 7616.99, as well as under other HTSUS chapters. In addition, fin evaporator coils may be classifiable under HTSUS numbers: 8418.99.80.50 and 8418.99.80.60. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this *Order* is dispositive.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). For a full description of the methodology underlying our preliminary results of review, *see* the Preliminary Decision Memorandum.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party or parties that requested a review withdraws the request within 90 days of the publication date of the notice of initiation of the requested review. As noted above, all requests for administrative review were timely withdrawn for certain companies. Therefore, in accordance with 19 CFR 351.213(d)(1), we are rescinding this administrative review with respect to 217 of the 243 companies named in the *Initiation Notice*.[9] *See* Appendix II for a list of these companies.[10]

Separate Rates

In the *Initiation Notice,* we informed parties of the opportunity to request a separate rate.[11] In proceedings involving non-market economy (NME) countries, Commerce begins with a rebuttable presumption that all companies within the NME country are subject to government control and, thus, should be assigned a single weighted-average dumping margin. It is Commerce's policy to assign all exporters of merchandise subject to an administrative review involving an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate. Companies that wanted to qualify for separate rate status in this administrative review were required to timely file, as appropriate, a separate rate application (SRA) or a separate rate certification (SRC) to demonstrate their eligibility for a separate rate. SRAs and SRCs were due to Commerce within 30 calendar days of the publication of the *Initiation Notice.*[12]

Of the 26 companies for which an administrative review was requested, and not withdrawn, Cosco[13] and Houztek[14] submitted SRAs. Cosco did not respond to Commerce's antidumping questionnaire; consequently, we preliminarily find that Cosco is ineligible for separate rate status.[15] Additionally we preliminarily find that Houztek's SRA was deficient and that the company has not established its eligibility for a separate rate; for a more detailed explanation of the deficiency, *see* the Preliminary Decision Memorandum.

Of the remaining 24 companies for which a review remains in place, none submitted an SRA, SRC, or certification of no shipments. We, therefore, preliminarily determine that the following companies have not demonstrated eligibility for a separate rate in this administrative review: (1) Activa International Inc.; (2) Belton (Asia) Development Ltd.; (3) Belton (Asia) Development Limited; (4) Changzhou Changzhen Evaporator Co., Ltd.; (5) Changzhou Changzheng Evaporator Co., Ltd.; (6) Changzhou Tenglong Auto Parts Co., Ltd.; (7) Changzhou Tenglong Auto Accessories Manufacturing Co. Ltd; (8) Changzhou Tenglong Auto Parts Co Ltd; (9) China Square; (10) China Square Industrial Co.; (11) China Square Industrial Ltd; (12) Cosco; (13) Cosco (JM) Aluminum Development Co. Ltd; (14) Dynamic Technologies China; (15) ETLA Technology (Wuxi) Co. Ltd; (16) Foshan Shanshui Fenglu Aluminum Co., Ltd.; (17) Global Hi- Tek Precision Co. Ltd; (18) Houztek; (19) Jangho Curtain Wall Hong Kong Ltd.; (20) Kromet International Inc.; (21) Kromet Intl Inc; (22) Kromet International; (23) Kunshan Giant Light Metal Technology Co., Ltd.; (24) Precision Metal Works Ltd.; (25) Sihui Shi Guo Yao Aluminum Co., Ltd.; and (26) Summit Heat Sinks Metal Co, Ltd.[16]

China-Wide Entity

We preliminarily find that the 26 companies listed above are part of the China-wide entity in this administrative review because 24 of the companies failed to submit a valid SRA, SRC, or certification of no shipments, Houztek did not submit a valid SRA, and Cosco failed to respond to Commerce's antidumping questionnaire after being selected as a mandatory respondent.

Commerce's policy regarding conditional review of the China-wide entity applies to this administrative review.[17] Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity in the instant review, the entity is not under review, and the entity's current rate, *i.e.,* 86.01 percent,[18] is not subject to change.

[9] *See Initiation Notice,* 83 FR at 32274–32277.

[10] *See* Preliminary Decision Memorandum for further details.

[11] *See Initiation Notice,* 83 FR at 32271–32272.

[12] *Id.*

[13] *See* Cosco Letter re: Aluminum Extrusions from the People's Republic of China: Quantity and Value Questionnaire (A–570–967); Separate Rate Application, dated September 4, 2018 (Cosco SRA).

[14] *See* Houztek Letter re: Aluminum Extrusions from the People's Republic of China: Separate Rates Application, dated September 7, 2018 (Houztek SRA).

[15] *See Initiation Notice,* 83 FR at 32272 (''For exporters and producers who submit a separate-rate status application or certification and subsequently are selected as mandatory respondents, these exporters and producers will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.'').

[16] *See* Preliminary Decision Memorandum.

[17] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963, 65970 (November 4, 2013).

[18] *See Aluminum Extrusions from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2015–2016,* 82 FR 52265, 52267 (November 13, 2017).

Adjustments for Countervailable Subsidies

Because no company established eligibility for an adjustment under section 777A(f) of the Act for countervailable domestic subsidies, for these preliminary results, Commerce did not make an adjustment pursuant to section 777A(f) of the Act for countervailable domestic subsidies for separate-rate recipients. Furthermore, because the China-wide entity is not under review, we made no adjustment for countervailable export subsidies for the China-wide entity pursuant to section 772(c)(1)(C) of the Act.

Disclosure and Public Comment

Normally, Commerce discloses to interested parties the calculations performed in connection with the preliminary results within five days of the 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). However, because Commerce did not calculate weighted-average dumping margins for any companies in this review, nor for the China-wide entity, there is nothing further to disclose.

Interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[19] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the case briefs are filed.[20] Parties who submit case or rebuttal briefs in this review are requested to submit with each argument (a) a statement of the issue, (b) a brief summary of the argument, and (c) a table of authorities.[21]

Any interested party may request a hearing within 30 days of publication of this notice.[22] Hearing requests should contain the following information: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the case and rebuttal briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.[23]

All submissions, with limited exceptions, must be filed electronically using ACCESS.[24] An electronically filed document must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time (ET) on the due date. Documents excepted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with the APO/Dockets Unit in Room 18022 and stamped with the date and time of receipt by 5 p.m. ET on the due date.[25]

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, which will include the results of our analysis of all issues raised in any briefs received, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results of this review, Commerce will determine, and CBP shall assess, AD duties on all appropriate entries covered by this review.[26] Commerce intends to issue assessment instructions to CBP 15 days after publication of the final results of this review.

We intend to instruct CBP to liquidate entries containing subject merchandise exported by the China-wide entity at the China-wide rate. Additionally, if Commerce determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number will be liquidated at the China-wide rate.[27]

For the companies for which this review is rescinded, AD duties shall be assessed at rates equal to the cash deposit of estimated AD duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue assessment instructions to CBP for those companies 15 days after publication of this notice.

Cash Deposit Requirements

The following cash deposit requirements for estimated AD duties, when imposed, will apply to all shipments of subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) If the companies preliminarily determined to be eligible for a separate rate receive a separate rate in the final results of this administrative review, their cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review, as adjusted for domestic and export subsidies (except, if that rate is *de minimis,* then the cash deposit rate will be zero); (2) for any previously investigated or reviewed Chinese and non-Chinese exporters that are not under review in this segment of the proceeding but that received a separate rate in the most recently completed segment of this proceeding, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the China-wide entity; (4) for the China-wide entity, the cash deposit rate will be 86.01 percent; and (5) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter.

These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of AD duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of AD duties occurred and the subsequent assessment of double AD duties.

Notification to Interested Parties

We are issuing and publishing notice of these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

[19] *See* 19 CFR 351.309(c)(1)(ii).

[20] *See* 19 CFR 351.309(d).

[21] *See* 19 CFR 351.309(c)(2) and (d)(2).

[22] *See* 19 CFR 351.310(c).

[23] *See* 19 CFR 351.310(d).

[24] *See generally* 19 CFR 351.303.

[25] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[26] *See* 19 CFR 351.212(b)(1).

[27] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

Dated: April 10, 2019.

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

List of Topics Discussed in the Preliminary Decision Memorandum

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Appendix II

Companies for Which This Administrative Review Is Being Rescinded

1. Acro Import and Export Co.
2. Activa Leisure Inc.
3. Allied Maker Limited
4. Alnan Aluminum Co., Ltd.
5. Alnan Aluminum Ltd.
6. Aluminicaste Fundicion de Mexico
7. AMC Ltd.
8. AMC Limited
9. Anji Chang Hong Chain Manufacturing
10. Anshan Zhongjda Industry Co., Ltd.
11. Aoda Aluminium (Hong Kong) Co., Limited
12. AsiaAlum Group
13. Atlas Integrated Manufacturing Ltd.
14. Birchwoods (Lin'an) Leisure Products Co., Ltd.
15. Bolnar Hong Kong Ltd.
16. Bracalente Metal Products (Suzhou) Co., Ltd.
17. Brilliance General Equipment Co., Ltd.
18. Changshu Changshen Aluminum Products Co., Ltd.
19. Changshu Changsheng Aluminum Products Co., Ltd.
20. China Zhongwang Holdings, Ltd.
21. Chiping One Stop Industrial & Trade Co., Ltd.
22. Classic & Contemporary Inc.
23. Clear Sky Inc.
24. Dalian Huacheng Aquatic Products
25. Dalian Liwang Trade Co., Ltd.
26. Danfoss Micro Channel Heat Exchanger (Jia Xing) Co., Ltd.
27. Daya Hardware Co. Ltd.
28. Dongguan Dazhan Metal Co., Ltd.
29. Dongguang Aoda Aluminum Co., Ltd.
30. Dongguan Golden Tiger Hardware Industrial Co., Ltd.
31. Dragonluxe Limited
32. Dynabright International Group (HK) Ltd.
33. Ever Extend Ent. Ltd.
34. Fenghua Metal Product Factory
35. First Union Property Limited
36. FookShing Metal & Plastic Co. Ltd.
37. Foreign Trade Co. of Suzhou New & High-Tech Industrial Development Zone
38. Foshan City Nanhai Hongjia Aluminum Alloy Co., Ltd.
39. Foshan Golden Source Aluminum Products Co., Ltd.
40. Foshan Guangcheng Aluminium Co., Ltd.
41. Foshan Jinlan Aluminum Co. Ltd.
42. Foshan JinLan Aluminum Co., Ltd.
43. Foshan JMA Aluminum Company Limited
44. Foshan Nanhai Niu Yuan Hardware Product Co., Ltd.
45. Foshan Shunde Aoneng Electrical Appliances Co., Ltd.
46. Foshan Yong Li Jian Aluminum Co., Ltd.
47. Fujian Sanchuan Aluminum Co., Ltd.
48. Fukang Aluminum & Plastic Import and Export Co., Ltd.
49. Fuzhou Sunmodo New Energy Equipment
50. Gaotang Xinhai Economy & Trade Co., Ltd.
51. Genimex Shanghai, Ltd.
52. Global PMX Dongguan Co., Ltd.
53. Global Point Technology (Far East) Limited
54. Gold Mountain International Development, Ltd.
55. Golden Dragon Precise Copper Tube Group, Inc.
56. Gran Cabrio Capital Pte. Ltd.
57. Gree Electric Appliances
58. GT88 Capital Pte. Ltd.
59. Guang Ya Aluminium Industries Co. Ltd.
60. Guang Ya Aluminum Industries Company Ltd
61. Guang Ya Aluminium Industries (HK) Ltd.
62. Guangcheng Aluminum Co., Ltd.
63. Guangdong Hao Mei Aluminum Co., Ltd.
64. Guangdong Jianmei Aluminum Profile Company Limited
65. Guangdong JMA Aluminum Profile Factory (Group) Co., Ltd.
66. Guangdong Midea
67. Guangdong Midea Microwave and Electrical Appliances
68. Guangdong Nanhai Foodstuffs Imp. & Exp. Co., Ltd.
69. Guangdong Weiye Aluminum Factory Co., Ltd.
70. Guangdong Whirlpool Electrical Appliances Co., Ltd.
71. Guangdong Xingfa Aluminum Co., Ltd.
72. Guangdong Xin Wei Aluminum Products Co., Ltd.
73. Guangdong Yonglijian Aluminum Co., Ltd.
74. Guangdong Zhongya Aluminum Company Ltd.
75. Guangzhou Jangho Curtain Wall System Engineering Co., Ltd.
76. Guangzhou Mingcan Die-Casting Hardware Products Co., Ltd.
77. Hangzhou Xingyi Metal Products Co., Ltd.
78. Hanwood Enterprises Limited
79. Hanyung Alcoba Co., Ltd.
80. Hanyung Alcobis Co., Ltd.
81. Hanyung Metal (Suzhou) Co., Ltd.
82. Hao Mei Aluminum Co., Ltd.
83. Hao Mei Aluminum International Co., Ltd.
84. Hebei Xusen Wire Mesh Products Co., Ltd.
85. Henan New Kelong Electrical Appliances Co., Ltd.
86. Henan Zhongduo Aluminum Magnesium New Material Co, Ltd.
87. Hong Kong Gree Electric Appliances Sales Limited
88. Hong Kong Modern Non-Ferrous Metal
89. Honsense Development Company
90. Hui Mei Gao Aluminum Foshan Co., Ltd.
91. Huixin Aluminum
92. IDEX Dinglee Technology (Tianjin) Co., Ltd.
93. IDEX Health
94. IDEX Technology Suzhou Co., Ltd.
95. Innovative Aluminum (Hong Kong) Limited
96. iSource Asia
97. Jackson Travel Products Co., Ltd.
98. Jiangmen Jianghai District Foreign Economic Enterprise Corp. Ltd.
99. Jiangmen Jianghai Foreign Ent. Gen.
100. Jiangmen Qunxing Hardware Diecasting Co., Ltd.
101. Jiangsu Changfa Refrigeration Co.
102. Jiangyin Suncitygaylin
103. Jiangyin Trust International Inc.
104. Jiangyin Xinhong Doors and Windows Co., Ltd.
105. Jiaxing Jackson Travel Products Co., Ltd.
106. Jiaxing Taixin Metal Products Co., Ltd.
107. Jiuyan Co., Ltd.
108. JMA (HK) Company Limited
109. Johnson Precision Engineering (Suzhou) Co., Ltd.
110. Justhere Co., Ltd.
111. Kam Kiu Aluminum Products Sdn Bhd
112. Kanal Precision Aluminum Product Co., Ltd.
113. Karlton Aluminum Company Ltd.
114. Kong Ah International Company Limited
115. Liaoning Zhong Da Industrial Aluminum Co., Ltd.
116. Liaoning Zhongwang Group Co., Ltd.
117. Liaoyang Zhongwang Aluminum Profile Co. Ltd.
118. Longkou Donghai Trade Co., Ltd.
119. Metal Tech Co. Ltd.
120. Metaltek Group Co., Ltd.
121. Metaltek Metal Industry Co., Ltd.
122. Midea Air Conditioning Equipment Co., Ltd.
123. Midea Electric Trading Co., Pte Ltd.
124. Midea International Trading Co., Ltd.
125. Midea International Training Co., Ltd.
126. Miland Luck Limited
127. Nanhai Textiles Import & Export Co., Ltd.
128. New Asia Aluminum & Stainless Steel Product Co., Ltd.
129. New Zhongya Aluminum Factory
130. Nidec Sankyo (Zhejang) Corporation
131. Nidec Sankyo Zhejiang Corporation
132. Nidec Sankyo Singapore Pte. Ltd.
133. Ningbo Coaster International Co., Ltd.
134. Ningbo Hi Tech Reliable Manufacturing Company
135. Ningbo Innopower Tengda Machinery
136. Ningbo Ivy Daily Commodity Co., Ltd.
137. Ningbo Yili Import and Export Co., Ltd.
138. North China Aluminum Co., Ltd.
139. North Fenghua Aluminum Ltd.
140. Northern States Metals
141. PanAsia Aluminum (China) Limited
142. Pengcheng Aluminum Enterprise Inc.
143. Permasteelisa Hong Kong Limited
144. Permasteelisa South China Factory
145. Pingguo Aluminum Company Limited
146. Pingguo Asia Aluminum Co., Ltd.
147. Popular Plastics Company Limited

148. Press Metal International Ltd.
149. Samuel, Son & Co., Ltd.
150. Sanchuan Aluminum Co., Ltd.
151. Sanhua (Hangzhou) Micro Channel Heat Exchanger Co., Ltd.
152. Shandong Fukang Aluminum & Plastic Co. LTD.
153. Shandong Huajian Aluminum Group
154. Shangdong Huasheng Pesticide Machinery Co.
155. Shangdong Nanshan Aluminum Co., Ltd.
156. Shanghai Automobile Air-Conditioner Accessories Co. Ltd.
157. Shanghai Automobile Air Conditioner Accessories Ltd.
158. Shanghai Canghai Aluminum Tube Packaging Co., Ltd.
159. Shanghai Dofiberone Composites Co. Ltd.
160. Shanghai Dongsheng Metal
161. Shanghai Shen Hang Imp & Exp Co., Ltd.
162. Shanghai Tongtai Precise Aluminum Alloy Manufacturing Co. Ltd.
163. Shanghai Top-Ranking Aluminum Products Co., LTD.
164. Shanghai Top-Ranking New Materials Co., Ltd.
165. Shenyang Yuanda Aluminum Industry Engineering Co. Ltd.
166. Shenzhen Hudson Technology Development Co.
167. Shenzhen Jiuyuan Co., Ltd.
168. Sincere Profit Limited
169. Skyline Exhibit Systems (Shanghai) Co. Ltd.
170. Southwest Aluminum (Group) Co., Ltd.
171. Summit Plastics Nanjing Co. Ltd.
172. Suzhou JRP Import & Export Co., Ltd.
173. Suzhou New Hongji Precision Part Co.
174. Tai-Ao Aluminum (Taishan) Co. Ltd.
175. Taishan City Kam Kiu Aluminium Extrusion Co., Ltd.
176. Taizhou Lifeng Manufacturing Co., Ltd.
177. Taitoh Machinery Shanghai Co. Ltd.
178. Taizhou United Imp. & Exp. Co., Ltd.
179. tenKsolar (Shanghai) Co., Ltd.
180. Tianjin Ganglv Nonferrous Metal Materials Co., Ltd.
181. Tianjin Jinmao Import & Export Corp., Ltd.
182. Tianjin Ruxin Electric Heat Transmission Technology Co., Ltd.
183. Tianjin Xiandai Plastic & Aluminum Products Co., Ltd.
184. Tiazhou Lifeng Manufacturing Corporation
185. Top-Wok Metal Co., Ltd.
186. Traffic Brick Network, LLC
187. Union Aluminum (SIP) Co.
188. Union Industry (Asia) Co., Ltd.
189. USA Worldwide Door Components (Pinghu) Co., Ltd.
190. Wenzhou Shengbo Decoration & Hardware
191. Wenzhou Yongtai Electric Co., Ltd.
192. Whirlpool (Guangdong)
193. Whirlpool Canada L.P.
194. Whirlpool Microwave Products Development Ltd.
195. Worldwide Door Components, Inc.
196. WTI Building Products, Ltd.
197. Wuxi Lutong Fiberglass Doors Co., Ltd,
198. Xin Wei Aluminum Co.
199. Xin Wei Aluminum Company Limited
200. Xinya Aluminum & Stainless Steel Product Co., Ltd.
201. Yuyao Haoshen Import & Export
202. Yuyao Fanshun Import & Export Co., Ltd.
203. Zahoqing China Square Industry Limited
204. Zhaoqing Asia Aluminum Factory Company Ltd.
205. Zhaoqing China Square Industry Limited
206. Zhaoqing China Square Industrial Ltd.
207. Zhaoqing New Zhongya Aluminum Co., Ltd.
208. Zhejiang Anji Xinxiang Aluminum Co., Ltd.
209. Zhejiang Lilies Industrial and Commercial Co.
210. Zhejiang Yili Automobile Air Condition Co., Ltd.
211. Zhejiang Yongkang Listar Aluminum Industry Co., Ltd.
212. Zhejiang Zhengte Group Co., Ltd.
213. Zhenjiang Xinlong Group Co., Ltd.
214. Zhongshan Daya Hardware Co., Ltd.
215. Zhongshan Gold Mountain Aluminum Factory Ltd.
216. Zhongya Shaped Aluminum (HK) Holding Limited
217. Zhuhai Runxingtai Electrical Equipment Co., Ltd.

[FR Doc. 2019–07542 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–958]

Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses From the People's Republic of China: Rescission of the Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the antidumping duty order on certain coated paper suitable for high-quality print graphics using sheet-fed presses (coated paper) from the People's Republic of China (China) for the period November 1, 2017, through October 31, 2018.

DATES: Applicable April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Shanah Lee, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6386.

SUPPLEMENTARY INFORMATION:

Background

On November 1, 2018, Commerce published a notice of opportunity to request an administrative review of the antidumping duty order on coated paper from China.[1] On November 30, 2018, Commerce received timely requests to conduct an administrative review of the antidumping duty order on coated paper from China from Verso Corporation, Sappi North America, Inc., and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC (collectively, the petitioners).[2] Based on this request, on February 6, 2019, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), Commerce published in the **Federal Register** a notice of initiation of an administrative review covering the period November 1, 2017, through October 31, 2018 covering 15 producers/exporters.[3] In the *Initiation Notice,* we noted that the deadline for parties to withdraw requests for administrative review was 90 days from the publication of the instant notice, *i.e.,* May 7, 2019. On March 29, 2019, the petitioners timely submitted a request to withdraw its request for administrative review with respect to all companies identified in the *Initiation Notice.*[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the party or parties who requested the review withdraw(s) the request within 90 days

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 83 FR 54912 (November 1, 2018).

[2] *See* letter from the petitioners, ''Administrative Review of the Antidumping Duty Order on Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses from the People's Republic of China (11/01/17–10/31/18),'' dated November 30, 2018.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 2159 (February 6, 2019) (*Initiation Notice*). Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019. *See* memorandum to the Record from 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, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. Accordingly, the deadline for issuing the *Initiation Notice* was tolled by 40 days.

[4] *See* letter from the petitioners, ''Administrative Review of the Antidumping Duty Order on Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses from the People's Republic of China (11/01/17–10/31/18): Withdrawal of Review Request,'' dated March 29, 2019.

of the date of publication of the notice of initiation of the requested review. As explained above, the petitioners timely withdrew their request for an administrative review of all companies listed in the *Initiation Notice* by the 90-day deadline, and no other party requested a review of these companies. Accordingly, we are rescinding this review in its entirety, pursuant to 19 CFR 351.2013(d)(1).

Assessment

Commerce will instruct CBP to assess antidumping duties on all appropriate entries of coated paper at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of the antidumping and/or countervailing duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order

This notice serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under an APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

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).

Dated: April 10, 2019.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the duties of the Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–07541 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–421–813]

Certain Hot-Rolled Steel Flat Products From the Netherlands: Rescission of Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the antidumping duty order on certain hot-rolled steel flat products from the Netherlands for the period October 1, 2017, through September 30, 2018.

DATES: Applicable April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Dmitry Vladimirov, 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) 482–0665.

SUPPLEMENTARY INFORMATION:

Background

On October 1, 2018, Commerce published a notice of opportunity to request an administrative review of the antidumping duty order on certain hot-rolled steel flat products (HR Steel) from the Netherlands for the period of review (POR) of October 1, 2017, through September 30, 2018.[1] On October 31, 2018, the petitioners, AK Steel Corporation, Steel Dynamics Inc., SSAB Enterprises, LLC, ArcelorMittal USA LLC, Nucor Corporation, and United States Steel Corporation, requested an administrative review of the order with respect to Tata Steel IJmuiden B.V. (TSIJ).[2] On December 11, 2018, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the order on HR Steel from the Netherlands with respect to TSIJ.[3]

Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019.[4] The revised deadline for the preliminary results of this review is August 13, 2019.

On March 28, 2018, the petitioners timely withdrew their request for an administrative review of TSIJ.[5] No other party requested a review.

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review ''in whole or in part, if a party that requested a review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review.'' In this case, the petitioners withdrew their request for review within the 90-day time limit. Because we received no other requests for review of TSIJ, and no other requests for the review of the order on HR Steel from the Netherlands with respect to other companies subject to the order, we are rescinding this administrative review of the order in full, in accordance with 19 CFR 351.213(d)(1).

Assessment

Commerce intends to instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of HR Steel products from the Netherlands during the POR at rates equal to the cash deposit rate of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 83 FR 49358 (October 1, 2018).

[2] *See* the petitioners' Letter, ''Re: Hot-Rolled Steel Flat Products from the Netherlands/Request for Administrative Review,'' dated October 31, 2018.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 63615 (December 11, 2018) (*Initiation Notice*).

[4] *See* Memorandum, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[5] *See* the petitioners' Letter, ''Re Hot-Rolled Steel Flat Products from the Netherlands/Withdrawal of Request for Administrative Review,'' dated March 28, 2019.

of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

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).

Dated: April 10, 2019.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–07538 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG500

Marine Mammals; Administration of the National Inventory of Marine Mammals

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

ACTION: Notice; extension of comment period.

SUMMARY: Notice is hereby given that NMFS is extending the public comment period for the request for comments on proposed policies and procedures for the administration of the National Inventory of Marine Mammals (NIMM).

DATES: Comments must be received by 11:59 p.m. Eastern on or before July 31, 2019.

ADDRESSES: You may submit comments, identified by NOAA–NMFS–2019–0012, by any of the following methods:

- *Electronic Submission:* Submit electronic public comments via the Federal e-Rulemaking Portal *www.regulations.gov.* To submit comments via the e-Rulemaking Portal, enter NOAA–NMFS–2019–0012 in the keyword search. Locate the document you wish to comment on from the resulting list and click on the ''Comment Now'' icon on the right of that line.
- *Mail:* Comments on the application should be addressed to: Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; ATTN: Jolie Harrison, Chief, Permits and Conservation Division.
- *Fax:* (301) 713–0376; ATTN: Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources.

Instructions: Comments must be submitted by one of the above methods. 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, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Amy Sloan, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On February 15, 2019, NMFS published notice (84 FR 4443) requesting public comment on proposed policies and procedures for the administration and maintenance of the online inventory database, NIMM, including maintenance of historical information, reporting births and stillbirths, reporting cause of death, and other administrative procedures for NIMM.

NMFS has decided to allow additional time for submission of public comments on this action and has extended the comment period through July 31, 2019. The original **Federal Register** notice and additional information is available at *https://www.fisheries.noaa.gov/action/proposed-policies-and-procedures-national-inventory-marine-mammals.*

Dated: April 11, 2019.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–07574 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG970

Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

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

ACTION: Notice; request for comments.

SUMMARY: The Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit application from Rutgers University contains all of the required information and warrants further consideration. This Exempted Fishing Permit would allow four charter/party vessels to collect black sea bass. Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notice to provide interested parties the opportunity to comment on applications for proposed Exempted Fishing Permits.

DATES: Comments must be received on or before May 1, 2019.

ADDRESSES: You may submit written comments by any of the following methods:

- *Email: NMFS.GAR.EFP@NOAA.gov.* Include in the subject line ''BSB Size at Maturity EFP.''
- *Mail:* Michael Pentony, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on BSB Size at Maturity EFP.''

FOR FURTHER INFORMATION CONTACT: Laura Hansen, Fishery Management Specialist, 978–281–9225.

SUPPLEMENTARY INFORMATION: Rutgers University submitted a complete application for an Exempted Fishing Permit (EFP) on March 21, 2019, to collect information on the effect of latitude and bottom temperature on black sea bass spawning body condition and size at maturity. The sampling is

designed around spawning activities and spatial/temporal energetic variability of black sea bass. The EFP would authorize four charter/party vessels to collect and retain up to 240 black sea bass for lab analysis. This EFP would exempt the participating vessels from the following Federal regulations:

1. Recreational black sea bass possession limits specified at 50 CFR 648.145; and

2. Commercial and party/charter minimum size limits for black sea bass specified at § 648.147(a) and (b).

Black sea bass would be captured using rod and reel gear. Sampling trips would occur every two weeks, 40–60 miles off the coast of Virginia. Black sea bass of both sexes, in the 190mm-400mm size range, would be sampled during each trip. Some of the collected fish will be under the recreational minimum size limit (12.5 in; 317.5 mm) for black sea bass. A blood sample would be collected from the sampled black sea bass, the fish would be euthanized, and transported to the Virginia Institute of Marine Sciences to be dissected. During dissection, tissue samples would be taken and preserved for later analysis at a Rutgers University lab. The researcher will be on board for all sampling trips and the exemptions would only apply to fish being collected for the Rutgers University study.

If approved, Rutgers University may request minor modifications and extensions to the EFP throughout the study period. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

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

Dated: April 11, 2019.

Alan D. Risenhoover,

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

[FR Doc. 2019–07576 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG969

Atlantic Coastal Fisheries Cooperative Management Act Provisions;

General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

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

ACTION: Notice; request for comments.

SUMMARY: The Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit application from the Commercial Fisheries Research Foundation contains all of the required information and warrants further consideration. This permit would facilitate research on the impact of increasing water temperature on female lobster size at maturity and growth.

Regulations under the Magnuson-Stevens Fishery Conservation and Management Act and the Atlantic Coastal Fisheries Cooperative Management Act require publication of this notice to provide interested parties the opportunity to comment on applications for proposed Exempted Fishing Permits.

DATES: Comments must be received on or before May 1, 2019.

ADDRESSES: You may submit written comments by any of the following methods:

- *Email: NMFS.GAR.EFP@noaa.gov.* Include in the subject line ''Comments on CFRF Lobster Size at Maturity EFP.''
- *Mail:* Michael Pentony, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on CFRF Lobster Size at Maturity Study.''

FOR FURTHER INFORMATION CONTACT: Laura Hansen, Fishery Management Specialist, 978–281–9225, *Laura.Hansen@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Commercial Fisheries Research Foundation (CFRF) submitted a complete application for an Exempted Fishing Permit (EFP) on March 8, 2019, to conduct fishing activities that the regulations would otherwise restrict. The EFP would authorize seven vessels to collect up to 480 female lobsters of different size classes including egg-bearing and v-notched lobsters. The participating vessels are currently authorized to use up to three ventless traps per trawl under a separate EFP. The modifications to a conventional lobster trap include a closed escape vent, single parlor, and smaller mesh size and entrance head, all to allow for the capture of undersized lobster.

Funding for this study has been awarded through the Atlantic States Marine Fisheries Commission. For this research, CFRF is requesting exemptions from the following Federal lobster regulations:

1. Possession restrictions in §§ 697.20(a), 697.20(d), and 697.20(g) to allow for retention of undersized, v-notched, and egg-bearing lobsters.

2. Dealer requirements in § 697.7(c)(1)(xviii), to allow the sale of lobsters to a research organization that is not a Federally permitted dealer.

If the EFP is approved, this research would take place from May to August, 2019. The participating vessels would be authorized to collect 240 female lobsters from both statistical areas 537 and 562. Twenty female lobsters would be collected from 12 distinct size bins, ranging from 53–113mm. Five vessels would sample in statistical area 537 and two would sample in statistical area 562. No more than 40 of the retained lobsters would be v-notched. Lobsters collected for the study would be identified with a different color band than the retained portion of their catch and transported by CFRF staff to the Massachusetts Division on Marine Fisheries laboratory for holding prior to dissection. Vessels would be compensated by CFRF for the female lobsters.

If approved, the applicant may request minor modifications and extensions to the EFP throughout the study period. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

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

Dated: April 11, 2019.

Alan D. Risenhoover,

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

[FR Doc. 2019–07575 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG881

Marine Mammals; File No. 22686

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

ACTION: Notice; extension of comment period.

SUMMARY: Notice is hereby given that the National Marine Fisheries Service is extending the public comment period associated with the notice of receipt for an application for a permit to import bottlenose dolphins (*Tursiops truncatus*) submitted by the Chicago Zoological Society.

DATES: Written, telefaxed, or email comments must be received on or before May 16, 2019.

ADDRESSES: The application and related application documents are available for review online at *https://www.fisheries.noaa.gov/action/permit-application-import-3-bottlenose-dolphins-file-no-22686-chicago-zoological-society* or upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. 22686 in the subject line of the email comment.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore and Courtney Smith, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On March 19, 2019 (84 FR 10044), the National Marine Fisheries Service (NMFS) published notice of a permit application submitted by the Chicago Zoological Society, Brookfield Zoo (Bill Zeigler, Responsible Party), 3300 Golf Road, Brookfield, IL 60513. The applicant is requesting to import up to three captive born bottlenose dolphins from Dolphin Quest Bermuda to either the Brookfield Zoo in Brookfield, IL or Coral World Ocean Park in St. Thomas, U.S. Virgin Islands for public display purposes. The requested duration of the permit is five years.

During the 30-day comment period, NMFS received several requests for a 60 day extension of the public comment period and for a public hearing. NMFS is extending the public comment period for an additional 30 days for commenters to review additional information received from the applicant. Regarding the public hearing, NMFS has determined that a public hearing is not warranted as comments and documentation related to this MMPA permit application can be provided in writing.

Dated: April 11, 2019.

Amy Sloan,

Acting Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–07532 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Marine Mammals and Endangered Species

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

ACTION: Notice; issuance of permits and permit amendments or modifications.

SUMMARY: Notice is hereby given that permits or permit amendments have been issued to the following entities under the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA), as applicable.

ADDRESSES: The permits and related documents are available for review upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone: (301) 427–8401; fax: (301) 713–0376.

FOR FURTHER INFORMATION CONTACT: Amy Sloan (Permit No. 22095); Erin Markin (Permit Nos. 20340–02 and 20528–01); Malcolm Mohead (Permit Nos. 19641–01, 20347–01, and 22671); and Sara Young (Permit Nos. 14327–01 and 16087) at (301) 427–8401.

SUPPLEMENTARY INFORMATION: Notices were published in the **Federal Register** on the dates listed below that requests for a permit or permit amendment had been submitted by the below-named applicants. To locate the **Federal Register** notice that announced our receipt of the application and a complete description of the research, go to *www.federalregister.gov* and search on the permit number provided in the table below.

Permit No.	RIN	Applicant	Previous **Federal Register** notice	Permit or amendment issuance date
14327–01	0648–XP18	National Marine Fisheries Service's Marine Mammal Laboratory, 7600 Sand Point Way, Seattle, WA 98115 (Responsible Party: John Bengston).	79 FR 51963, September 2, 2014.	March 21, 2019.
16087–02	0648–XA292	National Marine Fisheries Service's Marine Mammal Laboratory, 7600 Sand Point Way, Seattle, WA 98115 (Responsible Party: John Bengston).	79 FR 64174, October 28, 2014.	March 21, 2019.
19641–01	0648–XG517	Connecticut Department of Energy and Environmental Protection, Marine Fisheries, P.O. Box 719, Old Lyme, CT 06371 (Responsible Party: Tom Savoy).	83 FR 61375, November 29, 2018.	March 12, 2019.
20340–02	0648–XG517	New York State Department of Environmental Conservation, 205 Belle Mead Road, East Setuaket, NY 11733 (Responsible Party: Kim McKown).	83 FR 61375, November 29, 2018.	March 12, 2019.
20347–01	0648–XG517	University of Maine, School of Marine Sciences, 5741 Libby Hall, Room 202A, Orono, ME 04469 (Responsible Party: Gayle Zydlewski).	83 FR 61375, November 29, 2018.	March 12, 2019.

Permit No.	RIN	Applicant	Previous **Federal Register** notice	Permit or amendment issuance date
20528–01	0648–XG517	South Carolina Department of Natural Resources, 217 Fort Johnson Road, Charleston, SC 29412 (Responsible Party: Bill Post).	83 FR 61375, November 29, 2018.	March 12, 2019.
22095	0648–XG371	SeaWorld, LLC., 9205 SouthPark Center Loop, Suite 400, Orlando, FL 32819 (Responsible Party: Christopher Dold, DVM).	83 FR 54570, October 30, 2018.	March 13, 2019.
22671	0648–XG517	Conte Anadromous Fish Research Laboratory, U.S. Geological Survey, Biological Resources Discipline, 1 Migratory Way, Turners Fall, MA 01376 (Responsible Party: Adria Elskus).	83 FR 61375, November 29, 2018.	March 12, 2019.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

As required by the ESA, as applicable, issuance of these permit was based on a finding that such permits: (1) Were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in Section 2 of the ESA.

Authority: The requested permits have been issued under the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), as applicable.

Dated: April 11, 2019.

Amy Sloan,

Acting Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–07535 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG957

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

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

ACTION: Notice of public meeting.

SUMMARY: NMFS announces a public meeting of the Permanent Advisory Committee (PAC) to advise the U.S. Commissioners to the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (WCPFC) on June 10, 2019. Meeting topics are provided under the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: The meeting of the PAC will be held via conference call on June 10, 2019, from 10 a.m. to 12 p.m. Hawaii Standard Time (HST) (or until business is concluded). Members of the public may submit written comments on meeting topics or materials; comments must be received by June 5, 2019.

ADDRESSES: The public meeting will be conducted via conference call. For details on how to call in to the conference line or to submit comments, please contact Emily Reynolds, NMFS Pacific Islands Regional Office; telephone: 808–725–5039; email: *emily.reynolds@noaa.gov*. Documents to be considered by the PAC will be sent out via email in advance of the conference call. Please submit contact information to Emily Reynolds (telephone: 808–725–5039; email: *emily.reynolds@noaa.gov*) at least 3 days in advance of the call to receive documents via email.

FOR FURTHER INFORMATION CONTACT: Emily Reynolds, NMFS Pacific Islands Regional Office; 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818; telephone: 808–725–5039; facsimile: 808–725–5215; email: *emily.reynolds@noaa.gov.*

SUPPLEMENTARY INFORMATION:

In accordance with the Western and Central Pacific Fisheries Convention Implementation Act (16 U.S.C. 6901 *et seq.*), the Permanent Advisory Committee, or PAC, has been formed to advise the U.S. Commissioners to the WCPFC. The PAC is composed of: (i) Not less than 15 nor more than 20 individuals appointed by the Secretary of Commerce in consultation with the U.S. Commissioners to the WCPFC; (ii) the chair of the Western Pacific Fishery Management Council's Advisory Committee (or the chair's designee); and (iii) officials from the fisheries management authorities of American Samoa, Guam, and the Northern Mariana Islands (or their designees). The PAC supports the work of the U.S. National Section to the WCPFC in an advisory capacity. The U.S. National Section is made up of the U.S. Commissioners and the Department of State. NMFS Pacific Islands Regional Office provides administrative and technical support to the PAC in cooperation with the Department of State. More information on the WCPFC, established under the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean, can be found on the WCPFC website: *http://www.wcpfc.int.*

Meeting Topics

The purpose of the June 10, 2019, conference call is to discuss outcomes of the 2018 regular session of the WCPFC (WCPFC15), U.S. priorities leading up to the 2019 regular session of the WCPFC (WCPFC16), and potential management measures for tropical tunas and other issues of interest.

Special Accommodations

The conference call is accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Emily Reynolds at 808–725–5039 by May 27, 2019.

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

Dated: April 11, 2019.

Alan D. Risenhoover,

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

[FR Doc. 2019–07580 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG913

Marine Mammals; File Nos. 22289, 22293, and 22298

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Alaska Fisheries Science Center's Marine Mammal Laboratory (MML) 7600 Sand Point Way NE, Seattle, WA 98115–0070 (Responsible Party: John Bengston), Alaska Sea Life Center (ASLC) P.O. Box 1329, 301 Railway Avenue, Seward, AK 99664 (Responsible Party: Tara Reimer), and Alaska Department of Fish and Game (ADF&G) P.O. Box 25526, Juneau, AK 99802–5526 (Responsible Party: Michael Rehberg), have applied in due form for permits to conduct research on Steller sea lions (*Eumetopias jubatus*).

DATES: Written, telefaxed, or email comments must be received on or before May 16, 2019.

ADDRESSES: The applications and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File Nos. 22289 (MML), 22293 (ASLC), or 22298 (ADF&G) from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Sara Young or Shasta McClenahan, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permits are requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

For File No. 22289: MML proposes to conduct research to measure population status, vital rates, foraging ecology, habitat requirements, and effects of natural and anthropogenic factors impacting Steller sea lion populations pursuant to fulfilling the NMFS legal requirements under the MMPA and ESA, and to test hypotheses of mechanisms underlying population trends. Studies will occur in Alaska, Washington, Oregon and California. Proposed take activities include surveys (aerial, vessel, and land) including unmanned aircraft systems (UAS), capture and handling, marking, hot branding, sampling (including but not limited to blood, blubber, swabs of all mucus membranes and lesions, skin samples, vibrissae, feces, urine, hair, and nail), tagging, and incidental disturbance. Up to 36,200 animals may be disturbed by surveys, and up to 629 animals captured, sampled and released for vital rates, foraging ecology and/or health studies per year. MML requests two unintentional mortalities annually from each the eastern and western distinct population segments (eDPS and wDPS). Non-target species that may be disturbed incidentally to these studies include northern fur seals (*Callorhinus ursinus*), California sea lions (*Zalophus californianus*), northern elephant seals (*Mirounga angustirostris*), and harbor seals (*Phoca vitulina*). Collected tissue samples may be exported for analysis. The requested duration of this permit is five years.

For File No. 22293: ASLC proposes to conduct research to monitor population vital rates of the wDPS of Steller sea lions and determine what factors most affect vital rates and the potential for population recovery, focusing on population dynamics, health, diet, and behavior. Individuals may be taken in the Gulf of Alaska and Aleutian Islands by the following means with maximum number of takes per year in parentheses: disturbance associated with capture, observational studies, and material/scat/carcass collection (14,000); capture, restraint, and sampling (125); and remote biopsy (150). Captured sea lions will undergo morphometric measurements, blood and tissue collection, digital imaging, hot-branding, body condition measurement, whisker, hair, and milk sampling, temporary marking, and ultrasound exams. ASLC requests three unintentional mortalities annually from the wDPS. Non-target species that may be disturbed incidentally to these studies include harbor seals and California sea lions. The requested duration of this permit is five years.

For File No. 22298: ADF&G proposes to continue their long-term Steller sea lion research program, to investigate causes for recovery trends observed in the wDPS, collecting survival and reproduction data in both DPSs, investigating movement between and within DPSs, and monitoring the eDPS for various threats subsequent to delisting. Proposed methods include: incidental disturbance during aerial (including UAS), vessel and ground-based count and brand resight surveys (up to 190,640 disturbance takes) ; captures (up to 1,690 individuals) supporting marking, external instrument attachment, and physiology, toxicology, feeding ecology and health sampling; and permanent marking (hot branding) of pups and older age classes for describing vital rates and DPS movement. ADF&G requests three unintentional mortalities annually from each the wDPS and eDPS. Non-target species that may be disturbed incidentally to these studies include northern fur seals, California sea lions, and harbor, spotted (*Phoca largha*), ribbon (*Histriophoca fasciata*), ringed (*Pusa hispida*), and bearded (*Erignathus barbatus*) seals. The requested duration of this permit is five years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activities proposed are consistent with the Preferred Alternative in the Final Programmatic Environmental Impact Statement for Steller Sea Lion and Northern Fur Seal Research (NMFS 2007) and a supplemental environmental assessment (EA; NMFS 2014) prepared for the addition of unmanned aerial surveys to the suite of Steller sea lion research activities analyzed under the EIS that concluded that issuance of the permits would not have a significant adverse impact on the human environment. An environmental review memo is being prepared to summarize these findings.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the

application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: April 11, 2019.

Amy Sloan,

Acting Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–07529 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG854

Marine Mammals; File No. 22750

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Rachel Cartwright, Ph.D., Keiki Kohola Project, 1330 Sabal Lakes Road, Delray Beach, FL 33445, has applied in due form for a permit to conduct research on marine mammals.

DATES: Written, telefaxed, or email comments must be received on or before May 16, 2019.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 22750 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone: (301) 427–8401; fax: (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Shasta McClenahan or Carrie Hubard; phone: (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The applicant requests a five-year research permit to (1) monitor and describe relative abundance and patterns of habitat use for mother-calf humpback whale (*Megaptera novaeangliae*) pairs, (2) establish baseline health indicators for maternal humpback whales, (3) provide estimates of humpback calf survival rates, and (4) collect opportunistic data on marine mammals associated with or in overlapping areas with humpback whales. Up to 12 species of marine mammals may be taken during research including the following ESA-listed species: blue (*Balaenoptera musculus),* Hawaiian insular false killer (*Pseudorca crassidens*), and humpback whales. Research may occur year-round in the U.S. waters of Hawaii, California, and Alaska. Research may include vessel surveys and unmanned aircraft systems for counts, observations, photogrammetry, above water and underwater photography and video recording, and exhaled air sampling. See the application for complete numbers of animals requested by species and procedure.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: April 11, 2019.

Amy Sloan,

Acting Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–07536 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG831

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Lighthouse Repair and Tour Operations at Northwest Seal Rock, California

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

ACTION: Notice; issuance of an incidental harassment authorization renewal.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA), as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) Renewal to the St. George Reef Lighthouse Preservation Society (Society) to harass marine mammals incidental to aircraft operations, lighthouse renovations, and tour operations associated with preservation of the St. George Reef Lighthouse Station (Station) on Northwest Seal Rock (NWSR) in the northeast Pacific Ocean.

DATES: This IHA Renewal is valid from April 10, 2019 through April 9, 2020.

FOR FURTHER INFORMATION CONTACT: Amy Fowler, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the original application, renewal request, and supporting documents (including NMFS **Federal Register** notices of the original proposed and final authorizations, and the previous IHA), as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-research-and-other-activities.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The Marine Mammal Protection Act (MMPA, 16 U.S.C. 1361 *et seq.*) prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other

than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, notice of a proposed incidental take authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to here as ''mitigation measures''). Monitoring and reporting of such takings are also required. The meaning of key terms such as ''take,'' ''harassment,'' and ''negligible impact'' can be found in section 3 of the MMPA (16 U.S.C. 1362) and the agency's regulations at 50 CFR 216.103.

NMFS' regulations implementing the MMPA at 50 CFR 216.107(e), indicate that IHAs may be renewed for additional periods of time, not to exceed one year for each reauthorization. In the notice of proposed IHA for the initial authorization, NMFS described the circumstances under which we would consider issuing a renewal for this activity, and requested public comment on a potential Renewal IHA under those circumstances. Specifically, on a case-by-case basis, NMFS may issue a one-year IHA renewal when (1) another year of identical or nearly identical activities as described in the Specified Activities section is planned or (2) the activities would not be completed by the time the IHA expires and a second IHA would allow for completion of the activities beyond that described in the Dates and Duration section of the initial IHA. All of the following conditions must be met in order to issue a Renewal:

- A request for renewal is received no later than 60 days prior to expiration of the current IHA.
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted beyond the initial dates either are identical to the previously analyzed activities or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, take estimates, or mitigation and monitoring requirements; and

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

- Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures remain the same and appropriate, and the initial findings remain valid.

An additional public comment period of 15 days (for a total of 45 days), with direct notice by email, phone, or postal service to commenters on the initial IHA, is provided to allow for any additional comments on the proposed renewal. A description of the renewal process may be found on our website at: *https://www.fisheries.noaa.gov/iha-renewals.*

History of Request

On April 13, 2018, NMFS issued an IHA to the Society to take marine mammals incidental to the lighthouse maintenance and preservation project at NWSR, Del Norte County, California (83 FR 19254, May 2, 2018), effective from February 19, 2018 through February 18, 2019. On December 6, 2018, NMFS received an application for the Renewal of the initial IHA. As described in the application for renewal, the activities for which incidental take is requested are identical to those covered in the initial authorization. As required, the applicant also provided a preliminary monitoring report (available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-research-and-other-activities*) which confirms that the applicant has implemented the required mitigation and monitoring, and which also shows that no impacts of a scale or nature not previously analyzed or authorized have occurred as a result of the activities conducted. Notice of the proposed IHA Renewal was published in the **Federal Register** on March 7, 2019 (84 FR 8312).

Description of the Specified Activities and Anticipated Impacts

The Station is located on NWSR offshore from Crescent City, California in the northeast Pacific Ocean. NWSR rises approximately 5.18 meters (m) (17 feet (ft)) above sea level. Because NWSR has no safe landing for boats, the islet is accessed only by helicopter. The Society visits the Station to conduct lighthouse renovations and periodic maintenance on the Station's optical light system, as well as public tours of the historic lighthouse. Station visits occur one weekend per month (Friday, Saturday, and Sunday), from November through April. The following specific aspects of the Society's activities will likely result in the take of marine mammals: Acoustic and visual stimuli from (1) helicopter landings/takeoffs; (2) noise generated during restoration activities (*e.g.,* painting, plastering, welding, and glazing); (3) maintenance activities (*e.g.,* bulb replacement and automation of the light system); and (4) human presence. These activities are identical to those analyzed in the initial IHA issued by NMFS, described in detail in the **Federal Register** notice of proposed IHA (83 FR 8841, March 1, 2018). As in the initial authorization, NMFS anticipates that take, by Level B harassment only, of California sea lions (*Zalophus californianus*), harbor seals (*Phoca vitulina*), Steller sea lions (*Eumetopias jubatus*) of the eastern U.S. Stock, and northern fur seals (*Callorhinus ursinus*) could result from the specified activity (83 FR 19254, May 2, 2018).

Description of the Activity and Specific Geographic Region

A detailed description of the restoration, maintenance, and tour operations for which take is authorized may be found in the Notices of the Proposed and Final IHAs for the initial authorization (83 FR 8841, March 1, 2018; 83 FR 19254, May 2, 2018), along with the **Federal Register** Notice of the Proposed IHA Renewal (84 FR 8312; March 7, 2019). The location (as described in the *Specific Geographic Region* section of the initial IHA), timing, amount, and nature of the specified activities, including the types of equipment planned for use, are identical to those described in the previous notices.

Description of Marine Mammals

As noted in the **Federal Register** Notice of the Proposed IHA Renewal (84 FR 8312; March 7, 2019), a description of the marine mammals in the area of the activities for which incidental take is authorized here, including information on abundance, status, distribution, and hearing, may be found in the **Federal Register** Notice of the Proposed IHA for the initial authorization (83 FR 8841, March 1, 2018). NMFS has reviewed the monitoring data from the initial IHA, recent draft Stock Assessment Reports, information on relevant Unusual Mortality Events, and other scientific

literature. The draft 2018 Stock Assessment Report notes that the estimated abundance of California sea lions has decreased slightly, however, neither this nor any other new information affects which species or stocks have the potential to be affected or the pertinent information in the section *Description of Marine Mammals in the Area of Specified Activities* contained in the supporting documents for the initial IHA.

Potential Effects on Marine Mammals and Their Habitat

As noted in the **Federal Register** Notice of the Proposed IHA Renewal (84 FR 8312; March 7, 2019), the description of the potential effects of the specified activity on marine mammals and their habitat for the activities for which take is authorized here is found in the **Federal Register** Notice of the Proposed IHA for the initial authorization (83 FR 8841, March 1, 2018). All of that information and analysis remain applicable and valid. NMFS has reviewed the monitoring data from the initial IHA, recent draft Stock Assessment Reports, information on relevant Unusual Mortality Events, and other scientific literature, and determined that no new information affects our initial analysis of potential impacts on marine mammals and their habitat.

Public Comments

A notice of NMFS' proposal to issue a Renewal IHA to the Society was published in the **Federal Register** on March 7, 2019 (84 FR 8312). That notice both included information and referenced information from the initial IHA **Federal Register** notices on the Society's activities and the specific geographic region; the marine mammal species that had the potential to be affected by the activity; the potential effects on marine mammals and their habitat; the proposed amount and manner of take; the proposed mitigation, monitoring and reporting measures; and the preliminary determinations. We also sent direct notice to any party that had submitted comments on the initial IHA. NMFS received one comment letter, which was from the Marine Mammal Commission (Commission). The Commission provided comments as described below, concurred with NMFS's preliminary determinations, and recommended the issuance of the Renewal IHA to the Society, subject to the inclusion of the mitigation, monitoring, and reporting measures.

Comment: The Commission questioned whether the public notice provisions for IHA Renewals fully satisfy the public notice and comment provision in the MMPA and discussed the potential burden on reviewers of reviewing key documents and developing comments quickly. Therefore the Commission recommended that NMFS use the IHA Renewal process sparingly and selectively for activities expected to have the lowest levels of impacts to marine mammals and that require less complex analysis.

Response: NMFS has taken a number of steps to ensure the public has adequate notice, time, and information to be able to comment effectively on IHA Renewals within the limitations of processing IHA applications efficiently. The **Federal Register** notice for the initial proposed IHA had previously identified the conditions under which a one-year Renewal IHA might be appropriate. This information is presented in the *Request for Public Comments* section of the initial IHA proposal (citation) and thus encourages submission of comments on the potential of a one-year renewal as well as the initial IHA during the 30-day comment period. In addition, when we receive an application for a Renewal IHA, we publish notice of the proposed IHA Renewal in the **Federal Register** and provide an additional 15 days for public comment, making a total of 45 days of public comment. We will also directly contact all commenters on the initial IHA by email, phone, or, if the commenter did not provide email or phone information, by postal service to provide them the opportunity to submit any additional comments on the proposed Renewal IHA.

NMFS also strives to ensure the public has access to key information needed to submit comments on a proposed IHA, whether an initial IHA or a Renewal IHA. The agency's website includes information for all projects under consideration, including the application, references, and other supporting documents. Each **Federal Register** notice also includes contact information in the event a commenter has questions or cannot find the information they seek.

Regarding the Commission's comment that Renewal IHAs should be limited to certain types of projects, NMFS has explained on its website and in individual **Federal Register** notices that Renewal IHAs are appropriate where the continuing activities are identical, nearly identical, or a subset of the activities for which the initial 30-day comment period applied. Where the commenter has likely already reviewed and commented on the initial proposed IHA for these activities, the abbreviated additional comment period is sufficient for consideration of the results of the preliminary monitoring report and new information (if any) from the past year.

Comment: In order to increase efficiencies, the Commission recommended that NMFS authorize the incidental taking of marine mammals for the Society's future activities via an MMPA rulemaking rather than individual IHAs and IHA Renewals.

Response: We appreciate the interest that the Commission has shown in our efforts to streamline the MMPA authorization process. NMFS will discuss with the applicant the option of entering into a rulemaking for future incidental take authorizations.

Authorized Take

Detailed descriptions of the methods and inputs used to estimate take for the specified activity are found in the **Federal Register** Notices of the Proposed and Final IHAs for the initial authorization (83 FR 8841, March 1, 2018; 83 FR 19254, May 2, 2018). Specifically, the number of days of operation and marine mammal occurrence data applicable to this authorization remain unchanged from the previously issued IHA. Accordingly, all methodology and analysis in the **Federal Register** notices for the proposed and final initial IHA remain applicable and accurate, as explained in the **Federal Register** Notice of the Proposed IHA Renewal (84 FR 8312; March 7, 2019). We therefore determine that the species and stocks affected, methods of take, and types of take remain unchanged from the initial IHA, as do the number of takes for each species, which are indicated below in Table 1.

In their 2018 monitoring report, the Society reported a total of 40 takes of California sea lions, three takes of Steller sea lions, and zero takes of northern fur seals and harbor seals from four visits to NWSR. All takes qualified as Level B harassment in the form of behavioral disturbance. These take numbers fall far below the take authorized in the initial IHA (83 FR 19254, May 2, 2018) and the identical numbers authorized in this IHA Renewal, which are indicated below.

TABLE 1—AUTHORIZED TAKE OF MARINE MAMMALS

Species	Maximum observed per day	Days of proposed activity	Estimated take	Stock abundance	Percent of stock
California sea lion (*Zalophus californianus*)	160	18	2,880	257,606	1.1
Steller sea lion (*Eumetopias jubatus*)	155	18	2,790	41,638	6.7
Pacific harbor seal (*Phoca vitulina*)	2	18	36	30,968	0.35
Northern fur seal (*Callorhinus ursinus*)	1	18	18	14,050	0.12

Description of Required Mitigation, Monitoring, and Reporting Measures

As explained in the **Federal Register** Notice of the Proposed IHA Renewal (84 FR 8312; March 7, 2019), a complete discussion of mitigation, monitoring, and reporting measures under the MMPA, as well as the specific mitigation, monitoring, and reporting measures appropriate for the Society's activities, was provided in the **Federal Register** Notices of the Proposed IHA (83 FR 8841; March 1, 2018) and Final IHA. (83 FR 19254, May 2, 2018) for the initial IHA. All of that discussion remains applicable and valid for this renewal IHA. Additionally, the discussion of least practicable adverse impact included in those documents remains accurate. NMFS therefore determined that the mitigation, monitoring, and reporting measures included as requirements in the **Federal Register** Notice announcing the issuance of the initial IHA (83 FR 19254, May 2, 2018) are appropriate and would be continued in this Renewal IHA. The following measures, which are identical to those in the initial IHA, are included in the Renewal IHA:

The Society will conduct restoration and touring activities at a maximum of once per month over the course of the year, with the exception of between May 1, 2019 through October 31, 2019 when no restoration or touring activities would occur (barring potential emergency light repairs during this time). Each restoration session will last no more than three days. Maintenance of the light beacon will occur only in conjunction with restoration activities (except if an emergency light repair is needed from May 1, 2019 through October 31, 2019).

The Society will ensure that its helicopter approach patterns to the Station and timing techniques are conducted at times when marine mammals are less likely to be disturbed. To the extent possible, the helicopter should approach NWSR when the tide is too high for the marine mammals to haul out on NWSR. Additionally, since the most severe impacts (stampede) precede rapid and direct helicopter approaches, the Society's initial approach to the station must be offshore from the island at a relatively high altitude (*e.g.,* 800–1,000 ft, or 244–305 m). Before the final approach, the helicopter must circle lower and approach from the area with the lowest pinniped density. If for any safety reasons (*e.g.,* wind condition) the Society cannot conduct these types of helicopter approach and timing techniques, they must postpone the restoration and maintenance activities for that day.

The Society is required to instruct its members and restoration crews to avoid making unnecessary noise and avoid visual detection by pinnipeds around the base of the station. Although Crescent Coastal Research reported no impacts from these activities in a 2001 study (CCR 2001), it is relatively simple for the Society to avoid this potential impact. The door to the lower platform must remain closed and barricaded to all tourists and other personnel since the lower platform is used at times by pinnipeds.

A NMFS-approved, experienced biologist must be present on the first flight of each day of the activity. This observer must be able to identify all species of pinnipeds expected to use the island, and qualified to determine age and sex classes when viewing conditions allow. The observer will record data including species counts, numbers of observed disturbances, and descriptions of the disturbance behaviors during the activities, including location, date, and time of the event. In addition, the Society will record observations regarding the number and species of any marine mammals either observed in the water or hauled out.

Aerial photographic surveys provide an accurate means of documenting species composition, age, and sex class of pinnipeds using the project site during human activity periods. The Society must complete aerial photo coverage from the same helicopter used to transport the Society's personnel to the island during restoration trips. The Society will take photographs of all marine mammals hauled out on the island from an altitude greater than 300 m (984 ft) by a skilled photographer, on the first flight of each day of activities. These photographs will be forwarded to a biologist capable of discerning marine mammal species. The following shall be provided to NMFS: Data in the form of a report with a data table, any other significant observations related to marine mammals, and a report of restoration activities (see below). The original photographs will be made available to NMFS or other marine mammal experts for inspection and further analysis, if requested.

The Society is required to submit a draft report to NMFS' Office of Protected Resources no later than 90 days after the conclusion of restoration activities in April. The report must include a summary of the information gathered pursuant to the monitoring requirements described here and set forth in the final IHA. The Society must submit a final report to NMFS within 30 days after receiving comments from NMFS on the draft report. If the Society receives no comments from NMFS on the draft report, NMFS will consider the draft report to be the final report.

The report will describe the operations conducted and sightings of marine mammals near the project. The report must provide:

1. A summary and table of the dates, times, and weather during all activities;

2. Species, number, location, and behavior of any marine mammals observed throughout all monitoring activities;

3. An estimate of the number (by species) of marine mammals exposed to human presence associated with the Society's activities; and

4. A description of the implementation and effectiveness of the monitoring and mitigation measures of the IHA and full documentation of methods, results, and interpretation pertaining to all monitoring.

Findings and Determinations

The lighthouse restoration, maintenance, and public tour activities conducted by the Society are identical to those analyzed in the initial IHA, as are the number of days of activity, the method of taking, and the effects of the

action. The potential effects of the Society's activities are limited to Level B harassment in the form of behavioral disturbance. In analyzing the effects of the activities in the initial IHA, NMFS determined that the Society's activities would have a negligible impact on the affected species or stocks and that the authorized take numbers of each species or stock were small relative to the relevant stocks (*i.e.,* less than 7 percent of all stocks). The numbers of marine mammals authorized in this Renewal IHA are identical to those authorized in the initial IHA. The mitigation measures and monitoring and reporting requirements as described above also are identical to the initial IHA.

All of the information and analysis from the initial IHA remains applicable and valid for the findings and determinations under this Renewal IHA. In addition, there is no new information that substantively affects or suggests that our analysis or findings should change from those reached for the initial IHA. This includes consideration of the estimated abundance of California sea lions decreasing slightly. Based on the information and analysis contained here and in the referenced documents, NMFS has determined the following: (1) The required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; (4) the authorized takes will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by these activities; and (5) appropriate monitoring and reporting requirements are included.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an incidental harassment authorization) with respect to potential impacts on the human environment. This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental harassment authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of the Renewal IHA qualifies to be categorically excluded from further NEPA review.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat.

No incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

IHA Renewal

NMFS has issued an IHA Renewal that includes the previously described mitigation, monitoring, and reporting requirements to the Society for the harassment of small numbers of four species of marine mammals incidental to conducting lighthouse restoration, maintenance, and public tour operations at NWSR once per month, from November through April.

Dated: April 10, 2019.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–07511 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG961

Marine Mammals; File No. 22965

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Sea to Sea Productions Ltd., 477 Island View Drive, Boutiliers Point, Nova Scotia, Canada B3Z1R3 (Responsible Party: David Kent Nason), has applied in due form for a permit to conduct commercial or educational photography on gray seals (*Halichoerus grypus*).

DATES: Written, telefaxed, or email comments must be received on or before May 16, 2019.

ADDRESSES: These documents are available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Carrie Hubard or Sara Young, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to film up to 100 gray seals (*Halichoerus grypus*) near the Isles of Shoals, located offshore from Maine and New Hampshire. Underwater video would be taken for a television documentary on gray seals that will air in an episode of The Nature of Things on the Canadian Broadcasting Corporation. Up to 50 harbor seals (*Phoca vitulina*) may also be incidentally filmed. The permit would expire on August 31, 2019.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: April 10, 2019.

Amy Sloan,

Acting Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–07515 Filed 4–15–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2019–HQ–0015]

Proposed Collection; Comment Request

AGENCY: Army & Air Force Exchange Service (Exchange), DoD.

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Army & Air Force Exchange Service (Exchange) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by June 17, 2019.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket 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.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Army & Air Force Exchange Service, Office of the General Counsel, Compliance Division, ATTN: Teresa Schreurs, 3911 South Walton Walker Blvd., Dallas, TX 75236–1598 or call the Exchange Compliance Division at 800–967–6067.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Exchange Accounts Receivable Files; CRC 7429395—''Military Star Card Paper Application'' and Exchange Form 6450–005—''Exchange Credit Program Account Update''; OMB Number 0702–0137.

Needs and Uses: The information collection requirement is necessary to process, monitor, and post audit accounts receivables to the Army and Air Force Exchange Service; to administer the Federal Claims Collection Act and to answer inquiries pertaining thereto as well as collection of indebtedness and determination of customer's eligibility to cash checks at Exchange facilities.

Affected Public: Individuals or Households.

Annual Burden Hours: 45,829.

Number of Respondents: 916,574.

Responses per Respondent: 1.

Annual Responses: 916,574.

Average Burden per Response: 3 minutes.

Frequency: On occasion.

Respondents are Exchange patrons, potential patrons, or past patrons who are indebted to the Exchange. This may include dishonored checks, deferred payment plans, home layaway, pecuniary liability claims and credit.

Dated: April 10, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2019–07512 Filed 4–15–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2019–HQ–0005]

Submission for OMB Review; Comment Request

AGENCY: Office of the Administrative Assistant to the Secretary of the Army, Army Headquarters Services (OAA–AHS), 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 May 16, 2019.

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, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Authorization to Apply for a ''No-Fee'' Passport and/or request for visa; DD Form 1056; OMB Control Number 0702–0134.

Type of Request: Extension.

Number of Respondents: 175,000.

Responses per Respondent: 1.

Annual Responses: 175,000.

Average Burden per Response: 60 minutes.

Annual Burden Hours: 175,000.

Needs and Uses: The information collection requirement is necessary to obtain and record the personally identifiable information of official passport and/or visa applicants. This information is used to process, track, and verify no-fee passport and visa applications and requests for additional visa pages and Status of Forces Agreement (SOFA) endorsements.

Affected Public: Individuals or households.

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: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: April 11, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–07571 Filed 4–15–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2019–HQ–0006]

Submission for OMB Review; Comment Request

AGENCY: Department of the Army, 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 May 16, 2019.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Vlad Dorjets, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Corps of Engineers Flood Risk Management Surveys; OMB Control Number 0710–0017.

Type of Request: Extension.

Number of Respondents: 3,000.

Responses per Respondent: 1.

Annual Responses: 3,000.

Average Burden per Response: 36.5 minutes.

Annual Burden Hours: 1,825.

Needs and Uses: The data obtained from these surveys are used by the Army Corps of Engineers to more effectively provide flood risk management to communities, residents, and businesses at risk of flooding. The data are needed for estimating damage relationships for factors such as depth of flooding for different types of buildings and different occupancies of uses. The data are also used for estimating other costs of flooding. Results of surveys will help communities to better determine and communicate their flood risks. The models are also used for programmatic evaluation of the Corps' National Flood Risk Management Program.

Affected Public: Residents, property owners, business, nongovernmental organizations, Local Governments.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. Vlad Dorjets.

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: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: April 10, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–07495 Filed 4–15–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2019–HQ–0004]

Submission for OMB Review; Comment Request

AGENCY: Department of the Army, 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 May 16, 2019.

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, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Standard Tender of Freight Services; SDDC Form 364–R; OMB Control Number 0704–0261.

Type of Request: Extension.

Number of Respondents: 82,053.

Responses per Respondent: 1.

Annual Responses: 82,053.

Average Burden per Response: 20 minutes.

Annual Burden Hours: 27,351.

Needs and Uses: The information derived from the DoD tenders on file with the Military Surface Deployment and Distribution Command (SDDC) is used by SDDC subordinate commands and DoD shippers to select the best value carriers to transport surface freight shipments. Freight carriers furnish information in a uniform format so that the Government can determine the cost of transportation, accessorial, and security services, and select the best value carriers for 1.1 million Bill of Lading shipments annually. The DoD tender is the source document for the General Services Administration post-shipment audit of carrier freight bills.

Affected Public: Business or other for-profit.

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: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: April 10, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–07486 Filed 4–15–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2019–OS–0038]

Privacy Act of 1974; System of Records

AGENCY: Office of Secretary of Defense, DoD.

ACTION: Notice of a modified system of records.

SUMMARY: The Office of the Secretary of Defense proposes to modify the system of records, Defense Manpower Data Center Data Base, DMDC 01, by amending Routine Use 15 regarding disclosures to the Department of Education (ED) to accommodate disclosures for a new computer matching agreement with the ED. This new matching agreement with ED ensures that service members who have received imminent danger pay (IDP) or hostile fire pay (HFP) benefits and who have student loans under Part D, Title IV of the Higher Education Act of 1965 (HEA), as amended, receive the no interest accrual benefit on their eligible loans during the period of time they received IDP or HFP pay. The system of records, DMDC 01, contains personnel, employment, and pay data on current and former military and civilian personnel and survivors and dependents of military personnel. System data is used to conduct computer matches with various agencies in accordance with the Computer Matching and Privacy Protection Act of 1988. The proposed modification to the routine use will enable the computer match with the ED.

DATES: Comments will be accepted on or before May 16, 2019. This proposed action will be effective on the date following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal eRulemaking Portal: http://www.regulations.gov.*

Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number 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.

FOR FURTHER INFORMATION CONTACT: Ms. Luz D. Ortiz, Chief, Records, Privacy and Declassification Division (RPDD), 1155 Defense Pentagon, Washington, DC 20311–1155, or by phone at (571) 372–0478.

SUPPLEMENTARY INFORMATION: The OSD proposes to modify a system of records, Defense Manpower Data Center Data Base, DMDC 01, to enable a new Computer Matching Agreement (CMA) with the ED. Revisions to Routine Use 15 of DMDC 01 will allow for the dissemination of data per a new CMA with ED, where ED will use DoD data to identify service members that are eligible for a no interest accrual benefit on eligible Title IV of the HEA student loans during the period of time the service member received imminent danger pay or hostile fire pay.

The proposed systems reports, as required by the Privacy Act, as amended, were submitted on March 6, 2019, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to Section 6 of OMB Circular No. A–108, ''Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act,'' revised December 23, 2016 (December 23, 2016, 81 FR 94424).

Dated: April 11, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

SYSTEM NAME AND NUMBER

Defense Manpower Data Center Data Base, DMDC 01

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Naval Postgraduate School Computer Center, Naval Postgraduate School, Monterey, CA 93943–5000.

SYSTEM MANAGER(S):

Deputy Director, Defense Manpower Data Center, DoD Center Monterey Bay, 400 Gigling Road, Seaside, CA 93955–6771.

* * * * *

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

* * * * *

15. To the Department of Education to conduct computer matching programs regulated by the Privacy Act of 1974, as amended (5 U.S.C. 552a), for the purpose of:

a. Identifying dependent children of service members killed in Operation Iraqi Freedom and Operation Enduring Freedom (OIF/OEF) Afghanistan Only for possible benefits.

b. Ensuring eligibility of service members to receive the no-interest accrual benefit on their eligible student loans during the period of time the service members receive imminent danger pay or hostile fire pay, consistent with the Higher Education Act of 1965 (20 U.S.C. 1070 *et seq.*).

* * * * *

HISTORY:

March 11, 2019, 84 FR 8698; November 23, 2011, 76 FR 72391

[FR Doc. 2019–07531 Filed 4–15–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Child Care Access Means Parents in School Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2019 for the Child Care Access Means Parents in School (CCAMPIS) Program, Catalog of Federal Domestic Assistance (CFDA) number 84.335A. This notice relates to the approved information collection under OMB control number 1840–0737.

DATES:

Applications Available: April 16, 2019.

Deadline for Transmittal of Applications: May 31, 2019.

Deadline for Intergovernmental Review: July 30, 2019.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *https://www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Antoinette Clark Edwards, U.S. Department of Education, 400 Maryland Avenue SW, Room 278–50, Washington, DC 20202–4260. Telephone: (202) 453–7121. Email: *antoinette.edwards@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The CCAMPIS Program supports the participation of low-income parents in postsecondary education through the provision of campus-based child care services.

Background: Through the competitive preference priority in this competition, the Secretary seeks to encourage applicants to offer parents a variety of childcare options. For example, applicants may propose to provide student-parents with a greater range of options at which to direct their childcare funds. The grantee institution would still be responsible for fulfilling the requirements of the program, by either: (1) Proactively contracting with a select number of providers from which a parent could choose; or (2) contracting with each eligible provider selected by a parent. With access to a greater diversity of childcare settings, parents would have the opportunity to select an option that meets the unique developmental needs of their child and their own postsecondary educational needs, including with respect to transportation, work schedules, and obligations to other family members. Additionally, applicants may consider describing how their new or existing campus-based child care centers would offer flexible and affordable child care arrangements to low-income parents pursuing postsecondary education, such as part-time, drop-in, or evening child care services.

The first absolute priority requires projects to leverage local and institutional resources. The Department also encourages applicants to support student-parents in connecting with Federal and state resources that are available to help provide low-income parents with access to child care services. Applicants could also address how they have taken such resources into account when identifying the need for the project and in designing and targeting the project. We would like to note the other Federal investments in childcare, specifically the Child Care Development Block Grants that are available to help student-parents.

Priorities: This notice contains two absolute priorities, one competitive preference priority and an invitational priority. In accordance with 34 CFR 75.105(b)(2)(iv), the absolute priorities are from section 419N(d) of the Higher Education Act of 1965, as amended (HEA), 20 U.S.C. 1070e(d). The competitive preference priority is from the Final Supplemental Priorities and Definitions for Discretionary Grant Programs published on March 2, 2018 (83 FR 9096) (Supplemental Priorities).

Absolute Priorities: For FY 2019, and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3) we consider only applications that meet both priorities.

These priorities are:

Absolute Priority 1: Projects that are designed to leverage significant local or institutional resources, including in-kind contributions, to support the activities assisted under section 419N of the HEA.

Absolute Priority 2: Projects that are designed to utilize a sliding fee scale for child care services provided under section 419N of the HEA in order to support a high number of low-income parents pursuing postsecondary education at the institution.

Competitive Preference Priority: For FY 2019, and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i), we award up to an additional 5 points to an application, depending on how well the application meets this priority.

This priority is:

Projects that are designed to address increasing access to educational choice (as defined in this notice) for children in early learning settings.

Invitational Priority: For FY 2019, and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an invitational priority. Under 34 CFR 75.105(c)(1), we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

This priority is:

Spurring Investment in Opportunity Zones.

Under this priority, an applicant must—

(1) Propose to serve children or students who reside, or attend elementary or secondary schools or institutions of higher education, in a qualified opportunity zone as designated by the Secretary of the Treasury under section 1400Z–1 of the Internal Revenue Code, as amended by the Tax Cuts and Jobs Act (Pub. L. 115–97). An applicant must provide the census tract number of the qualified opportunity zone for which it proposes to serve children or students. A list of qualified opportunity zones, with census tract numbers, is available at *www.cdfifund.gov/Pages/Opportunity-Zones.aspx;* or

(2) Provide evidence in its application that it has received, or will receive, financial assistance from a qualified opportunity fund under section 1400Z–2 of the Internal Revenue Code, as amended by the Tax Cuts and Jobs Act, for a purpose directly related to its proposed project. An applicant must identify the qualified opportunity fund from which it has received or will receive financial assistance.

Definition: This definition is from the Supplemental Priorities.

Educational choice means the opportunity for a child or student (or a family member on their behalf) to create a high-quality personalized path for

learning that is consistent with applicable Federal, State, and local laws; is in an educational setting that best meets the child's or student's needs; and, where possible, incorporates evidence-based activities, strategies, or interventions. Opportunities made available to a student through a grant program are those that supplement what is provided by a child's or student's geographically assigned school or the institution in which he or she is currently enrolled and may include one or both of these options:

(1) Public educational programs or courses, including those offered by traditional public schools, public charter schools, public magnet schools, public online education providers, or other public education providers.

(2) Private or home-based educational programs or courses, including those offered by private schools, private online providers, private tutoring providers, community or faith-based organizations, or other private education providers.

Requirements: An institution of higher education desiring a grant under this competition must submit an application that—

(1) Demonstrates that the institution is an eligible institution;

(2) Specifies the amount of funds requested;

(3) Demonstrates the need of low-income students at the institution for campus-based child care services by including in the application—

(A) Information regarding student demographics;

(B) An assessment of child care capacity on or near campus;

(C) Information regarding the existence of waiting lists for existing child care;

(D) Information regarding additional needs created by concentrations of poverty or by geographic isolation; and

(E) Other relevant data;

(4) Contains a description of the activities to be assisted, including whether the grant funds will support an existing child care program or a new child care program;

(5) Identifies the resources, including technical expertise and financial support, the institution will draw upon to support the child care program and the participation of low-income students in the program, such as accessing social services funding, using student activity fees to help pay the costs of child care, using resources obtained by meeting the needs of parents who are not low-income students, and accessing foundation, corporate or other institutional support, and demonstrate that the use of the resources will not result in increases in student tuition;

(6) Contains an assurance that the institution will meet the child care needs of low-income students through the provision of services, or through a contract for the provision of services;

(7) Describes the extent to which the child care program will coordinate with the institution's early childhood education curriculum, to the extent the curriculum is available, to meet the needs of the students in the early childhood education program at the institution, and the needs of the parents and children participating in the child care program assisted under the applicant's project;

(8) In the case of an institution seeking assistance for a new child care program—

(A) Provides a timeline, covering the period from receipt of the grant through the provision of the child care services, delineating the specific steps the institution will take to achieve the goal of providing low-income students with child care services;

(B) Specifies any measures the institution will take to assist low-income students with child care during the period before the institution provides child care services; and

(C) Includes a plan for identifying resources needed for the child care services, including space in which to provide child care services, and technical assistance if necessary;

(9) Contains an assurance that any child care facility assisted under this section will meet the applicable State or local government licensing, certification, approval, or registration requirements; and

(10) Contains a plan for any child care facility assisted under this section to become accredited within three years of the date the institution first receives assistance under this section.

Program Authority: 20 U.S.C. 1070e.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The Supplemental Priorities.

Note: Because there are no program-specific regulations for the CCAMPIS Program, applicants are encouraged to carefully read the authorizing statute: title IV, part A, subpart 7, section 419N of the HEA (20 U.S.C. 1070e).

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $18,483,334.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent fiscal years from the list of unfunded applications from this competition.

Estimated Range of Awards: $30,000 to $375,000.

Estimated Average Size of Awards: $133,937.

Maximum Award: In accordance with section 419N(b)(2)(A) of the HEA, the maximum annual amount an applicant may receive under this program is one percent of the total amount of all Federal Pell Grant funds awarded to students enrolled at the institution for FY 2018. In the event that an applicant's maximum award amount is lower than the statutory minimum award of $30,000, the grant will be $30,000 for a single budget period of 12 months.

Estimated Number of Awards: 138.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 48 months.

III. Eligibility Information

1. *Eligible Applicants:* Institutions of higher education that awarded a total of $250,000 or more of Federal Pell Grant funds during FY 2018 to students enrolled at the institution.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

IV. Application and Submission Information

1. *Application Submission Instructions:* For information on how to submit an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *https://www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

2. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal

Programs under Executive Order 12372 is in the application package for this program.

3. *Funding Restrictions:* Funding restrictions are outlined in section 419N(b)(2)(B) of the HEA. We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative, Part III of the application, is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative, which includes the budget narrative, to no more than 50 pages and (2) use the following standards:

- A ''page'' is 8.5″ × 11″, on one side only, with 1″ margins.
- Double-space all text in the application narrative, and single-space titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a 12-point font.
- Use an easily readable font such as Times New Roman, Courier, Courier New, or Arial.

The recommended 50-page limit does not apply to Part I, the Application for Federal Assistance cover sheet (SF 424); Part II, the Budget Information Summary form (ED Form 524); Part III, the CCAMPIS Program Profile form and the one-page Project Abstract form; or Part IV, the assurances and certifications. The recommended page limit also does not apply to a table of contents, which you should include in the application narrative. You must include your complete response to the selection criteria in the application narrative.

Note: Applications that do not follow the page limit and formatting recommendations will not be penalized.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from section 419N of the HEA and the Department's regulations at 34 CFR 75.210 and are listed below.

We will award up to 100 points to an application under the selection criteria and up to 5 additional points to an application under the competitive preference priority, for a total score of up to 105 points. The maximum number of points available for each criterion is indicated in parentheses.

(a) *Need for the project.* (30 points)

In determining the need for the proposed project, the Secretary considers the extent to which the applicant demonstrates, in its application, the need for campus-based child care services for low-income students at the institution by including the following (see section 419N(c)(3) of the HEA):

(i) Information regarding student demographics.

(ii) An assessment of child care capacity on or near campus.

(iii) Information regarding the existence of waiting lists for existing child care.

(iv) Information regarding additional needs created by concentrations of poverty or by geographic isolation.

(v) Other relevant data.

(b) *Quality of project design.* (25 points)

In determining the quality of the design of the proposed project, the Secretary considers the following:

(i) The extent to which the applicant describes in its application the activities to be assisted, including whether the grant funds will support an existing child care program or a new child care program (see section 419N(c)(4) of the HEA).

(ii) The extent to which the services to be provided by the proposed project are focused on those with the greatest needs (see 34 CFR 75.210(d)(3)(xi)).

Note: For consistency in scoring applications, readers of applications will be instructed to include, in their assessment of focus on service of those with the greatest needs, the extent to which services are available during all hours that classes are in session, including evenings and weekends, to part-time students and to students who need only emergency drop-in child care in the event that regularly scheduled child care is unexpectedly unavailable.

(iii) The likely impact of the services to be provided by the proposed project on the intended recipients of those services (see 34 CFR 75.210(d)(3)(iv)).

(iv) Whether the application includes an assurance that the institution will meet the child care needs of low-income students through the provision of services, or through a contract for the provision of services (see section 419N(c)(6) of the HEA).

(v) The extent to which the child care program will coordinate with the institution's early childhood education curriculum, to the extent the curriculum is available, to meet the needs of the students in the early childhood education program at the institution, and the needs of the parents and children participating in the child care program assisted under this section (see section 419N(c)(7) of the HEA).

(vi) The extent to which the proposed project encourages parental involvement (see 34 CFR 75.210(c)(2)(xix)).

(vii) If the applicant is requesting grant assistance for a new child care program (see section 419N(c)(8) of the HEA)—

(1) Whether the applicant provides in its application a timeline, covering the period from receipt of the grant through the provision of the child care services, delineating the specific steps the institution will take to achieve the goal of providing low-income students with child care services;

(2) The extent to which the applicant specifies in its application the measures the institution will take to assist low-income students with child care during the period before the institution provides child care services; and

(3) The extent to which the application includes a plan for identifying resources needed for the child care services, including space in which to provide child care services and technical assistance if necessary.

(c) *Quality of management plan.* (25 points)

In determining the quality of the management plan for the proposed project, the Secretary considers the following:

(i) The extent to which the application includes a management plan that describes the resources, including technical expertise and financial support, the institution will draw upon to support the child care program and the participation of low-income students in the program, such as accessing social services funding, using student activity fees to help pay the costs of child care, using resources obtained by meeting the needs of parents who are not low-income students, and accessing foundation, corporate or other institutional support, and demonstrates that the use of the resources will not result in increases in student tuition (see section 419N(c)(5) of the HEA).

(ii) The qualifications, including relevant training and experience, of key project personnel (see 34 CFR 75.210(e)(3)(ii)).

(iii) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (see 34 CFR 75.210(g)(2)(i)).

(d) *Quality of project evaluation.* (15 points)

In determining the quality of the project evaluation, the Secretary considers the following:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and

outcomes of the proposed project (see 34 CFR 75.210(h)(2)(i)).

(ii) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible (see 34 CFR 75.210(h)(2)(iv)).

(iii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes (see 34 CFR 75.210(h)(2)(vi)).

(e) *Adequacy of resources.* (5 points)

In determining the adequacy of resources for the proposed project, the Secretary considers the following:

(i) The extent to which the budget is adequate to support the proposed project (see 34 CFR 75.210(f)(2)(iii)).

(ii) The extent to which the costs are reasonable in relation to the number of persons to be served and to the anticipated results and benefits (see 34 CFR 75.210(f)(2)(v)).

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

For this competition, a panel of non-Federal readers will review each application in accordance with the selection criteria, consistent with 34 CFR 75.217. The individual scores of the reviewers will be added and the sum divided by the number of reviewers to determine the peer review score received in the review process.

If there are insufficient funds for all applications with the same total scores, the Secretary will choose among the tied applications so as to serve geographical areas that have been underserved by the CCAMPIS Program.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition, the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.205(a)(2), we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we will notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we will notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* The success of the CCAMPIS Program will be measured by the postsecondary persistence and degree completion rates of the CCAMPIS Program participants.

All CCAMPIS Program grantees will be required to submit an annual performance report documenting the persistence and degree attainment of their participants. Since students may take different lengths of time to complete their degrees, multiple years of performance report data are needed to determine the degree completion rates of CCAMPIS Program participants. The Department will aggregate the data provided in the annual performance reports from all grantees to determine the accomplishment level.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at: *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: April 10, 2019.

Diane Auer Jones,

Principal Deputy Under Secretary Delegated To Perform the Duties of Under Secretary and Assistant Secretary for the Office of Postsecondary Education.

[FR Doc. 2019–07579 Filed 4–15–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[Certification Notice–255]

Notice of Filing of Self-Certification of Coal Capability Under the Powerplant and Industrial Fuel Use Act

AGENCY: Office of Electricity, DOE.

ACTION: Notice of filing.

SUMMARY: On April 1, 2019, Cricket Valley Energy Center, LLC (CVEC), as owner and operator of a new baseload power plant, the Cricket Valley Energy Project (Project), submitted a coal capability self-certification to the Department of Energy (DOE). The Powerplant and Industrial Fuel Use Act of 1978, as amended, and regulations thereunder require DOE to publish a notice of filing of self-certification in the **Federal Register**.

ADDRESSES: Copies of coal capability self-certification filings are available for public inspection, upon request, in the Office of Electricity, Mail Code OE–20, Room 8G–024, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Christopher Lawrence at (202) 586–5260.

SUPPLEMENTARY INFORMATION: On April 1, 2019, CVEC, as owner and operator of a new baseload power plant, submitted a coal capability self-certification to the Department of Energy (DOE) pursuant to section 201(d) of the Powerplant and Industrial Fuel Use Act of 1978 (FUA), as amended (42 U.S.C. 8311(d)), and DOE regulations at 10 CFR 501.61(a). The FUA and regulations thereunder require DOE to publish a notice of filing of self-certification in the **Federal Register** within fifteen days. 42 U.S.C. 8311(d)(1); 10 CFR 501.61(c). Section 201(a) of the FUA provides that ''no new electric powerplant may be constructed or operated as a base load powerplant without the capability to use coal or another alternate fuel as a primary energy source.'' 42 U.S.C. 8311(a). Pursuant to section 201(d) of the FUA, in order to meet the requirement of coal capability, the owner or operator of such a facility proposing to use natural gas or petroleum as its primary energy source must certify to the Secretary of Energy (Secretary), prior to construction or prior to operation as a baseload powerplant, that such powerplant has the capability to use coal or another alternate fuel. *See* 42 U.S.C. 8311(d)(1). Such certification establishes compliance with FUA section 201(a) as of the date it is filed with the Secretary. *Id.;* 10 CFR 501.61(b).

The following owner of a proposed new baseload electric generating powerplant has filed a self-certification of coal-capability with DOE pursuant to FUA section 201(d) and in accordance with DOE regulations at 10 CFR 501.61:

Owner: Cricket Valley Energy Center, LLC.

Design Capacity: 1,020 megawatts (MW).

Plant Location: Dover Plains, NY 12522.

In-Service Date: January 31, 2020.

Signed in Washington, DC on April 10, 2019.

Christopher Lawrence,

Program Management Analyst, Office of Electricity.

[FR Doc. 2019–07549 Filed 4–15–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

National Coal Council

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of open meetings.

SUMMARY: This notice announces a virtual meeting of the National Coal Council (NCC) via WebEx. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, May 15, 2019 11:30 a.m. to 12:15 p.m. EST.

ADDRESSES: This will be virtual meeting conducted through WebEx. If you wish to join the meeting you must register by close of business (5 p.m. EST) on Friday, May 10th by using the form available at the following URL: *http://www.nationalcoalcouncil.org/page-NCC-Events.html.* The email address you provide in the on-line registration form will be used to forward instructions on how to join the meeting using WebEx. WebEx requires a computer, web browser and an installed application (free). Instructions for joining the webcast will be sent to you two days in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Thomas Sarkus, National Energy Technology Laboratory, U.S. Department of Energy, Mail Stop 920–

125, 626 Cochrans Mill Road, Pittsburgh, PA 15236–0940; Telephone 412–386–5981 *thomas.sarkus@netl.doe.gov*

SUPPLEMENTARY INFORMATION:

Purpose of the Council: The National Coal Council provides advice and recommendations to the Secretary of Energy on general policy matters relating to coal and the coal industry.

Purpose of Meeting: The National Coal Council (the Council) will hold a virtual meeting via webcast at 11:30 a.m.–12:15 p.m. (EST) on May 15th, 2019 for the sole purpose of reviewing and voting on the following report: ''Coal in a New Carbon Age: Powering a Wave of Innovation in Advanced Products and Manufacturing.'' The Council membership will be asked to accept this report and forward it to the U.S. Secretary of Energy. The draft report is available on the National Coal Council website at the following URL: *http://www.nationalcoalcouncil.org/page-NCC-Studies.html.*

Tentative Agenda:

- Call to order by Thomas Sarkus, NCC Deputy Designated Federal Officer, Division Director Major Projects, National Energy Technology Laboratory, U.S. Department of Energy.
- NCC Report Presentation on ''Coal in a New Carbon Age: Powering a Wave of Innovation in Advanced Products and Manufacturing'' by report chairs Randall Atkins, Chairman and Chief Executive, Ramaco Carbon.
- Public Comment Period & Closing Remarks.
- Adjourn.

All attendees are requested to register in advance for the meeting at: *http://www.nationalcoalcouncil.org/page-NCC-Events.html.*

Public Participation: The meeting is open to the public. If you would like to file a written statement to be read during the virtual webcast, you may do so within five calendar days of the event. Please email your written statement to Thomas Sarkus at *thomas.sarkus@netl.doe.gov* by 5 p.m. EST on Friday, May 10th. If you would like to make an oral statement during the call regarding the reports being reviewed, you must both register to attend the webcast and also contact Thomas Sarkus 412–386–5981 or *thomas.sarkus@netl.doe.gov* to state your desire to speak. You must make your request for an oral statement by 5 p.m. (EST) on Friday, May 10th. Reasonable provision will be made to include oral statements at the conclusion of the meeting. However, those who fail to register in advance may not be accommodated. Oral statements are limited to 5-minutes per organization and per person.

Minutes: A recording of the call will be posted on the FACA Database website: *https://facadatabase.gov/committee/historymeetings.aspx?cid=408&fy=2017.*

Signed in Washington, DC on April 11, 2019.

Antoinette M. Watkins,

Acting Deputy Committee Management Officer.

[FR Doc. 2019–07556 Filed 4–15–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14633–001]

New England Hydropower Company, LLC; Notice of Application Accepted for Filing, and Soliciting Motions To Intervene and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Exemption From Licensing.

b. *Project No.:* 14633–001.

c. *Date filed:* October 1, 2018.

d. *Applicant:* New England Hydropower Company, LLC (NEHC).

e. *Name of Project:* Albion Dam Hydroelectric Project.

f. *Location:* On the Blackstone River, near the Towns of Cumberland and Lincoln, Providence County, Rhode Island. No federal or tribal lands would be occupied by project works or located within the project boundary.

g. *Filed Pursuant to:* Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 2705, 2708 (2012), *amended by* the Hydropower Regulatory Efficiency Act of 2013, Public Law 113–23, 127 Stat. 493 (2013).

h. *Applicant Contact:* Michael C. Kerr, 100 Cummings Center, Suite 451C, Beverly, MA 01915; (978) 360–2547 or email at *Michael@neydropower.com.*

i. *FERC Contact:* Patrick Crile, (202) 502–8042, or email at *Patrick.Crile@ferc.gov.*

j. *Deadline for filing motions to intervene and protests:* 60 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, 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–14633–001.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor 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.

k. This application has been accepted for filing, but is not ready for environmental analysis at this time.

l. The proposed Albion Dam Hydroelectric Project would consist of: (1) An approximately 266-foot-long existing concrete gravity dam with an ogee spillway; (2) an existing 20.4-acre impoundment with a normal storage capacity of 235 acre-feet at an operating elevation of approximately 87.0 feet North American Vertical Datum of 1988; (3) a new 51-foot-long, 45.75-foot-wide intake canal; (4) two new 14-foot-wide, 10.4-foot-high hydraulically-powered sluice gates, each equipped with a 15-foot-wide, 9.7-foot-high steel trashrack with 9-inch clear-bar spacing; (5) two new 30-foot-long, 15-foot-wide, 9.7-foot-high concrete penstocks; (6) a new 50-foot-long, 24-foot-wide, 18-foot-high concrete powerhouse containing two 210-kilowatt (kW) Archimedes Screw turbine-generator units, for a total installed capacity of 420 kW; (7) a new 50-foot-long concrete tailrace; (8) a new step-up transformer and 500-foot-long, above-ground transmission line connecting the project to the distribution system owned by the Narragansett Electric Company; (9) a new access road; and (10) appurtenant facilities. The existing Albion Dam and appurtenant works are owned by the State of Rhode Island.

NEHC proposes to operate the project in a run-of-river mode with an estimated annual energy production of approximately 2,034 megawatt-hours.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website 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 Online Support. A copy is also available

for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified intervention deadline date, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified intervention deadline date. Applications for preliminary permits will not be accepted in response to this notice.

A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit a development application. A notice of intent must be served on the applicant(s) named in this public notice.

Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests 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 protests or motions to intervene must be received on or before the specified deadline date for the particular application.

All filings must (1) bear in all capital letters the title ''PROTEST'', ''MOTION TO INTERVENE,'' ''NOTICE OF INTENT TO FILE COMPETING APPLICATION,'' or ''COMPETING APPLICATION;'' (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. 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.

o. Waiver of Pre-filing Consultation: Based on a review of the application, resource agency consultation letters, and comments filed to date, we accept the consultation that has occurred on this project as satisfying our requirements for the standard 3-stage consultation process under 18 CFR 4.38, and are waiving the requirement to conduct second stage consultation pursuant to section 4.38(c)(4) of the regulations, as requested by NEHC.

Dated: April 10, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–07534 Filed 4–15–19; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2018–0305, FRL- 9991–77–OLEM]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Applicants Requesting To Treat/Dispose of PCBs Using Incineration or an Alternative Method

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit a new information collection request (ICR) for Guidance for Applicants Requesting to Treat/Dispose of PCBs Using Incineration or an Alternative Method (EPA ICR No. 2596.01, OMB Control No. 2050–NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, the EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a request of a new collection. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before June 17, 2019.

ADDRESSES: Submit your comments, referencing by Docket ID No. EPA–HQ–OLEM–2018–0305, online using *www.regulations.gov* (our preferred method), by email to *rcra-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Josh Smeraldi, Office of Resource Conservation and Recovery (Mail Code 5303P), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 703–308–0441; email address: *smeraldi.josh@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to: (i) 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; (ii) 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; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, the EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Guidance documents were developed in 1986 for persons applying to EPA for approval to dispose of PCBs using incineration (§ 761.70) or a method alternative to incineration (§ 761.60(e)). The guidances are split into two document (thermal and non-thermal) and they present and discuss the format, content, and suggested level

of detail for approval applications, test plans, and test reports.

EPA is currently updating these guidance documents and will combine into a single document. This is a new Information Collection Request (ICR) that addresses reporting and recordkeeping requirements found in the updated guidance document identified above. The previous guidance documents released in 1986 were not required to conduct an ICR so a new ICR will be created for the updated guidance. While use of the updated guidance document is voluntary, the PRA still requires the reporting and recordkeeping of this guidance to be determined. This includes reading and using the tables provided in the guidance.

The overall reporting and recordkeeping requirements of a §§ 761.60(e) and 761.70 approval is reported in a separate ICR, ICR No.1446.12 (PCBs, Consolidated Reporting and Recordkeeping Requirements found in docket EPA–HQ–2017–0647). Although this ICR (2596.01) includes a burden increase in terms of reviewing and using the guidance document, EPA notes that the guidance will *reduce* the overall burden in ICR 1446.12 to respondents applying for a PCB disposal approval under §§ 761.60(e) and 761.70 through improved clarification and streamlining of the approval process.

Form Numbers: None.

Respondents/affected entities: Entities potentially affected by this ICR include respondents applying to the EPA for approval to treat/dispose PCBs using incinerator or an alternative method. This likely includes entities within the Waste Management and Remediation Services (NAICS 562) and Professional, Scientific, and Technical Services (NAICS 54) sectors and includes private entities.

Respondent's obligation to respond: Voluntary, for use in applying to EPA for approval under §§ 761.60(e) or 761.70.

Estimated number of respondents: Estimated eight respondents annually.

Frequency of response: As needed and desired by the respondent in applying to EPA for approval under §§ 761.60(e) or 761.70.

Total estimated burden: Burden is defined at 5 CFR 1320.03(b). The total estimated annual burden on applicants using the guidance is 9.9 hours per applicant.

Total estimated cost: The total estimated annualized labor costs for applicants using the guidance is $776 per applicant. The annualized capital and O&M costs are $0.

Dated: April 10, 2019.

Barnes Johnson,

Director, Office of Resource Conservation and Recovery.

[FR Doc. 2019–07567 Filed 4–15–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9992–16–OA]

National Environmental Education Advisory Council

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Under the Federal Advisory Committee Act, EPA gives notice of a teleconference meeting of the National Environmental Education Advisory Council (NEEAC). The NEEAC was created by Congress to advise, consult with, and make recommendations to the Administrator of the Environmental Protection Agency (EPA) on matters related to activities, functions and policies of EPA under the National Environmental Education Act (the Act).

The purpose of this meeting is to discuss specific topics of relevance for consideration by the council to provide advice and insights to the Agency on environmental education.

DATES: The National Environmental Education Advisory Council will hold a public meeting on Tuesday, June 11, 2019 and Wednesday June 12, 2019, from 9 a.m. until 4:30 p.m. Central Standard Time. The meeting will be held at: U.S. EPA Region 7, 11201 Renner Boulevard, Lenexa, KS 66209 (Lakeview Conference Room), 2.B–C.32.

FOR FURTHER INFORMATION CONTACT: Javier Araujo, Designated Federal Officer, *araujo.javier@epa.gov,* 202–564–2642, U.S. EPA, Office of Environmental Education, William Jefferson Clinton North Room, 1426, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

SUPPLEMENTARY INFORMATION: Members of the public wishing to gain access to the teleconference, make brief oral comments, or provide a written statement to the NEEAC must contact Javier Araujo, Designated Federal Officer, at *araujo.javier@epa.gov* or 202–564–2642 by 10 business days prior to each regularly scheduled meeting.

Meeting Access: For information on access or services for individuals with disabilities or to request accommodations, please contact Javier Araujo at *araujo.javier@epa.gov* or 202–564–2642, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: April 3, 2019.

Elizabeth (Tate) Bennett,

Associate Administrator, Office of Public Engagement and Environmental Education.

Javier Araujo,

(NEEAC) Designated Federal Officer.

[FR Doc. 2019–07572 Filed 4–15–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9991–87–OP]

National Environmental Justice Advisory Council; Notification of Public Meeting With Teleconference Option and Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), the U.S. Environmental Protection Agency (EPA) hereby provides notice that the National Environmental Justice Advisory Council (NEJAC) will meet on the dates and times described below. All meetings are open to the public. Members of the public are encouraged to provide comments relevant to the specific issues being considered by the NEJAC. For additional information about registering to attend the meeting or to provide public comment, please see ''REGISTRATION'' under **SUPPLEMENTARY INFORMATION**. Due to a limited space, seating at the NEJAC meeting will be on a first-come, first served basis. Pre-registration is highly suggested.

DATES: The NEJAC will convene a public meeting with a teleconference option beginning on Tuesday, April 30, 2019, starting at 6 p.m., Eastern Time. The NEJAC meeting will continue May 1–2, 2019, from 9 a.m. until 5 p.m., Eastern Time. The meeting discussion will focus on several topics including, but not limited to, EPA program offices providing updates on their efforts to integrate environmental justice into their programs and the discussion and deliberation of a charge to provide recommendations on the reuse and revitalization of Superfund and other contaminated sites. One public comment period relevant to the specific issues being considered by the NEJAC (see **SUPPLEMENTARY INFORMATION**) is scheduled for Tuesday, April 30, 2019, starting at 6 p.m., Eastern Time. Members of the public who wish to

participate during the public comment period are highly encouraged to pre-register by 11:59 p.m., Eastern Time on Sunday, April 21, 2019.

ADDRESSES: The NEJAC meeting will be held at the Hyatt Regency Bethesda, 7400 Wisconsin Ave., Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT: Questions or correspondence concerning the public meeting should be directed to Karen L. Martin, U.S. Environmental Protection Agency, by mail at 1200 Pennsylvania Avenue NW (MC2202A), Washington, DC 20460, by telephone at 202–564–0203, or email at *nejac@epa.gov.* Additional information about the NEJAC is available at *https://www.epa.gov/environmentaljustice/national-environmental-justice-advisory-council.*

SUPPLEMENTARY INFORMATION: The Charter of the NEJAC states that the advisory committee ''will provide independent advice and recommendations to the Administrator about broad, crosscutting issues related to environmental justice. The NEJAC's efforts will include evaluation of a broad range of strategic, scientific, technological, regulatory, community engagement and economic issues related to environmental justice.''

Registration: Registration for the April 30–May 02, 2019, public meeting will be processed at *https://nejac-public-meeting-april-2019.eventbrite.com.* Pre-registration is highly suggested. Registration for the April 30–May 02, 2019, public meeting teleconference option will be processed at *https://nejac-public-teleconference-meeting-april-2019.eventbrite.com.* Pre-registration is required. Registration for the April 30–May 2, 2019, meeting closes at 11:59 p.m., Eastern Time on Sunday, April 21, 2019. The deadline to sign up to speak during the public comment period, or to submit written public comments, is 11:59 p.m., Eastern Time on Sunday, April 21, 2019. When registering, please provide your name, organization, city and state, email address, and telephone number for follow up. Please also indicate whether you would like to provide public comment during the meeting, and whether you are submitting written comments before the Sunday, April 21, 2019, deadline.

A. Public Comment

Individuals or groups making remarks during the public comment period will be limited to seven (7) minutes. To accommodate the number of people who want to address the NEJAC, only one representative of a particular community, organization, or group will be allowed to speak. Written comments can also be submitted for the record. The suggested format for individuals providing public comments is as follows: Name of speaker; name of organization/community; city and state; and email address; brief description of the concern, and what you want the NEJAC to advise EPA to do. Written comments received by registration deadline, will be included in the materials distributed to the NEJAC prior to the teleconference. Written comments received after that time will be provided to the NEJAC as time allows. All written comments should be sent to Karen L. Martin, EPA, via email at *nejac@epa.gov.*

B. Information About Services for Individuals With Disabilities or Requiring English Language Translation Assistance

For information about access or services for individuals requiring assistance, please contact Karen L. Martin, at (202) 564–0203 or via email at *nejac@epa.gov.* To request special accommodations for a disability or other assistance, please submit your request at least fourteen (14) working days prior to the meeting, to give EPA sufficient time to process your request. All requests should be sent to the address, email, or phone number listed in the **FOR FURTHER INFORMATION CONTACT** section.

Dated: March 26, 2019.

Matthew Tejada,

Director for the Office of Environmental Justice.

[FR Doc. 2019–07568 Filed 4–15–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (''Act'') (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than May 2, 2019.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. J*ody J. Petrie, Carmel, Indiana, through joint ownership and as trustee of the Julia L. Petrie Irrevocable GST Trust 2010, the Emily J. Petrie Irrevocable GST Trust 2010, the Julia L. Petrie Irrevocable Trust 2010, and the Emily J. Petrie Irrevocable Trust 2010, individually, and as a group acting in concert with the Julia L. Petrie Irrevocable GST Trust 2010, the Emily J. Petrie Irrevocable GST Trust 2010, the Julia L. Petrie Irrevocable Trust 2010, and the Emily J. Petrie Irrevocable Trust 2010, John H. Petrie, Carmel, Indiana, Claranna Petrie and Robert G. Negrete, both of Henderson, Nevada, Conradine Riedel, Knoxville, Tennessee, George A. Petrie and Cristina P. Petrie, both of Tampa, Florida, and Matthew E. Kaercher, Carmel, Indiana;* to retain voting shares of Merchants Bancorp, Carmel, Indiana, and thereby indirectly retain shares of Merchants Bank of Indiana, Carmel, Indiana, and Farmers-Merchants Bank of Illinois, Joy, Illinois.

2. C*arey Rogers Kulongoski, Portland, Oregon, Randall D. Rogers, Jr., Indianapolis, Indiana, Katherine H. Rogers, Sedona, Arizona, the Katherine H. Rogers Irrevocable GST Trust 2011, the Carey Rogers Kulongoski Irrevocable GST Trust 2011, the Randall D. Rogers, Jr. Irrevocable GST Trust 2011, and Mary H. Rogers, Vero Beach, Florida, as trustee of the Katherine H. Rogers Irrevocable GST Trust 2011, the Carey Rogers Kulongoski Irrevocable GST Trust 2011, and the Randall D. Rogers, Jr. Irrevocable GST Trust 2011;* to retain voting shares of Merchants Bancorp, Carmel, Indiana, and thereby indirectly retain shares of Merchants Bank of Indiana, Carmel, Indiana, and Farmers-Merchants Bank of Illinois, Joy, Illinois.

B. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *The Linda Mitchell Bank Stock Trust, Wellington, Texas, to join the Holton Family Group, a group acting in concert;* to retain voting shares of WSB Bancshares, Inc., and indirectly retain shares of Wellington State Bank, both of Wellington, Texas.

Board of Governors of the Federal Reserve System, April 11, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–07558 Filed 4–15–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10330, CMS–276, and CMS–906]

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 May 16, 2019.

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.*

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

2. 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:* Extension of a currently approved collection; *Title of Information Collection:* Enrollment Opportunity Notice Relating to Lifetime Limits; Required Notice of Rescission of Coverage; and Disclosure Requirements for Patient Protection under the Affordable Care Act; *Use:* Sections 2712 and 2719A of the Public Health Service Act, as added by the Affordable Care Act, and the interim final regulations titled ''Patient Protection and Affordable Care Act: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections'' (75 FR 37188, June 28, 2010) contain rescission notice, and patient protection disclosure requirements that are subject to the Paperwork Reduction Act of 1995. The rescission notice will be used by health plans to provide advance notice to certain individuals that their coverage may be rescinded as a result of fraud or intentional misrepresentation of material fact. The patient protection notification will be used by health plans to inform certain individuals of their right to choose a primary care provider or pediatrician and to use obstetrical/gynecological services without prior authorization. The related provisions are finalized in the final regulations titled ''Final Rules under the Affordable Care Act for Grandfathered Plans, Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Dependent Coverage, Appeals, and Patient Protections''. The final regulations also require that, if State law prohibits balance billing, or a plan or issuer is contractually responsible for any amounts balanced billed by an out-of-network emergency services provider, a plan or issuer must provide a participant, beneficiary or enrollee adequate and prominent notice of their lack of financial responsibility with respect to amounts balanced billed in order to prevent inadvertent payment by the individual. *Form Number:* CMS–10330 (OMB Control Number: 0938–1094); *Frequency:* Occasionally; *Affected Public:* Private Sector, State, Local, or Tribal Governments; *Number of Respondents:* 920; *Number of Responses:* 71,268; *Total Annual Hours:* 524. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410–786–6650.)

2. Type of Information Collection Request: Revision of a currently approved information collection; *Title of Information Collection:* Prepaid Health Plan Cost Report; *Use:* Health Maintenance Organizations and Competitive Medical Plans (HMO/CMPs) contracting with the Secretary under Section 1876 of the Social Security Act are required to submit a budget and enrollment forecast, semi-annual interim report, 4th Quarter interim report (CMS has waived this annual submission), and a final certified cost report in accordance with 42 CFR 417.572–417.576. The submission, receipt and processing of the cost reports is imperative to determine if MCOs are paid on a reasonable basis for the covered services furnished to Medicare enrollees. CMS reviews the data submitted within the cost reports to establish monthly payment rates, monitor interim rates, and determine the final reimbursement. Health Care Prepayment Plans (HCPPs) contracting with the Secretary under Section 1833 of the Social Security Act are required to submit a budget and enrollment forecast, semi-annual interim report, and final cost report in accordance with 42 CFR 417.808 and 42 CFR 417.810. *Form Number:* CMS–276 (OMB control number: 0938–0165); *Frequency:* Quarterly; *Affected Public:* Businesses or other for-profits, Not-for-profit institutions; *Number of Respondents:* 57; *Total Annual Responses:* 67; *Total Annual Hours:* 1,800. (For policy

questions regarding this collection, contact Bilal Farrakh at 410–786–4456.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* The Fiscal Soundness Reporting Requirements; *Use:* All contracting organizations must submit audited annual financial statements one time per year. In addition, to the audited annual submission, Health Plans with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth must file quarterly financial statements for fiscal soundness monitoring. Part D organizations are required to submit three (3) quarterly financial statements. Lastly, PACE organizations are required to file four (4) quarterly financial statements for the first three (3) years in the program. After the first three (3) years, PACE organizations with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth must submit quarterly financial statements for fiscal soundness monitoring. CMS is responsible for overseeing the ongoing financial performance for all Medicare Health Plans, PDPs, and PACE organizations. Specifically, CMS needs the requested information collected in order to establish that contracting entities within those programs maintain fiscally sound operations. *Form Number:* CMS–906 (OMB control number: 0938–0469); *Frequency:* Yearly; *Affected Public:* Business or other for-profits, Not-for profits institutions; *Number of Respondents:* 767; *Total Annual Responses:* 1589; *Total Annual Hours:* 530. (For policy questions regarding this collection contact Christa Zalewski at 410–786–1971.)

Dated: April 11, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–07581 Filed 4–15–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10630]

Agency Information Collection Activities: Proposed Collection; Extension of Comment Period

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Agency information collection activities: Proposed collection; comment request; extension of comment period.

SUMMARY: This notice extends the comment period for a 60-day notice request for proposed information collection request associated with the notice [Document Identifier: CMS–10630] entitled ''Programs of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol'' that was published in the March 15, 2019 (84 FR 9526) **Federal Register**. The comment period for the information collection request, which would have ended on May 14, 2019, is extended to May 28, 2019.

DATES: The comment period for the information collection request published in the March 15, 2019, **Federal Register** (84 FR 9526) is extended to May 28, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

In the FR Doc. 2019–04895 of March 15, 2019 (84 FR 9526), we published a Paperwork Reduction Act notice requesting a 60-day public comment period for the document entitled ''Programs of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol''. There were technical delays with making the information collection request publicly available; therefore, in this notice we are extending the comment period from the date originally listed in the March 15, 2019, notice.

Dated: April 10, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–07474 Filed 4–15–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–1728–19]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by June 17, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and

recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–1728–19 Home Health Agency Cost Report

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Home Health Agency Cost Report; *Use:* Under the authority of sections 1815(a) and 1833(e) of the Social Security Act (42 U.S.C. 1395g), CMS requires that providers of services participating in the Medicare program submit information to determine costs for health care services rendered to Medicare beneficiaries. CMS requires that providers follow reasonable cost principles under 1861(v)(1)(A) of the Act when completing the Medicare cost report. Under the regulations at 42 CFR 413.20 and 413.24, CMS defines adequate cost data and requires cost reports from providers on an annual basis. The Form CMS–1728–19 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or from a provider. The Form CMS–1728–19 cost report is also used for annual rate setting and payment refinement activities, including developing a home health market basket. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the home health cost report data to calculate Medicare margins, to formulate recommendations to Congress regarding the HHA PPS, and to conduct additional analysis of the HHA PPS. Providers receiving Medicare reimbursement must provide adequate cost data based on financial and statistical records that can be verified by qualified auditors. *Form Number:* CMS–1728–19 (OMB control number: 0938–0022); *Frequency:* Yearly; *Affected Public:* Business or Other for-Profits, Not-for-Profit Institutions; *Number of Respondents:* 10,196; *Total Annual Responses:* 10,196; *Total Annual Hours:* 1,988,220. (For policy questions regarding this collection contact LuAnn Piccione at 410–786–5423.)

Dated: April 10, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–07500 Filed 4–15–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–P–0015A and CMS–10694]

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 *May 16, 2019.*

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.*

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

2. 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 with change of a previously approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey; *Use:* The Medicare Current Beneficiary Survey (MCBS) is the most comprehensive and complete survey available on the Medicare population and is essential in capturing data not otherwise collected through our operations. The MCBS is an in-person, nationally-representative, longitudinal survey of Medicare beneficiaries that we sponsor and is directed by the Office of Enterprise Data and Analytics (OEDA). The survey captures beneficiary information whether aged or disabled, living in the community or facility, or serviced by managed care or fee-for-service. Data produced as part of the MCBS are enhanced with our administrative data (*e.g.* fee-for-service claims, prescription drug event data, enrollment, etc.) to provide users with more accurate and complete estimates of total health care costs and utilization. The MCBS has been continuously fielded for more than 26 years, encompassing over 1 million interviews and more than 100,000 survey participants. Respondents participate in up to 11 interviews over a four year period. This gives a comprehensive picture of health care costs and utilization over a period of time. *Form Number:* CMS- P–0015A (OMB control number 0938–0568); *Frequency:* Occasionally; *Affected Public:* State, Local, and Tribal Governments; *Number of Respondents:* 13,656; *Total Annual Responses:* 35,998; *Total Annual Hours:* 42,610. (For policy questions regarding this collection contact William S. Long at 410.786.7927.)

2. Information Collection Request: New collection; *Title of Information Collection:* Testing of Web Survey Design and Administration for CMS Experience of Care Surveys; *Use:* This collection is a new generic clearance request which encompasses an array of research activities to add web administration protocols to a series of surveys conducted by the Centers for Medicare & Medicaid Services (CMS). This request seeks burden hours to allow CMS and its contractors to conduct cognitive in-depth interviews, focus groups, pilot tests, and usability studies to support a variety of methodological studies around web modes of data collection for programs such as the Emergency Department Experience of Care (EDPEC), Fee-for-Service (FFS) Consumer Assessment of Healthcare Providers and Systems (CAHPS), Hospital CAHPS (HCAHPS), Medicare Advantage and Prescription Drug (MA & PDP) CAHPS, Home Health (HH) CAHPS, Hospice CAHPS, In-Center Hemodialysis (ICH) CAHPS, the Health Outcomes Survey (HOS), and the Medicare Advantage and Part D Plan Disenrollment Reasons surveys. *Form Number:* CMS–10694 (OMB control number 0938-New); *Frequency:* Occasionally; *Affected Public:* State, Local, and Tribal Governments; *Number of Respondents:* 75,250; *Total Annual Responses:* 75,250; *Total Annual Hours:* 17,000. (For policy questions regarding this collection contact Elizabeth H.Goldstein at 410–786–6665.)

Dated: April 10, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–07493 Filed 4–15–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–1450]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by June 17, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the

proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–1045 Medicare Uniform Institutional Provider Bill and Supporting Regulations in 42 CFR 424.5

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Uniform Institutional Provider Bill and Supporting Regulations in 42 CFR 424.5; *Use:* Section 42 CFR 424.5(a)(5) requires providers of services to submit a claim for payment prior to any Medicare reimbursement. Charges billed are coded by revenue codes. The bill specifies diagnoses according to the International Classification of Diseases, Tenth Edition (ICD–10) code. Inpatient procedures are identified by ICD–10 codes, and outpatient procedures are described using the CMS Common Procedure Coding System (HCPCS). These are standard systems of identification for all major health insurance claims payers. Submission of information on the UB–04 CMS–1450 permits Medicare Part A MACs to receive consistent data for proper payment. Medicare receives over 99.97 percent of the claims submitted by institutional providers electronically. CMS only accepts electronic claims in the Accredited Standards Committee (ASC) Health Insurance Portability and Accountability Act (HIPAA) 837 format for institutional providers unless the provider meets CMS requirements to submit paper claims. With the uniform bill, we have been able to achieve a more uniform and a more automated bill processing system for Medicare institutional and providers. The UB–04 CMS–1450 is managed by the National Uniform Billing Committee (NUBC), sponsored by the American Hospital Association. Most payers are represented on this body, and the UB–04 is widely used in the industry. Medicare Part A MACs use the information on the UB–04 CMS–1450 to determine whether to make Medicare payment for the services provided, the payment amount, and whether or not to apply deductibles to the claim. The same method is also used by other payers. CMS is also a secondary user of data. CMS uses the information to develop a database, which is used to update, and revise established payment schedules and other payment rates for covered services. CMS also uses the information to conduct studies and reports. *Form Number:* CMS–1045 (OMB control number: 0938–0997); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 53,111; *Total Annual Responses:* 204,138,881; *Total Annual Hours:* 1,797,958. (For policy questions regarding this collection contact Mohammad B Ullah at 410–786–4143.)

Dated: April 10, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–07491 Filed 4–15–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0530]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tropical Disease Priority Review Vouchers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 16, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0822. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Tropical Disease Priority Review Vouchers

OMB Control Number 0910–0822—Revision

Section 524 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360n) is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world and makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease products. By enacting section

524 of the FD&C Act, Congress intended to stimulate new drug development for drugs to treat certain tropical diseases for which there are no or few available treatments by offering additional incentives for obtaining FDA approval for pharmaceutical treatments for these diseases. Under section 524 of the FD&C Act, a sponsor of a human drug application for a qualified tropical disease may be eligible for a voucher that can be used to obtain a priority review for any application submitted under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (the PHS Act).

Accordingly, we have developed the guidance document entitled, ''Guidance for Industry (GFI): Tropical Disease Priority Review Vouchers.'' The guidance explains how FDA will implement the provisions of section 524 of the FD&C Act, how sponsors may use priority review vouchers, and how priority review vouchers may be transferred to other sponsors. The guidance also explains eligibility criteria for tropical disease drug product applications submitted under section 505(b)(1) of the FD&C Act and section 351 of the PHS Act, and provides instructions to sponsors on how they may:

- Request a priority review voucher; and
- notify FDA of their intent to use a priority review voucher, including the date on which the sponsor intends to submit the application.

The guidance also explains that transfer of a priority review voucher from one sponsor to another is permitted and that each transfer should be documented with a letter of transfer. Finally, the guidance will be revised to include new information collection established by section 611 of the FDA Reauthorization Act of 2017 (FDARA). As amended, section 524 of the FD&C Act requires the sponsor of a tropical disease product application to include an attestation regarding its eligibility for a priority review voucher. The guidance is available at *https://www.fda.gov/downloads/Drugs/Guidances/UCM080599.pdf.*

Description of Respondents: Sponsors submitting applications under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act.

In the **Federal Register** of November 7, 2018 (83 FR 55720), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Priority Review Voucher Request	5	1	5	8	40
Notifications of Intent to Use a Voucher	5	1	5	8	40
Letters Indicating the Transfer of a Voucher Letter	2	1	2	8	16
Acknowledging the Receipt of a Transferred Voucher	2	1	2	8	16
Attestation of Eligibility	5	1	5	2	10
Total					122

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have increased our burden estimate since last approval to account for attestations added by FDARA; however, all other information collection elements remain unchanged.

Dated: April 10, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–07464 Filed 4–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0597]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 16, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0733. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring—21 CFR Parts 312 and 812

OMB Control Number 0910–0733—Extension

This information collection supports reporting and recordkeeping found in Agency guidance. Under parts 312 and 812 (21 CFR parts 312 and 812), sponsors are required to provide appropriate oversight of their clinical investigations to ensure adequate protection of the rights, welfare, and safety of human subjects and to ensure the quality and integrity of the resulting data submitted to FDA. As part of this oversight, sponsors of clinical investigations are required to monitor the conduct and progress of their clinical investigations. The regulations do not specify how sponsors are to

conduct monitoring of clinical investigations and are, therefore, compatible with a range of approaches to monitoring.

Accordingly, we developed the guidance document entitled ''Guidance for Industry—Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring'' (available at: *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm269919.pdf*). The guidance is intended to assist sponsors of clinical investigations in developing strategies for risk-based monitoring and plans for clinical investigations of human drug and biological products, medical devices, and combinations thereof. The guidance describes strategies for monitoring activities performed by sponsors or by contract research organizations (CROs) that focus on the conduct, oversight, and reporting of findings of an investigation by clinical investigators. The guidance also recommends strategies that reflect a risk-based approach to monitoring that focuses on critical study parameters and relies on a combination of monitoring activities to oversee a study effectively. Finally, the guidance specifically encourages greater reliance on centralized monitoring methods where appropriate.

Information collections for reports and records associated with clinical investigations under parts 312 and 812 are currently approved under OMB control numbers 0910–0014 and 0910–0078, respectively. These reporting and recordkeeping provisions cover general elements. The guidance discusses other elements sponsors and investigators should consider and include in developing a monitoring plan. As explained in the guidance, documentation of monitoring should include sufficient detail to allow verification that the monitoring plan was followed. The plan should provide adequate information to those involved with monitoring to effectively carry out their duties. All sponsor and CRO personnel who may be involved with monitoring (including those who review appropriate action, determine appropriate action, or both) regarding potential issues identified through monitoring should review the monitoring plan.

In the **Federal Register** of November 30, 2018 (83 FR 61646), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received; however, it was not responsive to any of the four information collection topics solicited in the notice.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Documentation included in comprehensive monitoring plan	88	1.5	132	4	528

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection, we have made no adjustments to our burden estimate. We estimate 88 sponsors will develop 132 comprehensive monitoring plans in accordance with the guidance. We believe the associated burden for each plan is approximately 4 hours and includes the time necessary to develop, and amend as appropriate, the monitoring plan.

Dated: April 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–07523 Filed 4–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4839]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Registering With the Center for Veterinary Medicine's Electronic Submission System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Center for Veterinary Medicine (CVM) Guidance for Industry (GFI) #108 entitled ''Registering with CVM's Electronic Submission System.''

DATES: Submit either electronic or written comments on the collection of information by June 17, 2019.

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 June 17, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 17, 2019. 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–4839 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Registering with the Center for Veterinary Medicine's Electronic Submission System.'' 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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@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.

Guidance for Industry on Registering With the Center for Veterinary Medicine's Electronic Submission System—21 CFR 11.2

OMB Control Number 0910–0454—Extension

FDA's Electronic Records; Electronic Signatures regulation (21 CFR part 11) requires that we identify in the Electronic Submission Docket (Docket No. FDA–1992–S–0039) the types of documents or parts of documents acceptable for official electronic submission. FDA's CVM has placed notifications in that docket identifying documents acceptable for electronic submission to the Center, as required by 21 CFR 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of FDA's Electronic Records; Electronic Signatures regulation.

The FDA Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of premarket and postmarket regulatory information for review. The FDA ESG is the central transmission point for sending information electronically to FDA. Within that context, the FDA ESG is a conduit along which submissions travel to reach the proper FDA Center or Office. CVM's Electronic Submission System (ESS) is a Center-wide solution for accepting electronic regulatory submissions. The CVM ESS is used to accept electronic submissions for animal and veterinary products.

Our guidance entitled ''Guidance for Industry (GFI) #108: Registering with the Center for Veterinary Medicine's Electronic Submission System'' outlines general standards to be used for the submission of any electronic information to CVM using the FDA ESG, including how to register with the CVM ESS using Form FDA 3538, Electronic Submission System Participant Management Form.

The reporting associated with new animal drug applications and related submissions is necessary to ensure that new animal drugs are in compliance with section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(1)). We use the information collected to review the data, labeling and manufacturing controls and procedures to evaluate the safety and effectiveness of the proposed new animal drug. The reporting associated with new animal drug applications is approved under OMB control number 0910–0032. Respondents use GFI #108

and Form FDA 3538 to facilitate the electronic submission of such information. We use the information collected with Form FDA 3538 to register respondents to use the CVM ESS.

Description of Respondents: The respondents are sponsors of new animal drug applications.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
11.2	Form FDA 3538	179	1.3	233	.08 (5 minutes)	19

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimates on our experience with the submission of electronic information using the CVM ESS and the number of electronic registration or change requests received between January 1, 2018, and November 30, 2018. Our estimated burden for the information collection reflects an overall increase of 16 hours and a corresponding increase of 195 responses. We attribute this adjustment to the reauthorizations of both the Animal Drug User Fee Act and the Animal Generic Drug User Fee Act, which require sponsors to submit information electronically to the CVM's Office of New Animal Drug Evaluation. Because of this requirement, sponsors are now registering to use the CVM ESS in greater numbers than in previous years.

Dated: April 10, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–07468 Filed 4–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–N–0742; FDA–2018–N–1967; FDA–2018–N–2970; FDA–2017–N–1779; FDA–2008–N–0500; FDA–2012–N–0129; FDA–2009–D–0268; FDA–2014–D–0609; and FDA–2011–N–0776]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	0910–0045	12/31/2021
Biosimilar User Fee Program	0910–0718	12/31/2021
Surveys and Interviews with Investigational New Drug Sponsors to Assess Current Communication Practices with FDA Review Staff Under the Sixth Authorization of the Prescription Drug User Fee Act	0910–0863	12/31/2021
Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion	0910–0864	12/31/2021
Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products	0910–0572	1/31/2022
General Licensing Provisions; Section 351(k) Biosimilar Applications	0910–0719	1/31/2022
Labeling of Certain Beers Subject to the Labeling Jurisdiction of the FDA	0910–0728	1/31/2022
Implementation of the Drug Supply Chain Security Act—Identification of Suspect Product and Notification	0910–0806	1/31/2022
Reclassification Petitions for Medical Devices	0910–0138	2/28/2022

Dated: April 10, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–07467 Filed 4–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Tobacco Regulatory Biomedical Science—Basic.

Date: May 30, 2019.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9694, *petersonjt@csr.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Lung Cellular, Molecular, and Immunobiology Study Section.

Date: June 4–5, 2019.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Radisson Hotel Baltimore Downtown, 101 West Fayette Street, Baltimore, MD 21201.

Contact Person: George M. Barnas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, 301–435–0696, *barnasg@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Imaging Guided Interventions and Surgery Study Section.

Date: June 4–5, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ileana Hancu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, Bethesda, MD 20817, 301–402–3911, *ileana.hancu@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Early Phase Clinical Trials in Imaging and Image-Guided Interventions.

Date: June 5, 2019.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ileana Hancu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, Bethesda, MD 20817, 301–402–3911, *ileana.hancu@nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Addiction Risks and Mechanisms Study Section.

Date: June 6–7, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Hotel, 1500 New Hampshire Avenue NW, Washington, DC 20036.

Contact Person: Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, (301) 496–0726, *prenticekj@mail.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Behavioral Medicine, Interventions and Outcomes Study Section.

Date: June 10–11, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street NW, Washington, DC 20037.

Contact Person: Lee S. Mann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3224, MSC 7808, Bethesda, MD 20892, 301–435–0677, *mannl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–18–018: Stimulating Innovations in Intervention Research for Cancer Prevention and Control.

Date: June 11, 2019.

Time: 10:30 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street NW, Washington, DC 20037.

Contact Person: Lee S. Mann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, 301–435–0677, *mannl@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: April 10, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–07555 Filed 4–15–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2019–0018]

Agency Information Collection Activities: REAL ID: Minimum Standards for Driver's Licenses and Identification Cards Acceptable by Federal Agencies for Office Purposes

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: 60-Day notice and request for comments; extension without change of a currently approved collection, 1601–0005.

SUMMARY: The Department of Homeland Security (DHS), Office of the Secretary, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted until June 17, 2019. This process is conducted in accordance with 5 CFR 1320.1

ADDRESSES: You may submit comments, identified by docket number DHS–2019–0018, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting comments.
- *Email: dhs.pra@hq.dhs.gov.* Please include docket number DHS–2019–0018 in the subject line of the message.

SUPPLEMENTARY INFORMATION: The REAL ID Act of 2005 (the Act) prohibits Federal agencies from accepting State-issued drivers' licenses or identification cards for any official purpose—defined by the Act and regulations as boarding commercial aircraft, accessing federal facilities, or entering nuclear power plants—unless the license or card is issued by a State that meets the requirements set forth in the Act. Title II of Division B of Public Law 109–13, codified at 49 U.S.C. 30301 note. The REAL ID regulations, which DHS issued in January 2008, establish the minimum standards that States must meet to comply with the Act. *See* 73 FR 5272, also 6 CFR part 37 (Jan. 29, 2008). These include requirements for presentation and verification of documents to establish identity and lawful status, standards for document issuance and security, and physical security requirements for driver's license production facilities. For a State to achieve full compliance, the Department of Homeland Security (DHS) must make a final determination that the State has met the requirements contained in the regulations and is compliant with the Act.[1] The regulations include new information reporting and record keeping requirements for States seeking a full compliance determination by DHS. As discussed in more detail below, States seeking DHS's full compliance determination must certify that they are meeting certain standards in the issuance of driver's licenses and

[1]

identification cards and submit security plans covering physical security of document production and storage facilities as well as security of personally identifiable information. 6 CFR 37.55(a). States also must conduct background checks and training for employees involved in the document production and issuance processes and retain and store applicant photographs and other source documents. 6 CFR 37.31 and 37.45. States must recertify compliance with REAL ID every three years on a rolling basis as determined by the Secretary of Homeland Security. 6 CFR 37.55.

Certification and Recertification Process Generally

Section 202(a)(2) of the REAL ID Act requires the Secretary to determine whether a State is meeting its requirements, ''based on certifications made by the State to the Secretary.'' To assist DHS in making a final compliance determination, 37.55 of the rule requires the submission of the following materials:

(1) A certification by the highest level Executive official in the state overseeing the DMV that the state has implemented a program for issuing driver's licenses and identification cards in compliance with the REAL ID Act.

(2) A letter from the Attorney General of the State confirming the State has the legal authority to impose requirements necessary to meet the standards.

(3) A description of a State's exceptions process to accept alternate documents to establish identity and lawful status and wavier process used when conducting background checks for individuals involved in the document production process.

(4) The State's security plan.

(5) State Certification Checklist

Additionally, after a final compliance determination by DHS, states must recertify compliance every three years on a rolling basis as determined by DHS. 6 CFR 37.55(b).

State REAL ID programs will be subject to DHS review to determine whether the state meets the requirements for compliance. States must cooperate with DHS's compliance review and provide any reasonable information requested by DHS relevant to determining compliance. Under the rule, DHS may inspect sites associated with the enrollment of applicants and the production, manufacture, personalization, and issuance of driver's licenses or identification cards. DHS also may conduct interviews of employees and contractors involved in the document issuance, verification, and production processes. 6 CFR 37.59(a).

Following a review of a State's certification/recertification package, DHS may make a preliminary determination that the State needs to take corrective actions to achieve full compliance. In such cases, a State may have to respond to DHS and explain the actions it took or plans to take to correct any deficiencies cited in the preliminary determination or alternatively, detail why the DHS preliminary determination is incorrect. 6 CFR 37.59(b).

Security Plans

In order for States to be in compliance with the Act, they must ensure the security of production facilities and materials and conduct background checks and fraudulent document training for employees involved in document issuance and production. REAL ID Act sec. 202(d)(7)–(9). The Act also requires compliant licenses and identification cards to include features to prevent tampering, counterfeiting, or duplication. REAL ID Act sec. 202(b). To document compliance with these requirements the regulations require States to prepare a security plan and submit it as part of their certification package. 6 CFR 37.41. At a minimum, the security plan must address steps the State is taking to ensure:

- The physical security of production materials and storage and production facilities;
- Security of personally identifiable information maintained at DMVs including a privacy policy and standards and procedures for document retention and destruction;
- Document security features including a description of the use of biometrics and the technical standards used;
- Facility access control including credentialing and background checks;
- Fraudulent document and security awareness training;
- Emergency response;
- Internal audit controls; and
- An affirmation that the State possesses the authority and means to protect the confidentiality of REAL ID documents issued in support of criminal justice agencies or similar programs.

Background Checks and Waiver Process

Within its security plans, the rule requires States to outline their approach to conducting background checks of certain DMV employees involved in the card production process. 6 CFR 37.45. Specifically, States are required to perform background checks on persons who are involved in the manufacture or production of REAL ID driver's licenses and identification cards, as well as on individuals who have the ability to affect the identity information that appears on the driver's license or identification card and on current employees who will be assigned to such positions. The background check must include a name-based and fingerprint-based criminal history records check, an employment eligibility check, and for newer employees a prior employment reference check. The regulation permits a State to establish procedures to allow for a waiver for certain background check requirements in cases, for example, where the employee has been arrested, but no final disposition of the matter has been reached.

Exceptions Process

Under the rule, a State DMV may choose to establish written, defined exceptions process for persons who, for reasons beyond their control, are unable to present all necessary documents and must rely on alternate documents to establish identity, and date of birth. 6 CFR 37.11(h). Alternative documents to demonstrate lawful status will only be allowed to demonstrate U.S. citizenship. The State must retain copies or images of the alternate documents accepted under the exceptions process and submit a report with a copy of the exceptions process as part of its certification package.

Recordkeeping

The rule requires States to maintain photographs of applicants and records of certain source documents. Paper or microfiche copies of these documents must be retained for a minimum of seven years. Digital images of these documents must be retained for a minimum of ten years. 6 CFR 37.31.

The collection of the information will support the information needs of DHS in its efforts to determine state compliance with requirements for issuing REAL ID driver's licenses and identification cards. States may submit the required documents in any format that they choose. DHS has not defined specific format submission requirements for states. DHS will use all of the submitted documentation to evaluate State progress in implementing the requirements of the REAL ID Final Rule. DHS has used information provided under the current collection to grant extensions and track state progress.

Submission of the security plan helps to ensure the integrity of the license and identification card issuance and production process and outlines the measures taken to protect personal information collected, maintained, and used by state DMVs. Additionally, the collection will assist other Federal and

State agencies conducting or assisting with necessary background and immigration checks for certain employees. The purpose of the name-based and fingerprint based CHRC requirement is to ensure the suitability and trustworthiness of individuals who have the ability to affect the identity information that appears on the license; have access to the production process; or who are involved in the manufacture or issuance of the licenses and identification cards.

In compliance with GPEA, States will be permitted to electronically submit the information for their security plans, certification packages, recertifications, extensions, and written exceptions processes. States will be permitted to submit electronic signatures but must keep the original signature on file. Additionally, because they contain sensitive security information (SSI), the security plans must be handled and protected in accordance with 49 CFR part 1520. 6 CFR 37.41(c). The final rule does not dictate how States must submit their employees' fingerprints to the FBI for background checks; however it is assumed States will do so via electronic means or another means determined by the FBI.

This information will be collected directly from the States to assist DHS in making REAL ID compliance determinations and is not otherwise available.

The information collection discussed in this analysis applies to states, state agencies, and certain employees involved in the card production process. Therefore, it is DHS's belief that the information collection does not have a significant impact on a substantial number of small businesses.

In accordance with the regulations, submission of certification materials and security plans will assist DHS in determining full compliance. DHS may also review documents, audit processes, and conduct inspections. Failure to make a compliance determination would prevent state-issued licenses and identification cards from being used for official purposes, which includes boarding commercial aircraft and accessing federal facilities. Additional requirements for recordkeeping, document retention and storage, as well as background checks for certain employees help to ensure the integrity of the card production and issuance process and will assist DHS during audits or inspections of a state's processes.

Information provided will be protected from disclosure to the extent appropriate under applicable provisions of the Freedom of Information Act, the Privacy Act of 1974, the Driver's Privacy Protection Act, as well as DHS's Privacy Impact Assessment for the REAL ID Act.

There has been no program changes or new requirements established as a result of this collection request.

The Office of Management and Budget is particularly interested in comments which:

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.

Analysis

Agency: Office of the Secretary, DHS.

Title: Agency Information Collection Activities: REAL ID: Minimum Standards for Driver's Licenses and Identification Cards Acceptable by Federal Agencies for Office Purposes.

OMB Number: 1601–0005.

Frequency: Annually.

Affected Public: State, local, and tribal governments.

Number of Respondents: 18.

Estimated Time per Respondent: 750 hours.

Total Burden Hours: 13,500 hours.

Dated: April 8, 2019.

Scott Ewalt,

Acting Executive Director, Enterprise Business Management Office.

[FR Doc. 2019–07565 Filed 4–15–19; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R6–ES–2019–N007; FXES11140600000–190–FF06E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments by May 16, 2019.

ADDRESSES:

Document availability and comment submission: Use one of the following methods to request documents or submit comments. Requests and comments should specify the applicant name(s) and application number(s) (*e.g.,* TE123456):

- *Email: permitsR6ES@fws.gov.*
- *U.S. Mail:* Marjorie Nelson, Chief, Division of Ecological Services, U.S. Fish and Wildlife Service, 134 Union Blvd., Suite 670, Lakewood, CO 80228.

FOR FURTHER INFORMATION CONTACT: Kathy Konishi, Recovery Permits Coordinator, Ecological Services, 303–236–4224 (phone), or *permitsR6ES@fws.gov* (email). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Background

The Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), prohibits certain activities with endangered and threatened species unless authorized by a Federal permit. The ESA and our implementing regulations in part 17 of title 50 of the Code of Federal Regulations (CFR) provide for the issuance of such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

We invite local, State, and Federal agencies; Tribes; and the public to comment on the following applications.

Application No.	Applicant, city, state	Species	Location	Activity	Permit action
TE049748–3	Utah State University, Logan, Utah.	June sucker (*Chasmistes liorus*)	Utah	Presence/absence surveys, population monitoring.	Renew.
TE057401–2	Bureau of Land Management, Grand Staircase Escalante National Monument, Utah.	Southwestern willow flycatcher (*Empidonax traillii extimus*).	Utah	Presence/absence surveys, nest monitoring.	Renew.
TE069553–2	USDA Forest Service, Wall Ranger District, Buffalo Gap National Grassland, South Dakota.	Black-footed ferret (*Mustela nigripes*)	South Dakota	Presence/absence surveys, capture, handle, mark, anesthetize, vaccinate, release.	Renew.
TE094832–2	U.S. Army Corps of Engineers, Omaha District, Pickstown, South Dakota.	Pallid sturgeon (*Scaphirhynchus albus*)	South Dakota	Display for scientific and educational purposes.	Renew.
TE131638–3	Loveland Living Planet Aquarium, Draper, Utah.	Loggerhead sea turtle (*Caretta caretta*), bonytail chub (*Gila elegans*), Colorado pikeminnow (*Ptychocheilus lucius*), humpback chub (*Gila cypha*), June sucker (*Chasmistes liorus*), razorback sucker (*Xyrauchen texanus*), Virgin River chub (*Gila robusta seminuda*), woundfin (*Plagopterus argentissimus*), green sea turtle (*Chelonia mydas*).	Utah	Display for educational purposes.	Renew.
TE131639–1	USDA Forest Service, Chadron, Nebraska.	Blowout penstemon (*Penstemon haydenii*) ...	Nebraska	Presence/absence surveys, remove and reduce to possession for propagation and reintroduction.	Renew.
TE26376D–0	Steve Forrest, Truckee, California.	Black-footed ferret (*Mustela nigripes*)	Arizona, Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, South Dakota, Texas, Utah, Wyoming.	Presence/absence surveys.	New.
TE61451C–1	Amy Hammesfahr	Indiana bat (*Myotis sodalis*), gray bat (*Myotis grisescens*).	Missouri	Presence/absence surveys, capture, handle, mark, biosample, release.	Amend.
TE26405D–0	Miranda Hanson, Lincoln, Nebraska.	American burying beetle (*Nicrophorus americanus*).	Kansas, Nebraska, South Dakota.	Presence/absence surveys.	New.
TE32556D–0	Stephen Yarbrough, Golden, Colorado.	New Mexico meadow jumping mouse (*Zapus hudsonius luteus*).	Colorado	Presence/absence surveys.	New.
TE26536D–0	U.S. Army Corps of Engineers, John Martin Reservoir, Colorado.	Interior least tern (*Sternula antillarum athalassos*).	Colorado	Presence/absence surveys, nest monitoring.	New.

Public Availability of Comments

Written comments we receive become part of the administrative record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Maria Boroja,

Acting Assistant Regional Director, Mountain-Prairie Region.

[FR Doc. 2019–07485 Filed 4–15–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–NWRS–2018–N164; FXRS12610900000–189–FF09R24000; OMB Control Number 1018–0162]

Agency Information Collection Activities; Non-Federal Oil and Gas Operations on National Wildlife Refuge System Lands

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before June 17, 2019.

ADDRESSES: Send your comments on the information collection request by mail to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov*. Please reference OMB Control Number 1018–0162 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503.

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 information collection request (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 Service; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Service enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Service 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: The authority of the Service to regulate non-Federal oil and gas operations on National Wildlife Refuge System (NWRS) lands is broadly derived from the Property Clause of the United States Constitution (Art. VI, Sec. 3), in carrying out the statutory mandates of the Secretary of the Interior, as delegated to the Service, to manage Federal lands and resources under the National Wildlife Refuge System Administration Act (NWRSAA), as amended by the National Wildlife Refuge System Improvement Act (NWRSIA; 16 U.S.C. 668dd *et seq.*), and to specifically manage species within the NWRS under the provisions of numerous statutes, the most notable of which are the Migratory Bird Treaty Act (MBTA; 16 U.S.C. 715 *et seq.*), the Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*), and the Fish and Wildlife Act of 1956 (FWA; 15 U.S.C. 742f).

The Service's rule at 50 CFR, part 29, subpart D provides for the continued exercise of non-Federal oil and gas rights while avoiding or minimizing unnecessary impacts to refuge resources and uses. Other land management agencies have regulations that address oil and gas development, including the Department of the Interior's National Park Service (NPS) and Bureau of Land Management (BLM), and the U.S. Department of Agriculture's Forest Service. These agencies all require the submission of information similar to the information requested by the Service.

The collection of information is necessary for the Service to properly balance the exercise of non-Federal oil and gas rights within refuge boundaries with the Service's responsibility to protect wildlife and habitat, water quality and quantity, wildlife-dependent recreational opportunities, and the health and safety of employees and visitors on NWRS lands.

The information collected under 50 CFR, part 29, subpart D identifies the owner and operator (the owner and operator can be the same) and details how the operator may access and develop oil and gas resources. It also identifies the steps the operator intends to take to minimize any adverse impacts of operations on refuge resource and uses. No information is submitted unless the operator wishes to conduct oil and gas operations.

We use the information collected to: (1) Evaluate proposed operations, (2) ensure that all necessary mitigation measures are employed to protect refuge resources and values, and (3) ensure compliance with all applicable laws and regulations, including the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its regulations (40 CFR parts 1500–1508), the NWRSAA, as amended by the NWRSIA, and to specifically manage species within the NWRS under the provisions of numerous statutes, the most notable of which are the MBTA, the ESA, the Fish and Wildlife Coordination Act (16 U.S.C. 661 *et seq.*), and the FWA.

Title of Collection: Non-Federal Oil and Gas Operations on National Wildlife Refuge System Lands, 50 CFR 29, Subpart D.

OMB Control Number: 1018–0162.

Form Number: FWS Form 3–2469.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Businesses that conduct oil and gas exploration on national wildlife refuges.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

Activity/requirement	Estimated number of annual responses	Completion time per response (hours)	Estimated total annual burden hours
Preexisting Operations (§ 29.61)	40	50	2,000
Temporary Access Permit Application (§ 29.71)	35	17	595

Activity/requirement	Estimated number of annual responses	Completion time per response (hours)	Estimated total annual burden hours
Accessing Oil and Gas Rights from Non-Federal Surface Location (§ 29.80)	5	1	5
Pre-application Meeting for Operations Permit (§ 29.91)	45	2	90
Operations Permit Application (§§ 29.94–29.97)	45	140	6,300
Financial Assurance (§§ 29.103(b), 29.150)	45	1	45
Identification of Wells and Related Facilities (§ 29.119(b))	45	2	90
Reporting (§ 29.121):			
Third-Party Monitor Report (§ 29.121(b))	300	17	5,100
Notification—Injuries/Mortality to Fish and Wildlife and Threatened/Endangered Plants (§ 29.121(c))	20	1	20
Notification—Accidents involving Serious Injuries/Death and Fires/Spills (§ 29.121(d))	20	1	20
Written Report—Accidents Involving Serious Injuries/Deaths and Fires/Spills (§ 29.121(d))	20	16	320
Report—Verify Compliance with Permits (§ 29.121(e))	240	4	960
Notification—Chemical Disclosure of Hydraulic Fracturing Fluids uploaded to FracFocus (§ 29.121(f))	5	1	5
Permit Modifications (§ 29.160(a))	10	16	160
Change of Operator:			
Transferring Operator Notification (§ 29.170)	20	8	160
Acquiring Operator's Requirements for Wells Not Under a Service Permit (§ 29.171(a))	19	40	760
Acquiring Operator's Acceptance of an Existing Permit (§ 29.171(b))	1	8	8
Extension to Well Plugging (§ 29.181(a)).			
Application for Permit	10	140	1,400
Modification	5	16	80
Public Information (§ 29.210):			
Affidavit in Support of Claim of Confidentiality (§ 29.210(c) and (d))	1	1	1
Confidential Information (§ 29.210(e) and (f))	1	1	1
Maintenance of Confidential Information (§ 29.210(h))	1	1	1
Generic Chemical Name Disclosure (§ 29.210(i))	1	1	1
Totals	934		18,122

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.*).

Dated: April 11, 2019.

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2019–07521 Filed 4–15–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/ A0A501010.999900253G]

Indian Gaming; Tribal-State Class III Gaming Compacts Taking Effect in the State of Oregon

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice announces that the Tribal-State Compacts between the State of Oregon and the Klamath Tribes and the Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians are taking effect.

DATES: These compacts take effect on April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA) Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Secretary took no action on the compacts between the State of Oregon and the Klamath Tribes and the Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians within 45 days of their submission. Therefore, the Compacts are considered to have been approved, but only to the extent they are consistent with IGRA. *See* 25 U.S.C. 2710(d)(8)(C).

Dated: January 29, 2019.

John Tahsuda,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2019–07472 Filed 4–15–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/ A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact Amendment in the State of Oregon

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the approval of the Amendment to the Amended and Restated (Highway 26) Tribal-State Compact for Regulation of Class III Gaming between the Confederated Tribes of the Warm Springs Reservation of Oregon (Tribe) and the State of Oregon (State), Amendment I (Amendment).

DATES: This compact amendment takes effect on April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian

Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA) Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Amendment modifies the definition of Video Lottery Terminal (VLT) and requires the Tribal Gaming Commission to develop and submit internal controls for the State's approval prior to offering a new VLT for play. The Amendment is approved.

Dated: March 13, 2019.

John Tahsuda,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2019–07488 Filed 4–15–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/ A0A501010.999900253G]

Indian Gaming; Tribal-State Class III Gaming Compact Taking Effect in the State of Wisconsin

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice announces that the Amendment to the Forest County Potawatomi Community of Wisconsin and the State of Wisconsin Class III Gaming Compact is taking effect.

DATES: This compact amendment takes effect on April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA) Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Secretary took no action on the Amendment to the Forest County Potawatomi Community of Wisconsin and State of Wisconsin Class III Gaming Compact within 45 days of its submission. Therefore, the Amendment to the Compact is considered to have been approved, but only to the extent it is consistent with IGRA. *See* 25 U.S.C. 2710(d)(8)(C).

Dated: March 13, 2019.

John Tahsuda,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2019–07490 Filed 4–15–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/ A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact Amendment in the State of Washington

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the approval of the Fifth Amendment to the Tribal-State Compact for Class III Gaming between the Muckleshoot Indian Tribe and the State of Washington.

DATES: This compact takes effect on April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA), Pub. L. 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Amendment prohibits cash dispensing machines at the Tribe's gaming facilities from accepting Electronic Benefits Cards, increases the Tribe's allocation of Player Terminals, specifies the calculation and payment of regulatory reimbursement costs to the State, and allocates funds to alleviate problem gambling and encourage smoking cessation and prevention. The Amendment also incorporates as part of the compact Appendix X2 Addendum Tribal Lottery System Terminal Allocations, which governs the total number of available Tribal Lottery Terminals, provides procedures for increasing the available allocations, and outlines dispute resolution procedures relating to the number of Tribal Lottery Terminals. The Secretary took no action on the compact between the Muckleshoot Indian Tribe and the State of Washington within 45 days of its submission. Therefore, the Compact is considered to have been approved, but only to the extent the Compact is consistent with IGRA. *See* 25 U.S.C. 2710(d)(8)(C).

Dated: February 7, 2019.

John Tahsuda,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2019–07473 Filed 4–15–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/ A0A501010.999900]

Ewiiaapaayp Band of Kumeyaay Indians Liquor Control Ordinance

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the Liquor Control Ordinance of the Ewiiaapaayp Band of Kumeyaay Indians. The Liquor Control Ordinance regulates and controls the possession, sale, manufacture, and distribution of alcohol in conformity with the laws of the State of California.

DATES: This ordinance shall take effect May 16, 2019.

FOR FURTHER INFORMATION CONTACT: Mr. Harley Long, Tribal Government Officer, Pacific Regional Office, Bureau of Indian Affairs, 2800 Cottage Way, Room W–2820, Sacramento, California 95825, Telephone: (916) 978–6000, Fax: (916) 978–6099.

SUPPLEMENTARY INFORMATION: Pursuant to the Act of August 15, 1953, Public Law 83–277, 67 Stat. 586, 18 U.S.C. 1161, as interpreted by the Supreme Court in *Rice* v. *Rehner,* 463 U.S. 713 (1983), the Secretary of the Interior shall certify and publish in the **Federal Register** notice of adopted liquor control ordinances for the purpose of regulating liquor transactions in Indian country. The Ewiiaapaayp Band of Kumeyaay Indians duly adopted Title 513, Ewiiaapaayp Band of Kumeyaay Indians

Liquor Control Ordinance on May 9, 2018.

This notice is published in accordance with the authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs. I certify that the Ewiiaapaayp Band of Kumeyaay Indians, California, duly adopted Title 513, Ewiiaapaayp Band of Kumeyaay Indians Liquor Control Ordinance, on May 9, 2018.

Dated: November 9, 2018.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

The Ewiiaapaayp Band of Kumeyaay Indian's Title 513, Ewiiaapaayp Band of Kumeyaay Indians Liquor Control Ordinance shall read as follows:

TITLE 513

EWIIAAPAAYP Band of Kumeyaay Indians Liquor Control Ordinance

Chapter One General Provisions

Article 1. Authority

513.01.1 This Ordinance is enacted pursuant to the Act of August 15, 1953 (Pub. L. 83–277, 67 Stat. 586, 18 U.S.C. 1161) and by powers vested in the General Council of the Ewiiaapaayp Band of Kumeyaay Indians (''General Council'') to develop, adopt and enforce ordinances as authorized under Article VI, Section 1 of the Constitution of the Ewiiaapaayp Band of Kumeyaay Indians approved on December 19, 1973 and amended on September 6, 2002.

Article 2. Purpose

513.01.2 The purpose of this Ordinance is to regulate and control the possession, sale, manufacture, distribution and taxation of liquor within Tribal Trust Lands, in order to permit alcohol sales by tribally owned and operated enterprises and private lessees, and at tribally approved special events. Enactment of a liquor control ordinance will help provide a source of revenue to fund the continued operation of the tribal government, the delivery of governmental services, the economic viability of tribal enterprises, and to fund health, safety and general welfare programs and services provided to Tribal citizens and residents of and visitors to land within the Tribe's territorial jurisdiction.

Article 3. Short Title

513.01.3 This Ordinance shall be known and cited as the ''Liquor Control Ordinance.''

Article 4. Jurisdiction

513.01.4 This Ordinance shall apply to all Tribal Trust Lands now or in the future under the governmental authority of the Tribe.

Article 5. Application of 18 U.S.C. 1161

513.01.5 (a) By adopting this Ordinance, the Tribe hereby regulates the sale, manufacturing, distribution, and consumption of liquor while ensuring that such activity conforms with all applicable laws of the State of California as required by 18 U.S.C. 1161 and the United States.

(b) (1) This Ordinance shall apply to the full extent of the sovereign jurisdiction of the Tribe.

(2) Compliance with this Subchapter is hereby made a condition of the use of any land or premises within the Tribe's Tribal Trust Lands.

(3) Any individual, person or entity who resides, conducts business, engages in a business transaction, receives benefits from the Tribe, acts under tribal authority, or enters the Tribe's Tribal Lands shall be deemed to have consented to the following:

(i) To be bound by the terms of this Ordinance;

(ii) To the exercise of the jurisdiction of the Tribe's Tribal Court for legal actions arising pursuant to this Ordinance; and

(iii) To service of summons and process, and search and seizure, in conjunction with legal actions arising pursuant to this Ordinance.

(4) No portion of this Ordinance shall be construed as contrary to Federal law.

Article 6. Declaration of Public Policy; Findings

513.01.6 The General Council enacts this Ordinance, based upon the following findings:

(a) The distribution, possession, consumption and sale of liquor on Tribal Trust Lands is a matter of special concern to the Tribe.

(b) The Tribe is the beneficial owner of Tribal Trust Lands, upon which the Tribe plans to construct and operate a gaming facility and related entertainment and lodging facilities.

(c) The Tribe's gaming facility will serve as an integral and indispensable part of the Tribe's economy, providing revenue to the Tribe's government and employment to tribal citizens and others in the local community.

(d) Federal law, as codified at 18 U.S.C. 1154 and 1161, currently prohibits the introduction of liquor into Indian country, except in accordance with State law and the duly enacted law of the Tribe.

(e) The Tribe recognizes the need for strict control and regulation of liquor transactions on Tribal Trust Lands because of potential problems associated with the unregulated or inadequate regulated sale, possession, distribution, and consumption of liquor.

(f) Regulating the possession, sale, distribution and manufacture of liquor within Tribal Trust Lands is also consistent with the Tribe's interest in ensuring the peace, safety, health, and general welfare of the Tribe and its citizens.

(g) Tribal control and regulation of liquor on Tribal Trust Lands is consistent with the Tribe's custom and tradition of controlling the possession and consumption of liquor on Tribal Trust Lands and at tribal events.

(h) The purchase, distribution, and sale of liquor on Tribal Trust Lands shall take place only at duly licensed (i) tribally owned enterprises, (ii) other enterprises operating pursuant to a lease or license with the Tribe, and (iii) tribally-sanctioned events.

(i) The sale or other commercial manufacture or distribution of liquor on Tribal Trust Lands, other than sales, manufacture, and distributions made in strict compliance with this Ordinance, is detrimental to the health, safety, and general welfare of the citizens of the Tribe, and is prohibited.

Chapter Two Definitions

Article 1. Definitions

513.02.1 All definitions of the Tribe's Tribal Code Title 001 ''Tribal Code Definitions'' apply herein unless the terms are otherwise defined in this Ordinance. For purposes of this Ordinance, whenever any of the following words, terms or definitions is used herein, they shall have the meaning ascribed to them in this Subchapter:

As used in this Ordinance, the terms below are defined as follows:

(a) *Alcohol* means ethyl alcohol, hydrated oxide of ethyl, or spirit of wine, in any form, and regardless of source or the process used for its production.

(b) *Alcoholic beverage* means all alcohol, spirits, liquor, wine, beer and any liquid or solid containing alcohol, spirits, liquor, wine, or beer, and which contains one-half of one percent or more of alcohol by volume and that is fit for human consumption, either alone or when diluted, mixed, or combined with any other substance(s).

(c) *Compact* means the Tribal-State compact between the State and the Tribe that governs the conduct of class III gaming activities on that portion of the Tribal Trust Lands recognized as ''Indian lands'' pursuant to the Indian Gaming Regulatory Act, 25 U.S.C. 2701, *et seq.*

(d) *Indian Country,* consistent with the meaning given in 18 U.S.C. 1151 means: (a) All land within the limits of the Ewiiaapaayp Indian Reservation under the jurisdiction of the United States government, notwithstanding the issuance of any patent, and, including rights of way running through the reservation; and (b) all Indian allotments or other lands held in trust for the Tribe or a member of the Tribe, including rights of way running through the same.

(e) *License* means, unless otherwise stated, a license issued by the Tribe in accordance with this Ordinance.

(f) *Liquor* means the four varieties of liquor (alcohol, spirits, wine, and beer), and all fermented, spirituous, vinous, or malt liquor, or combinations thereof, and mixed liquor, a part of which is fermented, spirituous, vinous or malt liquor, or otherwise intoxicating; and as such term.

(g) *Malt beverage* or *malt liquor* means any beverage such as beer, ale, lager beer, stout, and porter obtained by the alcoholic fermentation of an infusion or decoction of pure hops, or pure extract of hops and pure barley malt or other wholesome grain or cereal in pure water containing not more than eight percent of alcohol by weight, and not less than one-half of one percent of alcohol by volume. For purposes this Subchapter, any such beverage containing more than eight percent of alcohol by weight shall be referred to as ''strong beer.''

(h) *Manufacturer* means a person engaged in the preparation and manufacturing of liquor for sale, in any form whatsoever.

(i) *Person* means any individual or entity, whether Indian or non-Indian, receiver, assignee, trustee in bankruptcy, trust, estate, firm, corporation, partnership, joint corporation, association, society, or any group of individuals acting as a unit, whether mutual, cooperative, fraternal, non-profit or otherwise, and any other Indian tribe, band or group. The term shall also include the businesses of the Tribe.

(j) *Sale and sell* means the transfer for consideration of any kind, including by exchange or barter.

(k) *State* means the State of California.

(l) *Territory* means the term defined in the Tribe's Tribal Code of Title 001 § 001.02.66. and Title 100 § 100.01.1.D. wherein ''Territory'' is defined by Article II—Territory of the Tribe's Constitution, as amended, such that the territorial jurisdiction of the Tribe, is defined as all land within the exterior boundaries of the Ewiiaapaayp Indian Reservation, all land within the limits of dependent Ewiiaapaayp Indian communities, all Ewiiaapaayp Indian allotments, all land owned in fee by the Tribe, and all other land held in trust for, owned in fee by, or leased by the United States to the Tribe.''

(m) *Tribal retailer* means a liquor retailer wholly owned by the Ewiiaapaayp Band of Kumeyaay Indians and located on its Tribal Trust Lands.

(n) *Tribally-licensed retailer* means a person who has a business license from the Tribe to sell liquor at retail from a business located in Indian Country.

(o) *Tribe* means the term defined in the Tribe's Tribal Code of Title 001 § 001.01.1.51. wherein, Tribe means the ''Ewiiaapaayp Band of Kumeyaay Indians, formerly known as the Cuyapaipe Band of Mission Indians or the Cuyapaipe Community of the Diegueno Mission Indians of the Cuyapaipe Reservation, California, a federally recognized Indian Tribe organized under § 16 of the Indian Reorganization Act, 25 U.S.C. 476, *et seq.,* (48 Stat. 984) its enterprises, subdivisions, and departments, and its agents acting within the scope of their authority.''

Chapter Three Liquor Sales, Possession, & Manufacture

Article 1. Possession of Alcohol

513.03.1 The introduction and possession of alcoholic beverages shall be lawful within Tribal Trust Lands; provided that such introduction or possession is in conformity with the laws of the State.

Article 2. Retail Sales of Alcohol

513.03.2 The sale of alcoholic beverages shall be lawful within Tribal Trust Lands; provided that such sales are in conformity with the laws of the State and are made pursuant to a license issued by the Tribe.

Article 3. Manufacture of Alcohol

513.03.3 The manufacture of beer and wine shall be lawful within Tribal Trust Lands, provided that such manufacture is in conformity with the laws of the State and pursuant to a license issued by the Tribe.

Article 4. Age Limits

500.03.4 The legal age for possession or consumption of alcohol within Tribal Trust Lands shall be the same as that of the State, which is currently 21 years. No person under the age of 21 years shall purchase, possess or consume any alcoholic beverage. If there is any conflict between State law and the terms of the Compact regarding the age limits for alcohol possession or consumption, the age limits in the Compact shall govern for purposes of this Ordinance.

Chapter Four Licensing

Article 1. Licensing

513.04.1 The Tribe's General Council shall have the power to establish procedures and standards for tribal licensing of liquor sales within Tribal Trust Lands, including the setting of a license fee schedule, and shall have the power to publish and enforce such standards; provided that no tribal license shall issue except upon showing of satisfactory proof that the applicant is duly licensed by the State. The fact that an applicant for a tribal license possesses a license issued by the State shall not provide the applicant with an entitlement to a tribal license. The General Council may in its discretion set standards which are more, but in no case less, stringent than those of the State.

Chapter Five Enforcement

Article 1. Enforcement

513.05.1 The General Council shall have the power to develop, enact, promulgate, and enforce regulations as necessary for the enforcement of this Ordinance and to protect the public health, welfare, and safety of the Tribe, provided that all such regulations shall conform to and not be in conflict with any applicable tribal, Federal, or State law. Regulations enacted pursuant to this Ordinance may include provisions for suspension or revocation of tribal liquor licenses, reasonable search and seizure provisions, and civil penalties for violations of this Ordinance to the full extent permitted by Federal law and consistent with due process.

Tribal law enforcement personnel and security personnel duly authorized by the General Council shall have the authority to enforce this Ordinance by confiscating any liquor sold, possessed, distributed, manufactured, or introduced within Tribal Trust Lands in violation of this Ordinance or of any regulations duly adopted pursuant to this Ordinance.

The General Council shall have the exclusive jurisdiction to hold hearings on violations of this Ordinance and any procedures or regulations adopted pursuant to this Ordinance; to promulgate appropriate procedures governing such hearings; to determine and enforce penalties or damages for violations of this Ordinance; and to delegate to a subordinate hearing officer or panel the authority to take any or all of the foregoing actions on its behalf.

Chapter Six Taxes

Article 1. Taxation

513.06.1 The Tribe expressly reserves its inherent sovereign right to regulate the use and sale of liquor through the imposition of tribal taxes thereon. The General Council hereby authorizes and expressly reserves its authority to impose a tribal Liquor Tax on sales of all alcoholic beverages, including packaged and retail sales of liquor, wine, and beer, at a rate determined to be fair and equitable by the General Council through independent action. The Tribe retains the right to impose such taxes by appropriate ordinance to the full extent permitted by Federal law.

Chapter Seven Administration

Article 1. License Required of Tribal Retailers and Tribally-Licensed Retailers

513.07.1 Every person engaging in the business of selling, manufacturing, or distributing liquor within the Tribe's Tribal Trust Lands, including but not limited to a brewery, shall secure a business license from the Tribe in the manner provided for by Title 513 (''Business License Standards Code'') and otherwise comply with all provisions of Title 513.

Article 2. Prohibitions

513.07.2 (a) The manufacture, purchase, sale, and dealing in liquor within Tribe's Tribal Trust Lands by any person, party, firm, or corporation except pursuant to the control, licensing, and regulation of the General Council, is hereby declared unlawful. Without limitation as to any other penalties and fines that may apply, any violation of this subsection is an infraction punishable by a fine of up to five hundred dollars ($500.00).

(b) Every person engaging in the business of manufacturing, distributing or selling liquor within the Tribe's Tribal Trust Lands shall comply with the applicable provisions of the Tribe's Law and Order Code.

Article 3. Nondiscrimination

513.07.3 No provision of this Ordinance shall be construed as imposing a regulation or tax that discriminates on the basis of whether a retail liquor establishment is owned, managed or operated by a member of the Tribe.

Chapter Eight Miscellaneous Provisions

Article 1. Sovereign Immunity Preserved

513.08.1 Nothing contained in this Ordinance is intended to, nor does in any way, limit, alter, restrict, or waive the sovereign immunity of the Tribe or any of its agencies, agents or officials from unconsented suit or action of any kind.

Article 2. Conformance With Applicable Laws

513.08.2 All acts and transactions under this Ordinance shall be in conformity with the Compact and laws of the State to the extent required by 18 U.S.C. 1161 and with all Federal laws regarding alcohol in Indian Country.

Article 3. Effective Date

513.08.3 This Ordinance shall be effective as of the date on which the Secretary of the Interior certifies this Ordinance and publishes the same in the **Federal Register**.

Article 4. Repeal of Prior Acts

513.08.4 All prior enactments of the Tribal Council, including tribal resolutions, policies, regulations, or ordinances pertaining to the subject matter set forth in this Ordinance are hereby rescinded.

Article 5. Amendments

513.08.5 This Ordinance may only be amended pursuant to an amendment duly enacted by the General Council and certification by the Secretary of the Interior and publication in the **Federal Register**, if required.

Article 6. Severability and Savings Clause

513.08.6 If any part or provision of this Ordinance is held invalid, void, or unenforceable by a court of competent jurisdiction, such adjudication shall not be held to render such provisions inapplicable to other persons or circumstances. Further, the remainder of the Ordinance shall not be affected and shall continue to remain in full force and effect.

[FR Doc. 2019–07466 Filed 4–15–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact Amendment in the State of Oklahoma

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The State of Oklahoma entered into a compact amendment with the Modoc Tribe of Oklahoma governing certain forms of class III gaming; this notice announces the approval of the Model Tribal Gaming Compact Supplement between the Modoc Tribe and State of Oklahoma.

DATES: The compact amendment takes effect on April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA) Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by IGRA and 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The compact amendment authorizes the Tribe to engage in certain additional class III gaming activities, provides for the application of existing revenue sharing agreements to the additional forms of class III gaming, and designates how the State will distribute revenue sharing funds.

Dated: January 29, 2019.

John Tahsuda,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2019–07471 Filed 4–15–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900253G]

Indian Gaming; Extension of Tribal-State Class III Gaming Compact (Rosebud Sioux Tribe and the State of South Dakota)

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice announces the extension of the Class III gaming compact between the Rosebud Sioux Tribe and the State of South Dakota.

DATES: The extension takes effect on April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Assistant Secretary—Indian Affairs, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: An extension to an existing tribal-state Class III gaming compact does not require approval by the Secretary if the extension does not modify any other terms of the compact. 25 CFR 293.5. The Rosebud Sioux Tribe and the State of South Dakota have reached an agreement to extend the expiration date of their existing Tribal-State Class III gaming compact to July 22, 2019. This publishes notice of the new expiration date of the compact.

Dated: March 11, 2019.

John Tahsuda,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2019–07489 Filed 4–15–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact Amendment in the State of Oklahoma

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The State of Oklahoma entered into a compact amendment with the Kiowa Tribe of Oklahoma governing certain forms of class III gaming; this notice announces the approval of the Model Tribal Gaming Compact Supplement between the Kiowa Tribe and the State of Oklahoma.

DATES: The compact amendment takes effect on April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA) Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in class III gaming activities on Indian lands. As required by IGRA and 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The compact amendment authorizes the Tribe to engage in certain additional class III gaming activities, provides for the application of existing revenue sharing agreements to the additional forms of class III gaming, and designates how the State will distribute revenue sharing funds.

Dated: March 8, 2019.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2019–07470 Filed 4–15–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact Amendment in the State of Washington

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the approval of the Seventh Amendment to the Tribal-State Compact for Class III Gaming between the Nooksack Indian Tribe and the State of Washington.

DATES: The compact amendment takes effect on April 16, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Amendment authorizes Class III gaming at two facilities to be located on Tribal lands, requires the Tribe to initiate a problem gambling program, updates the Tribe's community contributions, updates the application of State law consistent with the compact, and provides for review and renegotiation of the compact on a regular basis. The Amendment is approved.

Dated: March 14, 2019.

John Tahsuda,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2019–07487 Filed 4–15–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO320000 L13300000 PO0000; OMB Control Number 1004–0121]

Agency Information Collection Activities; Leasing of Solid Minerals Other Than Coal and Oil Shale

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.

DATES: Interested persons are invited to submit comments on or before June 17, 2019.

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; or by email to *jesonnem@blm.gov.* Please reference OMB Control Number 1004–0121 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Alfred Elser by email at *at_aelser@blm.gov,* or by telephone at 202–912–7114.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the 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: Control number 1004–0121 authorizes the BLM to collect information pertaining to the leasing of solid minerals other than coal and oil shale, and the development of those leases.

Title of Collection: Leasing of Solid Minerals Other Than Coal and Oil Shale.

OMB Control Number: 1004–0121.

Form Numbers: 3504–1, 3504–3, 3504–4, 3510–1, 3510–2, and 3510–7.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Businesses that apply for leases for minerals other than coal and oil shale, and businesses that hold such leases.

Total Estimated Number of Annual Respondents: 507.

Total Estimated Number of Annual Responses: 507.

Estimated Completion Time per Response: Varies from 1 to 800 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 27,306 hours.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: $2,050,665.

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,

Information Collection Clearance Officer, Bureau of Land Management.

[FR Doc. 2019–07564 Filed 4–15–19; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR957000.L63100000. HD0000.19XL1116AF. HAG 19–0069]

Filing of Plats of Survey: Oregon/ Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management (BLM), Oregon State Office, Portland, Oregon, 30 calendar days from the date of this publication. The surveys, which were executed at the request of the BLM, are necessary for the management of these lands.

DATES: Protests must be received by the BLM prior to the scheduled date of official filing, May 16, 2019.

ADDRESSES: A copy of the plats may be obtained from the public room at the Bureau of Land Management, Oregon State Office, 1220 SW 3rd Avenue, Portland, Oregon 97204, upon required payment. The plats may be viewed at this location at no cost.

FOR FURTHER INFORMATION CONTACT: Kyle Hensley, 503–808–6124, Branch of Geographic Sciences, Bureau of Land Management, 1220 SW 3rd Avenue, Portland, Oregon 97204. 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: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management, Oregon State Office, Portland, Oregon:

Willamette Meridian, Oregon

T. 26 S, R. 3 W, accepted February 1, 2019.
T. 37 S, R. 6 W, accepted March 4, 2019.
T. 22 S, R. 1 W, accepted March 15, 2019.
T. 34 S, R. 34 E, accepted March 15, 2019.
T. 7 S, R. 8 W, accepted March 15, 2019.
T. 3 S, R. 7 W, accepted March 15, 2019.

Willamette Meridian, Washington

T. 40 N, R. 2 E, accepted March 15, 2019.

A person or party who wishes to protest one or more plats of survey identified above must file a written notice of protest with the Chief Cadastral Surveyor for Oregon/ Washington, Bureau of Land Management. The notice of protest must identify the plat(s) of survey that the person or party wishes to protest. The notice of protest must be filed before the scheduled date of official filing for the plat(s) of survey being protested. Any notice of protest filed after the scheduled date of official filing will be untimely and will not be considered. A notice of protest is considered filed on the date it is received by the Chief Cadastral Surveyor for Oregon/ Washington during regular business hours; if received after regular business hours, a notice of protest will be considered filed the next business day. A written statement of reasons in support of a protest, if not filed with the notice of protest, must be filed with the Chief Cadastral Surveyor for Oregon/ Washington within 30 calendar days after the notice of protest is filed. If a notice of protest against a plat of survey is received prior to the scheduled date of official filing, the official filing of the plat of survey identified in the notice of protest will be stayed pending consideration of the protest. A plat of survey will not be officially filed until the next business day following the resolution of all protests of the plat.

Before including your address, phone number, email address, or other personal identifying information in a notice of protest or statement of reasons, you should be aware that the documents you submit—including your personal identifying information—may be made publicly available in their entirety at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Mary J.M. Hartel,

Chief Cadastral Surveyor of Oregon/ Washington.

[FR Doc. 2019–07559 Filed 4–15–19; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LWO320000.L19900000.PP0000; OMB Control Number 1004–0114]

Agency Information Collection Activities; Recordation of Location Notices and Mining Claims; Payment of Fees

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.

DATES: Interested persons are invited to submit comments on or before June 17, 2019.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Jean Sonneman. U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW, Room 2134LM, Washington, DC 20240; or by email to *jsonneman@blm.gov.* Please reference OMB Control Number 1004–0114 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, please contact Elaine Guenaga, at 775–861–6539. Persons who use a telecommunication device for the deaf may call the Federal Information Relay Service at 1–800–877–8339, to leave a message for the above person.

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.

The following information pertains to this request:

Abstract: This control number applies to the location, recording and maintenance of mining claims and sites, in accordance with the Mining Law (30 U.S.C. 22–54), Section 314 of the Federal Land Policy and Management Act (FLPMA) (43 U.S.C. 1744), certain other statutes pertaining to specific Federal lands, and the Stock Raising Homestead Act (43 U.S.C. 299 and 301).

Title of Collection: Recordation of Location Notices and Mining Claims (43 CFR parts 3832, 3833, 3834, 3835, 3836, 3837, and 38380).

OMB Control Number: 1004–0114.

Forms:

- *3830–2, Maintenance Fee Waiver Certification;*
- *3830–3, Notice of Intent to Locate a Lode or Placer Mining Claim(s) and/or a Tunnel Site(s) on Lands Patented under the Stock Raising Homestead Act of 1916, As Amended by the Act of April 16, 1993; and*
- *3830–4, Affidavit of Annual Assessment Work.*

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Mining claimants.

Total Estimated Number of Annual Respondents: 27,800.

Total Estimated Number of Annual Responses: 191,492.

Estimated Completion Time per Response: Varies from 30 to 60 minutes per response.

Total Estimated Number of Annual Burden Hours: 95,821.

Respondent's Obligation: Required to obtain a benefit.

Frequency of Collection: On occasion, except Form 3830–2 (which may be filed annually) and annual FLPMA documents (are to be filed annually when required).

Total Estimated Annual Nonhour Burden Cost: $3,078,360.

The estimated annual burdens of this collection are itemized below:

A. Type of response	B. Number of responses	C. Hours per response	D. Total hours (Column B × Column C)
Notice of Intent to Locate Under the Stock Raising Homestead Act (43 CFR part 3838) Form 3830–3.	142	1 hour	142
Locating Mining Claims or Sites (43 CFR part 3832)	56,857	30 minutes ..	28,429
Recording a New Location Notice (43 CFR 3833, subpart A)	56,857	30 minutes ..	28,429
Amending a Location Notice (43 CFR part 3833, subpart B)	3,595	30 minutes ..	1,798
Transfer of Interest (43 CFR part 3833, subpart C) or Acquisition of a Delinquent Co-Claimant's Interest in a Mining Claim or Site (43 CFR part 3837).	22,546	30 minutes ..	11,273
Waiver from Annual Maintenance Fee (43 CFR part 3835, subpart A) Form 3830–2 and/or nonform data.	24,348	30 minutes ..	12,174
Annual FLPMA Documents (43 CFR part 3835, subpart C) Form 3830–4	27,142	30 minutes ..	13,571
Deferring Assessment Work (43 CFR part 3836, subpart B)	5	1 hour	5
Totals	191,492	.....	95,821

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,

Information Collection Clearance Officer, Bureau of Land Management.

[FR Doc. 2019–07563 Filed 4–15–19; 8:45 am]

BILLING CODE 4310–84–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–621 and 731–TA–1447 (Preliminary)]

Ceramic Tile From China; Institution of Anti-Dumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–621 and 731–TA–1447 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of ceramic tile from China, provided for in subheadings 6907.21.10, 6907.21.20, 6907.21.30, 6907.21.40, 6907.21.90, 6907.22.10, 6907.22.20, 6907.22.30, 6907.22.40, 6907.22.90, 6907.23.10, 6907.23.20, 6907.23.30, 6907.23.40, 6907.23.90, 6907.30.10, 6907.30.20, 6907.30.30, 6907.30.40, 6907.30.90, 6907.40.10, 6907.40.20, 6907.40.30, 6907.40.40, and 6907.40.90 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of China. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by May 28, 2019. The Commission's views must be transmitted to Commerce within five business days thereafter, or by June 4, 2019.

DATES: April 10, 2019.

FOR FURTHER INFORMATION CONTACT: Nathanael N. Comly ((202) 205–3174), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to a petition filed on April 10, 2019, by the Coalition for Fair Trade in Ceramic Tile.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Commission's Director of Investigations has scheduled a conference in connection with these investigations for 9:30 a.m. on Wednesday, May 1, 2019, at the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before April 29, 2019. Parties in support of the imposition of countervailing and antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

Written submissions.—As provided in sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before May 6, 2019, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on E-Filing, available on the Commission's website at *https://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In

making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission's rules.

By order of the Commission.

Issued: April 11, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–07573 Filed 4–15–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1128]

Certain Lithography Machines and Systems and Components Thereof (I) Termination of Investigation on the Basis of Settlement

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ'') initial determination (''ID'') (Order No. 15), granting a joint motion to terminate the investigation on the basis of settlement. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Sidney A. Rosenzweig, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–2532. Copies of non-confidential documents filed in connection with this investigation are or 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 *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.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 21, 2018, based on a complaint filed by Carl Zeiss SMT GmbH of Oberkochen, Germany. 83 FR 42317, 42318 (Aug. 21, 2018). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation, sale before importation, and sale in the United States after importation of certain lithography machines and systems and components thereof by reason of the infringement of certain claims of U.S. Patent No. 8,902,407 and U.S. Patent No. 9,280,058. *Id.* The notice of investigation named as respondents Nikon Corporation of Tokyo, Japan, as well as Nikon Research Corporation of America and Nikon Precision Inc., both of Belmont, California. *Id.* The Office of Unfair Import Investigations did not participate in this investigation.

On February 22, 2019, the parties jointly moved to terminate the investigation based on settlement. No responses were filed.

On March 18, 2019, the presiding ALJ issued the subject ID (Order No. 15) granting the motion. The ID finds that the motion complies with Commission Rule 210.21, *see* 19 CFR 210.21(a)–(b), and that the settlement agreement will not adversely affect the public interest, 19 CFR 210.50(b)(2). ID at 1–2.

No petitions for review of the ID were filed.

The Commission has determined not to review the ID. The investigation is terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: April 10, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–07514 Filed 4–15–19; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Agreement Approval Process for Use of Functional Affirmative Action Programs.

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Office of Federal Contract Compliance Programs (OFCCP) sponsored information collection request (ICR) titled, ''Agreement Approval Process for Use of Functional Affirmative Action Programs,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before May 16, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* website at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201902-1220-002* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OFCCP, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW, Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not

toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Agreement Approval Process for Use of Functional Affirmative Action Programs information collection. The regulations implementing Executive Order 11246 permit Federal supply and service contractors to develop affirmative action programs (AAPs) that are based on business functions or business units rather than AAPs based on establishments. Functional affirmative action programs (FAAPs) are designed to provide contractors with the option of creating AAPs that better fit their business needs. To develop and implement a FAAP, Federal contractors must receive written approval from the Director of OFCCP. This Information Collection Request (ICR) addresses the collection of information associated with the process for obtaining, modifying, updating, and renewing an agreement that allows contractors to develop and use functional AAPs. Executive Order 11246 authorizes this information collection. *See* 41 CFR 60–2.1(d)(4).

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. The DOL obtains OMB approval for this information collection under Control Number 1250–0006.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on 04/30/2019. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on September 11, 2018 (83 FR 45977).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1250–0006. The OMB 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–OFCCP.

Title of Collection: Agreement Approval Process for Use of Functional Affirmative Action Programs.

OMB Control Number: 1250–0006.

Affected Public: Private Sector.

Total Estimated Number of Respondents: 85.

Total Estimated Number of Responses: 85.

Total Estimated Annual Time Burden: 862 hours.

Total Estimated Annual Other Costs Burden: $21.25.

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

Frederick Licari,

Departmental Clearance Officer (Acting).

[FR Doc. 2019–07494 Filed 4–15–19; 8:45 am]

BILLING CODE 4510–CM–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (19–018)]

NASA Advisory Council; Regulatory and Policy Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Regulatory and Policy Committee of the NASA Advisory Council. This Committee reports to the NAC.

DATES: Wednesday, May 1, 2019, from 11:00 a.m.–4:30 p.m., Eastern Time.

ADDRESSES: NASA Headquarters, James Webb Memorial Auditorium, First Floor, 300 E Street SW, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Mr. Andrew Rowe, Designated Federal Officer, Office of Legislative and Intergovernmental Affairs, NASA Headquarters, Washington, DC 20546, (202) 358–4269 or *andrew.rowe@nasa.gov.*

SUPPLEMENTARY INFORMATION: This meeting will be open to the public up to the capacity of the meeting room. This meeting is also available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the toll number 1–720–259–6462 and then the numeric passcode 713620, followed by the # sign, or toll-free 1–844–467–6272 and then the numeric passcode 713620, followed by the # sign. *Note:* If dialing in, please ''mute'' your phone. To join via WebEx, the link is *https://nasaenterprise.webex.com/.* The meeting number is 903 548 068 and the meeting password is wWgfNC5@ (case sensitive).

The agenda for the meeting will include:

—Intellectual Property Reform
—International Space Station Commercialization
—Enabling Suborbital Human-Tended Payloads

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2019–07461 Filed 4–15–19; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of April 15, 22, 29, May 6, 13, 20, 2019.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of April 15, 2019

There are no meetings scheduled for the week of April 15, 2019.

Week of April 22, 2019—Tentative

Tuesday, April 23, 2019

10:00 a.m. Strategic Programmatic Overview of the Fuel Facilities and the Nuclear Materials Users Business Lines (Public Meeting) (Contact: Paul Michalak: 301–415–5804)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of April 29, 2019—Tentative

Tuesday, April 30, 2019

10:00 a.m. Briefing on the Annual Threat Environment (Closed Ex. 1)

Week of May 6, 2019—Tentative

There are no meetings scheduled for the week of May 6, 2019.

Week of May 13, 2019—Tentative

Tuesday, May 14, 2019

9:00 a.m. Briefing on Digital Instrumentation and Control (Public Meeting) (Contact: Jason Paige: 301–415–1474)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Thursday, May 16, 2019

10:00 a.m. Briefing on Security Issues (Closed Ex. 1)

2:00 p.m. Briefing on Security Issues (Closed Ex. 1)

Week of May 20, 2019—Tentative

There are no meetings scheduled for the week of May 20, 2019.

CONTACT PERSON FOR MORE INFORMATION: 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.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please 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 by email at *Wendy.Moore@nrc.gov.*

Dated at Rockville, Maryland, this 11th day of April, 2019.

For the Nuclear Regulatory Commission.

Glenn Ellmers,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2019–07636 Filed 4–12–19; 11:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0088]

Information Collection: Collection of Research Code Non-Disclosure Agreement Information

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on this proposed collection of information. The information collection is entitled, ''Collection of Research Code Non-disclosure Agreement Information.''

DATES: Submit comments by June 17, 2019. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2019–0088. Address questions about NRC dockets to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T6–A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0088 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website*: Go to *http://www.regulations.gov* and search for Docket ID NRC–2019–0088. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2019–0088 on this website.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML19099A416. The supporting statement is available in ADAMS under Accession No. ML18274A286.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

Please include Docket ID NRC–2019–0088 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in

comment submissions that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Collection of Research Code Non-Disclosure Agreement Information.

2. *OMB approval number:* An OMB control number has not yet been assigned to this proposed information collection.

3. *Type of submission:* New.

4. *The form number, if applicable:* Not applicable.

5. *How often the collection is required or requested:* As needed.

6. *Who will be required or asked to respond:* Domestic and foreign users of NRC's nuclear safety analytical computer codes.

7. *The estimated number of annual responses:* 640.

8. *The estimated number of annual respondents:* 640.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 640 hours.

10. *Abstract:* This information collection request is a non-disclosure agreement (NDA) used for domestic and foreign entities to obtain and use the U.S. Nuclear Regulatory Commission's (NRC's) nuclear safety analytical computer codes. NRC develops and uses computer codes to independently model and evaluate safety issues associated with the licensed use of radioactive materials. As a global leader in nuclear regulatory research and safety assessment, NRC is frequently approached by domestic and international organizations requesting copies of NRC computer codes. In general, to obtain an NRC code an individual or organization first agrees to not redistribute the code (*i.e.,* non-disclosure) through a non-disclosure agreement (NDA). The NDA also imposes terms and conditions for code use, and requires notification to NRC of code errors, code modifications, and updated user information. An officially signed and executed NDA of users agreeing to the terms and conditions is current NRC practice for access to NRC-developed computer codes. Once the NDA has been signed, received, reviewed, and accepted, the requesting individual or organization is given access to the requested code. The information collection enables the NRC to ensure that proper procedures and agreements are in place to guide the distribution and use of these codes according to NRC and U.S. Government policies and international agreements such as import-export restrictions and intellectual property rights. Further information collection on code errors and modifications by code users permits NRC to maintain control and quality of its codes in a timely and efficient manner.

Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the estimate of the burden of the information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 11th day of April 2019.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2019–07524 Filed 4–15–19; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, April 18, 2019.

PLACE: The meeting will be held at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

Commissioner Roisman, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matters of the closed meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Dated: April 11, 2019.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–07638 Filed 4–12–19; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85587; File No. SR–ICEEU–2019–007]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the ICE Clear Europe Delivery Procedures.

April 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

notice is hereby given that on March 26, 2019, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II and III below, which Items have been prepared by ICE Clear Europe. ICE Clear Europe filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(4)[4] thereunder, such that the proposed rule change was immediately 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

The principal purpose of the proposed amendments is for ICE Clear Europe to add delivery terms relating to the ICE Endex Central European Gas Hub AG (''CEGH'') Austrian VTP Natural Gas Futures Contracts.[5]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICE Clear Europe is proposing to amend its Delivery Procedures to add a new Part EE regarding delivery procedures relating to a new natural gas futures contract, the ICE Endex CEGH Austrian VTP Natural Gas Futures Contract (the ''Contract''), that would be traded on ICE Endex and cleared by ICE Clear Europe.

Proposed Part EE would set out the delivery specifications and procedures for deliveries under the Contract. Delivery would be effected by the transfer of rights to natural gas at the Virtual Trading Point (''VTP'') [6] from a Transferor (nominated by the Seller and which may be the Seller) to the Clearing House and from the Clearing House (via its nomination agent) to a Transferee (nominated by the Buyer and which may be the Buyer) through the input of Trade Nominations into the CEGH eletronic system. Under Part EE, Clearing Members would authorize the Clearing House to make Trade Nominations on their behalf. The amendments would also establish certain timing requirements for exchange of futures for physical and swap transactions under exchange rules.

Proposed Part EE would address certain the responsibilities of the Clearing House and relevant parties for delivery under the Contracts, supplementing the existing provisions of the Rules. Specifically, the Clearing House would not be responsible for the performance of CEGH. Further, neither the Buyer nor the Seller, nor their Transferees or Transferors, would have any claim against the Clearing House for any loss incurred as a result of the condition or operation of the Transmission Network unless provided in the ICE Endex Rules.

Proposed Part EE would address delivery contract security for the Buyer and Seller, invoicing with respect to the Contract and certain details of the delivery process, including processes relating to a failed delivery. Delivery under Contracts would be based on open contract positions at the cessation of trading and EFPs and EFSs posted up to one hour following the cessation of trading on the last trading day for which delivery is specified. The procedures would include a detailed timeframe for relevant notices of intent to deliver or receive, nominations of Transferors and Transferees, delivery confirmations, invoicing, provision of security and release of security following completion of delivery and other matters.

Proposed Part EE would also describe certain reports produced by the Clearing House that are made available to Buyers and Sellers and their timing.

(b) Statutory Basis

Section 17A(b)(3)(F) of the Act [7] 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, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest. The proposed amendments are designed to facilitate the clearing of a new physically settled natural gas futures contract that is being launched for trading by the ICE Endex exchange. The amendments would set out the obligations and roles of Clearing Members and the Clearing House. ICE Clear Europe believes that its financial resources, risk management, systems and operational arrangements are sufficient to support clearing of such contract (and to address physical delivery under such contract) and to manage the risks associated with such contract. As a result, in ICE Clear Europe's view, the amendments would be consistent with the prompt and accurate clearance and settlement of the Contract as set out in the proposed Delivery Procedures amendments, and the protection of investors and the public interest consistent with the requirements of Section 17A(b)(3)(F) of the Act.[8] (In ICE Clear Europe's view, the amendments would not affect the safeguarding of funds or securities in the custody or control of the clearing agency or for which it is responsible, within the meaning of Section 17A(b)(3)(F).[9])

In addition, Rule 17Ad–22(e)(10) [10] requires that each covered clearing agency establish and maintain transparent written standards that state its obligations with respect to the delivery of physical instruments, and establish and maintain operational practices that identify, monitor and manage the risks associated with such physical deliveries. As discussed above, the amendments to the Delivery Procedures relating to the delivery and settlement under the Contract and ICE Endex exchange contract terms would set out the obligations and roles of Clearing Members, the Clearing House and CEGH. The amendments would also adopt relevant procedures for such deliveries, which would facilitate identifying, monitoring and managing risks associated with delivery.

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule changes would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4).

[5] Capitalized terms used but not defined herein have the meaning specified in the ICE Clear Europe Clearing Rules (the ''Rules'').

[6] This is the virtual trading point as defined in the Austrian Natural Gas Act 2011, in respect of a Contract, being a notional point in the Austrian Eastern Market Area at which natural gas can be traded after injection and before offtake.

[7] 15 U.S.C. 78q–1(b)(3)(F).

[8] 15 U.S.C. 78q–1(b)(3)(F).

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] 17 CFR 240.17Ad–22(e)(10).

purposes of the Act. The changes are being proposed in order to update the Delivery Procedures in connection with the listing of the Contract for trading on the ICE Endex market. ICE Clear Europe believes that such contracts would provide opportunities for interested market participants to engage in trading activity in the Austrian VTP Natural Gas market. ICE Clear Europe does not believe the amendments would adversely affect competition among Clearing Members, materially affect the cost of clearing, adversely affect access to clearing in Contracts for Clearing Members or their customers, or otherwise adversely affect competition in clearing services. Accordingly, ICE Clear Europe does not believe that the amendments would impose any impact or burden on competition that is not appropriate in furtherance of the purpose of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any comments received with respect to the proposed amendments.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and paragraph (f) of Rule 19b–4 [12] 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.

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–ICEEU–2019–007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2019–007. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/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–ICEEU–2019–007 and should be submitted on or before May 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–07506 Filed 4–15–19; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85585; File No. SR–BX–2019–008]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Pilot Related to Rule 4121, Trading Halts Due to Extraordinary Market Volatility

April 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 9, 2019, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the pilot related to Rule 4121, Trading Halts Due to Extraordinary Market Volatility, to the close of business on October 18, 2019.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqbx.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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Rule 4121 provides a methodology for determining when to halt trading in all stocks due to extraordinary market volatility, *i.e.,* market-wide circuit breakers. The market-wide circuit breaker mechanism under Rule 4121 was approved by the Commission to operate on a pilot basis, the term of which was to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS (the ''LULD Plan''),[3] including any extensions to the pilot period for the LULD Plan.[4] The Commission published an amendment to the LULD Plan for it to operate on a permanent, rather than pilot, basis.[5]

The Exchange proposes to amend Rule 4121 to untie the pilot's effectiveness from that of the LULD Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019. The Exchange does not propose any additional changes to Rule 4121.

Market-wide circuit breakers under Rule 4121 provide an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when securities markets experience extreme broad-based declines. All U.S. equity exchanges have rules relating to market-wide circuit breakers, which are designed to slow the effects of extreme price movement through coordinated trading halts across securities markets when severe price declines reach levels that may exhaust market liquidity. Market-wide circuit breakers provide for trading halts in all equities and options markets during a severe market decline as measured by a single-day decline in the S&P 500 Index.

Pursuant to Rule 4121, a market-wide trading halt will be triggered if the S&P 500 Index declines in price by specified percentages from the prior day's closing price of that index. Currently, the triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2) and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 circuit breaker after 9:30 a.m. ET and before 3:25 p.m. ET would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. ET would not halt market-wide trading. A market decline that triggers a Level 3 circuit breaker, at any time during the trading day, would halt market-wide trading for the remainder of the trading day.

The Exchange intends to file a separate proposed rule change to operate Rule 4121 on a permanent, rather than pilot, basis. Extending the effectiveness of Rule 4121 to the close of business on October 18, 2019 should provide the Commission adequate time to consider whether to approve the Exchange's separate proposal to operate the market-wide circuit breaker mechanism under Rule 4121 on a permanent basis.

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 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 also believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning when and how to halt trading in all stocks as a result of extraordinary market volatility. Extending the market-wide circuit breaker pilot under Rule 4121 an additional six months would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Commission considers whether to approve the pilot on a permanent basis. The proposed rule change would thus promote fair and orderly markets and the protection of investors and the public interest. Based on the foregoing, the Exchange believes the benefits to market participants from the market-wide circuit breaker mechanism under Rule 4121 should continue on a pilot basis while the Commission considers whether to permanently approve Rule 4121.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change implicates any competitive issues because the proposal would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Commission considers whether to permanently approve the market-wide circuit breaker mechanism under Rule 4121. Further, the Exchange understands that FINRA and other national securities exchanges will file proposals to extend their rules regarding the market-wide circuit breaker pilot so that the market-wide circuit breaker mechanism may continue uninterrupted while the Commission considers whether to approve its operation on a permanent basis.

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 Act[8] and Rule 19b–4(f)(6) thereunder.[9]

A proposed rule change filed under Rule 19b–4(f)(6)[10] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii),[11] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30–day operative delay so that the proposal may become operative upon filing. Extending the pilot for an additional six months will allow the uninterrupted operation of the existing pilot to halt trading across the U.S. markets while the Commission considers whether to approve the pilot on a permanent basis. The extension simply maintains the status quo. Therefore, the Commission believes that

[3] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

[4] *See* Securities Exchange Act Release Nos. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–BX–2011–068) (Approval Order); and 68815 (February 1, 2013), 78 FR 9752 (February 11, 2013) (SR–BX–2013–009) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Delay the Operative Date of a Rule Change to Exchange Rule 4121).

[5] *See* Securities Exchange Act Release Nos. 84843 (December 18, 2018), 83 FR 66464 (December 26, 2018) (Amendment No. 18 Proposing Release).

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6).

[10] *Id.*

[11] 17 CFR 240.19b–4(f)(g)(iii).

waiving the 30–day operative delay is consistent with the protection of investors and the public interest. The Commission hereby designates the proposed rule change to be operative upon filing.[12]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule–comments@sec.gov.* Please include File Number SR–BX–2019–008 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–BX–2019–008. 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–2019–008, and should be submitted on or before May 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–07508 Filed 4–15–19; 8:45 am]

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[12] For purposes only of waiving the 30–day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85591; File No. SR–CboeBZX–2019–024]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Modify Its Fee Schedule

April 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 3, 2019, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to modify its fee schedule. The text of the proposed rule change is attached as Exhibit 5 [sic].

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the BZX Options fee schedule to modify the definitions of fee codes RQ and RR to include routing to a new options market, MIAX Emerald LLC (''MIAX Emerald''), effective April 3, 2019. The Exchange's current approach to routing fees is to set forth in a simple manner certain sub-categories of fees that approximate the cost of routing to other options exchanges based on the cost of transaction fees assessed by each venue as well as costs to the Exchange for routing (*i.e.,* clearing fees, connectivity and other infrastructure costs, membership fees, etc.) (collectively, ''Routing Costs''). The Exchange then monitors the fees charged as compared to the costs of its routing services and adjusts its routing fees and/or sub-categories to ensure that the Exchange's fees do indeed result in a rough approximation of overall Routing Costs, and are not significantly higher or lower in any area.

Currently, fee code RR is appended to Customer orders in non-Penny Pilot securities that are routed to ARCA, C2, ISE, ISE Gemini, MIAX Pearl or NOM and assessed a fee of $1.25 per contract. Additionally, fee code RQ is appended to Customer orders in Penny Pilot securities that are routed to ARCA, C2, ISE, ISE Gemini, MIAX Pearl or NOM and assessed a fee of $0.85 per contract. The Exchange proposes to modify the definitions of fee code RQ and PR to include MIAX Emerald. The Exchange

anticipates that the proposed fee structure will approximate the cost of routing orders to MIAX Emerald. The Exchange is proposing the charges set forth above to maintain a simple and fair fee schedule with respect to routing fees that approximate the total cost of routing, including Routing Costs.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the Section 6 of the Act,[3] in general, and Section 6(b)(4),[4] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. As explained above, the Exchange generally attempts to approximate the cost of routing to other options exchanges, including other applicable costs to the Exchange for routing. The Exchange believes its proposed fees are reasonable taking into account Routing Costs based on the rates charged by MIAX Emerald. The Exchange believes that a pricing model based on approximate Routing Costs is a reasonable, fair and equitable approach to pricing. Specifically, the Exchange believes that its proposal to adopt routing fees to MIAX Emerald is fair, equitable and reasonable because the fees are generally an approximation of the anticipated cost to the Exchange for routing orders to MIAX Emerald. The Exchange notes that routing through the Exchange is voluntary. The Exchange also believes that the proposed fee structure for orders routed to and executed at MIAX Emerald is fair and equitable and not unreasonably discriminatory in that it applies equally to all Members.

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 Exchange believes the proposed routing fee will not impose an undue burden on competition because the Exchange will uniformly assess the routing fee on all Members. The Exchange does not believe that the proposed changes represent a significant departure from routing fees offered by the Exchange's competitors. Additionally, Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value or if they view the proposed fee as excessive. Further, excessive fees for participation would serve to impair an exchange's ability to compete for order flow and members rather than burdening competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [5] and paragraph (f) of Rule 19b–4 [6] 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–CboeBZX–2019–024 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–2019–024. 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–2019–024 and should be submitted on or before May 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Eduardo A. Aleman,

Deputy Secretary.

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[3] 15 U.S.C. 78f.

[4] 15 U.S.C. 78f(b)(4).

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4(f).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85589; File No. SR–FINRA–2019–009]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt Remaining Legacy NASD and Incorporated NYSE Rules as FINRA Rules

April 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 8, 2019, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of the filing by 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

FINRA is proposing to adopt the following NASD Rules as FINRA Rules in the consolidated FINRA rulebook without any substantive changes: (1) The NASD Rule 1010 Series (Membership Proceedings) into the FINRA Rule 1000 Series; (2) NASD Rule 1090 (Foreign Members) as FINRA Rule 1021; (3) NASD Rule 2340 (Customer Account Statements) as FINRA Rule 2231; (4) NASD Rule 2510 (Discretionary Accounts) as FINRA Rule 3260; (5) NASD Rule 3140 (Approval of Change in Exempt Status Under SEA Rule 15c3–3) as FINRA Rule 1020; (6) NASD Rule 3150 (Reporting Requirements for Clearing Firms) as FINRA Rule 4540; and (7) NASD Rule IM–3150 (Exemptive Relief) as Supplementary Material to FINRA Rule 4540. In addition, the proposed rule change would adopt the remaining Incorporated NYSE Rules and Interpretations in the consolidated FINRA rulebook without any substantive changes as a separate Temporary Dual FINRA–NYSE Member Rule Series. FINRA also proposes to delete four Incorporated NYSE Rule definitions (Incorporated NYSE Rules—Rule 4 (''Stock''), Rule 5 (''Bond''), Rule 9 (''Branch Office Manager''), and Rule 12 (''Business Day'')) that are not used in the FINRA rule set as well as Incorporated NYSE Rule 375 and related Interpretation. Finally, the proposed rule change would update cross-references and make other non-substantive changes within FINRA rules, due in part to the adoption of new consolidated FINRA rules.

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

[3] 17 CFR 240.19b–4(f)(6).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA 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. FINRA 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

As part of the process of completing a consolidated rulebook (''Consolidated FINRA Rulebook''),[4] FINRA is proposing to adopt the following NASD Rules as FINRA Rules in the Consolidated FINRA Rulebook without any substantive changes: (1) The NASD Rule 1010 Series (Membership Proceedings) into the FINRA Rule 1000 Series; [5] (2) NASD Rule 1090 (Foreign Members) as FINRA Rule 1021; (3) NASD Rule 2340 (Customer Account Statements) as FINRA Rule 2231; (4) NASD Rule 2510 (Discretionary Accounts) as FINRA Rule 3260; (5) NASD Rule 3140 (Approval of Change in Exempt Status Under SEA Rule 15c3–3) as FINRA Rule 1020; (6) NASD Rule 3150 (Reporting Requirements for Clearing Firms) as FINRA Rule 4540; and (7) NASD Rule IM–3150 (Exemptive Relief) as Supplementary Material to FINRA Rule 4540. In addition, FINRA proposes to adopt the remaining Incorporated NYSE Rules and Interpretations in the Consolidated FINRA Rulebook without any substantive changes as a separate Temporary Dual FINRA–NYSE Member Rule Series. The Temporary Dual FINRA–NYSE Member Rule Series in the Consolidated FINRA Rulebook as the name suggests would apply solely to Dual Members.[6] Finally, FINRA proposes to update cross-references and make other non-substantive changes within FINRA rules.

FINRA is proposing to transfer these remaining NASD Rules and Incorporated NYSE rules and Interpretations into the FINRA Consolidated Rulebook without any substantive changes at this time to eliminate the Transitional Rulebook and provide greater clarity and regulatory efficiency to FINRA members.[7] FINRA will continue to review the substance of the rules addressed in this proposed rule change and expects to propose substantive changes to some or all of the rules as part of future rulemakings.

Membership Rules

The proposed rule change would adopt the NASD Rule 1010 Series (Membership Proceedings) (collectively, the ''MAP rules'') into the FINRA Rule 1000 Series without any substantive changes.[8] The NASD Rule 1010 Series (Membership Proceedings) governs FINRA's membership application process. Exchange Act Section 15A(b)(8) requires that FINRA establish rules providing a fair procedure for the denial of membership.[9] FINRA's MAP rules provide a means for FINRA, through its Membership Application Program (''MAP''), to assess the proposed business activities of its potential and current member firms. FINRA evaluates

[4] The current FINRA rulebook consists of: (1) FINRA Rules; (2) NASD Rules; and (3) rules incorporated from New York Stock Exchange LLC (''NYSE'') (''Incorporated NYSE Rules'') (together, the NASD Rules and Incorporated NYSE Rules are referred to as the ''Transitional Rulebook''). While the NASD Rules generally apply to all FINRA members, the Incorporated NYSE Rules apply only to those members of FINRA that are also members of the NYSE (''Dual Members''). The FINRA Rules apply to all FINRA members, unless such rules have a more limited application by their terms. For more information about the rulebook consolidation process, *see Information Notice,* March 12, 2008 (Rulebook Consolidation Process).

[5] The FINRA Rule 1000 Series exists in the FINRA rulebook and consists of FINRA Rule 1010. The proposed rule change amends FINRA Rule 1010 to update the rule cross reference by deleting the reference to NASD and updating the cross references to reflect the adoption of the consolidated FINRA registration rules. *See also infra* note 30.

[6] *See supra* note 4.

[7] Exhibit 4 presents the text of the proposed rule change with the changes marked against the existing NASD and Incorporated NYSE Rules and Interpretations to show the updated cross-references, deletions of references to NASD and similar changes. Exhibit 5 shows the text of the proposed rule change marked against the current rule text with the NASD rules show as deleted and the FINRA rules shown as new text.

[8] FINRA previously solicited comment on a proposal to adopt the consolidated FINRA Rule 1000 Series that would have transferred the NASD Rule 1010 Series and Incorporated NYSE Rules 311, 312, 313, 321, 416 and related supplementary material and rule interpretations, and Incorporated NYSE Rule 401/03 Interpretations to FINRA rules with significant changes. *See Regulatory Notices* 10–01 (January 2010), 13–29 (September 2013) and 18–23 (July 2018). C:\Users\adeolam\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\RMPEEONQ\FINRA [sic] FINRA is separately developing changes to the MAP rules in connection with the retrospective review of this rule set. *See Regulatory Notice* 18–23 (July 26, 2018) (requesting comment on a proposal regarding the MAP rules).

In addition, the proposed rule change corrects rule cross-references in the MAP rules.

[9] 15 U.S.C. 78*o*–3(b)(8).

an applicant's financial, operational, supervisory and compliance systems to ensure that each applicant meets the standards set forth in NASD Rule 1014.

NASD Rule 1011 (Definitions), proposed to be adopted as FINRA Rule 1011, sets forth the defined terms applicable to the membership application process. NASD Rule 1012 (General Provisions), proposed to be adopted as FINRA Rule 1012, sets forth the requirements for submitting membership applications and supporting documentation. The MAP rules require the filing of two distinct types of applications. One category is a new member application (''NMA'') filed by an applicant seeking membership in FINRA, which is filed pursuant to NASD Rule 1013 (New Member Application and Interview), proposed to be adopted as FINRA Rule 1013. The other category is a continuing membership application (''CMA''), which is filed pursuant to NASD Rule 1017 (Application for Approval of Change in Ownership, Control or Business Operations), proposed to be adopted as FINRA Rule 1017. NASD IM–1011–1 (Safe Harbor for Business Expansions), proposed to be adopted as FINRA IM–1011–1, specifies the parameters for increases a member may make in the number of its associated persons involved in sales, offices or markets made that is measured on a rolling 12-month period. The incremental changes a member may make in these three categories are presumed not to be a ''material change in business operations'' (as defined in Rule 1011) and thus do not require the filing of a CMA.

NASD IM–1013–1 (Membership Waive-In Process for Certain New York Stock Exchange Member Organizations) and NASD IM–1013–2 (Membership Waive-In Process for Certain NYSE Alternext US LLC Member Organizations)—proposed to be adopted as FINRA IM–1013–1 and FINRA IM–1013–2, respectively—set forth a streamlined application and review process for FINRA membership that applied to certain NYSE and NYSE American (formerly known as NYSE Alternext US) (''waived-in firms'').

To maintain the status quo for the waived-in firms, the proposed rule change would clarify that such firms would be subject to FINRA rules, other than FINRA Rules 1011 through 1016, 1019 through 1021, 2231, 3260 and 4540. With the exception of proposed FINRA Rule 1017, the proposed rule change would not require the waived-in firms to comply with the FINRA Rule 1000 Series, or FINRA Rules 2231, 3260 and 4540, because these FINRA rules will continue to have a corresponding Temporary Dual FINRA–NYSE Member rule to which the waived-in firms will be subject (namely Incorporated NYSE Rules 311, 312, 313, 408, 409, 416 and 416A and related interpretations). As the Temporary Dual FINRA–NYSE Member Rules are eliminated, these waived-in firms will become subject to the corresponding FINRA rule. In addition, as is the case today, if at any time a waived-in firm seeks to expand its business beyond the permitted floor activities, the firm must apply for and receive approval to engage in any such activity under proposed FINRA Rule 1017. Once approved, the firm must immediately comply with *all* FINRA rules.

All applications are evaluated to determine whether the applicant meets the 14 standards or criteria (*e.g.,* completeness and accuracy of the application and supporting documentation, the acquisition of all requisite licenses and registrations, a sufficient level of net capital, the establishment of necessary contractual agreements and business relationships, an adequate supervisory system) set forth in NASD Rule 1014 (Department Decision), proposed to be adopted as FINRA Rule 1014.

FINRA may grant in whole, in part (subject to restrictions), or deny an NMA or CMA. NASD Rule 1015 (Review by National Adjudicatory Council), proposed to be adopted as FINRA Rule 1015, permits an applicant to submit a request for a review by the National Adjudicatory Council of an adverse decision rendered on an NMA or CMA. NASD Rule 1016 (Discretionary Review by FINRA Board), proposed to be adopted as FINRA Rule 1016, also permits a Governor of the FINRA Board to call for a discretionary review of a membership proceeding. Finally, a person aggrieved by a final action of FINRA under the NASD Rule 1010 Series may apply for review by the SEC pursuant to NASD Rule 1019 (Application to Commission for Review), proposed to be adopted as FINRA Rule 1019.

Foreign Members

FINRA proposes to adopt NASD Rule 1090 (Foreign Members) as FINRA Rule 1021 without any substantive changes. NASD Rule 1090 provides that a member that does not maintain an office in the United States responsible for preparing and maintaining financial and other reports required to be filed with the SEC and FINRA must agree to a set of requirements that are necessary to effectively regulate foreign members' compliance with applicable securities laws and regulations, and with applicable FINRA rules. Such requirements include, among others, preparing all reports and maintaining a general ledger chart of account in English and U.S. dollars and having an individual fluent in English and knowledgeable in securities and financial matters to assist representatives of FINRA during examinations.

Customer Account Statements

FINRA proposes to adopt NASD Rule 2340 (Customer Account Statements) as FINRA Rule 2231 without any substantive changes.[10] NASD Rule 2340 generally requires each general securities member to send account statements to customers at least once each calendar quarter containing a description of any securities positions, money balances or account activity in the accounts since the prior account statements were sent, except if carried on a Delivery versus Payment/Receive versus Payment basis. The rule also sets forth requirements for disclosure of values for unlisted or illiquid direct participation programs and real estate investment trusts.

Discretionary Accounts

FINRA proposes to adopt NASD Rule 2510 (Discretionary Accounts) as FINRA Rule 3260 without any substantive changes.[11] NASD Rule 2510 addresses the obligations of members and associated persons that have discretionary power over a customer's account.[12] The rule prohibits a firm and its agents or employees that have discretionary power over a customer's account from effecting any excessive transactions in view of the financial resources and character of the account. The rule also provides that a member or registered representative may not exercise any discretionary power in such account unless the customer has given prior written authorization to a stated individual or individuals, and the

[10] FINRA previously filed a proposal with the SEC to adopt consolidated FINRA Rule 2231 that would have transferred NASD Rule 2340 and Incorporated NYSE Rule 409 (and its related interpretations) with significant changes, but such filing was subsequently withdrawn. *See* Securities Exchange Act Release No. 67588 (August 2, 2012), 77 FR 47470 (August 8, 2012) (Notice of Withdrawal of File No. SR–FINRA–2009–028). FINRA solicited comment on a revised proposal. *See Regulatory Notice* 14–35 (September 2014).

[11] FINRA previously solicited comment to adopt consolidated FINRA Rule 3260 that would have transferred NASD Rule 2510 and Incorporated NYSE Rule 408 and Interpretation 408/01 and/02 with significant changes. *See Regulatory Notices* 09–63 (November 2009) and 15–22 (June 2015).

[12] *See also* SEA Rule 15c1–7 (Discretionary Accounts).

account has been accepted in writing by the member or a designated partner, officer or manager of the member. In addition, a member or a designated partner, officer or manager must approve promptly in writing each discretionary order entered and review all discretionary accounts at frequent intervals to detect and prevent excessive transactions. The rule provides certain exceptions from its requirements.

Approval of Change in Exempt Status Under SEA Rule 15c3–3

FINRA proposes to adopt NASD Rule 3140 (Approval of Change in Exempt Status Under SEC Rule 15c3–3) as FINRA Rule 1020 without any substantive changes. NASD Rule 3140 provides that a member (as defined in paragraph (a)) operating pursuant to any exemptive provision in SEA Rule 15c3–3(k) shall not change its method of doing business in a manner which will change its exemptive status to a fully computing firm that is subject to all provisions of SEA Rule 15c3–3; or commence operations that will disqualify it for continued exemption under SEA Rule 15c3–3 without first having obtained the prior written approval of FINRA. The rule sets forth standards that FINRA staff considers in approving or denying such an application under the rule.

Reporting Requirement for Clearing Firms

FINRA proposes to adopt NASD Rule 3150 (Reporting Requirements for Clearing Firms) as FINRA Rule 4540 without any substantive changes. NASD Rule 3150 states that all clearing firms must report prescribed data to FINRA about the member and any member broker-dealers for which it clears. The member may report through a third-party but such member remains responsible for the compliance with the rule. In addition, the proposed rule change would incorporate without substantive change the provisions regarding the requirement to distinguish between data pertaining to all proprietary and customer accounts of an introducing member and of any member for which the introducing member is acting as an intermediary.

FINRA proposes to adopt NASD IM–3150 (Exemptive Relief) as Supplementary Material to proposed FINRA Rule 4540 without any substantive changes. NASD IM–3150 sets forth the circumstances under which FINRA would generally grant an exemption to the clearing firm reporting requirement in NASD Rule 3150 (proposed to be adopted as FINRA Rule 4540). The provision further requires that a member report to FINRA any change in the operation or nature of its business such that it no longer qualifies for an exemption previously granted under the rule.

Incorporated NYSE Rules and Interpretations

FINRA incorporated a set of NYSE rules and interpretations as Incorporated NYSE Rules and Interpretations when NASD and the NYSE consolidated their member regulation operations to form FINRA.[13] Since that time, FINRA has been amending NASD Rules and Incorporated NYSE Rules and Interpretations to establish a single set of rules. Given that FINRA would like to proceed with the rulebook consolidation process expeditiously to eliminate the Transitional Rulebook and provide greater clarity and regulatory efficiency to FINRA members, FINRA is proposing to adopt the remaining Incorporated NYSE Rules and Interpretations, as listed below, as FINRA Rules, without any substantive changes. The proposed rule change would retain the current numbering convention and add a ''T'' after the number to denote its placement in the Temporary Dual FINRA–NYSE Member Rule Series of the Consolidated FINRA Rulebook. FINRA also proposes to delete four Incorporated NYSE Rule definitions that are not used in the FINRA rule set as well as Incorporated NYSE Rule 375 and related Interpretation as discussed below. The Temporary Dual FINRA–NYSE Member Rule Series in the Consolidated FINRA Rulebook as the name suggests would apply solely to Dual Members. The proposed rule change would not impose any new requirements on any member firms.

- Incorporated NYSE Rule 1 (''The Exchange'') that defines the term ''the Exchange'' generally to mean the ''New York Stock Exchange LLC'' would be adopted as FINRA Rule 1T;
- Incorporated NYSE Rule 2 (''Member,'' ''Membership,'' ''Member Firm,'' etc.) that defines these terms to mean a person who has been approved by the Exchange and, among others, includes a definition for ''control'' to mean a person who can direct or cause the direction of the management or policies of a person and sets thresholds for a presumption of control, would be adopted as FINRA Rule 2T;
- Incorporated NYSE Rule 3 (''Security'') that defines the term ''security'' the same as used in the Exchange Act would be adopted as FINRA Rule 3T;
- Incorporated Rule 6 (''Floor'') that defines the term ''Floor'' to mean the trading floor at the applicable addresses listed therein would be adopted as FINRA Rule 6T;
- Incorporated NYSE Rule 8 (''Delivery'') that defines the term ''Delivery'' to mean the delivery of securities on Exchange contracts would be adopted as FINRA Rule 8T;
- Incorporated NYSE Rule 11 (Effect of Definitions) that provides that the terms defined in Exchange Rules shall have the meaning specified therein would be adopted as FINRA Rule 11T;
- Incorporated NYSE Rule 311 (Formation and Approval of Membership Organization) that details the requirements to be approved as a member organization would be adopted as FINRA Rule 311T.[14]
- Incorporated NYSE Rule 312 (Changes Within Member Organizations) that requires member organizations to give notice to the Exchange in certain circumstances, including, without limitation, when there is a change of stockholdings of the member or a change in directors or officers would be adopted as FINRA Rule 312T.[15]
- Incorporated NYSE Rule 313 (Submission of Partnership Articles—Submission of Corporate Documents) that requires the submission of certain corporate and partnership documents to the Exchange would be adopted as FINRA Rule 313T.[16]
- Incorporated NYSE Rule 321 (Formation or Acquisition of Subsidiaries) that requires approval for a member to form a subsidiary would be adopted as FINRA Rule 321T.[17]
- Incorporated NYSE Rule 408 (Discretionary Power in Customers' Accounts) that addresses the obligations of members that have discretionary power over customers' accounts would be adopted as FINRA Rule 408T; [18]
- Incorporated NYSE Rule 409 (Statements of Accounts to Customers) that requires a member to send customers statements of account would be adopted as FINRA Rule 409T; [19]
- Incorporated NYSE Rule 416 (Questionnaires and Reports) that requires members to submit reports as requested by the Exchange would be adopted as FINRA Rule 416T;

[13] *See* Securities Exchange Act Release No. 56147 (July 26, 2007), 72 FR 42166 (August 1, 2007) (Order Approving File No. SR–NASD–2007–054).

[14] *See supra* note 8.

[15] *See supra* note 8.

[16] *See supra* note 8.

[17] *See supra* note 8.

[18] *See supra* note 11.

[19] *See supra* note 8.

• Incorporated NYSE Rule 416A (Members and Member Organizations Profile Information Updates and Quarterly Certifications Via The Electronic Filing Platform) that requires that members supply to the Exchange's electronic filing platform certain profile information and certify to the Exchange quarterly, would be adopted as FINRA Rule 416AT;

• Incorporated NYSE Rule 435 (Miscellaneous Provisions) that provides that no member shall circulate rumors of a sensational character which might reasonably be expected to affect market conditions on the Exchange would be adopted as FINRA Rule 435T.[20]

• Incorporated NYSE Rule Interpretation 311(b), (f) and (g) that provides guidance on whether officers may be part time, criteria for the principal place of business of the member, and use of titles and division identification would be adopted as FINRA Rule 311T(b), (f) and (g).[21]

• Incorporated NYSE Rule Interpretation 401/01 through/04 that requires members notify the Exchange prior to certain events, including among others, changes in business activities, liquidity problems or capital problems would be adopted as FINRA Rule 401T/01 through/04.[22]

• Incorporated NYSE Rule Interpretation 408/01 and/02 that requires identification of discretionary orders and provides guidance for establishing automatic money market fund redemptions would be adopted as FINRA Rule 408T/01 and/02.[23]

• Incorporated NYSE Rule Interpretation 409/(a) and/(b) that dictates the disclosures that must be made in a customer account statement, including for externally held assets, and requirements for use of third party agents, logos, summary statements and holding foreign customer mail would be adopted as FINRA Rule 409T/(a) and/(b).[24]

• Incorporated NYSE Interpretation 435(5)/01 that states that the responsibility to prohibit the circulation of rumors extends to all member personnel would be adopted as FINRA Rule 435(5)T/01.[25]

FINRA proposes to delete the following Incorporated NYSE Rules—Rule 4 (''Stock''), Rule 5 (''Bond''), Rule 9 (''Branch Office Manager''), and Rule 12 (''Business Day'') as such definitions are not used in the Consolidated FINRA Rulebook or the remaining proposed Temporary Dual FINRA–NYSE Member Rule Series.

FINRA also proposes to delete Incorporated NYSE Rule 375 (Missing the Market) and Interpretation 375/01. Incorporated NYSE Rule 375 provides that a member or member organization that has accepted an order for execution and that, because of neglect to execute the order or otherwise, takes or supplies the securities that are the subject of the order for its own account, is not acting as a broker and shall not charge a commission, without the knowledge and consent of the customer. The purpose of this rule is to ensure that when a member misses the market and fails to execute a customer's order timely or as agent, the customer is notified and does not pay a commission unless the customer affirmatively consents.

Incorporated NYSE Rule Interpretation 375/01 provides that, when a member or member organization has ''missed the market'' on a customer order, the customer should be contacted, informed of the circumstances, and given the choice of either having the order filled at the price that prevailed ''as of'' the time the market was missed, or executed at the present market price. If the customer elects to have the order filled at the ''as of'' price, the member may effect the transaction for the customer's account on the floor of the NYSE[26] and make a cash price adjustment, or fill the customer's order from the firm's error account.[27] In both instances, the customer's confirmation shall carry the ''as of'' legend. In contrast to Incorporated NYSE Rule 375, which is focused on commissions, Rule Interpretation 375/01 is focused on the execution price of orders where a member has missed the market.

FINRA proposes to eliminate Incorporated NYSE Rule 375 and Incorporated NYSE Rule Interpretation 375/01 because they address a narrow range of conduct, which occurs in the context of an exchange and specify the remedial steps that must be taken to fill customer orders under such circumstances. In general, this NYSE Rule and Interpretation were primarily aimed at addressing the limited context of a specialist taking orders for transactions on the exchange on an agency basis. FINRA believes, this rule and interpretation are not necessary in light of the existing FINRA rules discussed below that cover a broader range of activities even though the FINRA rules do not specify remedial steps. FINRA believes FINRA's rules that establish a fairness standard both with respect to commission and execution prices provide adequate remedies.

Specifically, FINRA Rule 2121 (Fair Prices and Commissions) requires that members assess customers prices, service charges and commissions that are fair, whether acting as principal or agent. FINRA Rule 5320 (Prohibition Against Trading Ahead of Customer Orders) also prohibits a member from trading for its own proprietary account ahead of its customer order unless it immediately executes the customer order at the same or better price at which it traded for its own account [sic]. Additionally, Rule 5310 (Best Execution and Interpositioning) requires that a member exercise reasonable diligence to buy or sell so that the resultant price to the customer is as favorable as possible under prevailing market conditions.[28] Further, Supplementary Material .01 of Rule 5310 states that members must make every effort to execute a marketable customer order that it receives [sic] fully and promptly. As such, FINRA believes that the conduct encompassed by Incorporated NYSE Rule 375 and its accompanying interpretation is and will continue to be fully addressed by other FINRA rules, and the deletion of the Rule and its accompanying rule interpretation will increase regulatory efficiency by removing unnecessary provisions from the rules.[29]

Cross-Reference and Technical Updates

The proposed rule change would update cross-references and make other non-substantive changes within FINRA

[20] FINRA previously solicited comment on a proposal to adopt consolidated FINRA Rule 2030 that would have transferred Incorporated NYSE Rule 435 and Rule Interpretation 435(5)/01 with significant changes. *See Regulatory Notices* 08–68 (November 2008) and 09–29 (June 2009).

[21] *See supra* note 8.

[22] *See supra* note 8.

[23] *See supra* note 11.

[24] *See supra* note 10.

[25] *See supra* note 20.

[26] *See* NYSE Rule 6 for the definition of the NYSE floor.

[27] When the transaction is effected through a firm error account, the firm no longer acts as agent, as it is trading from a firm account as principal.

[28] FINRA also believes that Incorporated NYSE Rule 375 and Incorporated NYSE Rule Interpretation 375/01 are functionally obsolete, because, to FINRA's knowledge, neither NYSE nor FINRA has ever charged a violation of either the rule or its interpretation.

[29] FINRA previously solicited comment on a proposal to adopt consolidated FINRA Rule 2121 that would have transferred NASD Rule 2440, NASD IM 2440–1, NASD IM–2440–2, Incorporated NYSE Rule 375 and related Interpretation to the FINRA rulebook with significant changes. *See Regulatory Notices* 11–08 (February 2011) and 13–07 (January 2013). FINRA transferred NASD Rule 2440 and its Interpretative Materials into the Consolidated FINRA Rulebook as FINRA Rule 2121 without material change. *See* Securities Exchange Act Release No. 72208 (May 21, 2014), 79 FR 30675 (May 28, 2014) (Notice of filing and Immediate Effectiveness of File No. SR–FINRA–2014–023).

rules, due in part to the adoption of new consolidated FINRA rules.

The proposed rule change would update rule cross-references to reflect the adoption of the consolidated FINRA registration rules. The SEC approved the new rules on July 7, 2017. As part of that rule filing, FINRA adopted with amendments the NASD and Incorporated NYSE rules relating to qualification and registration requirements as FINRA rules in the Consolidated FINRA Rulebook. FINRA also deleted in their entirety the NASD Rule 1000 Series relating to registration of Principals and Representatives, Incorporated NYSE Rules 10, 344, 345, 472, and Incorporated NYSE Rule Interpretations 10, 344 and 345.[30] The consolidated FINRA registration rules were implemented on October 1, 2018.[31] As such, the proposed rule change would update references to the new rule numbers in Section 4 (Fees) and Section 12 (Application and Annual Fees for Statutorily Disqualified Member Firms, Statutorily Disqualified Applicants for Membership and Member Firms Seeking to Associate with Statutorily Disqualified Individuals) of Schedule A to the By-Laws of the Corporation; and FINRA Rules 1010 (Electronic Filing Requirements for Uniform Forms), 2210 (Communications with the Public), 2241 (Research Analysts and Research Reports), 2370 (Securities Futures), 3170 (Tape Recording of Registered Persons by Certain Firms), 9217 (Violations Appropriate for Disposition Under Plan Pursuant to SEA Rule 19d–1(c)(2)), 9610 (Application), 9620 (Decision), and 9630 (Appeal).

In addition, the proposed rule change would replace all references to NASD Rule 2340 in FINRA Rules 0150 (Application of Rules to Exempted Securities Except Municipal Securities), 2310 (Direct Participation Programs), and 9610 (Application) with references to proposed FINRA Rule 2231. The proposed rule change would also replace the references to NASD Rule 3150 in FINRA Rule 9610 with a reference to proposed FINRA Rule 4540. The proposed rule change would replace the references to NASD Rule 2510 in FINRA Rules 0150 (Application of Rules to Exempted Securities Except Municipal Securities), 2360 (Options), 2370 (Securities Futures), 4512 (Customer Account Information), 4515 (Approval and Documentation of Changes in Account Name or Designation) and 5121 (Public Offerings of Securities With Conflicts of Interest) with references to proposed FINRA Rule 3260. The proposed rule change would replace all references to NASD Rule 3140 in FINRA Rule 0150 and FINRA Rule 6630 (Applicability of FINRA Rules to Securities Previously Designated as PORTAL Securities) to a reference to proposed FINRA Rule 1020. The proposed rule change would replace all references to the NASD Rule 1010 Series in Rules 7410 (Definitions), 8313 (Release of Disciplinary Complaints, Decisions and Other Information), 9521 (Purpose and Definitions), 9522 (Initiation of Eligibility Proceeding; Member Regulation Consideration), and the Capital Acquisition Broker Rule 100 Series (Member Application and Associated Person Registration) to references to the proposed FINRA Rule 1000 Series. The proposed rule change would replace a reference to NASD Rule 1090 in Capital Acquisition Broker Rule 119 to a reference to proposed FINRA Rule 1021. The proposed rule change would also update the references to the Incorporated NYSE Rules in FINRA Rule 9217 (Violations Appropriate for Disposition Under Plan Pursuant to SEA Rule 19b–1(c)(2)) with the proposed FINRA Temporary Dual FINRA–NYSE Member Rule Series numbers. The proposed rule change would update the cross-references in FINRA Rule 5320 (Prohibition Against Trading Ahead of Customer Orders) to reflect the renumbering of Rule 7440(b)(19) as 7440(b)(20).[32]

The proposed rule change would correct a typographical error in FINRA Rule 7620A (FINRA/Nasdaq Trade Reporting Facility Reporting Fees). When Rule 7620A was amended pursuant to SR–FINRA–2018–042, Example 1 under Section II.4.B. inadvertently stated ''As to Tape B, the Retail Participant would pay the uncapped discounted monthly charges applicable to Tier 1 *its* activity. . .'' (emphasis added).[33] The proposed rule change would delete ''its'' before the word ''activity.''

The proposed rule change also would make technical changes to FINRA Rule 7640A (Data Products Offered By NASDAQ). Pursuant to SR–NASDAQ–2018–098, Nasdaq relocated its Rule 7000 Series (Equities Pricing) to the Equity 7 Pricing Schedule of the Nasdaq rulebook's shell structure.[34] As part of that proposed rule change, the Nasdaq rules referred to in paragraph (c) of FINRA Rule 7640A were renumbered. Specifically, Nasdaq Rule 7037 was renumbered as Equity 7 Pricing Schedule, Section 137; Nasdaq Rule 7039 was renumbered as Equity 7 Pricing Schedule, Section 139; and Nasdaq Rule 7047 was renumbered as Equity 7 Pricing Schedule, Section 147. The proposed rule change would make conforming changes to Rule 7640A(c) to update these references. The proposed rule change would also change ''NASDAQ'' to ''Nasdaq'' in the Rule's title to conform to the rest of the Rule.

Finally, the proposed rule change would add a reference to FINRA Rule 2030 (Engaging in Distribution and Solicitation Activities with Government Entities) to FINRA Rule 9610 (Application). FINRA Rule 2030 authorizes FINRA to exempt a covered member from Rule 2030(a) and, therefore, should be included in the list of rules in FINRA Rule 9610.[35]

FINRA has filed the proposed rule change for immediate effectiveness. The implementation date will be 30 days after the date of the filing.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[36] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change, which does not substantively change the rules, is consistent with the Act because it is being undertaken pursuant to the rulebook consolidation process, which is designed to provide additional clarity and regulatory efficiency to FINRA members by consolidating the applicable NASD Rules, Incorporated NYSE Rules and Interpretations, and FINRA rules into one rule set.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance

[30] *See* Securities Exchange Act Release No. 81098 (July 7, 2017), 82 FR 32419 (July 13, 2017) (Order Approving File No. SR–FINRA–2017–007).

[31] *See Regulatory Notice* 17–30 (October 2017).

[32] *See* Securities Exchange Act Release No. 77523 (April 5, 2016), 81 FR 21427 (April 11, 2016) (Order Approving File No. SR–FINRA–2016–006).

[33] *See* Securities Exchange Act Release No. 84901 (December 20, 2018), 83 FR 67408 (December 28, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2018–042).

[34] *See* Securities Exchange Act Release No. 84684 (November 29, 2018), 83 FR 62936 (December 6, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–NASDAQ–2018–098).

[35] *See* Securities Exchange Act Release No. 78683 (August 25, 2016), 81 FR 60051 (August 31, 2016) (Order Approving File No. SR–FINRA–2015–056).

[36] 15 U.S.C. 78*o*–3(b)(6).

of the purposes of the Act. As noted above, the proposed rule change will not substantively change either the text or application of the rules. FINRA would like to proceed with the rulebook consolidation process expeditiously, which will provide additional clarity and regulatory efficiency to members.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received with respect to the proposed rule change to transfer the above listed NASD Rules, Incorporated NYSE Rules and Interpretations into the Consolidated FINRA Rulebook without any substantive changes.[37]

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 Act[38] and Rule 19b–4(f)(6) thereunder.[39]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–FINRA–2019–009 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2019–009. 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 FINRA. 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–FINRA–2019–009 and should be submitted on or before May 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[40]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–07504 Filed 4–15–19; 8:45 am]

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[37] *But see supra* notes 8, 10, 11, 20 and 29.

[38] 15 U.S.C. 78s(b)(3)(A).

[39] 17 CFR 240.19b–4(f)(6).

[40] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85590; File No. SR–CboeEDGX–2019–018]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Modify Its Fee Schedule

April 10, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 3, 2019, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to modify its fee schedule. The text of the proposed rule change is attached as Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the EDGX Options fee schedule to modify the definitions of fee codes RQ and RR to include routing to MIAX Emerald LLC (''MIAX Emerald''), effective April 3, 2019. The Exchange's current approach to routing fees is to set forth in a simple manner certain sub-categories of fees that approximate the cost of routing to other options exchanges based on the cost of transaction fees assessed by each venue as well as costs to the Exchange for

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

routing (*i.e.,* clearing fees, connectivity and other infrastructure costs, membership fees, etc.) (collectively, ''Routing Costs''). The Exchange then monitors the fees charged as compared to the costs of its routing services and adjusts its routing fees and/or sub-categories to ensure that the Exchange's fees do indeed result in a rough approximation of overall Routing Costs, and are not significantly higher or lower in any area.

Currently, fee code RR is appended to Customer orders in non-Penny Pilot securities that are routed to ARCA, BZX Options, C2, ISE, ISE Gemini, MIAX Pearl or NOM and assessed a fee of $1.25 per contract. Additionally, fee code RQ is appended to Customer orders in Penny Pilot securities that are routed to ARCA, BZX Options, C2, ISE, ISE Gemini, MIAX Pearl or NOM and assessed a fee of $0.85 per contract. The Exchange proposes to modify the definitions of fee code RQ and PR to include MIAX Emerald. The Exchange anticipates that the proposed fee structure will approximate the cost of routing orders to MIAX Emerald. The Exchange is proposing the charges set forth above to maintain a simple and fair fee schedule with respect to routing fees that approximate the total cost of routing, including Routing Costs.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the Section 6 of the Act,[3] in general, and Section 6(b)(4),[4] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. As explained above, the Exchange generally attempts to approximate the cost of routing to other options exchanges, including other applicable costs to the Exchange for routing. The Exchange believes its proposed fees are reasonable taking into account Routing Costs based on the rates charged by MIAX Emerald. The Exchange believes that a pricing model based on approximate Routing Costs is a reasonable, fair and equitable approach to pricing. Specifically, the Exchange believes that its proposal to adopt routing fees to MIAX Emerald is fair, equitable and reasonable because the fees are generally an approximation of the anticipated cost to the Exchange for routing orders to MIAX Emerald. The Exchange notes that routing through the Exchange is voluntary. The Exchange also believes that the proposed fee structure for orders routed to and executed at MIAX Emerald is fair and equitable and not unreasonably discriminatory in that it applies equally to all Members.

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 Exchange believes the proposed routing fee will not impose an undue burden on competition because the Exchange will uniformly assess the routing fee on all Members. The Exchange does not believe that the proposed changes represent a significant departure from routing fees offered by the Exchange's competitors. Additionally, Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value or if they view the proposed fee as excessive. Further, excessive fees for participation would serve to impair an exchange's ability to compete for order flow and members rather than burdening competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [5] and paragraph (f) of Rule 19b–4 [6] 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–CboeEDGX–2019–018 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–CboeEDGX–2019–018. 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–CboeEDGX–2019–018 and should be submitted on or before May 7, 2019.

[3] 15 U.S.C. 78f.

[4] 15 U.S.C. 78f(b)(4).

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–07502 Filed 4–15–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85584; File No. SR–NYSEAMER–2019–10]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE American Options Fee Schedule

April 10, 2019.

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 April 1, 2019, NYSE American LLC (the ''Exchange'' or ''NYSE American'') 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 amend the NYSE American Options Fee Schedule (''Fee Schedule''). The Exchange proposes to implement the fee change effective April 1, 2019. 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 purpose of this filing is to modify the Fee Schedule to expand the types of transactions that may be included in the Firm Monthly Fee Cap for ATP Holders that achieve a certain increase in Complex CUBE Auction volume.[4]

Currently, Section I.I. of the Fee Schedule sets forth a Firm Monthly Fee Cap (''Fee Cap'') that limits, or caps, at $100,000 per month the fees incurred by Firms trading though a Floor Broker in open outcry (*i.e.,* manual transactions).[5] The Fee Cap may be lower than $100,000 for ATP Holders that achieve Tier 2 or higher of the American Customer Engagement (''ACE'') Program.[6] Once a Firm has reached the Fee Cap, an incremental service fee of $0.01 per contract for Firm Manual transactions will apply, except for the execution of QCC orders, which are not subject to the incremental service fee.[7]

The Exchange proposes to include a broader range of Exchange activity under the Fee Cap for any ATP Holder that achieves an increase over January 2019 Initiating Complex CUBE volume by at least 0.20% of TCADV (the ''Complex CUBE Cap Incentive''). ATP Holders that qualify for the Complex CUBE Cap Incentive will continue to be eligible for a reduced Monthly Fee Cap based on ACE Tier achieved,[8] but will also be able to aggregate the following transactions with their Firm Manual and Firm QCC transactions:

- Broker Dealer Manual transactions; and
- Broker Dealer QCC transactions.[9]

As proposed, ATP Holders that qualify for the Complex CUBE Cap Incentive and attain the Firm Fee Cap would not be assessed transaction fees on Firm or Broker Dealer Manual volume, including QCC transactions. Further, an incremental service fee of $0.01 per contract would apply to Broker Dealer Manual transactions [10] and for Broker Dealer QCC Transactions in excess of 25,000 contracts ADV, an incremental service fee of $0.10 per contract would apply.[11]

For example, an ATP Holder that executed 6,000 contracts per day ADV via Complex CUBE during the month of January 2019 would have to execute over 18,000 contracts a day ADV via Complex CUBE in April 2019 if the TCADV in April 2019 is 6 million contracts (*i.e.,* 6,000 + (0.2% * 6 million) = (6,000 + 12,000)). Thus, the qualifying ATP Holder would be able to aggregate its Broker Dealer QCC transactions and Manual transactions (together with its Firm QCC transactions and Manual transactions) under the Fee Cap.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[13] 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 Complex CUBE Cap Incentive is reasonable, equitable and not unfairly discriminatory for a number of reasons. First, the proposal is based on the amount of business transacted on the Exchange and ATP Holders can opt to try to achieve the Incentive or not. Second, the proposal is designed encourage ATP Holders to utilize (if they have not done so) or increase volume sent to the Complex CUBE Auction, which was adopted earlier this year. Further, ATP Holders that seek to or do achieve the Complex CUBE Incentive likewise would be incented to increase its Broker Dealer volume in Manual and QCC transaction in an effort

[7] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Rule 971.2NY (describing Complex CUBE Auction, which offers price improvement opportunities to Complex Orders); *see also* Fee Schedule, Section I.G, CUBE Auction Fees & Credits, *infra* note 5.

[5] *See* Fee Schedule, Section I. I. (Firm Monthly Fee Cap), *available here, https://www.nyse.com/publicdocs/nyse/markets/american-options/NYSE_American_Options_Fee_Schedule.pdf* (providing that an ATP Holder that achieves Tier 2, 3, 4 or 5 of the ACE Program is entitled to a Fee Cap of $85,000, $75,000, $70,000 or $65,000, respectively). The Fee Cap excludes volumes associated with Strategy Executions described in Section I.J., (*e.g.,* reversal and conversion, box spread, short stock interest spread, merger spread and jelly roll) and Firm Manual Facilitation trades (which are always free). Royalty Fees described in Section I. K. still apply to applicable transactions even once Fee Cap is reached. *See id.*

[6] *See* Fee Schedule, Section I.E. (describing ACE Program), *supra* note 5.

[7] *See supra* note 5.

[8] *See supra* note 5 (regarding reduced Fee Caps associated with ACE Tiers 2–5).

[9] *See* proposed Fee Schedule, Section I. I. (Firm Monthly Fee Cap).

[10] *See supra* note 5 (regarding incremental service fee applicable to Firm Manual transactions).

[11] *See* proposed Fee Schedule, Section I. I. (Firm Monthly Fee Cap).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4) and (5).

to meet the Fee Cap, which may, in turn, encourage more business to be brought to the Floor, which may extend beyond Manual and QCC transactions. To the extent that the proposed change attracts more Broker Dealer Manual and QCC transactions to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution.

Further, the proposed ten cent fee on Broker Dealer QCC transactions over 25,000 contracts ADV is likewise reasonable, equitable and not unfairly discriminatory. The Exchange assesses a QCC Transaction fee of $0.20 per contract on Broker Dealer and Firm volume.[14] Today, Firms that achieve the Fee Cap are charged $0.00 for Firm QCC volume beyond the Fee Cap, but are still charged $0.20 per contract for Broker Dealer QCC volume. As proposed, Firms that achieve the Complex CUBE Cap Incentive would more easily achieve the Fee Cap because the proposal allows Broker Dealer Manual and QCC volume (together with Firm Manual and QCC volume) to count towards the Fee Cap. For Firms that achieve the Complex CUBE Incentive Cap and the Fee Cap, Firm QCC volume beyond the Fee Cap will continue to be charged at $0.00 and the rate for Broker Dealer QCC volume will be reduced to $0.00 per contract for up to 25,000 contracts ADV and to $0.10 per contract with the proposed service fee for volume in excess of 25,000 contracts ADV. The proposed service fee is not unreasonable because it would apply to all similarly-situated firms. Moreover, the Exchange believes the proposed service fee is reasonable given that it is still a reduction in cost for Broker Dealer QCC volume (once the Complex CUBE Cap Incentive and Fee Cap are achieved) and should encourage more such volume to be directed to and executed on the Exchange.

Finally, the Exchange believes the proposed changes are consistent with the Act because to the extent the modifications permit the Exchange to continue to attract greater volume and liquidity (to the Floor or otherwise), the proposed change would improve the Exchange's overall competitiveness and strengthen its market quality for all market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed Complex CUBE Cap Incentive is pro-competitive as it is designed to incentivize increased volume and liquidity to the Exchange—for both Complex CUBE and Manual and QCC transactions—which would benefit all Exchange participants through increased opportunities to trade as well as enhancing price discovery.

Given the robust competition for volume among options markets, many of which offer the same (or similar) products, implementing programs to attract order flow, such as the proposed Complex CUBE Cap Incentive, are consistent with the above-mentioned goals of the Act.

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–4[16] 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 No. SR–NYSEAMER–2019–10 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–NYSEAMER–2019–10. 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–NYSEAMER–2019–10, and should be submitted on or before May 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–07509 Filed 4–15–19; 8:45 am]

BILLING CODE 8011–01–P

[14] *See* Fee Schedule, Section I. F. (QCC Fees & Credits) (setting forth transaction fees for market participants, including Non-Customers that are not Professional Customers or Specialists, *i.e.,* Firms and Broker Dealers).

[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).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85592; File No. SR–CBOE–2019–019]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Amend the Select Customer Options Reduction Program

April 10, 2019.

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 March 29, 2019, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend the Select Customer Options Reduction program. 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Select Customer Options Reduction program (''SCORe'') to (i) eliminate the use of product multipliers and (ii) increase certain discounts.[3] By way of background, SCORe is a discount program for Retail,[4] Non-FLEX Customer (''C'' origin code) volume in the following options classes: SPX (including SPXW), VIX, RUT, MXEA, MXEF & XSP (''Qualifying Classes''). The SCORe program is available to any Trading Permit Holder (''TPH'') Originating Clearing Firm or non-TPH Originating Clearing Firm that sign up for the program.[5] The SCORe program currently utilizes two measures for participation and discounts: (1) The Qualifying Tiers, which determine whether a firm qualifies for the discounts in either Tier A or Tier B and (2) the Discount Tiers, which determine the Originating Firm's applicable discount tiers and corresponding discounts.

To determine an Originating Firm's Qualifying Tier, the Originating Firm's total Retail volume in the Qualifying Classes will be divided by the Originating Firm's total Customer volume, Retail and non-Retail, in the Qualifying Classes. If an Originating Firm's Retail volume is between 20.00% and 69.99%, the Originating Firm will qualify for Tier B discounts. If an Originating Firm's Retail volume is at or above 70.00%, the Originating Firm will qualify for Tier A discounts. The Qualifying Tier that is applied in a given month is based on an Originating Firm's Retail volume in the prior month (*e.g.,* an Originating Firm's volume in March determines which Qualifying Tier applies in April).[6]

For the Discount Tier, an Originating Firm's Retail volume in the Qualifying Classes is divided by total Retail volume in the Qualifying Classes executed on the Exchange. Additionally, SCORe employs the use of ''product multipliers'' for the Discount Tier only. Multipliers are applied to MXEF, MXEA, RUT and XSP volume only. Specifically, Retail volume in these products are currently multiplied by the values set forth in the Fees Schedule so that any volume executed by an Originating Firm in these classes will be increased for purposes of the Discount Tier calculation, but not for purposes of calculating the Qualifying Tiers. Additionally, discounts are applied to executed volume only, not on multiplied volume. The Exchange no longer wishes to maintain multipliers in the SCORe program. As such, the Exchange proposes to amend the Fees Schedule to eliminate the multipliers for MXEF, MXEA, RUT and XSP.

The Exchange next proposes to increase the discounts in Qualifying Tiers A3–A1. Specifically, the Exchange proposes to increase Tier A3 from $0.15 per contract to $0.17 per contract; increase Tier A2 from $0.19 per contract to $0.21 per contract; and Tier A1 from $0.23 per contract to $0.25 per contract. The Exchange notes the proposed discount increases are designed to attract a greater number of customer orders in the Qualifying Classes. This increased volume creates greater trading opportunities that benefit all market participants by providing more trading opportunities and tighter spreads. The Exchange also believes the proposed changes continue to provide an incremental incentive for Originating Firms to strive for the highest tier level, which provides increasingly higher discounts.

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.[7] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] 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

[3] The proposed SCORe amendments will be effective April 1, 2019.

[4] For purposes of the program ''Retail'' orders will be defined as Customer orders for which the original order size (in the case of a simple order) or largest leg size (in the case of a complex order) is 100 contracts or less.

[5] For this program, an ''Originating Clearing Firm'' is defined as either (a) the executing clearing Options Clearing Corporation (''OCC'') number on any transaction which does not also include a Clearing Member Trading Agreement (''CMTA'') OCC clearing number or (b) the CMTA in the case of any transaction which does include a CMTA OCC clearing number.

[6] For example, in March, if an Originating Firm executes a total of 1,000,000 Customer (C) contracts in the Qualifying Classes, of which 600,000 contracts qualify as Retail volume, the Originating Firm would have a retail percentage of 60% and qualifies for the B Tier discounts to be applied to the Originating Firm's qualifying Retail Customer volume in April.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

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,[9] 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.

First, the Exchange believes the proposal to eliminate the availability of product multipliers is reasonable because it no longer wishes to offer this additional incentive for order flow in the multiplier classes and it is not required to do so. The Exchange also notes that such multipliers were only used for purposes of the Discount Tier calculation. The Exchange believes the proposed changes to Tiers A3–A1 are reasonable because it provides higher discounts for satisfying the qualifying thresholds. Further, the Exchange believes the proposed discounts are commensurate with the corresponding qualifying thresholds. As noted above, the Exchange believes SCORe continues to provide an incremental incentive for Originating Firms to strive for the highest tier level, which provides increasingly higher discounts. The proposed increased discounts are designed to encourage increased Retail volume in the Qualifying Classes, which provides increased volume and greater trading opportunities for all market participants. The Exchange believes the proposed change is equitable and not unfairly discriminatory because the qualifying volume thresholds apply to all registered Originating Firms uniformly.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed changes apply to all registered Originating Firms uniformly. The Exchange believes that the proposed rule change will not cause an unnecessary burden on intermarket competition because the Qualifying Classes are products that only trade on Cboe Options. To the extent that the proposed changes make the Exchange 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 Act [10] and paragraph (f) of Rule 19b–4 [11] 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–2019–019 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2019–019. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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–CBOE–2019–019, and should be submitted on or before May 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–07501 Filed 4–15–19; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85586; File No. SR–CboeBYX–2018–014]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Withdrawal of Proposed Rule Change To Make Permanent Exchange Rule 11.24, Which Sets Forth the Exchange's Pilot Retail Price Improvement Program

April 10, 2019.

On July 30, 2018, Cboe BYX Exchange, Inc. (''BYX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to make permanent Exchange Rule 11.24, which sets forth the Exchange's pilot Retail Price Improvement Program. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

proposed rule change was published for comment in the **Federal Register** on August 17, 2018.[3] On September 27, 2018, the Commission extended to November 15, 2018, the time period in which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change.[4] On November 15, 2018, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [5] to determine whether to approve or disapprove the proposed rule change.[6] On December 26, 2018, pursuant to Section 19(b)(2) of the Act,[7] the Commission extended to April 14, 2019 the time period in which to issue an order approving or disapproving the proposed rule change.[8] The Commission received no comments on the proposed rule change. On April 3, 2019, the Exchange withdrew the proposed rule change (SR–CboeBYX–2018–014).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–07507 Filed 4–15–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85597; File No. SR–NYSE–2019–15]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List To Modify the Supplemental Liquidity Provider Provide Tier 1 Credit for Securities Traded Pursuant to Unlisted Trading Privileges

April 10, 2019.

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 March 29, 2019, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II, below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List to modify the Supplemental Liquidity Provider (''SLP'') Provide Tier 1 credit for securities traded pursuant to United [sic] Trading Privileges (''UTP''). The Exchange proposes to implement these changes to its Price List effective April 1, 2019. 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Price List to modify the SLP Provide Tier 1 credit for UTP securities.

The Exchange proposes to implement these changes to its Price List effective April 1, 2019.

Proposed Rule Change

Currently, the Exchange offers tiered rates for displayed and nondisplayed orders by SLPs that add liquidity to the Exchange in UTP Securities priced at or above $1.00. Specifically, SLP Provide Tier 1 provides a $0.0032 per share credit per tape in an assigned UTP Security for SLPs adding displayed liquidity to the Exchange if the SLP (1) adds liquidity for all assigned UTP Securities in the aggregate of an CADV of at least 0.10% for Tape B and 0.075% for Tape C, and (2) quotes on an average daily basis, [sic] calculated monthly, in excess of the 10% average quoting requirement in 400 or more assigned UTP Securities in Tapes B and C combined pursuant to Rule 107B, and (3) meets the 10% average or more quoting requirement in an assigned UTP Security pursuant to Rule 107B.[4] For SLPs meeting these requirements, the Exchange proposes to lower the applicable credit to $0.0031 per share credit per tape.

* * * * *

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,[5] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[6] 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 the proposed lower Tier 1 credit for SLPs adding displayed liquidity to the Exchange is reasonable, equitable and not unfairly discriminatory because the proposed credit remains in line with the credits the Exchange currently credits SLPs for adding displayed and non-displayed liquidity in Tape A securities.[7] The Exchange notes that SLPs qualifying for the Tier 1 Adding Credit in UTP securities in both Tapes B and C on the Pillar Trading Platform would also be eligible for a lower adding liquidity requirement of 0.75% for SLP Tier 1 in Tape A. The Exchange further notes that SLPs that currently meet Tier 1 in both Tape B and Tape C receive a credit of $0.00005 per share in addition to the Tape A SLP credit in Tape A assigned securities where the SLP meets the 10% quoting requirement pursuant to Rule 107B.

The Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's

[3] *See* Securities Exchange Act Release No. 83831 (August 13, 2018), 83 FR 41128 (''Notice'').

[4] *See* Securities Exchange Act Release No. 84297, 83 FR 49959 (October 3, 2018).

[5] 15 U.S.C. 78(s)(b)(2)(B).

[6] *See* Securities Exchange Act Release No. 84600, 83 FR 58802 (November 21, 2018).

[7] 15 U.S.C. 78s(b)(2).

[8] *See* Securities Exchange Act Release No. 84972, 84 FR 867 (January 31, 2019).

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] SLP Provide Tier 1 also provides a $0.0014 per share credit per tape for SLPs adding non-displayed liquidity to the Exchange, and a $0.0025 per share credit for MPL Orders adding liquidity, in an assigned UTP Security if the SLP meets the 10% average or more quoting requirement in an assigned UTP Security pursuant to Rule 107B.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4) & (5).

[7] *See* page 5 of the current NYSE Price List, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Price_List.pdf.*

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,[8] 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 foster liquidity provision and stability in the marketplace, thereby promoting price discovery and transparency and enhancing order execution opportunities for member organizations. In this regard, the Exchange believes that the transparency and competitiveness of attracting additional executions on an exchange market would encourage competition.

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.

[8] 15 U.S.C. 78f(b)(8).

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)(ii) of the Act,[9] and subparagraph (f)(2) of Rule 19b–4 [10] 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) [11] 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–2019–15 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–2019–15. 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–NYSE–2019–15 and should be submitted on or before May 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–07510 Filed 4–15–19; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A)(ii).

[10] 17 CFR 240.19b–4(f)(2).

[11] 15 U.S.C. 78s(b)(2)(B).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85588; File No. SR–ICC–2019–003]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to ICC's Cash Investment Yield Schedule

April 10, 2019.

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 March 26, 2019, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by ICC. ICC filed the proposed rule change pursuant Section 19(b)(3)(A) of the Act [3] and rule 19b–4(f)(2) thereunder,[4] such that the proposed rule change was immediately effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(2).

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to revise ICC's cash investment yield schedule.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICC currently retains a portion of interest earned on cash balances, net of cash management expenses. The portion of interest retained is based on an established cash investment yield schedule, which is set forth in the ICC Collateral Management presentation available on the ICC website.[5] ICC proposes changes to its cash investment yield schedule. The proposed revisions to the cash investment yield schedule are set forth in Exhibit 5 hereto, and described in detail as follows.

Currently, ICC retains a certain basis points (''bps'') spread for interest rate market environments of zero bps or greater, net of expenses. ICC proposes to retain an additional 50 bps spread for non-customer Euro cash posted by Clearing Participants (''CPs'') in excess of certain amounts. ICC identifies Euro House Initial Margin (''IM'') and Euro Guaranty Fund (''GF'') requirements (collectively, the ''total Euro requirement'') for CPs who clear Euro denominated products, and US Dollar (''USD'') House IM and USD GF requirements (collectively, the ''total USD requirement'') for CPs who clear USD denominated products. A CP may meet up to 100% (but no less than 45%) of its total Euro requirement in Euro cash and up to 35% of its total USD requirement in Euro cash.[6] ICC proposes to retain an additional 50 bps spread for non-customer Euro cash posted by CPs in excess of their total Euro requirement to discourage excess Euro deposits since ICC faces difficulty securitizing Euro deposits and is exposed to the credit and counterparty risk of banks where Euro deposits are held.

ICC proposes to make such changes effective on or about June 1, 2019. ICC will issue a circular notification, in advance of the effective date.

(b) Statutory Basis

ICC believes that the proposed rule changes are consistent with the requirements of the Act, including Section 17A of the Act.[7] More specifically, the proposed rule changes change a member due, fee or other charge imposed by ICC under Section 19(b)(3)(A)(ii)[8] of the Act and Rule 19b–4(f)(2)[9] thereunder. ICC believes 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 17A(b)(3)(D),[10] because the proposed changes apply equally to all market participants and therefore the proposed changes provide for the equitable allocation of reasonable dues, fees and other charges among participants. As such, the proposed changes are appropriately filed pursuant to Section 19(b)(3)(A)[11] of the Act and paragraph (f)(2) of Rule 19b–4[12] thereunder.

(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. The changes to ICC's investment yield schedule will apply uniformly across all market participants. 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 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 for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)[13] of the Act and Rule 19b–4(f)(2)[14] thereunder, as the changes to ICC's investment yield schedule constitute a change to a due, fee, or other charge applicable only to a member. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICC–2019–003 on the subject line.

Paper Comments

Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–ICC–2019–003. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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,

[5] ICC Collateral Management presentation available at: *https://www.theice.com/publicdocs/clear_credit/ICE_Clear_Credit_Collateral_Management.pdf.*

[6] *See* Schedule 401 of the ICC Rules.

[7] 15 U.S.C. 78q–1.

[8] 15 U.S.C. 78s(b)(3)(A)(ii).

[9] 17 CFR 240.19b–4(f)(2).

[10] 15 U.S.C. 78q–1(b)(3)(D).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(2).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(2).

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–2019–003 and should be submitted on or before May 7, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–07505 Filed 4–15–19; 8:45 am]

BILLING CODE 8011–01–P

[15] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA) requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission. This notice also allows an additional 30 days for public comments.

DATES: Submit comments on or before May 16, 2019.

ADDRESSES: Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW, 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030 *curtis.rich@sba.gov*

Copies: A copy of the Form OMB 83–1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION: The SBA's Women's Business Centers represent a national network of over 100 educational centers designed to assist women in starting and growing small businesses. WBCs operate with the mission to ''level the playing field'' for women entrepreneurs, who still face unique obstacles in the world of business. Through the management and technical assistance provided by the WBCs, entrepreneurs (especially women who are economically or socially disadvantaged) are offered comprehensive training and counseling on a variety of topics in many languages to help them start and grow their own businesses. The SBA plans to conduct a web-based survey to understand to what degree the Agency's WBC programs and services help entrepreneurs start, manage, and grow businesses. The survey will help determine customer satisfaction and the outcomes of the delivered business assistance services. Surveys will be completed by a sample of clients who received business assistance services at least 1 year ago. A minimum 1-year lag is desired to allow the business outcomes of the services to be observed. Because WBCs offer both training and counseling services, clients who received either service will be included.

Solicitation of Public Comments

Title: Women's Business Center Client Outcome Survey.

Description of Respondents: Women's Business Center Program Services.

Form Number: N/A.

Estimated Annual Responses: 2,087.

Estimated Annual Hour Burden: 770.48.

Curtis Rich,

Management Analyst.

[FR Doc. 2019–07528 Filed 4–15–19; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA) requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission. This notice also allows an additional 30 days for public comments.

DATES: Submit comments on or before May 16, 2019.

ADDRESSES: Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW, 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030 *curtis.rich@sba.gov.*

Copies: A copy of the Form OMB 83–1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION: In accordance with regulations and policy, the Small Business Development Centers (SBDC's) must provide SBA semi-annual financial and programmatic reports-outlining expenditures and accomplishments. The information collected will be used to monitor the progress of the program.

Solicitation of Public Comments

SBA is requesting comments on (a) Whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Title: ''Federal Cash Transaction Report; Financial Status Report Program Income Report Narrative Program Report''.

Description of Respondents: SBDC Directors.

Form Number: 2113.

Estimated Annual Responses: 126.

Estimated Annual Hour Burden: 1,512.

Curtis Rich,

Management Analyst.

[FR Doc. 2019–07518 Filed 4–15–19; 8:45 am]

BILLING CODE 8025–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 754]

Oversight Hearing on Demurrage and Accessorial Charges

AGENCY: Surface Transportation Board.

ACTION: Notice of public hearing.

SUMMARY: The Surface Transportation Board (Board) will hold a public hearing on May 22, 2019, on railroad demurrage and accessorial charges. The hearing will be held in the Main Hearing Room of the U.S. International Trade Commission, located at 500 E Street SW, Washington, DC, near the Board's headquarters building. Representatives of Class I carriers are directed to appear at the hearing, and other interested parties, including shippers, receivers, third-party logistics providers, and representatives of shortline railroads, are invited to appear.

DATES: The hearing will be held on May 22, 2019, beginning at 9:30 a.m., in the Main Hearing Room (Room 101) of the U.S. International Trade Commission and will be open for public observation. Any person wishing to speak at the hearing should file with the Board a notice of intent to participate (identifying the party, proposed speaker, and time requested) as soon as possible but no later than April 24, 2019. Class I carriers are directed to file with the Board the information specified below by May 1, 2019. All hearing participants are required to submit written testimony by May 8, 2019. Written submissions by interested persons who will not appear at the hearing should also be filed by May 8, 2019.

ADDRESSES: All filings may be submitted either via the Board's e-filing format or in the traditional paper format. Any person using e-filing should attach a document and otherwise comply with the instructions at the E-filing link on the Board's website at *www.stb.gov.* Any person submitting a filing in the traditional paper format should send an original and 10 copies of the filing to: Surface Transportation Board, Attn: Docket No. EP 754, 395 E Street SW, Washington, DC 20423–0001.

Filings will be posted to the Board's website and need not be served on the other hearing participants or written commenters. Copies of the filings will also be available (for a fee) by contacting the Board's Chief Records Officer at (202) 245–0238 or 395 E Street SW, Washington, DC 20423–0001.

FOR FURTHER INFORMATION CONTACT: Sarah Fancher at (202) 245–0355. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The Board will hold a public hearing on May 22, 2019, to receive information from railroads, shippers, receivers, third-party logistics providers, and other interested parties about their recent experiences with demurrage and accessorial charges, including matters such as reciprocity, commercial fairness, the impact of operational changes on such charges, capacity issues, and effects on network fluidity.[1] This hearing arises from concerns expressed by users of the freight rail network and other stakeholders about changes to demurrage and accessorial tariffs being implemented by various Class I carriers, and follows related letter inquiries to Class I carriers, including requests for information on quarterly revenue from demurrage and accessorial charges for 2018 and 2019. This correspondence, the quarterly revenue information reported by the Class I carriers to date, and written communications received by the Board about demurrage and accessorial charges can be found on the Board's website under E-Library/Correspondence/Non-Docketed Public Correspondence.

The Board will hold a public hearing to further examine current demurrage and accessorial practices. Representatives of Class I carriers are directed to appear at the hearing through company officials knowledgeable about the information and topics specified below. To facilitate the Board's review, Class I carriers are directed to file the following information with the Board by May 1, 2019:

1. Provide a list of all material changes to your demurrage and accessorial tariffs since January 1, 2016, including but not limited to changes pertaining to (i) the amount of free time allowed for loading and unloading rail cars; (ii) rates for demurrage and accessorial charges; (iii) the nature and availability of credits or other relief, including for railroad errors and service failures; and (iv) procedures and time periods applicable to the process for raising and resolving disputed charges. For each such tariff change, please also specify (a) when notice of the change was given; (b) when the change became effective; and (c) the reason(s) for the change. The Board requests that this information be presented in a table.

2. Provide, for each of the past three calendar years, the total dollar amounts of charges billed and charges collected pursuant to (i) all demurrage tariffs combined and (ii) all accessorial tariffs combined.[2]

3. Provide a detailed explanation of the current process by which shippers, receivers, and other parties may dispute demurrage and accessorial charges. To the extent readily available, please also provide, for all demurrage tariff charges combined and all accessorial tariff charges combined, the percentage of charges, by dollar amount, that have been contested in the first quarter of 2019 and each of the past three calendar years.

4. Provide a detailed explanation of any system or practice under which credits or debits have been issued in connection with the assessment of demurrage or accessorial charges since January 1, 2016, and any changes thereto. Describe how credits and debits are calculated and any limits on the amount of credits or debits that may be available or incurred.

All hearing participants are required to submit written testimony by May 8, 2019. Written submissions by interested persons who will not appear at the hearing should also be filed by May 8, 2019. All participants and interested persons are invited and encouraged to address the following topics in their written testimony or submissions and at the hearing:

- Recent experience with demurrage and accessorial charges, including (i) the largest drivers of demurrage and accessorial charges; (ii) supply chain

[1] Demurrage is subject to Board regulation under 49 U.S.C. 10702, which requires railroads to establish reasonable rates and transportation-related rules and practices, and under 49 U.S.C. 10746, which requires railroads to compute demurrage charges, and establish rules related to those charges, in a way that will fulfill national needs related to freight car use and distribution and maintenance of an adequate car supply. Demurrage charges have both compensatory and punitive aspects and are intended to promote efficient use of rail resources. *Demurrage Liability,* EP 707, slip op. at 2 (STB served April 11, 2014); 49 CFR 1333.1. As used herein, the term ''demurrage charges'' corresponds to the definition of demurrage used for purposes of the R–1 Annual Report (*see* 49 CFR 1201, category 106).

Accessorial charges are not specifically defined by statute or regulation but are generally understood to include charges other than line-haul and demurrage charges. *See Revisions to Arbitration Procedures,* EP 730, slip op. at 7–8 (STB served Sept. 30, 2016) (describing a variety of charges that are considered accessorial charges). As used herein, the term ''accessorial charges'' includes, without limitation, charges for things such as diverting a shipment in transit, ordering a railcar but releasing it empty, weighing a railcar, tendering one railroad's car to another railroad without a line-haul move, special train or additional switching services, or releasing a railcar with incomplete or incorrect shipping instructions.

[2] Although the carriers have provided a subset of this data in response to the letter inquiries referenced above, for completeness, carriers should nonetheless provide a full dataset in response to this item.

visibility; (iii) the availability, effectiveness, and usability of online customer service tools that manage car orders, car supply, and demurrage and accessorial charges, including whether these tools make available adequate data to evaluate whether demurrage is being assessed properly and to dispute the charges when necessary; (iv) bunching, including bunching that occurs upstream; and (v) the ability to address demurrage through commercial arrangements.

- Impacts on shippers, receivers, third-party logistics providers, and shortline railroads flowing from recent (i) changes in Class I carrier demurrage and accessorial tariffs; (ii) changes in Class I carriers' enforcement policies for these tariffs; and (iii) operational changes implemented by Class I carriers including, in particular, changes in the frequency and timing of local service and/or shortline interchanges.
- Perspectives on whether demurrage and accessorial tariffs in effect during the past three years have created balanced and appropriate incentives for both customers and railroads, including views on the extent to which reciprocity should be incorporated into demurrage and accessorial charges.

Board Releases and Transcript Availability: Decisions and notices of the Board, including this notice, are available on the Board's website at *www.stb.gov.* The Board will issue a separate notice containing instructions for attendance at the hearing and the schedule of appearances. *Please note that streaming and recording systems will not be available to the Board for this hearing.* As soon as a transcript is available, it will be posted on the Board's website.

It is ordered:

1. A public hearing will be held on May 22, 2019, at 9:30 a.m., in the Main Hearing Room (Room 101) of the U.S. International Trade Commission, located at 500 E Street SW, Washington, DC, near the Board's headquarters.

2. By April 24, 2019, any person wishing to speak at the hearing shall file with the Board a notice of intent to participate identifying the party, the proposed speaker, and the time requested.

3. The Class I carriers are directed to file information by May 1, 2019, and to appear at the hearing through knowledgeable company officials, as specified above.

4. Written testimony by hearing participants, and written submissions by interested persons who will not appear at the hearing, shall be filed by May 8, 2019.

5. Filings will be posted to the Board's website and need not be served on any hearing participants or other commenters.

6. This decision is effective on its service date.

Decided: April 8, 2019.

By the Board, Allison C. Davis, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2019–07522 Filed 4–15–19; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–2019–0009]

Surface Transportation Project Delivery Program; Utah Department of Transportation Audit Report

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Notice; Request for comment.

SUMMARY: The Moving Ahead for Progress in the 21st Century Act (MAP–21) established the Surface Transportation Project Delivery Program that allows a State to assume FHWA's environmental responsibilities for environmental review, consultation, and compliance under the National Environmental Policy Act (NEPA) for Federal highway projects. When a State assumes these Federal responsibilities, the State becomes solely responsible and liable for carrying out the responsibilities it has assumed, in lieu of FHWA. This program mandates annual audits during each of the first 4 years of State participation to ensure compliance with program requirements. This notice announces and solicits comments on the second audit report for the Utah Department of Transportation (UDOT).

DATES: Comments must be received on or before May 16, 2019.

ADDRESSES: Mail or hand deliver comments to Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590. You may also submit comments electronically at *www.regulations.gov.* All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. Anyone can search the electronic form of all comments in 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, or labor union). The DOT posts these comments, without edits, 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: Ms. Deirdre Remley, Office of Project Development and Environmental Review, (202) 366–0524, *Deirdre.Remley@dot.gov,* or Mr. David Sett, Office of the Chief Counsel, (404) 562–3676, *David.Sett@dot.gov,* Federal Highway Administration, U.S. Department of Transportation, 60 Forsyth Street 8M5, Atlanta, GA 30303. Office hours are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this notice may be downloaded from the specific docket page at *www.regulations.gov.*

Background

The Surface Transportation Project Delivery Program, codified at 23 U.S.C. 327, commonly known as the NEPA Assignment Program, allows a State to assume FHWA's environmental responsibilities for review, consultation, and compliance for Federal highway projects. When a State assumes these Federal responsibilities, the State becomes solely liable for carrying out the responsibilities it has assumed, in lieu of FHWA. The UDOT published its application for NEPA assumption on October 9, 2015, and made it available for public comment for 30 days. After considering public comments, UDOT submitted its application to FHWA on December 1, 2015. The application served as the basis for developing a memorandum of understanding (MOU) that identified the responsibilities and obligations that UDOT would assume. The FHWA published a notice of the draft MOU in the **Federal Register** on November 16, 2016, with a 30-day comment period to solicit the views of the public and Federal agencies. After the close of the comment period, FHWA and UDOT considered comments and

proceeded to execute the MOU. Effective January 17, 2017, UDOT assumed FHWA's responsibilities under NEPA, and the responsibilities for NEPA-related Federal environmental laws described in the MOU.

Section 327(g) of title 23, U.S.C., requires the Secretary to conduct annual audits to ensure compliance with the MOU during each of the first 4 years of State participation and, after the fourth year, monitor compliance. The FHWA must make the results of each audit available for public comment. The first audit report of UDOT compliance was finalized on September 17, 2018. This notice announces the availability of the second audit report for UDOT and solicits public comment on the same.

Authority: Section 1313 of Public Law 112–141; Section 6005 of Public Law 109–59; 23 U.S.C 327; 23 CFR 773.

Issued on: April 8, 2019.

Brandye L. Hendrickson,

Deputy Administrator, Federal Highway Administration.

Surface Transportation Project Delivery Program

Draft FHWA Audit of the Utah Department of Transportation

June 10, 2017–June 30, 2018

Executive Summary

This report summarizes the results of the Federal Highway Administration's (FHWA) second audit of the Utah Department of Transportation's (UDOT) National Environmental Policy Act (NEPA) review responsibilities and obligations that FHWA has assigned and UDOT has assumed pursuant to 23 United States Code (U.S.C.) 327. Throughout this report, FHWA uses the term ''NEPA Assignment Program'' to refer to the program codified at 23 U.S.C. 327. Under the authority of 23 U.S.C. 327, UDOT and FHWA executed a memorandum of understanding (MOU) on January 17, 2017, to memorialize UDOT's NEPA responsibilities and liabilities for Federal-aid highway projects and certain other FHWA approvals for transportation projects in Utah. The FHWA's only NEPA responsibilities in Utah are oversight and review of how UDOT executes its NEPA Assignment Program obligations. The section 327 MOU covers environmental review responsibilities for projects that require the preparation of environmental assessments (EA), environmental impact statements (EIS), and non-designated documented categorical exclusions (DCE). A separate MOU, pursuant to 23 U.S.C. 326, authorizes UDOT's environmental review responsibilities for other categorical exclusions (CE), commonly known as CE Program Assignment. This audit does not cover the CE Program Assignment responsibilities and projects.

As part of its review responsibilities under 23 U.S.C. 327, FHWA formed a team (the ''Audit Team'') in July 2018 to plan and conduct an audit of NEPA responsibilities UDOT assumed. Prior to the on-site visit, the Audit Team reviewed UDOT's NEPA project files, UDOT's response to FHWA's pre-audit information request (PAIR), UDOT's self-assessment of its NEPA Program, UDOT's NEPA Quality Assurance/Quality Control (QA/QC) Guidance, its NEPA Assignment Training Plan, and its NEPA Assignment Self-Assessment Report. The Audit Team conducted an on-site review during the week of October 15 to October 18, 2018. The Audit Team conducted interviews with seven members of UDOT central office staff, three staff members of UDOT's legal counsel, and two staff members from the Utah State Historic Preservation Office as part of this on-site review.

Overall, the Audit Team found that UDOT is successfully adding DCE, EA, and EIS project review responsibilities to an already successful CE review program. The UDOT has made efforts to respond to FHWA findings of the first audit, including improving document management, internal communication, and use of terms related to Section 4(f). In the first audit, FHWA Audit Team made the observation that there was inconsistent understanding of QA/QC procedures among UDOT staff. In the second audit, FHWA Audit Team identified an observation related to four instances of UDOT's lack of adherence to its QA/QC procedures. In addition, although UDOT has improved its document management, the second audit found that UDOT continues to lack procedures for retaining draft and deliberative materials for project records.

The Audit Team identified two observations as well as several successful practices. The Audit Team finds UDOT is carrying out the responsibilities it has assumed and is in substantial compliance with the provisions of the MOU.

Background

The NEPA Assignment Program allows a State to assume FHWA's environmental responsibilities for review, consultation, and compliance for Federal-aid highway projects and certain FHWA approvals. Under 23 U.S.C. 327, a State that assumes these Federal responsibilities becomes solely responsible and solely liable for carrying them out. Effective January 17, 2017, UDOT assumed FHWA's responsibilities under NEPA and other related environmental laws. Examples of responsibilities UDOT has assumed in addition to NEPA include section 7 consultation under the Endangered Species Act and consultation under section 106 of the National Historic Preservation Act.

Following this second audit, FHWA will conduct two more annual audits to satisfy provisions of 23 U.S.C. 327(g) and Part 11 of the MOU. Audits are the primary mechanism through which FHWA may oversee UDOT's compliance with the MOU and the NEPA Assignment Program requirements. This includes ensuring compliance with applicable Federal laws and policies, evaluating UDOT's progress toward achieving the performance measures identified in MOU Section 10.2, and collecting information needed for the Secretary's annual report to Congress. The FHWA must present the results of each audit in a report and make it available for public comment in the **Federal Register**.

The Audit Team consisted of NEPA subject matter experts from FHWA Utah Division, as well as additional FHWA Division staff from California, the District of Columbia, Georgia, and Alaska. These experts received training on how to evaluate implementation of the NEPA Assignment Program.

Scope and Methodology

The Audit Team conducted an examination of UDOT's NEPA project files, UDOT responses to the PAIR, and UDOT self-assessment. The audit also included interviews with staff and reviews of UDOT policies, guidance, and manuals pertaining to NEPA responsibilities. All reviews focused on objectives related to the six NEPA Assignment Program elements: Program management; documentation and records management; QA/QC; legal sufficiency; training; and performance measurement.

The focus of the audit was on UDOT's process and program implementation. Therefore, while the Audit Team reviewed project files to evaluate UDOT's NEPA process and procedures, the Audit Team did not evaluate UDOT's project-specific decisions to determine if they were, in FHWA's opinion, correct or not. The Audit Team reviewed 23 NEPA Project files with DCEs, EAs, and EISs, representing all projects with decision points or other actionable items between June 10, 2017, and June 30, 2018. The Audit Team also

interviewed environmental staff in UDOT's headquarters office.

The PAIR consisted of 29 questions about specific elements in the MOU. The Audit Team used UDOT's response to the PAIR to develop specific follow-up questions for the on-site interviews with UDOT staff.

The Audit Team conducted seven in-person interviews with UDOT environmental staff, one in-person interview with two staff members of the UDOT State Historic Preservation Office, two phone interviews with UDOT's outside legal counsel, and one interview with legal counsel from the Utah Attorney General's office. The Audit Team invited UDOT staff, middle management, and executive management to participate to ensure the interviews represented a diverse range of staff expertise, experience, and program responsibility.

Throughout the document reviews and interviews, the Audit Team verified information on the UDOT NEPA Assignment Program including UDOT policies, guidance, manuals, and reports. This included the NEPA QA/QC Guidance, the NEPA Assignment Training Plan, and the NEPA Assignment Self-Assessment Report.

The Audit Team compared the procedures outlined in UDOT environmental manuals and policies to the information obtained during interviews and project file reviews to determine if there were discrepancies between UDOT's performance and documented procedures. The Audit Team documented observations under the six NEPA Assignment Program topic areas. Below are the audit results.

Overall, UDOT has carried out the environmental responsibilities it assumed through the MOU and the application for the NEPA Assignment Program, and, as such, the Audit Team finds UDOT is substantially compliant with the provisions of the MOU.

Observations and Successful Practices

This section summarizes the Audit Team's observations of UDOT's NEPA Assignment Program implementation, including successful practices UDOT may want to continue or expand. Successful practices are positive results FHWA would like to commend UDOT for developing. These may include ideas or concepts that UDOT has planned but not yet implemented. Observations are items the Audit Team would like to draw UDOT's attention to that may benefit from revisions to improve processes, procedures, or outcomes. The UDOT may have already taken steps to address or improve upon the Audit Team's observations, but, at the time of the audit, they appeared to be areas where UDOT could make improvements. This report addresses all six MOU topic areas as separate discussions. Under each area, this report discusses successful practices followed by observations.

This audit report provides an opportunity for UDOT to implement actions to improve their program. The FHWA will consider the status of areas identified for potential improvement in this audit's observations as part of the scope of Audit #3. The third audit report will include a summary discussion that describes progress since the last audit.

Program Management

Successful Practices

The UDOT and FHWA Division office meet on a quarterly basis to keep staff updated on current topics related to UDOT's implementation of the NEPA Assignment Program. During FHWA/UDOT quarterly meetings, the agencies work to ensure project delivery schedules of non-assigned Federal actions, such as Federal land transfers and Interstate access change requests as they relate to projects assigned to UDOT under the MOU. This meeting is also used to address program-level NEPA Assignment questions, such as clarifying starting dates of EAs for performance tracking.

Documentation and Records Management

Successful Practices

ProjectWise is a document database UDOT uses to maintain final project records for DCEs, EAs, and EISs. Though it was not developed specifically for producing and maintaining environmental documents, ProjectWise is accessible to all staff and can store final environmental documents and technical reports. Since the last audit, UDOT has started using organizational tools, such as subfolders in ProjectWise, to better organize final environmental documents. Once the environmental review process is complete for a project and the consultant has submitted final project files, UDOT uses project record checklists to confirm completeness of ProjectWise files.

Observation #1: Incomplete Retention of Environmental Project Records

The project reviews and interviews determined UDOT retains final environmental documents such as EAs, Draft EISs, Final EISs, Findings of No Significant Impact, and Records of Decision, and certain technical reports in ProjectWise. There is, however, no procedure for retaining other types of supporting materials that inform NEPA decisions and other environmental determinations. Other records, such as meeting summaries documenting coordination with resource agencies and stakeholders or telephone memos documenting conversations used to gather substantive information related to environmental decisions, were generally absent from the ProjectWise files reviewed. Some environmental staff said they store these types of documents on personal drives, local servers, or as hardcopy in filing cabinets. This dispersal and inconsistency of recordkeeping could result in document loss and difficulty of retrieval, hampering the ability to demonstrate support for Agency decisions, including compilation of administrative records in legal challenges.

Quality Assurance/Quality Control

Observation #2: Inconsistent Application of UDOT's QA/QC Procedures

Section 8.2.4 of the MOU requires UDOT to develop a QA/QC process. Project file reviews revealed that one of the two Draft EISs that UDOT approved for circulation during the audit period occurred prior to completion of the required QA/QC process. This approval was not in accordance with either the QA/QC Plan or the UDOT Manual of Instruction, which require the Environmental Document QC Form, signed by the Environmental Program Manager and the Director of Environment, be provided to the UDOT Signatory Official with the request for approval of the Draft EIS.

Project file reviews and interviews with UDOT staff revealed an inconsistent approach to conducting and documenting the QA/QC process for DCEs. The Audit Team reviewed project files for four DCEs. This review revealed three different approaches to conducting the required QA/QC for these projects. Two of these QA/QC reviews used one form, the third used a different form, and the fourth project had neither a form nor other documentation in ProjectWise. These inconsistencies in practice suggest that UDOT's QA/QC procedures may not be effective. The UDOT may also be unnecessarily increasing its risks when staff do not follow stipulated quality control reviews prior to making NEPA decisions.

Legal Sufficiency

Successful Practices

During the audit period, outside counsel issued two findings of legal sufficiency per the requirements of 23 CFR 771.125(b) and 23 CFR 774.7(d), copies of which were provided to the Audit Team. Through interviews, the Audit Team learned UDOT has continued using the legal sufficiency process it put in place for both Section 326 CE and section 327 NEPA Assignment, which is contracting with outside counsel who have extensive experience in NEPA, other environmental laws, and Federal environmental litigation. The UDOT Environmental Managers work directly with outside counsel without the need to go through the Utah Attorney General's (AG) Office. Nevertheless, an Assistant AG assigned to UDOT is kept apprised of all communications between UDOT staff and outside counsel and reviews all bills submitted by outside counsel. Outside counsel have been included as part of the ''project team'' from the start of projects, and some have reviewed draft notices of intent for EISs. In addition, the UDOT, an Assistant AG, and outside counsel hold quarterly meetings at which UDOT staff apprise counsel of upcoming project reviews and anticipated review deadlines.

Training

Successful Practices

The UDOT has created a training plan that is customized to each employee's needs and disciplines to provide more focused training opportunities by specialty. The UDOT provides training on general environmental topics, such as NEPA, and provides opportunities for subject matter experts to take training related to their disciplines.

Performance Measures

Successful Practices

The UDOT's self-assessment documented the performance management details of the NEPA Assignment program in Utah, which demonstrates UDOT's procedures under NEPA assignment have resulted in a 50 percent reduction in the time to complete DCEs, EAs, and EISs. The average time to complete environmental documents is 5 months for DCEs, 18 months for EAs, and 37 months for an EIS. Although these data are based on a limited number of completed UDOT NEPA reviews since January 2017 (nine DCEs, two EAs, and one EIS), UDOT's initial timeliness results are promising. The UDOT will continue to monitor its progress towards improving timeliness of environmental reviews as part of its performance under the NEPA Assignment Program.

Next Steps

The FHWA provided this draft audit report to UDOT for a 28-day review and comment period. The Audit Team considered UDOT comments in developing this draft audit report. The FHWA will publish a notice in the **Federal Register** for a 30-day comment period in accordance with 23 U.S.C. 327(g)(2)(A). No later than 60 days after the close of the comment period, FHWA will respond to all comments submitted to finalize this draft audit report pursuant to 23 U.S.C. 327(g)(2)(B). Once finalized, FHWA will publish the final audit report in the **Federal Register**.

[FR Doc. 2019–07561 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0051]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel DAY CHARTER SA; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 16, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0051 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0051 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0051, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel DAY CHARTER SA is:

—*Intended Commercial Use of Vessel:* ''Day Charters off the South Shore of Oahu. Private day sailing, snorkeling, whale watching, weddings and funerals, sunset cruises.''
—*Geographic Region Including Base of Operations:* ''Hawaii'' (Base of Operations: Honolulu, HI)
—*Vessel Length and Type:* 39′ catamaran

The complete application is available for review identified in the DOT docket as MARAD–2019–0051 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised

that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2019–0051 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: April 10, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–07476 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0055]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel SEA TURTLE; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 16, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0055 by any one of the following methods:

- Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Search MARAD–2019–0055 and follow the instructions for submitting comments.
- Mail or Hand Delivery: Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0055, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel SEA TURTLE is:

—*Intended Commercial Use of Vessel:* ''Whole boat charters—Scenic,Sunset and Private up to a maximum of 6 hours. We will be operating under a Six Pack License. Maximum 6 passengers on any given charter. We will be operating only 5–10 trips per week.''

—*Geographic Region Including Base of Operations:* ''Florida, Georgia, Massachusetts, Maine, New Hampshire'' (Base of Operations: Kennebunk, ME)

—*Vessel Length and Type:* 40′ sailing catamaran

The complete application is available for review identified in the DOT docket as MARAD–2019–0055 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0055 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: April 10, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–07482 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0056]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MAI TAI TWO; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 16, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0056 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0056 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0056, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MAI TAI TWO is:

—*Intended Commercial Use of Vessel:* ''Day Sailing Charter (6PAX/OUPV)''

—*Geographic Region Including Base Of Operations:* ''Louisiana'' (Base of Operations: New Orleans, LA)

—*Vessel Length and Type:* 41' sailboat

The complete application is available for review identified in the DOT docket as MARAD–2019–0056 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0056 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

* * * * *

Dated: April 10, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.

Secretary, Maritime Administration.

[FR Doc. 2019–07480 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0050]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MAI KA'I; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 16, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0050 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0050 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0050, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MAI KA'I is:

—*Intended Commercial Use of Vessel:* ''Sail charters along the Kona coast''

—*Geographic Region Including Base of Operations:* ''Hawaii'' (Base of Operations: Kona, HI)

—*Vessel Length and Type:* 38′ catamaran

The complete application is available for review identified in the DOT docket as MARAD–2019–0050 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0050 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

* * * * *

Dated: April 10, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–07479 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0049]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel SHIPFACED; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 16, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0049 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0049 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0049, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel SHIPFACED is:

—*Intended Commercial Use of Vessel:* ''Carrying paying passengers.''

—*Geographic Region Including Base of Operations:* ''Florida, Alabama, Louisiana, Texas, California'' (Base of Operations: Demopolis, AL)

—*Vessel Length and Type:* 55' sport fishing vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0049 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0049 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide

comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121

* * * * *

Dated: April 10, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–07483 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0048]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel RAVENCLAW; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 16, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0048 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Search MARAD–2019–0048 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0048, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov*.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel RAVENCLAW is:

—*Intended Commercial Use Of Vessel:* ''Time Charters''

—*Geographic Region Including Base of Operations:* ''Rhode Island, Massachusetts, New Hampshire, Maine, South Carolina, Georgia, Florida'' (Base of Operations: Newport, RI)

— *Vessel Length And Type:* 72′ sailboat

The complete application is available for review identified in the DOT docket as MARAD–2019–0048 at *http://www.regulations.gov*. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0048 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy*. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

* * * * *

Dated: April 10, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–07481 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0052]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel SIDE HUSTLE; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 16, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0052 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0052 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0052, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel SIDE HUSTLE is:

—*Intended Commercial Use of Vessel:* ''Vessel will be used for recreational charters including sunset cruises, day cruises, and rare overnight excursions upon the waters of Marina del Rey and Santa Monica Bay from Paradise Cove to Santa Catalina Island, California. The majority of the time the boat operation will be within 10 nautical miles of Marina del Rey.''

—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: Marina Del Ray, CA)

—*Vessel Length and Type:* 70′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0052 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES.** Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2019–0052 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: April 10, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–07484 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0054]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel FLAUNA II; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 16, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0054 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0054 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0054, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel FLAUNA II is:

—*Intended Commercial Use of Vessel:* ''6 passenger charters for fishing, camping, nature tours, and photography''

—*Geographic Region Including Base of Operations:* ''Alabama, Florida, Mississippi, Louisiana, Texas'' (Base of Operations: Soldiers Creek, Lillian, AL)

—*Vessel Length and Type:* 45′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0054 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0054 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: April 10, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–07477 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0053]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel ACE CHARTERS II; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 16, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0053 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0053 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0053, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel ACE CHARTERS II is:

—*Intended Commercial Use of Vessel:* ''OUPV Charter Boat up to Six Passengers''
—*Geographic Region Including Base of Operations:* ''Massachusetts, New York (excluding New York Harbor)'' (Base of Operations: Adams, MA)
—*Vessel Length and Type:* 28′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0053 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0053 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: April 10, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–07475 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0057]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel GREEN EYED LADY; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 16, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0057 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0057 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of

Transportation, MARAD–2019–0057, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel GREEN EYED LADY is:

—*Intended Commercial Use of Vessel:* ''Day sails''
—*Geographic Region Including Base of Operations:* ''Virginia, Maryland, Delaware, Florida'' (Base of Operations: St Augustine, FL)
—*Vessel Length and Type:* 33′ catamaran

The complete application is available for review identified in the DOT docket as MARAD–2019–0057 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0057 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

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, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: April 10, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–07478 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2017–0034; Notice 2]

Michelin North America, Inc., Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: Michelin North America, Inc. (MNA), has determined that certain BFGoodrich gForce Rival S summer performance tires do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 139, *New Pneumatic Radial Tires for Light Vehicles.* MNA filed a noncompliance report dated April 17, 2017. MNA also petitioned NHTSA on May 5, 2017, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. NHTSA is granting the petition for the reasons stated in this decision.

FOR FURTHER INFORMATION CONTACT: Abraham Diaz, Office of Vehicle Safety Compliance, NHTSA, telephone (202) 366–5310, facsimile (202) 366–5930.

SUPPLEMENTARY INFORMATION:

I. Overview: MNA has determined that certain BFGoodrich gForce Rival S summer performance tires do not fully comply with paragraph S5.2(d) of FMVSS No. 139, *New Pneumatic Radial Tires for Light Vehicles* (49 CFR 571.139). MNA filed a noncompliance report dated April 17, 2017, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* MNA also petitioned NHTSA on May 5, 2017, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety.

Notice of receipt of the petition was published, with a 30-day public comment period, on July 11, 2017, in the **Federal Register** (82 FR 32049). No

comments were received. To view the petition and all supporting documents, log onto the Federal Docket Management System (FDMS) website at: *http://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2017–0034.''

II. Tires Involved: Approximately 370 BFGoodrich gForce Rival S summer performance tires, size P335/30ZR18 95W LL, manufactured between March 2, 2017, and March 30, 2017, are potentially involved.

III. Noncompliance: MNA explains that the noncompliance is that the tire size designation markings on the sidewalls of the subject tires do not contain the tire type code designator symbol from the United States Tire and Rim Association (USTRA) yearbook, as required by paragraph S5.2(d) of FMVSS No. 139. Specifically, the subject tire size reads ''335/30ZR18 95W LL'' but should read ''P335/30ZR18 95W LL.''

IV. Rule Requirements: Paragraph S5.2(d) of FMVSS No. 139 titled ''Performance Requirements'' includes the requirements relevant to this petition:

Each tire shall conform to each of the following:

- Its load rating shall be that specified either in a submission made by an individual manufacturer, pursuant to paragraph S4, or in one of the publications described in paragraph S4 for its size designation, type and each appropriate inflation pressure.
- If the maximum load rating for a particular tire size is shown in more than one of the publications described in paragraph S4, each tire of that size designation shall have a maximum load rating that is not less than the published maximum load rating, or if there are differing maximum load ratings for the same tire size designation, not less than the lowest published maximum load rating.

V. Summary of MNA's Petition: MNA described the subject noncompliance and stated its belief that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, MNA submitted the following reasoning:

(a) Application—The subject tires are marked with the correct maximum load [1], pressure, and load index, to ensure proper application. Additionally, the tires have the correct tread sticker label showing the correct size designation, part number, etc. to ensure proper application.

(b) Usage—These tires are marketed as performance tires and normally used for competition events on tracks or autocross courses. Thus, the tires are normally operated at the lightest loads possible for performance optimization.

(c) Other Markings—All other markings conform to the applicable regulations.

(d) Performance—The subject tires meet all performance requirements of FMVSS No. 139. In the event, because of the missing ''P'' prefix, the tires are used to replace a 335/30ZR18 size tire, which has a higher load carrying capacity than a P335/30ZR18 tire, there should be no performance concerns.[2] The tires have been tested to FMVSS No. 139 using the higher standard load as a basis and they fulfill all performance requirements.

MNA concluded by expressing the belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and that its petition to be exempt from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

VI. NHTSA'S Analysis: NHTSA has evaluated the merits of the inconsequential noncompliance petition submitted by MNA and has determined that this particular noncompliance is inconsequential to motor vehicle safety. Specifically, NHTSA considered the following factors when analyzing the risk to safety for these noncompliant tires:

(a) Application—Because the subject tires are marked with the load in accordance with the USTRA publications, and certified to the higher load indicated by ETRTO and corresponding to the missing ''P'', the omission of the letter ''P'' would not have an impact on safety with respect to the application of the subject tires. With respect to the tires having a sticker showing the correct size designation, part number, and tire information at the point of sale, the agency does not find this information compelling in terms of granting this petition since once a tire is mounted on a vehicle, a motorist will rely on what is marked on the tire sidewall and not on the sticker at the point of sale.

(b) Usage—The petitioner contends that the subject tires are marketed and normally used for competition events on tracks or autocross courses. The petitioner further states that when used for competition events, the tires are normally used in a lightly loaded condition to optimize performance during the event. NHTSA does not find this argument compelling because the tires are available for purchase by the public and use of the tires in other circumstances, such as driving to and from such competition events with multiple passengers onboard, is foreseeable.

(c) Other Markings—MNA states they properly marked the subject tires with the correct tire size, maximum pressure, intended load (1521 lbs/690 kgs), and load index. NHTSA finds these additional markings will mitigate the potential risk that consumers will load the tires to the higher load that applies to the ETRTO designation for tires having the same size, without the ''P'' designation.

(d) Performance—MNA provided evidence that they certified these tires to FMVSS No. 139 using the ETRTO specifications required for tires without the ''P'' designation. NHTSA finds this a compelling argument to support that, in the event the tires are used with the ETRTO specification, due to the missing ''P,'' there is a basis to believe they would be safe. This basis data was provided to the Agency and indicates that the tires have been tested to the loads specified by ETRTO specifications and thus are able to perform safely using the USTRA specifications.

Together, these factors have led NHTSA to conclude that it would be unlikely that an end user would disregard the tire load marked on the sidewall of the tire and instead rely on the load specified in the ETRTO yearbook. Furthermore, if a consumer were to load the tire to the load specified in the ETRTO books, the tires are designed and manufactured to comply with FMVSS No. 139 under those conditions, so there would be no increased risk to safety.

VII. NHTSA's Decision: In consideration of the foregoing, NHTSA has decided that Michelin North America has met its burden of persuasion that the FMVSS No. 139 noncompliance for the replacement tires identified in MNA's Noncompliance Information Report is inconsequential to motor vehicle safety. Accordingly, MNA's petition is hereby granted and MNA is consequently exempted from the obligation of providing notification of and free remedy for, that

[1] The petitioner referred to ''Light Load'' meaning the maximum load and pressure specified by USTRA publications.

[2] The standard load index for size 335/30ZR18 tire is 102 according to the European Tyre and Rim Technical Organization (ETRTO) yearbook, which corresponds to a maximum load capacity of 850 kg. The P335/30ZR18 tire size according to the USTRA yearbook has a load index of 95, which corresponds to a maximum load capacity of 690 kg.

noncompliance under 49 U.S.C. 30118 AND 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject tires that MNA no longer controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve equipment distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after MNA notified them that the subject noncompliance existed.

Authority: (49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8).

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2019–07520 Filed 4–15–19; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List (SDN List) and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

On April 11, 2019, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individual

1. CHAMS, Kassem (a.k.a. CHAMS, Qassim Muhammed; a.k.a. SHAMS, Kassem Mohammed; a.k.a. SHAMS, Qasim Muhammed), Hermel, Lebanon; Chams Building, 3rd Floor Jalal, Chtaura, Zahle, Lebanon; DOB 20 Mar 1962; POB Lebanon; citizen Lebanon; Gender Male (individual) [SDNTK] (Linked To: CHAMS MONEY LAUNDERING ORGANIZATION; Linked To: CHAMS EXCHANGE COMPANY SAL). Identified as a significant foreign narcotics trafficker pursuant to section 805(b)(1) of the Foreign Narcotics Kingpin Designation Act (''Kingpin Act''), 21 U.S.C. 1901(b)(1).

Entities

1. CHAMS EXCHANGE COMPANY SAL (a.k.a. ALI MOHAMED CHAMS & PARTNER; a.k.a. ALI MOHAMED CHAMS AND PARTNER; a.k.a. CHAMS EXCHANGE), Sahata Choutra, Chtaura, Lebanon; Chams Building, 3rd Floor, Jalal, Chtaura, Zahle, Lebanon [SDNTK]. Designated pursuant to section 805(b)(2) of the Kingpin Act, for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Kassem CHAMS, a foreign person identified as a significant foreign narcotics trafficker pursuant to the Kingpin Act; also designated pursuant to section 805(b)(3) of the Kingpin Act for being owned, controlled, or directed by, or acting for or on behalf of. Kassem CHAMS, a foreign person identified as a significant foreign narcotics trafficker pursuant to the Kingpin Act.

2. CHAMS MONEY LAUNDERING ORGANIZATION (a.k.a. CHAMS MLO), Lebanon [SDNTK]. Designated pursuant to section 805(b)(3) of the Kingpin Act for being owned, controlled, or directed by, or acting for or on behalf of Kassem CHAMS, a foreign person identified as a significant foreign narcotics trafficker pursuant to the Kingpin Act.

Dated: April 11, 2019.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2019–07548 Filed 4–15–19; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Publication of Nonconventional Source Production Credit Reference Price for Calendar Year 2018

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: Publication of the reference price for the nonconventional source production credit for calendar year 2018.

FOR FURTHER INFORMATION CONTACT: Martha Garcia, CC:PSI:6, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224, Telephone Number (202) 317–6853 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The credit period for nonconventional source production credit ended on December 31, 2013 for facilities producing coke or coke gas (other than from petroleum based products). However, the reference price continues to apply in determining the amount of the enhanced oil recovery credit under section 43 of title 26 of the U.S.C., the marginal well production credit under section 45I of title 26 of the U.S.C., and the percentage depletion in case of oil and natural gas produced from marginal properties under section 613A of title 26 of the U.S.C.

The reference price under section 45K(d)(2)(C) of title 26 of the U.S.C. for calendar year 2018 applies for purposes of sections 43, 45I, and 613A for taxable year 2019.

Reference Price: The reference price under section 45K(d)(2)(C) for calendar year 2018 is $61.41.

Christopher T. Kelley,

Special Counsel, (Passthroughs and Special Industries).

[FR Doc. 2019–07557 Filed 4–15–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0495]

Agency Information Collection Activity Under OMB Review: Marital Status Questionnaire

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before May 16, 2019.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0495'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Danny S. Green at (202) 421–1354.

SUPPLEMENTARY INFORMATION:

Authority: 8 U.S.C. 101(3), 103.

Title: Marital Status Questionnaire, VA Form 21P–0537.

OMB Control Number: 2900–0495.

Type of Review: Extension without change of a currently approved collection.

Abstract: The Department of Veterans Affairs (VA), through its Veterans Benefits Administration (VBA), administers an integrated program of benefits and services established by law for Veterans, service personnel, and their dependents and/or beneficiaries. VA Form 21P–0537 Marital Status Questionnaire is used to confirm the marital status of a surviving spouse in receipt of Dependency and Indemnity Compensation (DIC) benefits. If a surviving spouse remarries, he or she is no longer entitled to DIC unless the marriage began after age 57 or has been terminated. Information is requested by this form under the authority of 38 U.S.C. 101(3) and 38 U.S.C. 103.

VA Form 21P–0537 is used by VBA to verify a surviving spouse's current marital status to determine his or her continuing entitlement to DIC benefits. The form letter is automatically generated and mailed to DIC beneficiaries. Agency action depends on the information provided by the beneficiary. If the information provided supports the beneficiary's continued entitlement to benefits, no action is taken. If the information provided by the beneficiary does not support continued entitlement to benefits, VA will act to terminate benefit payments, based on the facts found.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 84 FR 2949 on February 8, 2019, page 2949.

Affected Public: Individuals or Households.

Estimated Annual Burden: 1,484.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 17,808.

By direction of the Secretary.

Danny S. Green,

VA Interim Clearance Officer, Office of Quality, Performance, and Risk, Department of Veterans Affairs.

[FR Doc. 2019–07462 Filed 4–15–19; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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No. 73 April 16, 2019

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 422, 423, 438, et al.

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422, 423, 438, and 498

[CMS–4185–F]

RIN 0938–AT59

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will revise the Medicare Advantage (MA) program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to implement certain provisions of the Bipartisan Budget Act of 2018; improve quality and accessibility; clarify certain program integrity policies for MA, Part D, and cost plans and PACE organizations; reduce burden on providers, MA plans, and Part D sponsors through providing additional policy clarification; and implement other technical changes regarding quality improvement. This final rule will also revise the appeals and grievances requirements for certain Medicaid managed care and MA special needs plans for dual eligible individuals to implement certain provisions of the Bipartisan Budget Act of 2018.

DATES: *Effective Dates:* These regulations are effective on January 1, 2020, except for the amendments to §§ 422.107(c)(9), (d), (e)(2), 422.560(a)(4) and (b)(5), 422.566(a), 422.629 through 422.634, 422.752(d), 438.210, 438.400, and 438.402, which are effective January 1, 2021, and for the amendments to §§ 422.222(a)(2), 423.120(c)(6)(iv), and 498.5(n)(1), which are effective June 17, 2019.

FOR FURTHER INFORMATION CONTACT: Theresa Wachter, (410) 786–1157, or Cali Diehl, (410) 786–4053, MA/Part C Issues. Elizabeth Goldstein, (410) 786–6665, Parts C and D Quality Ratings Issues. Kari Gaare, (410) 786–8612, Prescription Drug Plan Access to Parts A and B Data Issues. Vanessa Duran, (410) 786–8697, D–SNP Issues. Frank Whelan, (410) 786–1302, Preclusion List Issues.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this final rule is to revise the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our continued experience in the administration of the Part C and Part D programs and to implement certain provisions of the Bipartisan Budget Act of 2018. The changes are necessary to—

- Implement the Bipartisan Budget Act of 2018 provisions;
- Improve program quality and accessibility;
- Clarify program integrity policies; and
- Implement other changes.

This final rule will meet the Administration's priorities to reduce burden across the Medicare program by reducing unnecessary regulatory complexity, and improve the regulatory framework to facilitate development of Part C and Part D products that better meet the individual beneficiary's healthcare needs. Because the Bipartisan Budget Act of 2018 requires the Secretary to establish procedures, to the extent feasible, for integration and unification of the appeals and grievance processes for dual eligible individuals who are enrolled in Medicaid and in MA special needs plans for dual eligible individuals (D–SNPs), this final rule also includes provisions to revise the appeals and grievances requirements for Medicaid managed care and MA D–SNPs. While the Part C and Part D programs have high satisfaction among beneficiaries, we continually evaluate program policies and regulations to remain responsive to current trends and newer technologies, and provide increased flexibility to serve patients. Specifically, this final rule meets the Secretary's priorities to: (1) Reform health insurance by increasing access to personalized health care, (2) transform our healthcare system to be value-based and innovative by promoting health information technology, and (3) support boosting transparency around price and quality. These changes being finalized will promote more convenient, cost-effective access to care within Part C and D plans, improve accountability and bolster program integrity, allow plans to innovate in response to patients' needs, and promote coordination within MA D–SNPs.

2. Summary of the Major Provisions

a. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Section 50323 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) created a new section 1852(m) of the Social Security Act (the Act), which allows MA plans the ability to provide ''additional telehealth benefits'' (referred to as ''MA additional telehealth benefits'' in this rule) to enrollees starting in plan year 2020 and treat them as basic benefits. The statute limits these authorized MA additional telehealth benefits to services for which benefits are available under Medicare Part B, but that are not payable under section 1834(m) of the Act and have been identified for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (referred to as ''electronic exchange'' in this rule). Under this final rule, MA plans will be permitted to offer—as part of the basic benefit package—MA additional telehealth benefits beyond what is currently allowable under the original Medicare telehealth benefit (referred to as ''Medicare telehealth services'' in this rule). In addition, MA plans will continue to be able to offer MA supplemental benefits (that is, benefits not covered by original Medicare) via remote access technologies and/or telemonitoring (referred to as ''MA supplemental telehealth benefits'' in this rule) for those services that do not meet the requirements for coverage under original Medicare or the requirements for MA additional telehealth benefits.

Section 1852(m)(4) of the Act mandates that enrollee choice is a priority. If an MA plan covers a Part B service as an MA additional telehealth benefit, then the MA plan must also provide access to such service through an in-person visit and not only through electronic exchange. The enrollee must have the option whether to receive such service through an in-person visit or, if offered by the MA plan, through electronic exchange. In addition, section 1852(m)(2)(A)(ii) of the Act excludes from MA additional telehealth benefits capital and infrastructure costs and investments relating to such benefits. These statutory provisions have guided our rule.

In this final rule, we establish regulatory requirements that will allow MA plans to cover Part B benefits furnished through electronic exchange but not payable under section 1834(m) of the Act as MA additional telehealth

benefits—and as part of the basic benefits defined in § 422.101 instead of separate MA supplemental benefits. We believe MA additional telehealth benefits will increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access benefits. We solicited comments from stakeholders on various aspects of our proposal, which informed how we are implementing the MA additional telehealth benefits in this final rule.

b. Dual Eligible Special Needs Plans Provisions (§§ 422.2, 422.60, 422.102, 422.107, 422.111, 422.560 Through 422.562, 422.566, 422.629 Through 422.634, 422.752, 438.210, 438.400, and 438.402)

Section 50311(b) of the Bipartisan Budget Act of 2018 amends section 1859 of the Act to require integration of the Medicare and Medicaid benefits provided to enrollees in Dual Eligible Special Needs Plans (D–SNPs). In particular, the statute requires: (1) Development of unified grievance and appeals processes for D–SNPs; and (2) establishment of new standards for integration of Medicare and Medicaid benefits for D–SNPs.

The statute specifies a number of key elements for unified D–SNP grievance and appeals processes and grants the Secretary discretion to determine the extent to which unification of these processes is feasible. In particular, the unified processes must adopt the provisions from section 1852(f) and (g) of the Act (MA grievances and appeals) and sections 1902(a)(3) and (5), and 1932(b)(4) of the Act (Medicaid grievances and appeals, including managed care) that are most protective to the enrollee, take into account differences in state Medicaid plans to the extent necessary, easily navigable by an enrollee, include a single written notification of all applicable grievance and appeal rights, provide a single pathway for resolution of a grievance or appeal, provide clear notices, employ unified timeframes for grievances and appeals, establish requirements for how the plan must process, track, and resolve grievances and appeals, and with respect to benefits covered under Medicare Parts A and B and Medicaid, incorporate existing law that provides continuation of benefits pending appeal for items and services covered under Medicare and Medicaid. The statute requires the Secretary to establish unified grievance and appeals procedures by April 1, 2020 and requires D–SNP contracts with state Medicaid agencies to use the unified procedures for 2021 and subsequent years.

Regarding the establishment of new standards for integration of Medicare and Medicaid benefits, the statute requires that all D–SNPs meet certain new minimum criteria for such integration for 2021 and subsequent years, either by covering Medicaid benefits through a capitated payment from a state Medicaid agency or meeting a minimum set of requirements as determined by the Secretary. The law also stipulates that for the years 2021 through 2025, if the Secretary determines that a D–SNP failed to meet one of these integration standards, the Secretary may impose an enrollment sanction, which would prevent the D–SNP from enrolling new members. In describing the ''additional minimum set of requirements'' established by the Secretary, the statute directs the Federally Coordinated Health Care Office in CMS to base such standards on input from stakeholders. We implement these new statutory provisions and clarify definitions and operating requirements for D–SNPs in this final rule.

c. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i) and 423.186(i))

In the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Final Rule (hereafter referred to as the April 2018 final rule), CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and advance notice regarding enhancements to the Part C and D Star Ratings program.

At this time, we are finalizing enhancements to the cut point methodology for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures. We are also making substantive updates to the specifications for a few measures for the 2022 and 2023 Star Ratings, and finalizing rules for calculating Star Ratings in the case of extreme and uncontrollable circumstances. Data would be collected and performance measured using these final rules and regulations for the 2020 measurement period and the 2022 Star Ratings, except for the Plan All-Cause Readmission measure where the applicability date is the 2021 measurement period as described in section II.B.1.d.(1).(c) of this final rule.

d. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))

In the April 2018 final rule, CMS removed several requirements pertaining to MA and Part D provider and prescriber enrollment that were to become effective on January 1, 2019. We stated in that final rule our belief that the best means of reducing the burden of the MA and Part D provider and prescriber enrollment requirements without compromising our payment safeguard objectives would be to focus on providers and prescribers that pose an elevated risk to Medicare beneficiaries and the Trust Funds. That is, rather than require the enrollment of MA providers and Part D prescribers regardless of the level of risk they might pose, we would prevent payment for MA items or services and Part D drugs that are, as applicable, furnished or prescribed by demonstrably problematic providers and prescribers. We therefore established in the April 2018 final rule a policy under which: (1) Such problematic parties would be placed on a ''preclusion list''; and (2) payment for MA services and items and Part D drugs furnished or prescribed by these individuals and entities would be rejected or denied, as applicable. The MA and Part D enrollment requirements, in short, were replaced with the payment-oriented approach of the preclusion list.

This final rule will make several revisions and additions to the preclusion list provisions we finalized in the April 2018 final rule. We believe these changes will help clarify for stakeholders CMS' expectations regarding the preclusion list.

3. Summary of Costs and Benefits

Provision	Description	Impact
Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264).	Consistent with section 50323 of the Bipartisan Budget Act of 2018, MA plans have the ability to provide ''additional telehealth benefits'' to enrollees starting in plan year 2020 and treat them as basic benefits.	MA additional telehealth benefits are expected to produce $557 million in savings for enrollees over 10 years from reduced travel time to and from providers. The impact of paying for MA additional telehealth benefits out of the Medicare Trust Fund (as basic benefits) versus out of the rebates (as supplemental benefits) results in a transfer of $80 million from the Medicare Trust Fund to enrollees over 10 years.
Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752).	Consistent with section 50311(b) of the Bipartisan Budget Act of 2018, we are establishing, effective 2021, Medicare and Medicaid integration standards D–SNPs. Effective 2021 through 2025, we will require the imposition of an intermediate sanction of prohibiting new enrollment into a D–SNP if CMS determines that the D–SNP is failing to comply with these integration standards. Finally, we are creating new and modifying existing regulatory definitions that relate to D–SNPs.	For the initial year of implementation, we estimate a $3.4 million cost to MA plans and a $0.5 million cost to state Medicaid agencies, half of which is transferred to the federal government, in order to transition to the new requirements. After that, we estimate that impact will be negligible.
Unified Grievances and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560–562, 422.566, 422.629–422.634, 438.210, 438.400, and 438.402).	Consistent with section 50311(b) of the Bipartisan Budget Act of 2018, we are unifying Medicare and Medicaid grievance and appeals procedures for certain D–SNPs that enroll individuals who receive Medicare and Medicaid benefits from the D–SNP and a Medicaid managed care organization offered by the D–SNP's MA organization, the parent organization, or subsidiary owned by the parent organization. Medicare and Medicaid grievance and appeals processes differ in several key ways, which in effect creates unnecessary administrative complexity for health issuers participating across product lines. This will allow enrollees to follow one resolution pathway at the plan level when filing a complaint or contesting an adverse coverage determination with their plan regardless of whether the matter involves a Medicare or Medicaid covered service.	The provision gives rise to both savings, from the increased efficiency of a unified process, and costs from the requirement to provide benefits while appeals are pending. Over 10 years there are three anticipated effects: (1) Plans will save $0.7 million from the increased efficiency of unified appeals and grievance processes; this savings is passed to the Medicare Trust Fund; (2) the Medicare Trust Fund will incur a $4.2 million expense for providing benefits while appeals are pending; and (3) enrollees will incur an extra $0.7 million in cost sharing for benefits while appeals are pending.
MA and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), 422.166(a) and 423.186(a), 422.164 and 423.184, and 422.166(i)(1) and 423.186(i)(1)).	We are finalizing several measure specification updates, adjustments due to extreme and uncontrollable circumstances, and an enhanced cut point methodology. The measure changes are routine and do not have a significant impact on the ratings of contracts. The policy for disasters will hold contracts harmless from decreases in ratings from the prior year when there are extreme and uncontrollable circumstances affecting them. The methodology to set Star Ratings cut points will help increase the stability and predictability of cut points from year to year.	Negligible impact.
Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6)).	We are making several revisions to the MA and Part D preclusion list policies that we finalized in the April 2018 final rule.	Negligible impact.

B. Background

We received approximately 180 timely pieces of correspondence containing multiple comments on the proposed rule titled ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021'' which published November 1, 2018, in the **Federal Register** (83 FR 54982). While we intend to address the Risk Adjustment Data Validation (RADV) proposals in subsequent rulemaking (due to an extended comment period for these proposals until April 30, 2019, per 83 FR 66661), we are finalizing all other provisions with changes varying from minor clarifications to more significant modifications based on comments received. We also note that some of the public comments received were outside of the scope of the proposed rule. These

out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate headings. However, we note that in this final rule we are not addressing comments received with respect to the RADV provision of the proposed rule that we are not finalizing at this time. Rather, we will address these comments in subsequent rulemaking, as appropriate.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

A. Implementing the Bipartisan Budget Act of 2018 Provisions

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Technologies that enable healthcare providers to deliver care to patients in locations remote from the providers (hereinafter referred to as ''telehealth'') are increasingly being used to complement face-to-face patient-provider encounters. Telehealth visits among rural Medicare beneficiaries participating in original Medicare have increased more than 25 percent a year from 2004 to 2013.[1] In Medicare Advantage (MA), about 81 percent of MA plans offered supplemental telehealth benefits in the form of remote access technologies in 2018, an increase from 77 percent in 2017.[2] This shows that the healthcare industry has made significant advances in technology that enable secure, reliable, real-time, interactive communication and data transfer that were not possible in the past. Moreover, the use of telehealth as a care delivery option for MA enrollees may improve access to and timeliness of needed care, increase convenience for patients, increase communication between providers and patients, enhance care coordination, improve quality, and reduce costs related to in-person care.[3]

MA basic benefits are structured and financed based on what is covered under Medicare Parts A and B (paid through the capitation rate by the government) with coverage of additional items and services and more generous cost sharing provisions financed as MA supplemental benefits (paid using rebate dollars or supplemental premiums paid by enrollees). Traditionally, MA plans have been limited in how they may deliver telehealth services outside of the original Medicare telehealth benefit under section 1834(m) of the Act (hereinafter referred to as ''Medicare telehealth services'') because of this financing structure; only services covered by original Medicare under Parts A and B, with actuarially equivalent cost sharing, are in the basic benefit bid paid by the capitation rate. Section 1834(m) of the Act and § 410.78 generally limit payment for Medicare telehealth services by authorizing payment only for specified services provided using an interactive audio and video telecommunications system that permits real-time communication between a Medicare beneficiary and either a physician or specified other type of practitioner, and by specifying where the beneficiary may receive telehealth services (eligible originating sites). Eligible originating sites are limited as to the type of geographic location (generally rural) and the type of care setting. The statute grants the Secretary the authority to add to the list of Medicare telehealth services based on an established annual process but does not allow for exceptions to the restrictions on types of practitioners that can furnish those services or on the eligible originating sites. Because sections 1852(a), 1853, and 1854 of the Act limit the basic benefits covered by the government's capitation payment to only Parts A and B services covered under original Medicare with actuarially equivalent cost sharing, telehealth benefits offered by MA plans in addition to those covered by original Medicare are currently offered as MA supplemental benefits and funded through the use of rebate dollars or supplemental premiums paid by enrollees.

On February 9, 2018, President Trump signed the Bipartisan Budget Act of 2018 (Pub. L. 115–123) into law. Section 50323 of the Bipartisan Budget Act of 2018 created a new section 1852(m) of the Act, which allows MA plans the ability to provide ''additional telehealth benefits'' (hereinafter referred to as ''MA additional telehealth benefits'') to enrollees starting in plan year 2020 and treat them as basic benefits (also known as ''original Medicare benefits'' or ''benefits under the original Medicare fee-for-service program option''). The statute limits these authorized MA additional telehealth benefits to services for which benefits are available under Medicare Part B but that are not payable under section 1834(m) of the Act and have been identified for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (hereinafter referred to as ''electronic exchange''). While MA plans have always been able to offer more telehealth services than are currently payable under original Medicare through MA supplemental benefits, this change in how such MA additional telehealth benefits are financed (that is, accounted for in the capitated payment) makes it more likely that MA plans would offer them and that more enrollees would use the benefit.

We are adding a new regulation at § 422.135 to implement the new section 1852(m) of the Act and amending existing regulations at §§ 422.100, 422.252, 422.254, and 422.264. Specifically, we are codifying a new regulation at § 422.135 to allow MA plans to offer MA additional telehealth benefits, to establish definitions applicable to this new classification of benefits, and to enact requirements and limitations on them. Further, we are amending § 422.100(a) and (c)(1) to include MA additional telehealth benefits in the definition of basic benefits and adding a cross-reference to new § 422.135 to reflect how these benefits may be provided as part of basic benefits. Finally, we are amending the bidding regulations at §§ 422.252, 422.254, and 422.264 to account for MA additional telehealth benefits in the basic benefit bid.

We proposed that, beginning in contract year 2020, MA plans will be permitted to offer—as part of the basic benefit package—MA additional telehealth benefits beyond what is currently allowable under Medicare telehealth services. Pursuant to section 1852 of the Act and the regulation at § 422.100(a), MA plans are able to offer Medicare telehealth services including those described in existing authority at section 1834(m) of the Act and §§ 410.78 and 414.65 of the regulations. We proposed that in addition to Medicare telehealth services, MA plans will be able (but not required) to offer MA additional telehealth benefits described in this final rule and at section 1852(m) of the Act. In addition, we proposed to continue authority for MA plans to offer MA supplemental benefits (that is, benefits not covered by original Medicare) via remote access technologies and telemonitoring (as

[1] Mehrotra, A., Jena, A., Busch, A., Souza, J., Uscher-Pines, L., Landon, B. (2016). ''Utilization of Telemedicine Among Rural Medicare Beneficiaries.'' *JAMA,* 315(18): 2015–2016.

[2] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html*

[3] Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy,* March 2018.

currently named in the plan benefit package (PBP) software; hereinafter referred to as ''MA supplemental telehealth benefits'') for those services that do not meet the requirements for coverage under original Medicare (for example, for Medicare telehealth services under section 1834(m)) or the requirements for MA additional telehealth benefits, such as the requirement of being covered by Part B when provided in-person. For instance, an MA plan may offer, as an MA supplemental telehealth benefit, a videoconference dental visit to assess dental needs because services primarily provided for the care, treatment, removal, or replacement of teeth or structures directly supporting teeth are not currently covered Part B benefits and thus would not be allowable as MA additional telehealth benefits.

We proposed to establish regulatory requirements that will allow MA plans to cover Part B benefits furnished through electronic exchange but not payable under section 1834(m) of the Act as MA additional telehealth benefits—and as part of the basic benefits defined in § 422.101 instead of separate MA supplemental benefits. We believe MA additional telehealth benefits will increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access benefits.

Section 1852(m)(2)(A)(i) of the Act, as added by the Bipartisan Budget Act of 2018, defines ''additional telehealth benefits'' as services—(1) for which benefits are available under Part B, including services for which payment is not made under section 1834(m) of the Act due to the conditions for payment under such section; and (2) that are identified for the applicable year as clinically appropriate to furnish using electronic information and telecommunications technology (which we refer to as ''through electronic exchange'') when a physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not at the same location as the plan enrollee. In addition, section 1852(m)(2)(A)(ii) of the Act excludes from ''additional telehealth benefits'' capital and infrastructure costs and investments relating to such benefits. This statutory definition of ''additional telehealth benefits'' guided our proposal.

We proposed a new regulation at § 422.135 to authorize and govern the provision of MA additional telehealth benefits by MA plans, consistent with our interpretation of the new statutory provision. First, we proposed definitions for the terms ''additional telehealth benefits'' and ''electronic exchange'' in § 422.135(a). We proposed to define ''additional telehealth benefits'' as services that meet the following: (1) Are furnished by an MA plan for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and (2) have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange. For purposes of this specific regulation and addressing the requirements and limitations on MA additional telehealth benefits, we proposed to define ''electronic exchange'' as ''electronic information and telecommunications technology'' as this is a concise term for the statutory description of the means used to provide the MA additional telehealth benefits. We did not propose specific regulation text that defines or provides examples of electronic information and telecommunications technology because the technology needed and used to provide MA additional telehealth benefits would vary based on the service being offered. Examples of electronic information and telecommunications technology (or ''electronic exchange'') may include, but are not limited to, the following: Secure messaging, store and forward technologies, telephone, videoconferencing, other internet-enabled technologies, and other evolving technologies as appropriate for non-face-to-face communication. We believe this broad and encompassing approach will allow for technological advances that may develop in the future and avoid tying the authority in the regulation to specific information formats or technologies that permit non-face-to-face interactions for furnishing clinically appropriate services.

We did not propose specific regulation text defining ''clinically appropriate;'' rather, we proposed to implement the statutory requirement for MA additional telehealth benefits to be provided only when ''clinically appropriate'' to align with our existing regulations for contract provisions at § 422.504(a)(3)(iii), which requires each MA organization to agree to provide all benefits covered by Medicare ''in a manner consistent with professionally recognized standards of health care.'' We proposed to apply the same principle to MA additional telehealth benefits, as MA additional telehealth benefits must be treated as if they were benefits under original Medicare per section 1852(m)(5) of the Act.

The statute limits MA additional telehealth benefits to those services that are identified for the applicable year as clinically appropriate to furnish through electronic exchange. The statute does not specify who or what entity identifies the services for the year. Therefore, we proposed to interpret this provision broadly by not specifying the Part B services that an MA plan may offer as MA additional telehealth benefits for the applicable year, but instead allowing MA plans to independently determine each year which services are clinically appropriate to furnish in this manner. Thus, our definition of MA additional telehealth benefits at § 422.135(a) provides that it is the MA plan (not CMS) that identifies the appropriate services for the applicable year. We believe that MA plans are in the best position to identify each year whether MA additional telehealth benefits are clinically appropriate to furnish through electronic exchange. MA plans have a vested interest in and responsibility for staying abreast of the current professionally recognized standards of health care, as these standards are continuously developing with new advancements in modern medicine. As professionally recognized standards of health care change over time and differ from practice area to practice area, our approach is flexible enough to take those changes and differences into account.

Furthermore, § 422.111(b)(2) requires the MA plan to annually disclose the benefits offered under a plan, including applicable conditions and limitations, premiums and cost sharing (such as copayments, deductibles, and coinsurance) and any other conditions associated with receipt or use of benefits. MA plans satisfy this requirement through the Evidence of Coverage, or EOC, document provided to all enrollees. This disclosure requirement would have to include applicable MA additional telehealth benefit limitations. That is, any MA plan offering MA additional telehealth benefits must identify the services that can be covered as MA additional telehealth benefits when provided through electronic exchange. We believe that it is through this mechanism (the EOC) that the MA plan would identify each year which services are clinically appropriate to furnish through electronic exchange as MA additional telehealth benefits.

We solicited comment on this proposed implementation of the statute and our reasoning. We noted in the proposed rule how we had considered whether CMS should use the list of Medicare telehealth services payable by original Medicare under section 1834(m) of the Act as the list of services that are clinically appropriate to be

provided through electronic exchange for MA additional telehealth benefits. In that circumstance, services on the list could be considered as clinically appropriate to be provided through electronic exchange for MA additional telehealth benefits without application of the location limitations of section 1834(m) of the Act. However, we do not believe that is the best means to take full advantage of the flexibility that Congress has authorized for the MA program. The list of Medicare telehealth services for which payment can be made under section 1834(m) of the Act under the original Medicare program includes services specifically identified by section 1834(m) of the Act as well as other services added to the Medicare telehealth list using criteria and an annual process established by CMS. We stated in the proposed rule that we believe these limitations and criteria should not apply to MA additional telehealth benefits under new section 1852(m) of the Act for MA plans.

The statute requires the Secretary to solicit comment on what types of items and services should be considered to be MA additional telehealth benefits. Therefore, we also solicited comments on whether we should place any limitations on what types of Part B items and services (for example, primary care visits, routine and/or specialty consultations, dermatological examinations, behavior health counseling, etc.) can be MA additional telehealth benefits provided under this authority.

An enrollee has the right to request MA additional telehealth benefits through the organization determination process. If an enrollee is dissatisfied with the organization determination, then the enrollee has the right to appeal the decision. We believe these rights help ensure access to medically necessary services, including MA additional telehealth benefits offered by an MA plan as described in this rule. In addition, CMS audits plan performance with respect to timeliness and clinical appropriateness of organization determinations and appeals.

While the MA plan would make the ''clinically appropriate'' decision in terms of coverage of an MA additional telehealth benefit, we note that each healthcare provider must also provide services that are clinically appropriate. We acknowledge that not all Part B items and services would be suitable for MA additional telehealth benefits because a provider must be physically present in order to properly deliver care in some cases (for example, hands-on examination, administering certain medications). As stated earlier, we proposed that MA plans would independently determine each year which services are clinically appropriate to furnish in this manner. Behavioral health, in particular, is a prime example of a service that could be provided remotely through MA plans' offering of MA additional telehealth benefits under this rule. The President's Commission on Combating Drug Addiction and the Opioid Crisis recommends telehealth as useful in the effort to combat the opioid crisis when clinically appropriate, especially in geographically isolated regions and underserved areas where people with opioid use disorders and other substance use disorders may benefit from remote access to needed treatment.[4]

We proposed in paragraph (b) the general rule to govern how an MA plan may offer MA additional telehealth benefits. Specifically, we proposed that if an MA plan chooses to furnish MA additional telehealth benefits, the MA plan may treat these benefits as basic benefits covered under the original Medicare fee-for-service program as long as the requirements of proposed § 422.135 are met. We also proposed in § 422.135(b) that if the MA plan fails to comply with the requirements of § 422.135, then the MA plan may not treat the benefits provided through electronic exchange as MA additional telehealth benefits, but may treat them as MA supplemental telehealth benefits, subject to CMS approval of the MA supplemental telehealth benefits. For example, a non-Medicare covered service provided through electronic exchange cannot be offered as an MA additional telehealth benefit because it does not comply with § 422.135, which is limited to furnishing through electronic exchange otherwise covered Part B covered services, but it may be offered it as an MA supplemental telehealth benefit.

Section 1852(m)(4) of the Act mandates that enrollee choice is a priority. If an MA plan covers a Part B service as an MA additional telehealth benefit, then the MA plan must also provide access to such service through an in-person visit and not only through electronic exchange. We proposed to codify this statutory mandate preserving enrollee choice in regulation text at § 422.135(c)(1), which requires that the enrollee must have the option to receive a service that the MA plan covers as an MA additional telehealth benefit either through an in-person visit or through electronic exchange. Section 1852(m)(5) of the Act mandates that MA additional telehealth benefits shall be treated as if they were benefits under the original Medicare fee-for-service program option. In proposed regulation text at § 422.135(f), we proposed to allow MA plans to maintain different cost sharing for the specified Part B service(s) furnished through an in-person visit and the specified Part B service(s) furnished through electronic exchange.

We proposed § 422.135(c)(2) to require MA plans to use their EOC (at a minimum) to advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange. We proposed, at § 422.135(c)(3), that MA plans would have to use their provider directory to identify any providers offering services for MA additional telehealth benefits and in-person visits or offering services exclusively for MA additional telehealth benefits. We stated in the proposed rule that these notifications in the EOC and the provider directory are important to ensure choice, transparency, and clarity for enrollees who might be interested in taking advantage of MA additional telehealth benefits. We requested comments on what impact, if any, MA additional telehealth benefits should have on MA network adequacy policies. Specifically, we were looking for the degree to which MA additional telehealth benefit providers should be considered in the assessment of network adequacy (including for certain provider types and/or services in areas with access concerns) and any potential impact on rural MA plans, providers, and/or enrollees.

Section 1852(m)(3) of the Act requires the Secretary to specify limitations or additional requirements for the provision or furnishing of MA additional telehealth benefits, including requirements with respect to physician or practitioner qualifications, factors necessary for the coordination of MA additional telehealth benefits with other items and services (including those furnished in-person), and other areas identified by the Secretary. We recognize the potential for MA additional telehealth benefits to support coordinated health care and increase access to care in both rural and urban areas. We stated in the proposed rule how we expect MA plans would use these types of benefits to support an effective, ongoing doctor-patient relationship and the efficient delivery of needed care.

We proposed in regulation text at § 422.135(c)(4) to require an MA plan

[4] Retrieved at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Meeting%20Draft%20of%20Final%20Report%20-%20November%201%2C%202017.pdf.*

offering MA additional telehealth benefits to comply with the provider selection and credentialing requirements provided in § 422.204. An MA plan must have written policies and procedures for the selection and evaluation of providers and must follow a documented process with respect to providers and suppliers, as described in § 422.204. Further, we proposed that the MA plan, when providing MA additional telehealth benefits, must ensure through its contract with the provider that the provider meet and comply with applicable state licensing requirements and other applicable laws for the state in which the enrollee is located and receiving the service. We recognize, however, that it is possible for a state to have specific provisions regarding the practice of medicine using electronic exchange; our proposal reflected our intent to ensure that MA network providers comply with these laws and that MA plans ensure compliance with such laws and only cover MA additional telehealth benefits provided in compliance with such laws. We solicited comment on whether to impose additional requirements for qualifications of providers of MA additional telehealth benefits, and if so, what those requirements should be.

In order to monitor the impact of the MA additional telehealth benefits on MA plans, providers, enrollees, and the MA program as a whole, we also proposed to require MA plans to make information about coverage of MA additional telehealth benefits available to CMS upon request, per proposed § 422.135(c)(5). We proposed that this information may include, but is not limited to, statistics on use or cost of MA additional telehealth benefits, manner(s) or method(s) of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the requirements in § 422.135. We explained in our proposed rule that the purpose of requiring MA plans to make such information available to CMS upon request would be to determine whether CMS should make improvements to the regulation and/or guidance regarding MA additional telehealth benefits.

In § 422.135(d), we proposed to require that MA plans furnishing MA additional telehealth benefits may only do so using contracted (that is, network) providers. We believe limiting service delivery of MA additional telehealth benefits to contracted providers offers MA enrollees access to these covered services in a manner more consistent with the statute because plans would have more control over how and when such services are furnished. The regulation at § 422.204 requires MA plans to have written policies and procedures for the selection and evaluation of providers and that such policies conform with MA specific credentialing requirements outlined in § 422.204. We explained in the proposed rule that these policies would also be a means to ensure additional oversight of providers' performance, thereby increasing plans' ability to provide covered services such as MA additional telehealth benefits. We also proposed to specify that if an MA plan covers benefits furnished by a non-contracted provider through electronic exchange, then those benefits may only be covered as MA supplemental telehealth benefits. These benefits are not MA additional telehealth or basic benefits if furnished by a non-contracted provider through electronic exchange. We requested comment on whether the contracted providers' restriction should be placed on all MA plan types or limited only to certain plan types, such as local/regional preferred provider organization (PPO) plans, medical savings account (MSA) plans, and/or private fee-for-service (PFFS) plans. Currently, pursuant to § 422.4(a)(1)(v), PPO plans must provide reimbursement for all plan-covered medically necessary services received from non-contracted providers without prior authorization requirements. We explained in the proposed rule our view that without an opportunity to review the qualifications of the non-contracted provider and to impose limits on how only clinically appropriate services are provided as MA additional telehealth benefits, PPO plans would not be able to meet the proposed requirements. Therefore, we solicited comment on whether to require just PPOs (or MSA plans, PFFS plans, etc.), instead of all MA plan types, to use only contracted providers for MA additional telehealth benefits.

Per section 1852(m)(2)(A)(ii) of the Act, the term ''additional telehealth benefits'' does not include capital and infrastructure costs and investments relating to such benefits. We proposed to codify this requirement in § 422.254(b)(3)(i) as a restriction on how MA plans include MA additional telehealth benefits in their bid submission. We stated that we believe that the statutory limit is tied only to the cost to the government, which is tied to how MA additional telehealth benefits may be included in the bid as basic benefits. Therefore, our proposal was to eliminate from the basic benefit bid those capital and infrastructure costs and investments that are required or used to enable the provision of MA additional telehealth benefits. We did not propose specific definitions of capital and infrastructure costs or investments related to such benefits because the costs and investments needed and used to provide MA additional telehealth benefits would vary based on the individual MA plan's approach to furnishing the benefits. In the proposed rule, we provided some examples of capital and infrastructure costs, including, but not limited to, high-speed internet installation and service, communication platforms and software, and video conferencing equipment. We also solicited comment on what other types of capital and infrastructure costs and investments should be excluded from the bid and how CMS should operationalize this statutory requirement in the annual bid process. We proposed to provide a more detailed list of examples in this final rule, based on feedback received from stakeholders.

We explained in the proposed rule that our proposal at § 422.254(b)(3)(i) meant that MA plans must exclude any capital and infrastructure costs and investments specifically relating to MA additional telehealth benefits from their bid submission for MA additional telehealth services offered directly by the plan sponsor and by a third party provider. Accordingly, we explained our proposal meant that the projected expenditures in the MA bid for services provided via MA additional telehealth benefits must not include the corresponding capital and infrastructure costs and that any items provided to the enrollee in the administration of MA additional telehealth benefits must be directly related to the care and treatment of the enrollee for the Part B benefit. In the proposed rule, we provided an example of this provision, noting that MA plans would not be able to provide enrollees with internet service or permanently install telecommunication systems in an enrollee's home as part of administration of MA additional telehealth benefits.

In addition to our proposal at § 422.135, we also proposed to amend paragraphs (a) and (c)(1) of § 422.100 to explicitly address how MA additional telehealth benefits may be offered by an MA plan. Section 1852(a)(1)(A) of the Act requires that each MA plan shall provide enrollees benefits under the original Medicare fee-for-service program option. As amended by the Bipartisan Budget Act of 2018, section 1852(a)(1)(B) of the Act defines ''benefits under the original Medicare fee-for-service program option'' to mean—subject to subsection (m) (regarding provision of MA additional

telehealth benefits)—those items and services (other than hospice care or coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B to individuals entitled to benefits under Part A and enrolled under Part B. Since this definition is subject to the statutory provision for MA additional telehealth benefits, this means that all of the same coverage and access requirements that apply with respect to basic benefits also apply to any MA additional telehealth benefits an MA plan may choose to offer. Therefore, we proposed to amend § 422.100(c)(1) to include MA additional telehealth benefits in the definition of basic benefits and to cross-reference § 422.135, which provides the rules governing MA additional telehealth benefits. We proposed to further clarify the regulation text in § 422.100(c)(1) to track the statutory language described earlier more closely in addressing both kidney acquisition and hospice in the definition of basic benefits. Finally, we proposed to make corresponding technical revisions to § 422.100(a) to reference the new paragraph (c)(1) for basic benefits (clarifying that MA additional telehealth benefits are voluntary benefits for MA plans to offer but are not required) and paragraph (c)(2) for MA supplemental benefits (instead of § 422.102 because MA supplemental benefits are listed as a benefit type in (c)(2)). We also proposed a small technical correction in the last sentence of § 422.100(a) to replace the reference to § 422.100(g) with ''this section'' because there are a number of provisions in § 422.100—not just paragraph (g)—that are applicable to the benefits CMS reviews.

Additionally, we proposed amendments to the bidding regulations at §§ 422.252, 422.254, and 422.264 to account for MA additional telehealth benefits and to correct the inconsistent phrasing of references to basic benefits (for example, these regulations variously use the terms ''original Medicare benefits,'' ''benefits under the original Medicare program,'' ''benefits under the original Medicare FFS program option,'' etc.). In order to make the MA additional telehealth benefits part of the basic benefit bid and included in the ''monthly aggregate bid amount'' as part of the original Medicare benefits that are the scope of the basic benefit bid, we proposed to update these various phrases to consistently use the phrase ''basic benefits as defined in § 422.100(c)(1).'' We also proposed a few minor technical corrections to the bidding regulations. Finally, we proposed a paragraph (e) in new § 422.135 to state that an MA plan that fully complies with § 422.135 may include MA additional telehealth benefits in its bid for basic benefits in accordance with § 422.254. This provision means that inclusion in the bid is subject to the bidding regulations we proposed to amend.

In offering MA additional telehealth benefits, MA plans must comply with existing MA rules, including, but not limited to: Access to services at § 422.112; recordkeeping requirements at § 422.118 (for example, confidentiality, accuracy, timeliness); standards for communications and marketing at § 422.2268 (for example, inducement prohibition); and non-discrimination at §§ 422.100(f)(2) and 422.110(a). Further, in addition to §§ 422.112, 422.118, 422.2268, 422.100(f)(2), and 422.110(a), MA plans must also ensure compliance with other federal non-discrimination laws, such as Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and section 1557 of the Affordable Care Act. We did not propose specific reference to these existing requirements in new § 422.135 because we do not believe that to be necessary. Compliance with these existing laws is already required; we merely note, as an aid to MA plans, how provision of MA additional telehealth benefits must be consistent with these regulations. We solicited comment on this policy choice, specifically whether there were other existing regulations that CMS should revise to address their application in the context of MA additional telehealth benefits.

Finally, section 1852(m)(2)(B) of the Act instructed the Secretary to solicit comments on the implementation of these MA additional telehealth benefits by November 30, 2018; in addition to the proposed regulations to implement section 1852(m) of the Act, we used the proposed rule and the associated comment period to satisfy this statutory requirement. We thank commenters for their input to help inform CMS's next steps related to implementing the MA additional telehealth benefits. We received the following comments on this proposal, and our response follows:

Comment: Many commenters suggested that CMS's approach to MA additional telehealth benefits align with CMS's existing approaches to what is currently available via telehealth under original Medicare. These commenters referenced the ''Medicare telehealth services'' definition in section 1834(m) of the Act, payment for remote patient monitoring (RPM) services outside of section 1834(m) of the Act, as well as the new communication technology-based services not subject to section 1834(m) restrictions, described in the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019 (83 FR 59452, Nov. 23, 2018; hereinafter referred to as the Calendar Year 2019 Physician Fee Schedule final rule). Commenters also requested that CMS clarify the distinction between MA additional telehealth benefits and the various services in original Medicare that use communications technology (including Medicare telehealth services under section 1834(m) of the Act). Specifically, some commenters recommended that CMS state in the final rule that MA additional telehealth benefits are subject to the technological specifications for Medicare telehealth services furnished under section 1834(m) of the Act, that is, two-way audio and visual real-time and interactive services. Further, commenters requested that CMS explicitly state that under current original Medicare rules, MA plans may already include other clinically appropriate virtual services that are not subject to the location limitations of section 1834(m) of the Act—such as RPM technology—as part of basic benefits because such services are payable under Part B for original Medicare.

Response: We understand commenters' concerns that differences between telehealth services under original Medicare and MA additional telehealth benefits be clearly distinguished and explained. We appreciate the input offered by commenters and provide a thorough and clear discussion here.

First, we must emphasize that the term ''additional telehealth benefits'' is a term of art with a specific meaning in the MA program; it is defined in section 1852(m)(A) of the Act and in the regulation we finalize here at § 422.135(a). We are finalizing the regulatory definition with changes from the proposed rule to delete ''are furnished by an MA plan'' and to include the statutory provisions that MA additional telehealth benefits are services for which benefits are available under Part B and are provided when specific healthcare providers and enrollees are in different locations. As finalized, the definition reads that additional telehealth benefits means services:

(1) For which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and

(2) That have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not in the same location as the enrollee. We are focused here on the first part of this definition.

Second, determining whether a service may be offered by an MA plan as part of basic benefits requires addressing two questions: (1) Is the service covered and payable under Part A or Part B?; and (2) if not, is the reason it is not payable under Part B solely because of the limits in section 1834(m) of the Act? If the answer to the first question is yes, then the service is already a benefit under the original Medicare fee-for-service program option and, unless it is hospice care or coverage for organ acquisitions for kidney transplants, must be provided under current law at section 1852(a) of the Act and the MA regulations in 42 CFR part 422. If the answer to the second question is yes, then provision of the service through electronic exchange may be covered as an MA basic benefit under section 1852(m) of the Act, as added by the Bipartisan Budget Act of 2018, and the regulations (at §§ 422.100, 422.135, 422.252, 422.254, and 422.264) we are finalizing in this rule. We note that these regulations include other conditions that must also be satisfied in order for the service to be MA additional telehealth benefits that may be included as basic benefits, but our focus for this specific discussion is on the relationship to Part B coverage. We turn now to Part B coverage of telehealth services.

Under original Medicare, Part B provides for coverage and payment of services (and items, which are not relevant for purposes of this discussion), including services furnished in an in-person encounter between a physician or other practitioner, services furnished as Medicare telehealth services as specified under section 1834(m) of the Act, and certain other services that can be furnished in full without the patient being present. ''Medicare telehealth services,'' as defined in section 1834(m) of the Act and the implementing regulations at §§ 410.78 and 414.65 include professional consultations, office visits, office psychiatry services, and other similar services that must ordinarily be furnished in-person but instead may be furnished using interactive, real-time telecommunication technology subject to the restrictions on Medicare telehealth services specified under section 1834(m) of the Act. Also under section 1834 of the Act, synchronous ''store and forward'' telehealth services may be furnished as part of federal telemedicine demonstration projects in Alaska and Hawaii. Medicare telehealth services under section 1834(m) of the Act are limited in that they must only be furnished by physicians and other specified types of practitioners, and can be furnished and paid only when the beneficiary is located at an eligible originating site.

As we explained in the Calendar Year 2019 Physician Fee Schedule final rule, we have generally regarded the Medicare telehealth services for which payment can be made under section 1834(m) of the Act as being limited to services that must ordinarily be furnished in-person during an encounter between a clinician and the patient, but are instead furnished using telecommunication technology as a substitute for that in-person encounter (83 FR 59482–59483). There are other services under original Medicare that use telecommunication technology, but are not considered Medicare telehealth services as defined under section 1834(m) of the Act, for example, RPM and remote interpretation of diagnostic tests, chronic care management services, transitional care management services (other than the included evaluation and management service), and behavioral health integration services.

Additionally, as established in the Calendar Year 2019 Physician Fee Schedule final rule, effective January 1, 2019, original Medicare now makes separate payment for new ''communication technology-based services.'' These services are not subject to the limitations of section 1834(m) of the Act because they are not a substitute for an in-person, face-to-face encounter between a clinician and a patient. As such, these services are inherently non-face-to-face, are paid under the Physician Fee Schedule like other physicians' services, and are not subject to the restrictions on Medicare telehealth services specified under section 1834(m) of the Act. The communication technology-based services include brief communication technology-based service (virtual check-in), remote evaluation of pre-recorded patient information, and interprofessional internet consultation. These three services and their corresponding Healthcare Common Procedure Coding System (HCPCS) codes are described in detail in the Calendar Year 2019 Physician Fee Schedule final rule at 83 FR 59482 through 59491. That rule also finalized separate payment under the Physician Fee Schedule for chronic care remote physiologic monitoring services.

In the Calendar Year 2019 Physician Fee Schedule final rule, CMS also implemented sections 50302 and 50325 of the Bipartisan Budget Act of 2018 to remove certain section 1834(m) limitations on geography and originating site (patient setting) for certain services. Specifically, the policies under section 50302 of the Bipartisan Budget Act of 2018 added renal dialysis facilities and the homes of beneficiaries as allowable originating sites and removed the geographic restrictions for hospital-based or critical access hospital-based renal dialysis centers, renal dialysis facilities, and beneficiary homes, for purposes of monthly ESRD-related clinical assessments for patients receiving home dialysis. The policies under section 50325 of the Bipartisan Budget Act of 2018 added mobile stroke units as allowable originating sites and removed the originating site type and geographic restrictions, for acute stroke-related telehealth services. Both are effective January 1, 2019.

Additionally, CMS revised the Medicare telehealth regulations to reflect the amendments made to section 1834(m) of the Act by section 2001(a) of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271) to remove the originating site geographic requirements for all originating sites described in section 1834(m)(4)(C)(ii) of the Act, except for renal dialysis facilities that are only permissible originating sites for purposes of monthly ESRD-related clinical assessments for patients receiving home dialysis, and to add the home of an individual as a permissible originating site, with respect to telehealth services furnished for purposes of the treatment of an individual with a substance use disorder diagnosis or co-occurring mental health disorder, effective July 1, 2019 (83 FR 59494 through 59496).

All of the telehealth services and other non-face-to-face services furnished via communication technology described earlier are covered and paid under original Medicare. Therefore, MA plans must cover these services because they are required basic benefits. Any services falling outside the scope of these services that an MA plan wishes to offer may potentially be covered as MA additional telehealth benefits, effective January 1, 2020, assuming they meet the requirements under section 1852(m) of the Act. In other words, MA additional telehealth benefits can

include an even broader range of telehealth services for enrollees in an MA plan offering MA additional telehealth benefits, beyond original Medicare benefits. An examination conducted using videoconferencing and/or other telecommunications systems to relay information (such as images and vital signs) may be covered as a primary care visit when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) and enrollee are in different locations that do not meet the requirements under section 1834(m) of the Act. As a practical matter, we do not expect MA plans to find implementation and compliance difficult because, if a service provided by the physician or practitioner is a Part B covered service for which payment could be made, but for the limitations in section 1834(m) of the Act, it may be an MA additional telehealth benefit if the MA plan complies with § 422.135 as finalized. If a service or item provided by a physician or practitioner is covered under Part B by the original Medicare program and payment is not prohibited based on the limitations in section 1834(m) of the Act, then the service or item is a basic benefit without consideration of whether § 422.135 could apply. Finally, if a service is not covered under Part B, even if the limitations in section 1834(m) of the Act are taken into account, then the service may only be covered by an MA plan as an MA supplemental telehealth benefit, and not offered as an MA additional telehealth benefit. In addition, we clarify in this final rule that if a service is covered under Part B and provided through electronic exchange but otherwise does not comply with § 422.135 (for example, if it is provided by an out-of-network healthcare provider), then the service may be covered only as an MA supplemental telehealth benefit per § 422.135(b). For example, a nursing hotline staffed by nurses, that are not practitioners specified in section 1842(b)(18)(C)[5] of the Act, that provides assistance in identifying when to seek additional medical help would not be covered under Part B even if the assistance were provided in person. We discuss these issues in more detail in our responses to comments below.

We thank commenters for their feedback on how to reconcile the telehealth differences between MA and original Medicare, and we hope our response provides adequate clarification and removes any misinterpretation. Please note, CMS intends to release more detailed sub-regulatory guidance relating to telehealth for both the original Medicare and MA programs.

Comment: Several commenters supported CMS's explicit recognition that MA plans may continue to offer other telehealth services through MA supplemental telehealth benefits. A commenter questioned whether non-contracted providers will be allowed to provide MA additional telehealth benefits as supplemental benefits.

Response: We thank commenters for their support for continuing to allow MA plans to offer MA supplemental telehealth benefits for those services that do not meet the requirements for coverage under original Medicare or as MA additional telehealth benefits. We are finalizing our proposal, at § 422.135(d), to require that MA additional telehealth benefits only be furnished using contracted providers. As discussed in the preamble of the proposed rule, an MA plan may still cover out-of-network services that would be considered MA additional telehealth benefits (and thus offered as MA basic benefits) when provided by a contracted provider, but these out-of-network services may only be covered as MA supplemental telehealth benefits because the MA plan has not complied with § 422.135(d). These services are not MA additional telehealth benefits if furnished by a non-contracted provider through electronic exchange.

Comment: Many commenters supported CMS's proposed definition for the term ''electronic exchange'' in proposed regulation text at § 422.135(a). The commenters stated that CMS's broad definition, which defines electronic exchange as ''electronic information and telecommunications technology,'' is reasonable as it allows MA plans to use evolving technology to provide MA additional telehealth benefits. Further, some commenters strongly urged CMS to rescind the electronic exchange examples listed in the proposed rule preamble, but finalize as proposed the definition of ''electronic exchange'' in the regulation text at § 422.135(a). Commenters stated CMS could not provide a list of electronic exchange examples that adequately takes in to account future technological innovation. Commenters also explained that a limited list of electronic exchange examples would cause confusion in the marketplace because plans and providers would be uncertain about permissible forms of electronic exchange technology.

Response: We appreciate all of the comments received on the proposed definition for the term ''electronic exchange.'' Our definition is based on how section 1852(m)(2) of the Act uses the phrase ''electronic information and telecommunications technology'' to describe how the services are provided when the physician or practitioner and the patient are not in the same location. In § 422.135(a) as finalized, we define ''electronic exchange'' as ''electronic information and telecommunications technology.'' We agree that this definition of ''electronic exchange'' allows MA plans the use of various forms of technology to provide MA additional telehealth benefits to enrollees. Our purpose in defining ''electronic exchange'' in this manner is to allow modernization in the MA program and the provision of evidence-based, effective health care. As noted in the proposed rule, we did not propose specific regulation text that defines or provides examples of electronic information and telecommunications technology. We stated that we believe this broad and encompassing approach will allow for technological advances that may develop in the future.

While our list of electronic exchange examples in the proposed rule preamble was not intended to be a comprehensive list for purposes of the final rule, we acknowledge that the list of electronic exchange examples does not take into account future technological innovation, and we seek to allow plans the flexibility to develop forms of electronic exchange without unnecessary burden. We are finalizing as proposed the definition of ''electronic exchange'' in the regulation text at § 422.135(a). We believe this more general approach allows for MA plan flexibility and innovation, does not inadvertently restrict MA plans to certain forms of electronic exchange, and avoids the possibility of overlap with original Medicare telehealth coverage. We explicitly clarify here that future technology that is within the scope of the phrase ''electronic information and telecommunications technology'' as used in the statute may be used for purposes of providing MA additional telehealth benefits.

Comment: Many commenters supported CMS's decision not to propose specific regulation text that defines or provides examples of electronic information and telecommunications technology because

[5] Such practitioners include: (i) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5)) of the Act; (ii) A certified registered nurse anesthetist (as defined in section 1861(bb)(2)); (iii) A certified nurse-midwife (as defined in section 1861(gg)(2)); (iv) A clinical social worker (as defined in section 1861(hh)(1)); (v) A clinical psychologist (as defined by the Secretary for purposes of section 1861(ii)) and (vi) A registered dietitian or nutrition professional.

the technology needed and used to provide MA additional telehealth benefits will vary based on the service being offered. A commenter suggested there be a governing body to review and certify the telehealth technology used and to ensure proper telehealth provider training.

Response: We agree with commenters' position that specific regulation text that defines or provides examples of electronic information and telecommunications technology should not be included in the final rule. We do not include this specific regulation text in the final rule because technology will vary based on user and over time. As discussed earlier, we believe this broad and encompassing approach will allow for technological advances that may develop in the future and avoid tying the authority in the new regulation to specific information formats or technologies.

We appreciate the commenter's suggestion that there be a governing body to review and certify the telehealth technology used and to ensure proper telehealth provider training. We are not requiring a governing body to conduct oversight of telehealth technology and providers at this time, but we will use authority codified in this final rule at § 422.135(c)(4) to review information about coverage of MA additional telehealth benefits, which may include, but is not limited to, statistics on use or cost, manner(s) or method of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the requirements of this final rule.

Comment: Many commenters supported CMS allowing MA plans to independently determine each year which services are clinically appropriate to furnish through electronic exchange as MA additional telehealth benefits. These commenters stated that MA plans should have authority to make these determinations because plans and healthcare providers work directly with enrollees and are more aware of evolving methods of delivering care. A few commenters recommended that CMS authorize healthcare providers, rather than or in addition to MA plans, to make the annual determination of which services are clinically appropriate to furnish through MA additional telehealth benefits.

Response: We are finalizing our proposal that MA plans have the discretion to determine which Part B services are clinically appropriate to provide through electronic exchange and to make that determination for each applicable plan year. Such services, when the other requirements in § 422.135 are met, would be permissible MA additional telehealth benefits. As professionally recognized standards of health care change over time, we believe MA plans have an interest in working with providers to develop and use the methods of modern medicine necessary to provide MA additional telehealth benefits to enrollees who choose to have their health benefits delivered in this manner. MA plans are required, per § 422.202(b), to consult with their contracted network providers regarding the MA plan's medical policy; this would include any applicable MA additional telehealth benefits policy, and we believe that is sufficient for establishing the required involvement of healthcare providers. We encourage MA plans to involve their contracted providers when making determinations about which services are clinically appropriate to furnish through MA additional telehealth benefits beyond the consultation required under that regulation, but we are not adopting such a requirement in this final rule.

Furthermore, we note that in accordance with § 422.112(b)(3), all MA coordinated care plans are required to coordinate MA benefits with community and social services generally available in the plan service area. Therefore, we expect MA coordinated care plans offering MA additional telehealth benefits to coordinate care for enrollees receiving the specified Part B service(s) through electronic exchange in the same manner as for enrollees receiving the service in-person.

Comment: Many commenters opposed CMS placing limitations on the types of Part B items and services that can be MA additional telehealth benefits. Specifically, commenters urged CMS to use only the MA plan annual determination and medical review to define the types of items and services to be included as MA additional telehealth benefits. They explained that any definition of items or services will lock CMS into an approach supported by today's evidence, which will hinder CMS's ability to update its policies for future evidence-based innovation.

Response: We agree with the commenters that adopting a specific list of services that could be MA additional telehealth benefits when provided through electronic exchange creates a risk of not being sufficiently flexible in the future. We proposed and are finalizing regulation text that allows MA plans flexibility to determine which services are clinically appropriate to furnish through MA additional telehealth benefits on an annual basis consistent with the limits in the statute and § 422.135.

Comment: Some commenters supported CMS's proposal to allow MA plans offering MA additional telehealth benefits to maintain different cost sharing for in-person visits and visits through electronic exchange, while several commenters opposed differential cost sharing. Commenters expressed concerns that low-income enrollees living in rural, underserved areas without internet access may be disadvantaged because they would have to choose the in-person option, which may have higher cost sharing as compared to the alternative visit through electronic exchange. A few commenters, including the Medicare Payment Advisory Commission, recommended CMS ensure access to in-person services is not made prohibitively expensive by differential cost sharing as it could be discriminatory if undue financial burden is imposed on enrollees who choose in-person services instead of accessing services through electronic exchange. Further, commenters requested that CMS actively monitor differential cost sharing amounts to ensure they fairly reflect actual cost differentials and are not used to steer enrollees away from preferred methods of care. Commenters stated that enrollees lacking internet access should be able to get in-person services without facing an increase in out-of-pocket costs. Some commenters also requested that CMS clarify that a Qualified Medicare Beneficiary (QMB) would be protected from billing for cost sharing for all Part A/B services delivered via telehealth.

Response: As discussed in the proposed rule, section 1852(m)(5) of the Act mandates that MA additional telehealth benefits shall be treated as if they were benefits under the original Medicare fee-for-service program option. We acknowledged in the proposed rule that CMS has traditionally interpreted section 1852(a)(1)(B)(i) and (iii)–(v) of the Act to mean that, subject to certain exceptions, MA plans must cover basic benefits using cost sharing that is actuarially equivalent to the Part A and B cost sharing from a plan-level (not enrollee-level) perspective. MA plans are not required, in most cases, to have the exact same cost sharing as in original Medicare. Subject to certain beneficiary protections and limits on cost sharing for certain specific services,[6] MA plans have great flexibility in setting the cost sharing for specific benefits. Further, for in-network services, CMS has limited authority to set the payment structure, including the payment amount, an MA

[6] See 42 CFR 422.100(f), (j) and (k).

plan uses to pay its contracted providers; to some extent, the amount the MA plan has negotiated to pay its contracted providers may influence the cost sharing amount that the MA plan sets for the associated services. In addition, MA plans must have uniform cost sharing per § 422.100(d)(2). CMS has taken a broad and flexible approach to the uniformity requirement, including permitting MA plans to set up ''preferred'' networks that carry lower cost sharing for specific services.[7] In response to comments on this topic, we are clarifying the rationale for § 422.135(f).

In the context of original Medicare Part B, services furnished in an in-person encounter between a clinician and a patient are subject to different rules than those delivered through electronic exchange; in effect, the statutory provisions governing payment for original Medicare telehealth services treat services furnished through electronic exchange as different services than the in-person services, rather than as the same services delivered through different modalities. Section 1834(m) of the Act limits Part B payment for services furnished through electronic exchange to only certain healthcare services delivered through certain technology by specified types of clinicians to beneficiaries located in originating sites that meet specific conditions. Under the statutory scheme of section 1834(m) of the Act, services furnished through electronic exchange, where the physician or practitioner is not in the same location as the patient, are distinct and different services from those furnished in-person and in the same location.

We interpret the current law regulating the cost sharing in the MA context to mean that MA plans must charge enrollees the same cost sharing for the same item or service delivered by the same provider, and we view a service delivered in-person versus a service delivered via electronic exchange as different services because they are delivered differently. In order words, delivering a Part B service via electronic exchange is inherently different (for example, in modality and required infrastructure) than delivering the Part B service in-person under Medicare coverage rules; therefore, we consider these to be sufficiently different services for purposes of the MA requirement that cost sharing be uniform, and thus the services can be treated differently from a cost sharing perspective. Further, the cost of providing the service via electronic exchange might be lower, so having lower cost sharing is acceptable. For example, an MA plan may offer a dermatology exam using store-and-forward technology as an MA additional telehealth benefit, and the cost of this electronic exchange would likely be lower than the cost of an in-person dermatology exam. Thus, differential cost sharing for the electronic exchange versus the in-person visit would be appropriate in this scenario. This overall reasoning is consistent with our traditional interpretation of the Medicare statute and the applicable provisions in Part C, therefore we are finalizing the regulation text at § 422.135(f) as proposed.

We understand commenters' apprehensions about enrollee discrimination and enrollee access to MA additional telehealth benefits. The anti-discrimination requirements in current CMS regulations at § 422.100(f)(2) and § 422.110(a) are traditionally related to discrimination based on health status. Other federal non-discrimination laws, such as Title VI of the Civil Rights Act of 1964, focus on specific protected classes (such as race and age). Economic status or geographic location (rural/urban) are not protected classes under those laws, nor under current CMS regulations. Consequently, we do not have clear authority to enforce anti-discrimination rules based solely on an enrollee's economic status or geographic location.

However, the statutory requirement (section 1852(m)(4) of the Act) and our corresponding regulatory requirement in this final rule (§ 422.135(c)(1)) protecting the enrollee's choice to receive covered services in-person control how an MA plan offers MA additional telehealth benefits. An MA plan offering MA additional telehealth benefits must preserve the enrollee's right to choose whether to access the service in-person or, if offered by the MA plan, through electronic exchange. MA plans may not circumvent or limit enrollee choice by using differential cost sharing to steer beneficiaries or inhibit access to services. We view such steering and inhibiting access as violations of § 422.100(f)(2) because of how those activities would inhibit an enrollee from exercising his or her rights under section 1852(m)(4) of the Act and § 422.135(c). If an MA plan chooses to maintain differential cost sharing for MA additional telehealth benefits, we expect the primary purpose would be to parallel the actual cost of administering the service and not to steer beneficiaries or inhibit access. We will actively monitor complaints regarding differential cost sharing for MA additional telehealth benefits. If we identify a problem with enrollee access or steering, we may take compliance or enforcement actions, as necessary, and we may modify our policy to address the issue.

As discussed previously, MA plans have great flexibility in setting cost sharing for specific benefits. We believe that restricting this flexibility for certain plans that offer MA additional telehealth benefits, for example in cases where an MA plan operates in a rural or underserved area, could result in MA plans choosing not to offer MA additional telehealth benefits in rural service areas. Given this, and given the existing beneficiary cost sharing protections described previously, we do not believe it is appropriate to limit MA plans' existing flexibility to set cost sharing for MA additional telehealth benefits. However, we encourage MA plans to take issues like this into consideration in establishing cost sharing for MA additional telehealth benefits.

Finally, we appreciate the comments regarding QMB cost sharing protections. However, we believe that the current requirements at § 422.504(g)(1)(iii) requiring MA plans to take steps to ensure that QMBs are protected from providers billing cost sharing are adequate. This regulation prohibits MA plans from imposing cost sharing on dual eligible individuals when the state is responsible for paying for the cost sharing and from imposing cost sharing on such enrollees that is higher than the cost sharing permitted by the state Medicaid plan. For more information on cost sharing protections provided under the Act for QMBs and other dual eligible individuals, we refer readers to the CMS website for the QMB program at: *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/QMB.html.*

Comment: In accordance with section 1852(m)(4) of the Act, if an MA plan covers a Part B service as an MA additional telehealth benefit, then the MA plan must also provide access to such service through an in-person visit and not only through electronic exchange. We proposed § 422.135(c)(2) to require MA plans to use their EOC (at a minimum) to advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange. We also proposed, at § 422.135(c)(3), that MA plans would have to use their provider directory to identify any

[7] See Announcement of Calendar Year 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.

providers offering services for MA additional telehealth benefits and in-person visits or offering services exclusively for MA additional telehealth benefits. While we received some support for our proposed disclosure (that is, EOC and provider directory) requirements for MA additional telehealth benefits, other commenters believed that these requirements would be overly restrictive, burdensome, and/or time consuming.

Several commenters recommended that CMS provide more flexibility in how MA plans can disclose information about MA additional telehealth benefits to enrollees. For example, commenters suggested that CMS allow plans to use more general terminology instead of explicitly listing each service in the EOC, and allow plans to describe in the EOC how enrollees can obtain information on telehealth services. In terms of the provider directory, a commenter believed CMS should let plans make the determination regarding inclusion of telehealth providers in a way the plan believes optimizes clarity for enrollees, especially since the common industry approach is for telehealth vendors to contract with licensed providers, and the list of providers is not static. Another commenter requested that CMS require only an indication of which providers are exclusively available via telehealth in directories, and allow sufficient lead-time for plans to implement any new directory requirements. A commenter suggested CMS work with plans on alternative ways to responsibly share information on MA additional telehealth benefits with enrollees. A few commenters requested clear guidance (for example, model language) on the proposed disclosure requirements and clarification, such as whether provider directory updates would need to be made for all providers or only a specific subset.

Response: We appreciate commenters' concerns about the proposed disclosure requirements being too restrictive and onerous on plans, and we thank those who offered alternative solutions and ideas for more flexibility. As discussed in the proposed rule, we believe that choice, transparency, and clarity are vital when it comes to disclosing MA additional telehealth benefits to enrollees. However, we also recognize that there are various ways to effectively communicate with enrollees consistent with the mandatory disclosure and information requirements in § 422.111. CMS has traditionally discussed specific required elements for mandatory disclosures (for example, the provider directory and EOC) and marketing materials in sub-regulatory guidance to explain and interpret the applicable regulations as well as describe best practices for MA plans and Part D sponsors.

We agree with commenters that more flexibility may be needed, and sub-regulatory guidance provides an opportunity for flexibility in applying the applicable regulations where possible and for regular updates as necessary to account for changes in technology or evolving methods of compliance. Therefore, we are not finalizing our proposed regulation text for the provider directory requirement at proposed § 422.135(c)(3). Instead, we will address any provider directory elements pertaining to plans offering MA additional telehealth benefits in future sub-regulatory guidance. We note that the provider directory requirements in § 422.111 are not being amended and continue to apply. Therefore, provider directories must be complete, accurate, and updated timely to identify the healthcare providers currently under contract with the MA plan to furnish covered services to enrollees. In response to comments claiming that the common industry approach is for telehealth vendors to contract with licensed providers and that the list of providers is not static, we remind MA plans of the requirement to issue provider directories and notify enrollees of network changes per § 422.111. As the providers of MA additional telehealth services must be contracted providers, we expect that they will be identified as contracted providers in provider directories.

We intend to be as clear as possible in our sub-regulatory guidance to assist plans with their enrollee communications and to address how the existing provider directory requirements apply in the context of MA plan obligations in connection with furnishing MA additional telehealth benefits. We note that, as discussed in more detail below, we are finalizing our proposal that only contracted (that is, in-network) providers may be used by an MA plan to furnish MA additional telehealth benefits.

For similar reasons, we are also not finalizing our reference to the EOC at proposed regulation text § 422.135(c)(2). The regulation at § 422.111 establishing what information must be provided to enrollees (and when) regarding benefits covered by the MA plan is sufficient. We have historically used sub-regulatory guidance to address the specific level of detail required by that regulation and will issue guidance specific to how MA additional telehealth benefits must be addressed in mandatory communication materials such as the EOC and the Annual Notice of Change. None of our other regulations about specific benefits require specific content in the EOC. We believe that it is appropriate to follow that practice for addressing how information about MA additional telehealth benefits must be disclosed and provided to enrollees.

However, we are finalizing the remaining text at (c)(2), which requires an MA plan furnishing MA additional telehealth benefits to advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange. We have decided to maintain this general enrollee disclosure requirement (without reference to the EOC) because of the statutory requirement at section 1852(m)(4)(B) of the Act that the enrollee must have that choice. We believe the MA plan must disclose this right of choice to enrollees in a transparent manner in order to ensure that the right is meaningfully provided. We plan to issue sub-regulatory guidance specifically for § 422.135(c)(2) regarding the requirement that an MA plan advise enrollees that they may receive the specified Part B service(s) through an in-person visit or through electronic exchange; we will also issue guidance on disclosure requirements of MA plans, including model language for both the EOC and the provider directory, in the context of MA additional telehealth benefits.

Comment: In the proposed rule, we sought comment on what impact, if any, MA additional telehealth benefits should have on MA network adequacy policies, and the comments we received were mixed. Commenters who were supportive of a change to network adequacy policies for MA additional telehealth benefits stated that CMS should allow telehealth providers to be considered in the network adequacy assessment, either in the network criteria itself or through the exceptions process. Some suggested CMS update the network criteria to account for how MA plans may offer MA additional telehealth benefits (for example, allow telehealth providers to count in the network review or comprise a certain percentage of a plan's providers per specialty) or eliminate the time and distance standard and maintain just the minimum number per enrollee standard for telehealth providers. Others believed the current exceptions process was sufficient, that is, commenters expressed that through the current exceptions process, CMS could potentially allow plans to substitute telehealth providers for in-person providers only where there is a shortage

of specialty providers. A commenter suggested CMS consider telehealth exceptions for network adequacy when a plan can demonstrate that access to certain specialties would otherwise be problematic without permitting the MA plan to use telehealth providers to meet the network adequacy requirements; the commenter believed such policy would allow for more competition and more attractive MA plan options. Some commenters indicated that incorporating telehealth into network adequacy would improve enrollee choice and access in MA, particularly in rural/underserved areas, for certain specialties like behavioral health, and through an increase in after-hours and weekend care. A few commenters further encouraged CMS to provide flexibility regarding time and distance standards and allow telehealth to fill in network gaps, which might in turn streamline the network review process.

Other commenters asserted that a telehealth provider should not carry the same weight as an in-person provider and should only be used as a supplement, not a replacement, for in-person services. A few commenters suggested CMS continue basing network adequacy only on in-person services given the disparity in internet access.

Still others suggested CMS do a complete study to assess data in light of increased telehealth utilization, which could inform future changes to network adequacy policies and measurement options. A commenter recommended that, minimally, CMS should wait to reevaluate network criteria until there is a higher market saturation of telehealth providers for Part B services. Another commenter believed CMS should collect specific feedback on current plan-provider telehealth arrangements and current enrollee experience and satisfaction with telehealth providers, both within and outside MA.

Response: We thank the commenters for their feedback on MA additional telehealth benefits' potential impact on network adequacy. We will consider these comments as we perform further research on the issue and update sub-regulatory guidance to reflect any applicable changes in policy. We are not using this final rule to announce or adopt changes in current policies for evaluating MA network adequacy under § 422.112 because CMS interprets the requirements at § 422.112 through the MA network adequacy criteria, which have traditionally been addressed in sub-regulatory guidance.

Comment: Many commenters supported CMS's proposal to require MA plans to ensure through their provider contracts that providers meet and comply with applicable state licensing requirements and other applicable laws for the state in which the enrollee is located and receiving the service. Specifically, the commenters suggested CMS allow plan providers to utilize state-based credentialing standards for telehealth services as opposed to federal standards for MA provider participants authorized in § 422.204(b). A commenter believed that plans should be allowed to apply additional provider requirements.

Response: We support requiring the MA plan to ensure through its contract with the provider that the provider meet and comply with applicable state licensing requirements and other applicable laws for the state in which the enrollee is located and receiving the service. This standard is codified in the final rule at § 422.135(c)(3). We believe creating additional provider licensing requirements is unnecessary, but we acknowledge that states may have specific provisions regarding the practice of medicine using electronic exchange. We remind readers and MA plans that existing provider credentialing and network participation requirements, specifically in §§ 422.200 through 422.224, continue to apply. As this final rule requires MA plans to use only contracted (that is, in-network) physicians and practitioners to furnish MA additional telehealth benefits, those existing regulations will apply.

Comment: Several commenters expressed an openness to CMS occasionally collecting data on MA additional telehealth benefits, per the proposal to require MA plans to make information about coverage of MA additional telehealth benefits available to CMS upon request. However, these commenters were leery of the potential for administrative burden on MA plans. Some voiced concern about CMS collecting confidential or sensitive information and specifically requested that CMS exclude information that could be held under contractual consideration. For example, a commenter stated that specific information on use or cost of MA additional telehealth benefits is proprietary and commercially sensitive, and revealing contract-specific details would be anti-competitive. Another commenter concurred with CMS collecting data on the costs and benefits of MA plans' MA additional telehealth benefits as long as it was not overly onerous on plans.

Response: We understand commenters' concerns about burden and confidentiality when it comes to CMS data collection. However, we note that the regulation text at proposed § 422.135(c)(5)—finalized at § 422.135(c)(4)—includes the language ''upon request,'' which implies that CMS does not intend to establish uniform data collection at this time, but instead reserves the right to ask for this information from MA plans. We encourage readers to refer to section III.B.1. of this final rule, which provides additional detail and explicitly states that the information collection provision at § 422.135(c)(4) is exempt from the requirements of the Paperwork Reduction Act (PRA) since we estimate fewer than 10 respondents. Thus, we do not anticipate a significant increase in plan burden due to § 422.135(c)(4). We also remind readers that any uniform request to more than nine MA plans would require further review and would be subject to public comment under the PRA requirements.

Comment: A few commenters questioned whether CMS will allow MA plans (including PPO plans) to use only contracted providers for MA additional telehealth benefits. Some commenters believed that the contracted providers' restriction should apply to all MA plan types. Some commenters rejected CMS's proposal that all plan types be required to use only contracted providers. A few commenters recommended CMS limit this requirement to HMOs, thus allowing PPOs to use both contracted and non-contracted providers for MA additional telehealth benefits. Other commenters recommended that CMS extend the allowable providers beyond just contracted, in-network providers, stating that the issue of no oversight of out-of-network providers exists whether or not telehealth is involved.

Response: We are finalizing the proposal at § 422.135(d) to require that all MA plan types, including PPO plans, use only contracted providers to provide MA additional telehealth benefits. We are clarifying that if a PPO plan furnishes MA additional telehealth benefits consistent with the requirements at § 422.135, then the PPO plan requirement at § 422.4(a)(1)(v) (that the PPO must furnish all services both in-network and out-of-network) will not apply to the MA additional telehealth benefits; all other benefits covered by the PPO must be covered on both an in-network and out-of-network basis. In other words, a PPO plan is not required to furnish its MA additional telehealth benefits out-of-network, as is the case for all other plan-covered services. However, if a PPO plan would like to cover a service delivered through electronic exchange on an out-of-network basis, then the PPO plan has that option but may only cover the service as an MA supplemental

telehealth benefit, consistent with the regulation text at § 422.135(d).

In response to comments that recommended CMS extend the allowable providers beyond contracted providers because the issue of no oversight for non-contracted providers exists whether or not telehealth is involved, we note that MA plans must be able to review and pre-certify the qualifications and compliance of contracted providers to ensure that telehealth services are furnished consistent with clinically appropriate standards of care for the MA additional telehealth benefits offered by the MA plan and that all state licensure and credentialing requirements are met. We are therefore finalizing the proposed regulation text at paragraph (d), that an MA plan must furnish MA additional telehealth benefits only using contracted providers. Therefore the regulation will require that all MA plans, including PPOs that cover benefits provided by non-contracted providers, use only contracted providers for MA additional telehealth benefits.

Comment: Commenters recommended that CMS remain flexible in the ultimate determination of what will be considered capital and infrastructure costs and investments to be excluded from their bid submissions relative to MA additional telehealth benefits. Some commenters offered ideas to operationalize the exclusions. One suggestion was for CMS to stipulate a percentage that represents the industry average of allowed fees as representative of the capital and infrastructure costs, which could be trended over time. Another commenter suggested that CMS align the definition of capital and infrastructure costs and investments with a traditional understanding, such that those items that would add permanent or depreciable value to the plan or enrollee would be excluded, thus allowing the cost of necessary support items or services for telehealth delivery. A few commenters mentioned the 15 percent used in the Regulatory Impact Analysis of the proposed rule as a proxy for these costs. A commenter stated that the percentage was too high while another stressed that it was too low.

Commenters also raised concerns about the difficulty of identifying with specificity (for bid purposes) the capital and infrastructure components of MA additional telehealth benefits for services offered directly by the plan or through downstream entities such as providers and third party vendors. Specifically, a few commenters were concerned with the difficulty in excluding these costs from their claims capture and data reporting and in obtaining this information from contracted providers and vendors absent an additional contractual provision. Commenters also stated that capital and infrastructure costs would vary significantly from provider to provider. These commenters pointed out that currently there is no incentive for providers or vendors to accurately identify these costs, and plans would not be able to verify if the costs were reasonably stated. Consequently, commenters expressed, this lack of standardization and reliability could lead to challenges of plans' actuarial attestations and potential inequitable reporting in the bid. Another commenter also opposed the exclusion of capital and infrastructure costs from MA plans' basic benefit bid.

Response: We appreciate the comments concerning the exclusion of capital and infrastructure costs relating to MA additional telehealth benefits from the basic benefit bid submission. Section 1852(m)(2)(A)(ii) of the Act excludes from MA additional telehealth benefits capital and infrastructure costs and investments related to MA additional telehealth benefits. We are codifying this requirement in § 422.254(b)(3)(i) as a restriction on how MA plans include MA additional telehealth benefits in their bid submission. We believe the statutory limit is tied only to the cost to the government, which is tied to how MA additional telehealth benefits may be included in the bid as basic benefits. Therefore, our proposal was to eliminate from the basic benefit bid those capital and infrastructure costs and investments that are required or used to enable the provision of MA additional telehealth benefits.

We appreciate the concerns raised by commenters about broad interpretations of the statutory exclusion of capital and infrastructure costs and investments. In recognition of these challenges, we are clarifying in regulation text that the exclusion from the bid of capital and infrastructure costs and investments relating to MA additional telehealth benefits, codified at § 422.254(b)(3)(i), applies to capital and infrastructure costs and investments ''directly incurred or paid by the MA plan.'' The bid for basic benefits submitted by an MA plan cannot include such capital and infrastructure costs or investments for MA additional telehealth benefits.

We do not propose a specific definition of capital and infrastructure costs or investments related to such benefits here because the costs and investments needed and used to provide MA additional telehealth benefits would vary based on the individual MA plan's approach to furnishing the benefits.

We also thank the commenters for providing lists of capital and infrastructure examples. Although we stated in the proposed rule that we would provide a more detailed list of examples in this final rule based on stakeholder feedback, after further consideration we have chosen not to do so. We made this decision in acknowledgment of the variety of potential capital and infrastructure models, for which a given MA plan could incur or pay costs, related to MA additional telehealth benefits.

Comment: Many commenters requested clarification on how the annual bid submission process will work for MA additional telehealth benefits. Specifically, commenters questioned how plans will be expected to file MA additional telehealth benefits in the PBP.

Response: We appreciate this request for greater clarity concerning how the annual bid submission process will be impacted by MA additional telehealth benefits. We will take these comments into consideration when developing the annual bid guidance, which we consider to be a more appropriate place to provide instruction for completing the bid.

Comment: Several commenters supported CMS's proposal to allow MA plans to provide MA additional telehealth benefits because the proposal does not include geographic and originating site limitations. A few commenters believed CMS should extend authority for MA additional telehealth benefits to original Medicare, specifically to eliminate geographic and originating site limitations applicable in original Medicare. Some commenters requested that CMS make efforts to ensure parity for original Medicare beneficiaries, claiming they would be disadvantaged since they cannot access MA additional telehealth benefits as MA enrollees can. Some commenters urged CMS to reference and ensure alignment with the Part B definition of telecommunications systems and note that the section 1834(m) originating site and geographic restrictions do not apply to MA additional telehealth benefits.

Response: This final rule will allow MA plans the ability to offer—as part of the basic benefit package—MA additional telehealth benefits beyond what is currently allowable under Medicare telehealth services; this is authorized by section 1852(m) of the Act, which was added by section 50323 of the Bipartisan Budget Act of 2018. Neither the statute nor this final rule includes geographic or originating site

limitations as part of defining or authorizing MA additional telehealth benefits. With regard to comments regarding coverage and payment under the original Medicare program, we note that we are constrained by the statutory requirements and that the original Medicare program is not within the scope of this final rule.

Comment: A commenter requested that CMS provide permissible MA additional telehealth benefit designs to ensure MA plan compliance with CMS's final rule.

Response: We appreciate the commenter's request for permissible MA additional telehealth benefit designs. However, we do not provide any specific MA additional telehealth benefit designs in the final rule in order to provide MA plans with the discretion to develop their plan benefit offerings.

Comment: A commenter requested information regarding whether MA additional telehealth benefits can be used to furnish the Medicare Diabetes Prevention Program (MDPP) services. A few commenters referenced CMS previously declining to test online MDPP diabetes self-management training.

Response: As discussed above, we are finalizing this rule to define ''additional telehealth benefits'' as services that: (1) Are furnished by an MA plan for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and (2) have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not in the same location as the enrollee. Because this definition requires MA additional telehealth benefits to be services provided by a physician or practitioner, and MDPP services, pursuant to § 410.79, must be provided by an MDPP supplier, MDPP services cannot be offered as MA additional telehealth benefits. Existing guidance about how MDPP services may be provided on a virtual basis or through electronic exchange still applies and can be covered as a supplemental benefit.

Comment: Some commenters requested that CMS include in the definition of a telehealth provider specific specialty types such as pharmacists, audiologists, speech-language pathologists, home health care aides, and telerehabilitation providers.

Response: We appreciate comments requesting additional specificity in identifying permissible telehealth provider types. However, we did not define a telehealth provider in the proposed rule and will not finalize such a definition here. Section 1852(m)(2)(A)(i)(2) uses the term ''physician'' as defined in section 1861(r) of the Act and the term ''practitioner'' described in section 1842(b)(18)(C) of the Act. We have codified these statutory requirements in our final definition of ''additional telehealth benefits'' at § 422.135(a)(2), described previously. Both the statute and this final rule limit MA additional telehealth benefits to services furnished by physicians and practitioners as so defined. Further, the statute and regulation require that the service be clinically appropriate to furnish through electronic exchange, which in some cases may prohibit certain services from being covered as MA additional telehealth benefits. Finally, in § 422.135(d), we are codifying the requirement that MA plans furnishing MA additional telehealth benefits only do so using contracted providers.

Comment: A few commenters questioned how MA additional telehealth benefits will interact with encounter data and risk adjustment. For example, commenters recommended CMS establish rules or clarify the criteria under which diagnoses obtained through telehealth encounters can be considered and submitted for risk adjustment purposes. A commenter specifically requested that CMS allow telehealth encounters to be included for MA risk adjustment, while other requestors requested future guidance on telehealth encounter data submissions.

Response: We appreciate commenters raising this particular issue. This regulation does not change the existing obligation to submit encounters. Consistent with the requirements under § 422.310, MA plans must submit risk adjustment data that characterize the context and purpose of each item and service provided to an MA enrollee, and must also conform to CMS's requirements for submitting these data. We will be releasing guidance regarding MA additional telehealth benefits and encounter data and risk adjustment in the future.

Summary of Regulatory Changes

We received a range of comments pertaining to this proposal, the majority of which reflected support for the regulations. After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments summarized earlier, we are finalizing the proposed changes to §§ 422.100, 422.252, 422.254, and 422.264 and new regulation at § 422.135, with the following modifications:

- In proposed regulation text § 422.135(a), we are removing the phrase ''that meet the following.'' Thus, we are revising § 422.135(a) to read as follows: ''*Definitions.* For purposes of this section, the following definitions apply: *Additional telehealth benefits* means services:''
- In proposed regulation text § 422.135(a)(1), we are removing the phrase ''are furnished by an MA plan'' but finalizing the remaining text in (a)(1). Thus, we are revising (a)(1) to read as follows: ''For which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and''
- In proposed regulation text § 422.135(a)(2), we are adding the word ''That'' and adding the phrase ''when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C)) of the Act) providing the service is not in the same location as the enrollee.'' Thus, we are revising (a)(2) to read as follows: ''That have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C)) of the Act) providing the service is not in the same location as the enrollee.''
- In proposed regulation text § 422.135(c)(2), we are removing the phrase ''at a minimum in the MA plan's Evidence of Coverage required at § 422.111(b)'' but finalizing the remaining text in (c)(2). Thus, we are revising (c)(2) to read as follows: ''Advise each enrollee that the enrollee may receive the specified Part B service(s) through an in-person visit or through electronic exchange.''
- We are not finalizing our proposed regulation text for the provider directory requirement at proposed § 422.135(c)(3). Thus, we are removing proposed (c)(3) in its entirety, redesignating proposed (c)(4) as (c)(3), and redesignating proposed (c)(5) as (c)(4).
- In proposed regulation text § 422.254(b)(3)(i), we are adding the phrases ''directly incurred or paid by the MA plan'' and ''for the unadjusted MA statutory non-drug monthly bid amount.'' Thus, we are revising (b)(3)(i) to read as follows: ''MA plans offering additional telehealth benefits as defined in § 422.135(a) must exclude any capital and infrastructure costs and investments directly incurred or paid by the MA plan relating to such benefits from their bid submission for the unadjusted MA

statutory non-drug monthly bid amount.''

2. Dual Eligible Special Needs Plans

Special needs plans (SNPs) are MA plans created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Under the law, SNPs are able to restrict enrollment to: (1) Institutionalized individuals, who are defined in § 422.2 as those residing or expecting to reside for 90 days or longer in a long term care facility; (2) individuals entitled to medical assistance under a state plan under Title XIX; or (3) other individuals with certain severe or disabling chronic conditions who would benefit from enrollment in a SNP. As of June 2018, the CMS website listed 297 SNP contracts with 641 SNP plans that have at least 11 members.[8] These figures included 190 Dual Eligible SNP contracts (D–SNPs) with 412 D–SNP plans with at least 11 members, 49 Institutional SNP contracts (I–SNPs) with 97 I–SNP plans with at least 11 members, and 58 Chronic or Disabling Condition SNP contracts (C–SNPs) with 132 C–SNP plans with at least 11 members. This final rule implements the provisions of the Bipartisan Budget Act of 2018 that establish new requirements for D–SNPs for the integration of Medicare and Medicaid benefits and unification of Medicare and Medicaid grievance and appeals procedures that are effective in 2021. This final rule also clarifies definitions and operating requirements for D–SNPs that will be applicable to D–SNPs starting January 1, 2020, as specified earlier in this final rule.

a. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

Beneficiaries who are dually eligible for both Medicare and Medicaid can face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in: (1) Missed opportunities to provide appropriate, high-quality care and improve health outcomes, and (2) ineffective care, such as avoidable hospitalizations and a poor beneficiary experience of care. Advancing policies and programs that integrate care for dual eligible individuals is one way in which we seek to address such fragmentation. Under plans that offer integrated care, dual eligible individuals can receive the full array of Medicaid and Medicare benefits through a single delivery system, thereby improving care coordination, quality of care, beneficiary satisfaction, and reducing administrative burden. Some studies have shown that highly integrated managed care programs perform well on quality of care indicators and enrollee satisfaction.[9]

D–SNPs are a type of MA plan that is intended to integrate or coordinate care for this population more effectively than standard MA plans or original Medicare by focusing enrollment and care management on dual eligible individuals. As of June 2018, approximately 2.3 million dual eligible individuals (1 out of every 6 dual eligible individuals) were enrolled in 412 D–SNPs. About 170,000 dual eligible individuals are enrolled in fully integrated dual eligible special needs plans, or FIDE SNPs (that is, where the same organization receives capitation to cover both Medicare and Medicaid services).[10] A number of states, including Arizona, Idaho, Hawaii, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Pennsylvania, Tennessee, Texas, Virginia, and Wisconsin, operate Medicaid managed care programs for dual eligible individuals in which the state requires that the Medicaid managed care organizations serving dual eligible individuals offer a companion D–SNP product.

As summarized in our proposed rule, since the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) first authorized D–SNPs' creation, subsequent legislation has been enacted that has extended their authority to operate and set forth additional programmatic requirements, including sections 164 and 165 of the Medicare Improvements for Patients and Providers Act (MIPPA) (Pub. L. 110–275), which amended sections 1859(f) and 1852(a) of the Act, and section 3205 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), which revised section 1853(a)(1)(B) of the Act. Regulations promulgated following the enactment of these laws implemented these statutory provisions.

Using the contract that D–SNPs are required to have with states under section 1859(f)(3)(D) of the Act, implemented in the regulation at § 422.107, state Medicaid agencies are able to establish requirements that surpass the minimum standards set in federal regulations for D–SNPs with regard to integration and coordination of Medicare and Medicaid benefits. To that end, we have seen states leverage their contracts with D–SNPs to limit D–SNP enrollment to individuals who also receive Medicaid benefits through the same organization, collect certain data from the D–SNP, and integrate beneficiary communication materials and care management processes to provide D–SNP enrollees a more seamless, coordinated experience of care.[11] CMS supports states that have an interest in pursuing integrated care models for dual eligible individuals, including through the use of their contracts with MA organizations offering D–SNPs, and provides technical assistance to states seeking to develop solutions tailored to their local market conditions, beneficiary characteristics, and policy environment.

Through this final rule, we are adopting new requirements in accordance with section 50311(b) of the Bipartisan Budget Act of 2018, which amended section 1859 of the Act to require that all D–SNPs meet certain new minimum criteria for Medicare and Medicaid integration for 2021 and subsequent years. Beyond the newly enacted amendments to the Act, we are

[8] Centers for Medicare & Medicaid Services (2018, June). SNP Comprehensive Report. Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

[9] *See:* Kim, H., Charlesworth, C.J., McConnell, K.J., Valentine, J.B., and Grabowski, D.C. (2017, November 15). *Comparing Care for Dual-Eligibles Across Coverage Models: Empirical Evidence From Oregon.* Retrieved from *http://journals.sagepub.com/doi/abs/10.1177/1077558717740206;* Anderson, W.L., Feng, Z., & Long, S.K. (2016, March 31). *Minnesota Managed Care Longitudinal Data Analysis,* prepared for the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE). Retrieved from *https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis;* Health Management Associates (2015, July 21). *Value Assessment of the Senior Care Options (SCO) Program.* Retrieved from *http://www.mahp.com/wp-content/uploads/2017/04/SCO-White-Paper-HMA-2015_07_20-Final.pdf;* and Medicare Payment Advisory Committee (2012, June 16). ''*Care coordination programs for dual-eligible beneficiaries.*'' In *June 2012 Report to Congress: Medicare and Health Care Delivery System.* Retrieved from *http://www.medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0.*

[10] Centers for Medicare & Medicaid Services (2018, June). *SNP Comprehensive Report.* Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

[11] Verdier, J, Kruse, A., Sweetland Lester, R., Philip, A.M., & Chelminsky, D. (2016, November). ''State Contracting with Medicare Advantage Dual Eligible Special Needs Plans: Issues and Options.'' Retrieved from *http://www.integratedcareresourcecenter.com/PDFs/ICRC_DSNP_Issues__Options.pdf.*

also using this final rule to add requirements and clarifications to existing regulations to codify guidance and policy since D–SNPs were established nearly 15 years ago and to update certain aspects of the regulations. Under the newly enacted section 1859(f)(8)(D)(i) of the Act, the statute calls for D–SNPs, for 2021 and subsequent years, to meet one or more of three specified requirements, to the extent permitted under state law, for integration of benefits:

- A D–SNP must, in addition to meeting the existing requirement of contracting with the state Medicaid agency under section 1859(f)(3)(D) of the Act, coordinate long-term services and supports (LTSS), behavioral health services, or both, by meeting an additional minimum set of requirements for integration established by the Secretary based on input from stakeholders. Such requirements for integration could include: (1) Notifying the state in a timely manner of hospitalizations, emergency room visits, and hospital or nursing home discharges of enrollees; (2) assigning one primary care provider for each enrollee; or (3) data sharing that benefits the coordination of items and services under Medicare and Medicaid.
- A D–SNP must either: (1) Meet the requirements of a fully integrated dual eligible special needs plan described in section 1853(a)(1)(B)(iv)(II) of the Act (other than the requirement that the plan have similar average levels of frailty as the PACE program); or (2) enter into a capitated contract with the state Medicaid agency to provide LTSS, behavioral health services, or both.
- The parent organization of a D–SNP that is also the parent organization of a Medicaid managed care organization providing LTSS or behavioral services must assume ''clinical and financial responsibility'' for benefits provided to beneficiaries enrolled in both the D–SNP and Medicaid managed care organization.

Section 50311(b) of the Bipartisan Budget Act of 2018 also authorizes the Secretary, in section 1859(f)(8)(D)(ii) of the Act, to impose an enrollment sanction on an MA organization offering a D–SNP that has failed to meet at least one of these integration standards in plan years 2021 through 2025. In the event that the Secretary imposes such a sanction, the MA organization must submit to the Secretary a plan describing how it will come into compliance with the integration standards.

We received a number of comments on our proposals to implement these new integration requirements, both in general and with regard to specific proposals. We summarize and respond to the comments below.

Comment: We received numerous comments in support of our integration proposal, with many commenters citing the proposal's fulfillment of statutory intent and expressing appreciation for the flexibility afforded to states to define what integrated care looks like in their state. For example, some of these commenters noted the diversity of state policies, which impact what the D–SNP market looks like in each state, and cautioned against any proposal that upon implementation would disrupt existing integrated care models and beneficiaries' coverage. A subset of commenters, while supportive of our proposal, also encouraged CMS to raise the bar of integration even further. One commenter encouraged CMS to help states move toward integration and not penalize plans and states that are not yet able to integrate further, advising that focus should also remain on minimizing administrative burden and reducing complexity for beneficiaries. The Medicare Payment Advisory Commission (MedPAC) stated its belief that the proposed rule will do little to promote greater integration, citing in particular the first of the proposed new standards for integration—requiring D–SNPs to share information on inpatient and SNF admissions—as having a very limited impact on improving care coordination, as discussed in more detail in the comments we received on proposed § 422.107(d). Another commenter objected to our integration proposal and recommended that CMS leave all decision-making to the states, including granting them the ability to opt out of any of the D–SNP integration requirements.

Response: We appreciate the widespread support we received for our proposal. We believe that the requirements we are finalizing in this rule strike an appropriate balance between increasing integrated care in D–SNPs for dual eligible individuals and preserving state flexibility, within the framework established by the amendments to section 1859(f)(8) of the Act made by section 50311(b) of the Bipartisan Budget Act of 2018. While our aim is to support states that are operating successful programs and assist those seeking to establish more integrated programs, we also recognize that our proposal must account for the current state of integrated care and the need to meet states where they are by setting reasonable and achievable integration benchmarks. As the D–SNP landscape evolves, we will continue to consider ways to advance integrated care, including further rulemaking. Finally, we note that the statute does not authorize CMS or states to disregard a D–SNP's obligation to meet one or more of the integration requirements, and imposes consequences for non-compliance, as discussed in response to comments on proposed § 422.752(d).

Comment: One commenter expressed concern about D–SNPs' ability to meet the integration requirements by 2021 due to the potential for delayed decision-making on the part of states. Another commenter requested a one-year delay in the effective date in consideration of the time required to negotiate and execute contracts between states and D–SNPs and to develop new processes, which will vary depending on each state's capabilities. Conversely, another commenter stated that 2021 is an achievable date for meeting one of the three integration requirements.

Response: The statute requires that D–SNPs comply with the integration requirements by 2021. As discussed throughout this preamble, the Medicare-Medicaid Coordination Office provides technical assistance to states on integration issues, and we expect to continue to engage states, plans, and other stakeholders as we implement the requirements in this final rule.

Comment: One commenter observed that CMS does not make any additional funding available for the coordination activities that D–SNPs perform today and that adding to these requirements could create burdens on plans and CMS or cause D–SNPs to exit the market. Another commenter urged CMS to establish nationwide standards to ensure plans can scale best practices and that beneficiaries receive the same high quality service no matter where they live.

Response: While we believe that states are well positioned to drive innovation in care delivery for dual eligible individuals, we also recognize that the Bipartisan Budget Act of 2018 set forth a minimum level of integration for all D–SNPs to meet. We believe that the proposal we set forth is a reasonable one that preserves state flexibility while fulfilling our statutory obligation. While we recognize the desirability of having national standards, particularly for MA organizations that operate D–SNPs in multiple markets across the country, we have to balance this desire with the differences that exist in states' capabilities, ranging from states where some or all dual eligible individuals may be precluded from enrolling in any capitated plan for their Medicaid services to states with highly integrated D–SNP models. Notwithstanding our reluctance to mandate the use of

national standards, we are committed to cataloguing and disseminating best practice information as part of the final rule's implementation and our ongoing administrative alignment efforts, discussed later in the preamble to this final rule.

Comment: Several commenters supported our D–SNP integration proposals but considered them only a starting point for ensuring better alignment and encouraged CMS to build upon these requirements in the future. Several commenters also recommended that CMS provide strong oversight to ensure that integration requirements are being met and that dual eligible individuals enrolled in D–SNPs are actually benefiting from increased integration. One commenter urged CMS to go further in recognizing states' authority and options to implement even more robustly integrated programs.

Response: We appreciate these commenters' perspectives on our proposal. We acknowledge the importance of working in close partnership with states to advance integration within each state-specific context. CMS will monitor the implementation of these provisions to determine market and beneficiary impacts and assess the need for additional rulemaking to modify or expand upon the integration standards we are finalizing in this rule.

Comment: One commenter recommended that CMS conduct a comprehensive review of basic operational processes to determine where Medicare and Medicaid could be further aligned to enhance care delivery and quality and to reduce burdens on plans, providers, and beneficiaries and to facilitate plans' moving along the integration continuum toward a FIDE SNP or HIDE SNP status. This commenter further suggested that CMS advance integration using all available statutory authorities, including seeking clarification from Congress regarding its intent in enacting provisions in the Bipartisan Budget Act of 2018 related to the Medicare-Medicaid Coordination Office.

Several commenters recommended that CMS extend to D–SNPs processes and flexibilities developed under the Financial Alignment Initiative for MMPs and under the Minnesota Demonstration to Align Administrative Functions for Improvements in Medicare-Medicaid Beneficiary Experience, including use of the contract management team structure for joint oversight of plans, integrated beneficiary communications materials, joint CMS-state marketing reviews, coordinated enrollment processes and timelines, integrated MOCs, dual eligible-specific network adequacy requirements, and streamlined and plan-level reporting processes. Several commenters suggested other areas in which CMS could create additional administrative and policy incentives to reward states for moving toward further Medicare-Medicaid alignment, including year-round marketing to dual eligible individuals; expansion of current passive enrollment and default enrollment authorities; establishment of a Special Election Period for enrollment in integrated plans; plan payment reforms, including changes to the frailty adjustment for FIDE SNPs; an increase of the enhanced Medicaid match for care coordination and IT activities; and alignment of state and federal contracting cycles. A commenter recommended that CMS improve its messaging about D–SNPs in its beneficiary-centered materials and tools.

Response: We thank commenters for their robust feedback about additional alignment opportunities for D–SNPs. Since 2013, the Financial Alignment Initiative and Minnesota demonstration have provided us with opportunities to test a number of programmatic and administrative flexibilities for MMPs and some D–SNPs, and many of these flexibilities have been positively received by beneficiaries, states, and health plans. We will continue to consider additional ways to promote better outcomes and experiences for dual eligible individuals.

As we have indicated in the CY 2016 Draft and Final Call Letters, the CY 2019 Draft and Final Call Letters, and the CY 2020 Draft Call Letter,[12] CMS remains committed to providing administrative flexibility that facilitates efforts by state Medicaid agencies and MA organizations to use D–SNPs to integrate coverage of Medicare and Medicaid benefits, including in the areas of integrated beneficiary communications, D–SNP models of care, and enrollment processes. That commitment is also evidenced by our recent CY 2019 final rule (CMS–4182–F, Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program) codifying our authority to permit default enrollment of newly Medicare-eligible individuals into integrated D–SNPs at § 422.66(c)(2) and, at § 422.60(g)(1)(iii), to allow passive enrollment to preserve continuity of care and integrated care related to D–SNP non-renewals or state Medicaid managed care organization procurements. We have also worked with states and integrated D–SNPs to develop integrated beneficiary communications materials, integrate model of care requirements and reviews with states, and provide state Medicaid agencies with technical assistance and information on plan performance and audit results of their contracted D–SNPs so that the quality of Medicare services delivered by those D–SNPs can inform state contracting strategies. We look forward to continuing our work in this area with additional states and plans.

Comment: A number of commenters recommended CMS consideration of additional regulatory and operational policies on a number of issues related to dual eligible individuals that were not related to the D–SNP integration requirements in the proposed rule. One commenter urged CMS to make funds available for ombudsman programs to serve dual eligible individuals in integrated D–SNPs. Several commenters recommended that CMS continue to work with plans on identifying a long-term solution impacting dual eligibility status and socioeconomic factors in Medicare Advantage Star Ratings. One commenter reiterated the need for CMS to develop a risk adjustment model that adequately accounts for the costs of serving beneficiaries with functional limitations. Another commenter urged CMS to consider how D–SNPs should be designed to minimize cost-sharing obligations that are ultimately unpaid and to consider a more holistic approach to coverage for dual eligible individuals that does not simply transfer cost-sharing liability to providers. Another commenter noted the critical importance of home and community-based service (HCBS) eligibility barriers when determining how the D–SNP-to-Medicaid transition should occur and recommended that the federal government ease this transition through reform of the Medicaid HCBS eligibility requirements. One commenter requested that CMS consider recognizing Part B premium buy-downs in Puerto Rico D–SNPs as part of plans' bids to provide Parts A and B benefits, rather than requiring plans to use rebate dollars to buy down the Part B premium as a supplemental benefit. Another commenter recommended cost-sharing integration processes for dual eligible individuals at the pharmacy counter or, in the shorter-term, implementation of real time beneficiary eligibility solutions for use within the NCPDP Telecommunication standard.

Response: These recommendations are not within the scope of our final rule

[12] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf.*

provisions establishing integration criteria for D–SNPs effective in 2021, and some of them are beyond our programmatic authority. We do, however, appreciate the many comments and suggestions related to programmatic improvements for dual eligible individuals, including those enrolled in D–SNPs.

Comment: A range of commenters, including the Medicaid and CHIP Payment and Access Commission (MACPAC), expressed concern that the market entry of non-D–SNP MA plans designed and marketed exclusively to dual eligible individuals—so-called ''D–SNP look-alike plans''—threatens to undermine efforts by CMS, states, and D–SNPs to increase integration and coordination of Medicare and Medicaid services. Some of these commenters recommended that CMS address this issue including by requiring MA plans with a minimum percentage of dual eligible members to meet all D–SNP requirements, including the obligation to contract with the states in which the plans operate.

Response: Although the issue of D–SNP look-alike plans is beyond the scope of this rule, we share the commenters' concern with the impact of such plans on our efforts to increase Medicare-Medicaid integration. We call attention to the CY 2020 Draft Call Letter [13] in which we sought comment on the impact of D–SNP look-alike plans in order to inform future policy development.

Comment: A commenter recommended that CMS continue and expand efforts to help states adopt policies and incentives that assist D–SNPs in moving toward higher levels of integration (including FIDE SNP or HIDE SNP status with better aligned enrollments) for dual eligible individuals.

Response: States and CMS both play important roles in implementing more integrated care delivery systems for dual eligible individuals. The Medicare-Medicaid Coordination Office facilitates this technical assistance and dialogue with states, including through its Integrated Care Resource Center (see *https://www.integratedcareresourcecenter.com/*). We are committed to continuing our work with states based on their specific policy priorities following the implementation of this final rule.

Comment: One commenter reaffirmed their support for Medicare-Medicaid Plans (MMPs) offered under the Financial Alignment Initiative and urged CMS to make them permanent. The same commenter urged CMS to develop a common statutory and regulatory framework for all forms of integrated plans, including MMPs, PACE organizations, and FIDE SNPs, that would include uniform rules on marketing, enrollment processes, claims reporting, rate-setting, and risk adjustment.

Response: We appreciate the commenter's support for our work with states and MMPs in the Financial Alignment Initiative. CMS will continue to explore ways within our programmatic authority to improve the current regulatory framework for integrated care as we gain experience and gather data about the impacts of the FAI capitated model and other demonstrations, our administrative alignment efforts, streamlining of the PACE program, and the implementation of new D–SNP integration requirements finalized in this rule.

Comment: We received comments from one organization expressing concerns about CMS' sole reliance on the D–SNP delivery model and urging us to consider other plan types (including Institutional SNPs (I–SNPs) and fee-for-service Medicare) that can help achieve integrated care goals. This commenter expressed concern that sole reliance on D–SNPs would result in unnecessary disruptions to care.

Response: We support beneficiary choice in selecting the health care delivery system that best meets each individual's needs. The final rule focuses on the specific requirements added to section 1859(f) of the Act for D–SNPs by section 50311 of the Bipartisan Budget Act. Comments related to fee-for-service Medicare and I–SNPs are therefore outside the scope of this final rule.

Comment: A few commenters requested that CMS consider providing guidance on how the integration requirements will affect the operations of MMPs.

Response: We clarify that there is no direct impact on MMPs as a result of this final rule. The D–SNP requirements in this final rule are not applicable to MMPs, and MMP policy and operations will continue to be established in three-way contract agreements among CMS, health plans, and states.

(1) Definitions of a ''Dual Eligible Special Needs Plan'', ''Fully Integrated Dual Eligible Special Needs Plan'', ''Highly Integrated Dual Eligible Special Needs Plan'', and ''Aligned Enrollment'' (§ 422.2)

D–SNPs are described in various sections of 42 CFR part 422, including provisions governing the definition of specialized MA plans for special needs individuals in § 422.2, the supplemental benefit authority for D–SNPs that meet a high standard of integration and minimum performance and quality-based standards in § 422.102(e), state Medicaid agency contracting requirements in § 422.107, and specific benefit disclosure requirements in § 422.111(b)(2)(iii). In the proposed rule, we proposed to consolidate statutory and regulatory references to D–SNPs; we also proposed to establish a definition for such a plan in § 422.2. In addition to proposing a new definition for the term ''dual eligible special needs plan,'' we also proposed a revised definition of the term ''fully integrated dual eligible special needs plan,'' and new definitions of the terms ''highly integrated dual eligible special needs plan'' and ''aligned enrollment,'' for purposes of part 422 (that is, the rules applicable to the MA program) and the proposed rule.

In our proposed definition at § 422.2, we described a dual eligible special needs plan as a type of specialized MA plan for individuals who are eligible for Medicaid under Title XIX of the Act that provides, as applicable, and coordinates the delivery of Medicare and Medicaid services, including LTSS and behavioral health services, for individuals who are eligible for such services; has a contract with the state Medicaid agency consistent with § 422.107 that meets the minimum requirements in paragraph (c) of such section; and satisfies at least one of following integration requirements:

- It meets the additional state Medicaid agency contracting requirement we proposed at § 422.107(d) (described in section II.A.2.a.(2) of the proposed rule) that surpasses the minimum requirements in current regulations at § 422.107(c);
- It is a highly integrated dual eligible special needs plan (HIDE SNP), as described in further detail later in this section; or
- It is FIDE SNP.

In addition, we proposed additional performance requirements for D–SNPs that we did not incorporate into the definition; for example, a D–SNP would provide assistance to individuals filing a grievance or appeal for a Medicaid services in accordance with proposed

[13] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf.*

§ 422.562(a)(5) (described in section II.A.2.b.(1) of the proposed rule). As discussed in the proposed rule, we believed this proposed definition identified the minimum requirements for an MA plan to be a D–SNP under section 1859 of the Act as amended by the Bipartisan Budget Act of 2018. We also explained that the proposed definition would clarify the applicability of the separate regulatory provisions that establish the minimum standards for D–SNPs. We solicited comment on whether our proposed definition met these goals or should be revised to include other regulatory provisions that establish requirements for D–SNPs.

We discussed in the proposed rule and reiterate here that it is important to clarify through this final rule the meaning of the requirement in section 1859(f)(3)(D) of the Act, which is currently codified at § 422.107(b), that the MA organization have responsibility under the contract for providing benefits or arranging for benefits to be provided for individuals entitled to Medicaid. Prior to our proposed rule, we had not adopted a specific interpretation of this statutory language, ''arranging for benefits,'' in previous rulemaking or in subregulatory guidance. We proposed to interpret ''arranging for benefits'' as requiring a D–SNP, at a minimum, to coordinate the delivery of Medicare and Medicaid benefits. We proposed to relocate this requirement to our proposed D–SNP definition. As stated in the proposed rule, while our interpretation is consistent with the new statutory integration standards, the proposed clarification was based on requirements for D–SNPs that existed prior to the enactment of the Bipartisan Budget Act of 2018 that we believe should be strengthened. We believe coordination would encompass a wide range of activities that a D–SNP may engage in for their dual eligible members and provided some examples of such coordination in the preamble to the proposed rule. If a D–SNP identifies through an enrollee's health risk assessment and/or individualized care plan, as required by § 422.101(f), functional limitations or mental health needs, the D–SNP could: (1) Verify the enrollee's eligibility for LTSS and/or behavioral health services under Medicaid; (2) determine how the enrollee receives such services (through FFS Medicaid or through another Medicaid managed care product); or (3) make arrangements with the applicable Medicaid program (state Medicaid agency or managed care plan) for the provision of such services by the appropriate payer or provider. We solicited comment on whether our proposed definition should be more prescriptive in identifying which plan activities constitute coordination or whether it should remain broadly defined as proposed.

We proposed revising the definition of fully integrated dual eligible special needs plan (FIDE SNP) at § 422.2 to align with the proposed definition of a D–SNP and to codify current policy. Specifically, we proposed the following:

- Striking the reference to a ''CMS approved MA–PD'' plan in the current FIDE SNP definition and paragraph (1), which refers to the individuals eligible for enrollment in a FIDE SNP, because those provisions duplicate elements of the new proposed definition of a D–SNP at § 422.2;
- Replacing the reference to ''dual eligible beneficiaries'' with ''dual eligible individuals'' in newly redesignated paragraph (1) to align with the terminology used in section 1935(c) of the Act;
- Adding to newly redesignated paragraph (2) that a FIDE SNP's capitated contract with a state Medicaid agency may include specified behavioral health services, as well as replacing the term ''long-term care'' benefits with ''long-term services and supports'' to better describe the range of such services FIDE SNPs cover in capitated contracts with states. We also proposed codifying in paragraph (2) the current policy that the FIDE SNP's capitated contract with the state provide coverage of nursing facility services for at least 180 days during the plan year; [14]
- Striking references to coordination of covered Medicare and Medicaid ''health and long-term care'' and referring more broadly to Medicare and Medicaid services in in newly redesignated paragraph (3); and
- Replacing the reference to ''member'' materials with ''beneficiary communication materials,'' consistent with the definition of ''communication materials'' at § 422.2260.

We proposed to codify a definition of highly integrated dual eligible special needs plan (HIDE SNP) at § 422.2. Under the proposed definition, a HIDE SNP would be a type of D–SNP offered by an MA organization that has—or whose parent organization or another entity that is owned and controlled by its parent organization has—a capitated contract with the Medicaid agency in the state in which the D–SNP operates that includes coverage of LTSS, behavioral health services, or both, consistent with state policy. We solicited comment on this proposed definition, including on whether additional requirements for HIDE SNPs should be addressed in the definition.

We also proposed to establish at § 422.2 a definition for the term aligned enrollment, as many of the other D–SNP proposals in the proposed rule were based on this concept. Under our proposal, aligned enrollment is when a full-benefit dual eligible individual is a member of a D–SNP and receives coverage of Medicaid benefits from the D–SNP or from a Medicaid managed care organization, as defined in section 1903(m) of the Act, that is: (1) The same organization as the MA organization offering the D–SNP; (2) its parent organization; or (3) another entity that is owned and controlled by the D–SNP's parent organization. Aligned enrollment, as we proposed to define it, would not arise where the MA organization or its parent organization solely has a contract with the applicable state to offer a prepaid inpatient health plan (PIHP) or prepaid ambulatory health plan (PAHP) in the state's Medicaid program. Unlike a Medicaid MCO, these other Medicaid managed care plans cover only a specific and non-comprehensive set of services. In the event that it is the policy of the state Medicaid agency to limit a D–SNP's membership to individuals with aligned enrollment, we proposed describing this practice as ''exclusively aligned enrollment,'' which was embedded in the proposed definition of ''aligned enrollment.'' As noted in the proposed rule, some states limit D–SNP enrollment to full-benefit dual eligible individuals who also choose to receive Medicaid benefits through the D–SNP or a Medicaid MCO operated by the same entity (that is, by the MA organization) or by the MA organization's parent organization. Such a limitation would be included in the state Medicaid agency contract with the D–SNP. Exclusively aligned enrollment is relevant to how we proposed to apply the integrated grievance and appeals requirements described in section II.A.2.b. of the proposed rule. We solicited comment on our proposed definition of aligned enrollment given its relevance to the category of D–SNPs to which the integrated grievance and appeals procedures apply. We also solicited comment on whether we should consider other types of Medicaid managed care arrangements beyond companion Medicaid MCOs, as defined

[14] Following the April 2, 2012 issuance of the ''Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,'' Chapter 16b of the Medicare Managed Care Manual was revised to include this policy.

in section 1903(m) of the Act and codified at § 438.2, operated by a HIDE SNP's parent organization.

Finally, we proposed in our definition of a D–SNP at § 422.2 to codify that an MA organization seeking to offer a D–SNP must satisfy any one (or more) of the three integration requirements in section 1859(f)(3)(D)(i) of the Act. We noted that the statutory language requires that plans meet one or more statutorily identified integration requirements to the extent permitted under state law. We explained in the proposed rule how we interpreted the integration standard in section 1859(f)(8)(D)(i)(II) of the Act (that the D–SNP be a FIDE SNP or have a capitated contract with the state Medicaid agency to provide LTSS or behavioral health services, or both) to mean that the D–SNP is a FIDE SNP or HIDE SNP; we also explained how we interpreted the integration standard in section 1859(f)(8)(D)(i)(III) of the Act (that clinical and financial responsibility for Medicare and Medicaid benefits for enrollees of the D–SNP be borne by an entity that is both the parent organization of the D–SNP and of the Medicaid managed care organization providing LTSS or behavioral health services under a contract under section 1903(m) of the Act) means that the D–SNP is a HIDE SNP or FIDE SNP with exclusively aligned enrollment. We interpreted the phrase ''to the extent permitted under state law'' as acknowledging and respecting the flexibility provided to states under the Medicaid program while imposing on D–SNPs integration requirements that Congress has deemed necessary. Given this flexibility, we proposed to interpret this statutory provision in a way that provides multiple avenues for a MA plan to qualify as a D–SNP. However, we considered other interpretations of this particular provision. For example, we considered whether ''to the extent permitted under state law'' should mean that in states that have Medicaid managed care programs for dual eligible individuals, all MA organizations seeking to offer a D–SNP could do so only if they were under contract with the state to offer a companion Medicaid managed care plan in that state, on the grounds that such an opportunity is permitted under state law. We solicited comments on our proposed interpretation as well as alternatives. We also requested comment on whether and how our proposed definition could or should be revised consistent with our statutory interpretation.

As discussed in the proposed rule, our intent was for the proposed definitions to describe different types of D–SNPs based on the degree to which they integrate Medicaid benefits at the plan level. Under section 1859(f)(8)(D)(i) of the Act, those D–SNPs that are neither FIDE SNPs nor HIDE SNPs must meet an additional state Medicaid contracting requirement beginning in 2021. Our proposed definition of a D–SNP addressed this in paragraph (1), cross-referencing the new requirement proposed to be codified in paragraph (d) of § 422.107. This proposed new requirement, which involves the provision of notice when an individual who belongs to a group of high-risk dual eligible individuals has a hospital and skilled nursing facility admission, is discussed in section II.A.2.a.(2) of this final rule in greater detail. We solicited comments on this proposal and, in particular, on alternative approaches to classifying D–SNPs consistent with requirements of section 1859(f)(8)(D)(i) of the Act.

We received the following comments on these proposed definitions and respond to them below:

Comment: Many commenters expressed support for CMS' proposed regulatory framework for defining D–SNPs, whereby a D–SNP could satisfy any one or more of three integration requirements: (1) As a D–SNP subject to the hospital and skilled nursing facility admission notification requirement in proposed § 422.107(d); (2) as a HIDE SNP; or (3) as a FIDE SNP. In justifying their support, several of these commenters cited one or more of the following:

- The benefits that accrue to beneficiaries and taxpayers when there is a market that permits an array of D–SNPs to compete with each other, rather than one that limits the types of D–SNPs that can compete in that market;
- The need for state flexibility in promoting integration in a manner that is incremental and minimizes market disruption;
- The importance of preserving a pathway for D–SNPs that do not hold a Medicaid managed care contract in the state or operate in states where no such Medicaid managed care market exists; or
- The opportunity for D–SNPs to make the transition on a gradual basis to greater, and eventually full, integration. Another commenter indicated that this proposal would create a spectrum of integration and give states and plans clear starting points from which to better define their goals and objectives.

Response: We appreciate the commenters' support of our proposal to create multiple pathways for an MA plan to qualify as a D–SNP, which—as discussed later in this preamble—we are finalizing in this final rule.

Comment: Several commenters raised objections to the alternative we discussed in the proposed rule to require, in states that have Medicaid managed care programs for dual eligible individuals, all MA organizations seeking to offer a D–SNP to be under contract as a Medicaid managed care plan. One commenter did not believe that the statute granted CMS authority to implement this restriction, while others noted that it would constrain state decision-making on integration, unnecessarily limit plan choice and reduce competition, lead D–SNPs to cease operating, or create a disincentive for D–SNPs to invest in care models and infrastructure. Another commenter advised that CMS should recognize that integration is contingent on state decision-making and incent the states to move state Medicaid policy toward more integrated models. Conversely, other commenters supported this alternative interpretation and encouraged CMS to reconsider its rejection of it. According to one commenter, without a policy that requires the parent organization of a D–SNP to contract with the state Medicaid agency, a beneficiary in a non-aligned D–SNP has no option other than enrolling in a Medicaid managed care plan operated by another sponsor (or, if permitted, receiving fee-for-service Medicaid services); where there is no alignment of Medicare and Medicaid coverage, the opportunity for effective care coordination is reduced. Commenters also noted the potential of such a policy to promote aligned enrollment and coordinate the full spectrum of needs for this population as well as the greater familiarity with Medicaid of organizations that operate in both Medicare and Medicaid markets in states, which is helpful in assisting beneficiaries.

Response: We appreciate the feedback on this alternative on which we requested comment and acknowledge that without such a policy there may be a missed opportunity to support the integration of Medicare and Medicaid services in states that adopt managed care delivery systems for their dual eligible population. We also recognize the concerns raised by commenters relative to the potential for adverse impacts on beneficiaries. We will take all of these comments into consideration should we decide to address this issue in future rulemaking. However, we are not moving forward with the alternative in this final rule.

Comment: We received significant comment on our proposed D–SNP, HIDE

SNP, and FIDE SNP definitions. Several commenters expressed appreciation for CMS' effort to create regulatory definitions for the different types of D–SNPs that exist in the marketplace today. A commenter supported our proposal under the HIDE SNP definition to permit arrangements in which the MA organization offering the D–SNP or its parent organization has a contract to offer a PIHP or PAHP in the state's Medicaid program. Many commenters expressed appreciation for the ability of D–SNPs to be defined as HIDE SNPs. One commenter noted that the proposed modifications provide far greater clarity for states and D–SNPs and offer the appropriate amount of detail to inform agreements between MAOs and state Medicaid agencies. Another commenter noted that the proposed D–SNP definition is a good first step but that it alone is insufficient, as truly meaningful integration for dual eligible individuals whose enrollment is not aligned requires a whole host of additional requirements and activities in key areas, including, but not limited to, integrated administrative, information technology, communications, reporting, and financial systems; integrated assessment and care coordination processes and data sharing; and integrated transition activities.

Response: We appreciate the support of our proposal, which, as we explained earlier in this preamble, reflects our desire to create a framework in which we are able to distinguish among the types of D–SNPs based on the way they integrate Medicaid services and, as applicable, align enrollment across Medicare and Medicaid, while also accounting for variation in how states cover these Medicaid services.

Comment: Several commenters supported our proposal to interpret the meaning of the statutory language in section 1859(f)(3)(D) of the Act, ''arranging for benefits,'' as requiring a D–SNP to coordinate the delivery of Medicare and Medicaid benefits and to relocate this requirement within our proposed D–SNP definition. One commenter commended CMS for the example of coordination included in the preamble to the proposed rule that interpreted such activities to include verifying dual eligible individuals' eligibility for LTSS or behavioral health services, determining how the individual receives such services, and making arrangements with the LTSS or behavioral health payer for the provision of services. A few commenters supported CMS' example of D–SNPs playing an active role in helping beneficiaries access Medicaid services as necessary.

Response: We thank the commenters for their support of our proposed interpretation and coordination examples.

Comment: One commenter opposed any requirement that D–SNPs extensively coordinate Medicaid benefits, citing the lack of additional compensation or clear expectations, and recommended that CMS instead work with states to address barriers to accessing Medicaid benefits. This commenter opposed any requirement that D–SNPs assist enrollees with such activities as completing paperwork or securing financial, medical, or other documentation needed to access Medicaid benefits or any other benefits not covered by the plan (housing, food stamps, utility assistance), instead recommending that plans undertake these activities at their discretion.

Response: While we agree that reducing barriers to access in Medicaid is important, we believe that for all enrollees who are eligible for Medicaid services, the D–SNP must fulfill its statutory responsibility to arrange for the provision of Medicaid benefits by facilitating a beneficiary's meaningful access to such benefits. As we discussed in the proposed rule, we believe it would be insufficient for a D–SNP to limit its coordination activity simply to telling a beneficiary to call or write their Medicaid managed care plan or state agency without giving specific contact information, giving specific coaching on the roles of the Medicaid program (that is, the state agency or Medicaid managed care plan versus the D–SNP), and offering additional support if needed. As discussed in section II.A.2.b.(1) of this final rule, we believe that an important aspect of D–SNPs' statutory responsibilities includes providing assistance to dual eligible individuals with Medicaid-related coverage issues and grievances. We also note that our proposed coordination requirement in the definition of a D–SNP is specific to Medicaid benefits and did not extend to some of the services and programs referenced by this commenter.

Comment: One commenter expressed overall support for our inclusion of a coordination requirement in the definition of a D–SNP, but noted that states, unaffiliated Medicaid managed care organizations, and non-contracted providers may present barriers to information-sharing that is necessary to make such coordination work. A few commenters endorsed the development of a system or process for collecting information about D–SNP enrollee Medicaid coverage and enrollment (when enrollment is not aligned) in order to meaningfully implement this provision. One of these commenters recommended that CMS establish a process by which states must provide individual-level data on the D–SNP's enrollees, including the enrollee's Medicaid coverage and plan name (if applicable) and specific contacts within each organization (names, phone numbers, emails, leadership contact information), in order to facilitate this coordination across Medicare and Medicaid.

Response: We appreciate the commenters' concern about access to information about their enrollees' Medicaid coverage. Establishing a standardized system or process such as the one suggested by these commenters is an option for states and CMS to consider. However, as discussed in section II.A.2.b.(1) of this final rule, there are other ways in which plans can endeavor to obtain information or connect enrollees with the appropriate resources to facilitate coordination of their Medicare and Medicaid benefits.

Comment: Several commenters supported the proposed rule's approach of broadly requiring D–SNPs to coordinate the delivery of Medicare and Medicaid benefits without specifying particular types of coordination activities in the regulatory definition of a D–SNP, citing the need for flexibility to accommodate differences in plans and state policies. One commenter appreciated the broad requirement as a way of ensuring that D–SNPs have ownership in coordinating the points where the D–SNP's services end and those provided under Medicaid begin and are not simply acting as an additional layer in the process. However, more commenters requested that CMS be more specific in identifying specific plan activities that constitute coordination, including several commenters who requested additional specificity within the regulation text. One commenter suggested that, without additional specificity in the definition about the types of activities that constitute coordination, plans might misinterpret or misunderstand the requirements. Another commenter anticipated that plans could face barriers in arranging Medicaid benefits for enrollees, especially if such benefits are managed by other health plans, and cited Tennessee's requirements that D–SNPs use the TennCare Online System to coordinate benefits for enrollees who are eligible for Medicaid.

A few commenters requested that CMS incorporate elements of person-centered care as part of the D–SNP care coordination requirements. One of these commenters stated that D–SNPs should

be held accountable for actively coordinating benefits and linking plan members to services (including those services that are not provided by the D–SNP). The other commenter encouraged CMS to emphasize that coordination for D–SNPs with aligned members that require LTSS or behavioral health services includes assessment and care planning processes that are: (1) At a minimum, compliant with the person-centered requirements of sections 1915(c), 1915(i), and 1915(k) of the Act, which were added in two January 16, 2014 final rules (CMS–2249–F and CMS–2296–F),[15] and (2) incorporate the provision of needed LTSS and/or behavioral health either directly or in close coordination with the entity owned or controlled by the D–SNP's parent organization that has contractual responsibility for LTSS and behavioral health benefits. Another commenter stated that in order for coordination to be effective, D–SNP personnel must have sufficient training related to the suite of services available under Medicaid and through the D–SNP and a thorough understanding of how to assist a beneficiary in navigating the delivery system to access services. One commenter recommended that CMS include in the D–SNP definition the following activities: Staffing plans with care coordinators who meet specific criteria; providing comprehensive information about Medicare, Medicaid, and plan benefits through plan materials, customer service, and care coordinators; ensuring that members have a primary care physician and that their providers are actively communicating through models such as interdisciplinary care teams; sharing information about claims, service authorizations, and care plans with the state, providers, beneficiaries, and beneficiaries' appointed representatives; and providing assistance with filing grievances and appeals and comprehensive explanations of the appeals process. Another commenter suggested that further clarification would be helpful around the role of the D–SNP related to transitions of care, the responsibilities of the D–SNP regarding arrangements for follow up care, and coordination with the discharging entity. Another commenter encouraged CMS to work with plans and states to ensure that provisions related to improved care transitions are effective and consequential for individuals with dementia.

Response: We appreciate the comments about additional activities CMS should consider to be essential for D–SNPs in coordinating their members' Medicare and Medicaid benefits. We do not agree at this time with the commenters who recommended including additional detail regarding those coordination activities in our regulatory definition of a D–SNP. Wide variation in the level of integration of Medicaid benefits across D–SNPs, local market conditions, and state initiatives to integrate care for dual eligible individuals leads us to believe that it is not prudent to add specific coordination responsibilities and requirements in this regulatory definition at this time. Further, some of the specific recommendations raise issues related to compliance with privacy rules protecting beneficiary information or other regulations governing D–SNPs (such as mandatory disclosure requirements), which are more appropriately addressed in other regulations. Our goal in this final rule is to establish an explicit requirement of coordination in regulation for the first time since D–SNPs were established in 2006 and to implement a flexible approach to coordination that allows plans to test approaches that best work for them and in their specific state context. We are therefore finalizing a coordination requirement in the definition of a D–SNP.

Comment: A number of commenters requested additional clarification of the role of D–SNPs in coordinating Medicare and Medicaid benefits, including in subregulatory guidance, guiding principles, and additional examples, to inform states and their contracted D–SNPs as they collaborate to identify specific plan activities that might differ by program or type of service. One commenter specifically requested that any list of coordination activities promulgated by CMS be considered a set of minimum requirements. Another commenter suggested that CMS provide a set of standardized approaches or acceptable frameworks that would assist states and plans in developing aligned approaches to this requirement, including best practices for data transfers and tips on overcoming administrative hurdles. Another commenter urged CMS to provide more clarity, citing concerns about burden on providers.

Response: We appreciate the commenters' request for clarification and anticipate issuing subregulatory guidance to further clarify the requirement that D–SNPs coordinate Medicare and Medicaid benefits for the dual eligible individuals enrolled in their plans.

Comment: A commenter suggested that CMS provide ongoing support to states in the implementation of our coordination requirements. Another commenter suggested that CMS consider whether further guidance regarding D–SNP coordination could serve as a means of persuading states to standardize their approaches to the alignment of their Medicaid programs with the MA program. This commenter suggested that CMS could, for example, issue further guidance on how states can work to establish viable health information exchanges as a means of facilitating communication and data exchange between plans and state Medicaid agencies, as such actions could qualify as ''coordinating the delivery of'' these services.

Response: CMS supports states that have an interest in pursuing integrated care models for dual eligible individuals, including through the use of their contracts with MA organizations offering D–SNPs, and provides technical assistance to states seeking to develop solutions tailored to their local market conditions, beneficiary characteristics, and policy environment. We are committed to continuing our work with states based on their specific policy priorities following the implementation of this final rule.

Comment: A few commenters stated that D–SNPs should be held accountable for actively coordinating benefits and linking plan members with services, both when those services are provided by the D–SNP or its affiliate and when they are provided by an unaffiliated third party. One of these commenters suggested that CMS look into the extent to which D–SNPs without Medicaid contracts may primarily serve partial-benefit dual eligible individuals [16] for whom there is no need or opportunity to coordinate Medicaid benefits.

[15] Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community First Choice and Home and Community-Based Services (HCBS) Waivers (79 FR 3029, January 16, 2014). Accessible at: *https://www.govinfo.gov/content/pkg/FR–2014–01–16/pdf/2014–00487.pdf.*

[16] Partial-benefit dual eligible programs are commonly referred to collectively as the ''Medicare Savings Program'' (MSP). The MSP includes 4 eligibility groups: Qualified Medicare Beneficiary Program without other Medicaid (QMB Only) for whom Medicaid pays their Medicare Part A premiums, if any, Medicare Part B premiums, and to the extent consistent with the Medicaid State plan, Medicare Part A and B deductibles, coinsurance and copays for Medicare services provided by Medicare providers; Specified Low-Income Medicare Beneficiary Program without other Medicaid (SLMB Only) and Qualifying Individual (QI) Program for whom Medicaid pays the Part B premiums; Qualified Disabled and Working Individual (QDWI) Program for whom Medicaid pays the Part A premiums.

Response: As we stated in the preamble to the proposed rule, we recognize that not all D–SNP membership will be eligible for the full complement of Medicaid services, particularly those who are partial-benefit dual eligible individuals whose Medicaid eligibility is limited to payment of their Medicare premiums, and, if applicable, deductibles and cost-sharing. Coordination approaches for partial-benefit dual eligible individuals will, of necessity, be different than those for members will full Medicaid benefits. However, for all enrollees who are eligible for Medicaid services, the D–SNP must fulfill its statutory responsibility to arrange for the provision of Medicaid benefits by facilitating a beneficiary's meaningful access to such benefits, regardless of their source or scope of Medicaid coverage. We discuss the issue of D–SNPs assisting their members with Medicaid benefit issues in more detail in section II.a.2.b.(1) of this final rule.

Comment: Several commenters emphasized the need for CMS to monitor D–SNPs' efforts at coordination and gauge their effectiveness.

Response: We agree that CMS oversight and monitoring of D–SNPs' coordination responsibilities are important. As we implement the provisions of this final rule, we will identify ways in which we can leverage current tools, including audits, model of care requirements, and reporting requirements, to ensure that D–SNPs assist dual eligible individuals in connecting with the Medicaid benefits to which they are entitled.

Comment: A few commenters expressed concern about the construction of the proposed D–SNP definition insofar that it could be misread or misinterpreted to require all D–SNPs to provide LTSS and behavioral health services.

Response: We did not intend our proposed definition to impose a new obligation on D–SNPs to provide coverage of Medicaid services. Therefore, we are finalizing the proposed definition of a D–SNP with modifications to the text to clarify this point and otherwise make grammatical and organizational changes to improve the regulation text. Specifically, a D–SNP is a plan offered by an MA organization for dual eligible individuals that, as provided in new paragraph (1), coordinates the delivery of Medicare and Medicaid services for individuals eligible for such Medicaid services; as provided in new paragraph (2), may provide coverage of Medicaid services, including LTSS and behavioral health services (for individuals eligible for such services); as provided in new paragraph (3), has a contract with the state Medicaid agency consistent with the requirements of § 422.107 that meets the minimum requirements detailed in § 422.107(c); and (4) beginning January 1, 2021, satisfies one of the three criteria for integration of Medicare and Medicaid benefits detailed in the proposed rule (and now designated as paragraphs (4)(i) through (iii)). We intend through these revisions to clarify that, regardless of whether a D–SNP provides coverage of Medicaid services under a capitated or other arrangement with the state Medicaid agency, it at minimum must coordinate the enrollee's Medicare and Medicaid services.

As discussed in section II.A.2.a.(2) of this final rule, to better align with our proposed definition of a D–SNP, we proposed a change to § 422.107(c)(1) to specify that the contract between a state Medicaid agency and a D–SNP must document the MA organization's responsibility to provide, as applicable, and coordinate the delivery of Medicaid benefits, including LTSS and behavioral health services, for individuals who are eligible for such services. In response to the concerns raised by these commenters, we are finalizing § 422.107(c)(1) with minor changes that express our intent more clearly and parallel the revisions we are finalizing in the D–SNP definition described earlier. Specifically, we are restructuring paragraph (c)(1) to avoid any misinterpretation that D–SNPs must cover LTSS and behavioral health services. We clarify in paragraph (c)(1)(i) that the D–SNP must document its responsibility to coordinate the delivery of Medicaid services for individuals who are eligible for such services, and in paragraph (c)(1)(ii) that, to the extent a D–SNP provides coverage of Medicaid benefits—including LTSS and behavioral health services (for individuals eligible for such services)—it must also document in the state Medicaid agency contract its responsibility to do so. We believe this revision clarifies that, in some cases, the D–SNP may cover (that is, provide directly or pay health care providers for providing) Medicaid benefits under a capitated contract with the state Medicaid agency; however in all cases it must coordinate the delivery of Medicaid benefits.

Comment: A few commenters were concerned about the introduction of a new term, HIDE SNP, which did not exist in regulations previously. Two of these commenters noted that it is already difficult for consumers and advocates to determine which plans are D–SNPs and what type of D–SNP they are. They noted that clear, consistent regulatory definitions can make important differences between the plan types and beneficiary options more understandable.

Response: While we sympathize with commenters' reluctance to create another regulatory definition, we believe that the definition of HIDE SNP is meaningful, as it correlates directly with our interpretation of the D–SNP integration standard that appears in section 1859(f)(8)(D)(i)(II) of the Act (D–SNPs that enter into a capitated contract with the state Medicaid agency to provide LTSS or behavioral health services, or both). We agree with the commenters that making these terms understandable to stakeholders, especially beneficiaries, is an important aim.

Comment: A commenter recommended that the proposed definition of HIDE SNP be redrafted to allow for risk-sharing arrangements other than capitation. This commenter noted that the state or D–SNP may wish to contract initially on a shared savings/shared risk or performance-based model as opposed to a full capitation model. Another commenter recommended that CMS consider creating another regulatory standard of integration other than a HIDE SNP that would describe D–SNPs that are at risk for a set of Medicaid services other than LTSS or behavioral health services, which can serve as stepping stones to further alignment.

Response: We appreciate that there are varying levels of integration, including, for example, arrangements in which a state Medicaid agency may capitate payment for Medicaid cost-sharing or a subset of services. However, the statute is clear that D–SNPs seeking to meet the integration standard at section 1859(f)(8)(D)(i)(II) of the Act must either be a FIDE SNP or enter into a capitated contract with the state Medicaid agency for the provision of LTSS, behavioral health services, or both. We proposed the definition of HIDE SNP to align with this statutory standard of integration, and therefore we are not making revisions to the HIDE SNP definition based on these specific recommendations. As discussed in the proposed rule (83 FR 54994), a D–SNP could satisfy the requirements of a HIDE SNP if its parent organization offered a companion Medicaid product that covered only LTSS, behavioral health services, or both, under a capitated contract. We believe that this definition is appropriate for purposes of addressing and aligning with the statutory integration standards and for

establishing which D–SNPs are eligible, pursuant to §§ 422.60(g)(2)(i) and 422.102(e), to receive passive enrollments or offer supplemental benefits, respectively.

We may consider for future rulemaking the merits of having a more detailed classification system that identifies variations of D–SNPs other than FIDE SNPs and HIDE SNPs relative to the extent to which they coordinate Medicare and Medicaid benefits. We note that technical assistance resources are available through the Integrated Care Resource Center that provide information about the varied approaches states have taken to coordinate with D–SNPs operating in their states.

Comment: A commenter suggested that CMS consider a HIDE SNP as a temporary model that could be utilized as part of a state's longer term strategy toward integration of Medicaid benefits in which all HIDE SNPs transition to a FIDE SNP model once full integration is achieved.

Response: We are supportive of states and plans that wish to pursue a FIDE SNP model; however, as stated earlier in this preamble, section 1859(f)(8)(D)(i) of the Act recognizes a level of integration that does not meet the requirements of a FIDE SNP with respect to the breadth of services provided under a Medicaid capitated contract with the state (that is, D–SNPs that cover LTSS, behavioral health services, or both, under a capitated contract) as meeting one of the three required integration standards. We therefore believe it is useful to codify a term that encompasses this statutory standard.

Comment: A commenter requested that CMS clarify that enrollment in a HIDE SNP be open to all dual eligible individuals, including those not yet eligible for LTSS and/or behavioral health services, on the grounds that their needs may change over the course a year such that they attain eligibility for these services. According to the commenter, a plan can play a role in helping the individual navigate their options.

Response: The proposed HIDE SNP definition stated that the MA organization offering the D–SNP, or the MA organization's parent organization or another entity that is owned or controlled by its parent organization, must have a capitated contract with the Medicaid agency that includes coverage of LTSS, behavioral health services, or both, consistent with state policy. The HIDE SNP definition, as proposed and finalized in this rule, does not itself require that the plan limit its MA enrollment to dual eligible individuals who qualify for LTSS, behavioral health services, or both. However, it is important to note that these plans are financially responsible under a capitated contract for covering these services for individuals who are eligible for them, and a state Medicaid agency may elect to impose enrollment restrictions on the D–SNP consistent with its contracting authority in § 422.107.

Comment: A commenter observed that the proposed definition of HIDE SNP appears to exclude a plan offered by an organization that subcontracts on a capitated basis with an organization or county agency to which the state Medicaid agency has ''delegated Medicaid financial and administrative responsibility.'' According to the commenter, this type of arrangement is common in California where counties use different Medicaid managed care models and recommended that CMS amend the HIDE SNP definition to encompass such an arrangement. The commenter further noted that while the organization that does not have a direct, capitated contract with the state, even though it is providing LTSS, behavioral health services, or both, under the Medicaid program, it can provide highly integrated benefits and should be considered a HIDE SNP. Relatedly, this commenter recommended that the definition of aligned enrollment be expanded to accommodate this arrangement, noting that aligned enrollment could occur for D–SNP enrollees who receive their Medicaid benefits from the D–SNP's parent organization via this subcontract.

Response: We believe that the commenter is referring to situations where the county or another entity has a contract with the state Medicaid agency to furnish Medicaid benefits to eligible individuals on a risk basis; we disagree that such a contract amounts to a delegation of financial or administrative responsibility for the Medicaid program. A county or entity with a managed care contract with the state Medicaid agency may subsequently subcontract certain aspects of the managed care contract to another entity under § 438.230. In such situations where that subcontractor also is a D–SNP, we recognize that there may be a level of integration for enrollees that is greater than that of a D–SNP that has no contract—directly or indirectly—with a state to provide LTSS, behavioral health services, or both. However, we do not believe that the subcontractor in that situation should be treated as a HIDE SNP. Our proposed definition of a HIDE SNP at § 422.2 requires a contract between the state and the D–SNP, its parent organization, or another subsidiary of its parent organization and is more consistent with the statutory language at section 1859(f)(8)(D)(i)(II) of the Act, which requires that a D–SNP enter into a capitated contract with a state to provide LTSS, behavioral health services, or both. The relationship between a D–SNP and its parent organization (or another plan owned and operated by the same parent organization) is one where we believe it is appropriate to attribute those other contract arrangements to the D–SNP itself for purposes of evaluating integration in the management, provision, and coordination of benefits for enrollees. That statutory provision is the basis for our codification of this definition. We therefore decline the commenter's recommendations that the definitions of a HIDE SNP and aligned enrollment be modified to accommodate this particular contracting arrangement.

Comment: A commenter requested more information about the eligibility for each type of D–SNP for passive enrollment, seamless conversion, and the frailty adjuster. Several commenters inquired about how CMS would designate each type of D–SNP.

Response: We intend to release guidance prior to the effective date of these provisions that explains how D–SNPs will be designated as FIDE SNPs and HIDE SNPs consistent with the terms of this final rule. As noted later in this final rule, we are amending § 422.60(g)(2)(i) to clarify that HIDE SNPs are eligible to receive passive enrollments; this is not a change in policy, per se, but a technical update to use the newly defined term where we previously used different language. Chapter 2 of the Medicare Managed Care Manual provides additional information for MA organizations about passive and default enrollment.[17] Eligibility for the frailty adjustment is governed by section 1853(a)(1)(B)(iv) of the Act and § 422.308(c)(4), which limit the payment adjustment to FIDE SNPs that have a similar average level of frailty, as determined by the Secretary, as the PACE program; the eligibility of plans for the frailty adjustment is not impacted by this rulemaking.

Comment: Commenters were generally supportive of our proposal to account for differences in how states cover Medicaid services, including states' decisions to carve out particular Medicaid services and deliver them through a separate arrangement. However, a number of these

[17] Chapter 2 of the Medicare Managed Care Manual can be accessed here: *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html.*

commenters also urged us to clarify our use of the phrase ''consistent with State policy,'' which appears in the proposed definitions of HIDE SNP and FIDE SNP. In particular, they wanted to understand how this phrase impacts D–SNPs that are seeking to be defined as a HIDE SNP or FIDE SNP and how HIDE SNPs were different from FIDE SNPs in relation to carve-outs. A commenter questioned whether a state's carve-out of LTSS services from its Medicaid managed care program would that mean that no D–SNP in that state can qualify as a FIDE SNP, since FIDE SNPs must cover some element of LTSS. A commenter requested clarification about the obligation of FIDE SNPs to provide comprehensive Medicaid services and whether that same obligation applied to HIDE SNPs, while other commenters requested clarification about whether a D–SNP would still be considered a HIDE SNP if the state were to carve out behavioral health services or offered a limited scope of behavioral health services for dual eligible individuals, assuming all other HIDE SNP requirements were met. Yet another commenter cited its experience using Medicaid benefit carve-outs and the potential for the misalignment of incentives, which may result in inappropriate utilization or gaps in care.

Response: We proposed to interpret the phrase ''consistent with State policy'' as allowing CMS to permit certain carve-outs where consistent with or necessary to accommodate state policy, except for where specifically prohibited (such as the minimum of 180 days of coverage of nursing facility services during the plan year in the FIDE SNP definition). For A FIDE SNP, a carve-out by the state of a minimal scope of services is permissible so long as the applicable services, as described in the FIDE SNP definition, are covered under a Medicaid managed care organization contract under section 1903(m)(2) of the Act. This means that if a state opted to carve out LTSS entirely from capitation, in that state no D–SNP could qualify as a FIDE SNP. Similarly for a HIDE SNP, a carve-out by the state of a minimal scope of services is permissible so long as the applicable services, as described in the HIDE SNP definition, are covered under a capitated Medicaid contract with the D–SNP or the affiliated Medicaid managed care plan. For example, if a state were to carve out certain targeted case management services for full-benefit dual eligible individuals receiving behavioral health services, a D–SNP could still satisfy the FIDE SNP or HIDE SNP definition, provided that: (1) LTSS were covered under the capitated contract; or (2) behavioral health services, other than the carved-out case management, were covered under the capitated contract.

Our intent is to apply the phrase ''consistent with State policy,'' to HIDE SNPs as we have done historically for D–SNPs seeking FIDE SNP status. In the case of FIDE SNPs, our policy for determining whether a D–SNP meets the FIDE SNP definition at 42 CFR 422.2 was first addressed in the April 2, 2012, ''Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter'' and later memorialized in section 20.2.5 of Chapter 16b of the Medicare Managed Care Manual.[18] Under this policy, CMS permits long-term care benefit carve-outs or exclusions only if the plan can demonstrate that it—

- Is At risk for substantially all of the services under the capitated rate;
- Is at risk for nursing facility services for at least six months (180 days) of the plan year;
- Does not disenroll an individual from the plan as a result of exhausting the service covered under the capitated rate; and
- Remains responsible for managing all benefits including any carved-out service benefits, notwithstanding the method of payment (for example, fee-for-service, separate capitated rate) received by the plan (we note that we interpret ''managing all benefits'' to be equivalent to coordinating the delivery of Medicare and Medicaid services, consistent with changes made elsewhere in this final rule, including in the definition of a D–SNP).

Also under this policy, FIDE SNPs are not required to cover behavioral health services in cases where the state decides to carve out or exclude behavioral health services from the capitated rate. We believe that the phrase ''consistent with State policy'' in the FIDE SNP and HIDE SNP definitions serves as an important acknowledgement of variation in how states elect to cover Medicaid services under their capitated contracts with D–SNPs and Medicaid managed care plans. As such, among the states that have capitated contracts with D–SNPs or the D–SNPs' parent organizations, CMS has the ability to determine that D–SNPs operating in such states meet the FIDE SNP or HIDE SNP definition notwithstanding this variation. However, in consideration of the request for clarification, we are making a minor modification to the HIDE SNP and FIDE SNP definitions in § 422.2 to change the placement of the phrase ''consistent with State policy,'' so that it appears prior to the categories of services to which it applies, as opposed to placement after them.

Comment: A commenter recommended that CMS clarify that HIDE SNPs are not required to cover under a capitated contract both LTSS and behavioral health services. Another commenter recommended that CMS remove the requirement that the contract with the state Medicaid agency include coverage of LTSS, behavioral health services, or both, and consider instead the existence of a contract with the Medicaid agency to cover an overlapping or potentially overlapping Medicaid population as the D–SNP, on the basis that such a plan already understands the Medicaid market in which it operates and is well situated to serve as a platform as states move to advance integrated care models for dual eligible individuals.

Response: HIDE SNPs are not required to cover *both* LTSS and behavioral health services but must cover at least one of those categories of services. We are finalizing the HIDE SNP definition at § 422.2 to require that a HIDE SNP cover LTSS, behavioral health services, or both, consistent with state policy. While we recognize that there is a variety of ways in which D–SNPs coordinate with Medicaid agencies, including coverage of Medicare cost-sharing and Medicaid services other than LTSS or behavioral health, we disagree with the comment that HIDE SNP status should be met without coverage of either LTSS or behavioral health services. Our intent in establishing a definition for HIDE SNPs is to describe one of the two types of D–SNPs that satisfies the integration requirement at section 1859(f)(8)(D)(i)(II) of the Act. Under this provision, the integration requirement is satisfied if the D–SNP meets the requirements of a FIDE SNP (other than the requirement that it has a similar level of frailty as the PACE program) or enters into a capitated contract with the state Medicaid agency to provide LTSS or behavioral health services, or both. We note that we are electing to make a non-material change to how we refer to the coverage of LTSS, behavioral health services, or both, in our HIDE SNP definition. We are finalizing the regulation with the phrase ''provides coverage'' instead of ''includes coverage.''

[18] See *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf* and *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c16b.pdf.*

Comment: A commenter urged CMS to work with states that have carve-outs to ensure that states are committed to coordinating carved-out services with D–SNPs. This commenter believed that state carve-outs, although conceptually a barrier to integration, are in some cases well-established and provide quality services. Though longer term integration is a goal, a hurried dismantling of those systems would be unwise and could cause beneficiary harm.

Response: We agree that it is an essential element of any D–SNP to coordinate the delivery of all Medicaid services, irrespective of how they are covered by the state Medicaid agency. Therefore, as discussed elsewhere in this final rule, we have made such coordination a requirement in § 422.2 for any plan that operates as a D–SNP.

Comment: A few commenters requested that CMS clarify the differences between HIDE SNPs and FIDE SNPs, and raised questions about any notable differences in types of contracting arrangements that are permitted (or not) and categories of services that the plan must cover, including the requirement that FIDE SNPs cover behavioral health services.

Response: Conceptually, we proposed to distinguish D–SNPs based on the degree to which they integrate Medicaid benefits at the plan level. FIDE SNPs that limit enrollment to full-benefit dual eligible individuals and require (or have) exclusively aligned enrollment across Medicare and Medicaid constitute the most extensive level of integration, with the greatest potential for holistic and person-centered care coordination, integrated appeals and grievances, comprehensive beneficiary communication materials, and quality improvement. HIDE SNPs with exclusively aligned enrollment are plans that share much of this potential but may integrate a narrower set of Medicaid benefits than FIDE SNPs. FIDE SNPs and HIDE SNPs where aligned enrollment is possible—but not required—under the state contract with the D–SNP and the state's administration of its Medicaid managed care program would constitute another form of integration, albeit to a lesser degree. The table below highlights some of the key differences between HIDE SNPs and FIDE SNPs. First, from a contracting perspective, a FIDE SNP's Medicare and Medicaid benefits are covered under a single legal entity that contracts (1) with CMS to operate as an MA plan; and (2) with the state to operate as a Medicaid MCO. This latter requirement means that the FIDE SNP has a contract under section 1903(m) of the Act to provide a comprehensive set of services. In the case of a HIDE SNP, however, there is no stipulation that a single legal entity must hold the Medicare and Medicaid contracts, only that the parties to the capitated contract are the state Medicaid agency (or state Medicaid agency's contractor) and one of the following: (1) The MA organization itself; (2) the MA organization's parent organization; or (3) another entity that is owned and controlled by the MA organization's parent organization. Additionally, with respect to a HIDE SNP, the entity or entities holding the MA contract and the Medicaid contract may provide coverage of Medicaid services as a PIHP, PAHP, or Medicaid MCO. Second, as noted in an earlier response to a comment, the breadth of coverage provided by FIDE SNPs and HIDE SNPs is different. For example, FIDE SNPs must provide at least 180 days of nursing facility coverage; as reflected in the definitions of the terms in § 438.2, PIHPs and PAHPs cover less comprehensive sets of services than MCOs and are distinguished from each other based on whether inpatient or ambulatory services are covered.

TABLE 1—ATTRIBUTES OF FIDE SNPS AND HIDE SNPS

	FIDE SNP	HIDE SNP
Must have a contract with the state Medicaid agency that meets the requirements of a managed care organization as defined in section 1903(m) of the Social Security Act.	Yes	No.
May provide coverage of Medicaid services via a PIHP or a PAHP.	No	Yes.
Must provide coverage of applicable Medicaid benefits through the same entity that contracts with CMS to operate as an MA plan.	Yes	No. The state Medicaid contract may be with: (1) The MA organization offering the D–SNP; (2) the MA organization's parent organization; or (3) another entity owned and controlled by the MA organization's parent organization.
Must have a capitated contract with the state Medicaid agency to provide coverage of long-term services and supports (LTSS), consistent with state policy.	Yes	No, if it otherwise covers behavioral health services.
Must have a capitated contract with the state Medicaid agency to provide coverage of behavioral health services, consistent with state policy.	No. Complete carve-out of behavioral health coverage by the state Medicaid agency is permitted.	No, if it otherwise covers LTSS.
Must have a capitated contract with the state Medicaid agency to provide coverage of a minimum of 180 days of nursing facility services during the plan year.	Yes	No.

In consideration of these comments, we are electing to make one additional change to our FIDE SNP definition to mirror language that appears in the HIDE SNP definition. Specifically, in paragraph (2) of the FIDE SNP definition, we are finalizing the regulation with the phrase ''provides coverage'' instead of ''includes coverage,'' which will make references to the provision of coverage consistent between the HIDE SNP and FIDE SNP definition.

Comment: A commenter recommended that CMS replace in its definition of FIDE SNP ''aligned'' care management processes with ''fully integrated'' care management processes, with the expectation that either a single person is responsible for coordination of the full continuum of Medicare and Medicaid benefits, or the health plan uses an integrated team approach, with clear lines of communication and

accountability, and with integrated care management data systems that facilitate timely access to information needed to facilitate integrated care management processes.

Response: While we support the approaches to care identified by this commenter, we do not believe that such a change to the FIDE SNP definition is necessary. Our use of the phrase ''aligned care management processes'' in paragraph (3) of the FIDE SNP definition at § 422.2 is intended to encompass the variety of ways in which FIDE SNPs seek to coordinate care for full-benefit dual eligible individuals.

Comment: We received several comments concerning the requirement that FIDE SNPs cover nursing facility services for at least 180 days during the plan year and whether this signified a change in existing FIDE SNP coverage policy or an expansion of the Medicare skilled nursing facility benefit.

Response: As noted in a prior response to a comment, it has been longstanding CMS policy for a FIDE SNP to be at risk for providing coverage of at least 180 days of nursing facility services, and this rulemaking codifies rather than revises or reinterprets this policy. If a state were to carve out institutionally-based LTSS from its capitated contract, it would not be possible for an MA plan to operate as a FIDE SNP in that state, although it may be possible to qualify as a HIDE SNP, assuming all applicable requirements were met. Similarly, if a state were to carve out community-based LTSS from its contract because the state opted to provide coverage of these services under a separate arrangement, it would not be possible for such a plan to qualify as a FIDE SNP because section 1853(a)(1)(B)(iv) of the Act establishes that FIDE SNPs must cover long-term care under a capitated contract with the state for Medicaid benefits. Community-based LTSS are long-term care services and essential to the coverage model offered by a FIDE SNP.

Comment: A few commenters supported our proposed definition of aligned enrollment and its applicability to particular types of plans. MedPAC and another commenter agreed with our proposal to limit the definition of aligned enrollment to Medicaid coverage provided by a comprehensive Medicaid MCO instead of including plans that provide more limited Medicaid services as PIHPs or PAHPs. A few commenters agreed with our proposal to account for not only D–SNPs whose Medicaid benefits are covered by the plan directly but also by a Medicaid MCO operated by the same organization, its parent organization, or another entity that is owned and controlled by its parent organization. One commenter recommended that we explicitly incorporate in the definition the concept from the statute that such plans have clinical and financial responsibility for any individual enrolled in both programs and expressed concern that a parent company could sponsor Medicaid plans and D–SNP products that might be operated quite separately with little or no coordination while still accepting ''clinical and financial responsibility with respect to any individual enrollee.''

Response: We thank commenters for their support of how we defined aligned enrollment. We disagree, however, with the commenter about the necessity of including the phrase ''clinical and financial responsibility for any individual enrolled in both programs'' in the definition of aligned enrollment.

Under our proposed definition, we stated that aligned enrollment refers to full-benefit dual eligible D–SNP enrollees whose Medicaid benefits are covered by that D–SNP or by a Medicaid MCO that is the same organization, its parent organization, or another entity that is owned and controlled by its parent organization. When a full-benefit dual eligible individual is enrolled in aligned plans, one entity (or entities that share a parent organization) provides coverage of Medicare benefits and Medicaid benefits such as LTSS, behavioral health services, or both. By virtue of the provision of coverage under these types of contractual relationships, the relevant entity intrinsically has clinical and financial responsibility for the covered Medicare and Medicaid services provided to enrollees. We believe that explicitly using the phrase ''clinical and financial responsibility for benefits'' in the definition of aligned enrollment might imply otherwise and suggest that a contractual obligation to cover benefits does not mean financial and clinical responsibility for those benefits.

We are finalizing the proposed definition of the term ''aligned enrollment'' with some modifications to clarify this relationship. Rather than referring to the enrollee's Medicaid benefits as being covered by the D–SNP or by a Medicaid MCO, the final regulation text refers to the enrollee's Medicaid benefits as being covered by the D–SNP under a Medicaid MCO contract between the state and: (1) The MA organization offering the D–SNP; (2) the D–SNP's parent organization; or (3) another entity that is owned and controlled by the D–SNP's parent organization. We believe this regulation text change clarifies the meaning and adequately addresses that financial and clinical responsibility for the enrollees is held by the MA organization or its parent organization.

Comment: One commenter, while supportive of how we intended to incorporate exclusively aligned enrollment relative to unifying Medicare and Medicaid grievance and appeal procedures, encouraged us to consider developing additional incentives and tools for states and plans to move toward increased alignment. This commenter expressed interest in the creation of a combination of rewards, incentives, new tools, and pathways to facilitate improvement in enrollment alignment, which is not a pervasive practice among states.

Response: The commenter's point is well taken. We intend to exercise the administrative authority we have under current law to support states that wish to pursue this particular integrated care strategy and will consider the necessity of future rulemaking consistent with our programmatic authority. We will also continue to make technical assistance resources available to states through the Integrated Care Resource Center.

Comment: A commenter expressed concern that the definition of exclusively aligned enrollment may limit state flexibility insofar that it would be difficult for one-hundred percent of a D–SNP's membership to be aligned. According to the commenter, a D–SNP that failed to meet this threshold wouldn't be able to benefit from unified appeals and grievance processes. This commenter would be opposed to a policy of having to disenroll members anytime misalignment occurred. Another commenter requested that CMS confirm that HIDE SNPs and exclusively aligned HIDE SNPs are different types of plans.

Response: We clarify that through this rulemaking, the concept of exclusively aligned enrollment is only relevant to how we define an applicable integrated plan, which must unify its Medicare and Medicaid grievance and appeals procedures consistent with rules described in §§ 422.629 through 422.634. Unifying grievance and appeals procedures is most feasible when everyone in the plan is receiving Medicare and Medicaid services from the same organization (or through a companion product offered by the parent organization or through a common ownership relationship with the parent organization). In the absence of aligned enrollment, D–SNP enrollees may be enrolled in and receiving coverage from two or more plans simultaneously, complicating

coordination of care and the beneficiary experience. For FIDE SNPs and HIDE SNPs, this situation of receiving coverage from two or more plans may be true for only some enrollees. Even if this lack of alignment exists for some and not all of the D–SNP's enrollees, there would be at least two (if not more) sets of grievance and appeals rules applying to the D–SNP's members. State Medicaid agencies have the ability to take other steps to integrate grievance and appeals procedures through their contracts with D–SNPs. We welcome the opportunity to partner with states in developing and implementing these strategies.

Comment: MedPAC advised that aligned enrollment should be a requirement for D–SNPs that provide significant Medicaid services and meet both the second and third integration standards at sections 1859(f)(8)(D)(i)(II) and (III) of the Act, respectively, where our proposal only contemplated applying a requirement of exclusively aligned enrollment to the third integration standard (where the parent organization of the enrollee's D–SNP is also the parent organization of the enrollee's Medicaid MCO). MedPAC further stated that the second integration standard in the statute should apply to plans where states have capitated Medicaid contracts directly with D–SNPs and the D–SNPs provide Medicaid services, and the third standard should apply to situations where states have capitated Medicaid contracts with another legal entity (a Medicaid managed care plan) that is part of the same parent organization as the D–SNP.

Response: We agree with MedPAC insofar that alignment of Medicare and Medicaid coverage, which occurs when a full-benefit dual eligible individual is receiving Medicare and all or substantially all Medicaid services from one organization, constitutes the most extensive level of integration. As we noted in the preamble of the proposed rule, this arrangement offers the greatest potential for holistic and person-centered care coordination, integrated appeals and grievances, comprehensive beneficiary communication materials, and quality improvement. However, we remain concerned about imposing such a requirement at this time, as states that have contracts with Medicaid MCOs and D–SNPs currently have the authority to require aligned enrollment but for policy or other reasons, do not impose one. Finally, we believe that the most salient differentiator between the second and third integration standards at sections 1859(f)(8)(D)(i)(II) and (III) of the Act is exclusively enrolled alignment, rather than whether the state contract is with the D–SNP directly or a related entity. We are therefore not adopting this recommendation.

Comment: A commenter recommended that CMS codify the third integration requirement, which appears in section 1859(f)(8)(D)(i)(III) of the Act, and stipulates that a D–SNP's parent organization assumes clinical and financial responsibility for the provision of Medicare and Medicaid benefits. While this commenter was supportive of our interpretation that such clinical and financial responsibility was only possible in FIDE SNPs and HIDE SNPs where there was exclusively aligned enrollment, the commenter was concerned that our interpretation only existed in preamble and not the regulation text itself.

Response: As noted by the commenter, in the proposed rule, we did not explicitly cite or summarize the integration requirement at section 1859(f)(8)(D)(i)(III) of the Act in our definition of a D–SNP. Instead, we interpreted the statutory language on assuming clinical and financial responsibility for benefits to mean that an entity can only truly hold ''clinical and financial responsibility'' for the provision of Medicare and Medicaid benefits, as described at section 1859(f)(8)(D)(i)(III) of the Act, in the scenarios of exclusively aligned enrollment. Therefore, the D–SNPs that meet this integration standard would be FIDE SNPs and HIDE SNPs that have exclusively aligned enrollment. As implemented in our definitions, section 1859(f)(8)(D)(i)(II) of the Act also establishes being a FIDE SNP or a HIDE SNP as a means to satisfy the new, minimum integration requirements for D–SNPs. We believe that our proposed definitions and requirements are clearer without adding the statutory terminology from section 1859(f)(8)(D)(i)(III) of the Act. As we interpreted the statute and proposed the new rules, any plan that meets the requirement for clinical and financial responsibility for the provision of Medicare and Medicaid benefits would already meet the second integration requirement because it would be a FIDE SNP or HIDE SNP. As discussed in section II.A.2.b.(2) of this final rule, the combination of terms that we proposed is relevant to how we define an applicable integrated plan that must unify grievance and appeals procedures for Medicare and Medicaid services. Therefore, we believe that adding the statutory terminology would complicate the definitions and requirements relative to any benefits.

After considering the comments we received, we are finalizing the provisions related to D–SNP definitions as proposed with the following modifications:

- In the definition of aligned enrollment at § 422.2, we are finalizing the regulatory text with some modifications to clarify our intended meaning regarding financial and clinical responsibility for enrollees. The final regulation text refers to the enrollee's Medicaid benefits as being covered by the D–SNP under a Medicaid MCO contract between the state and: (1) The MA organization offering the D–SNP; (2) the D–SNP's parent organization or (3) another entity that is owned and controlled by the D–SNP's parent organization.
- In the definition of a D–SNP at § 422.2, we are finalizing the substance of our proposed definition with modifications that are primarily organizational. In the final regulation text, we are inserting ''title'' prior to ''XIX of the Act,'' which was inadvertently excluded in the proposed rule. We are also using a new paragraph (1) to clarify that a D–SNP coordinates the delivery of Medicare and Medicaid services for individuals eligible for such Medicaid services, and a new paragraph (2) to clarify that a D–SNP may provide coverage of Medicaid services, including LTSS and behavioral health services. The requirement that a D–SNP have a contract with the state Medicaid agency consistent with the requirements of § 422.107 and that meets the minimum requirements detailed in § 422.107(c) is now contained in new paragraph (3), and the requirement that the D–SNP satisfy, beginning January 1, 2021, one of the three criteria for integration of Medicare and Medicaid benefits detailed in the proposed rule is now contained in new paragraph (4), with the specific integration requirements redesignated as paragraphs (4)(i) through (iii)).
- In paragraph (2) of the definition of a FIDE SNP at § 422.2, we are finalizing the definition with a change in the placement of the phrase ''consistent with State policy'' so that it modifies the verb phrase ''provides coverage'' and appears prior to the categories of services to which it applies. Also in paragraph (2), we are using ''provides'' in place of ''includes'' prior to the phrase ''coverage, consistent with State policy.''
- In the definition of a HIDE SNP at § 422.2, we are finalizing the proposal with non-substantive modifications. First, we are changing the placement of the phrase ''consistent with State policy'' so that it modifies the verb

phrase ''provides coverage'' and appears prior to the categories of services to which it applies. Second, we are reorganizing the text to use new paragraphs (1) and (2) to identify the options for the capitated contract to provide Medicaid services. A HIDE SNP's capitated contract to cover LTSS, behavioral services, or both, must be between: (1) The MA organization and the Medicaid agency; or (2) the MA organization's parent organization (or another entity that is owned and controlled by its parent organization) and the Medicaid agency. Third, we are using ''provides'' in place of ''includes'' prior to the phrase, ''consistent with State policy, of long-term services and supports, behavioral health services, or both. . .''

(2) Dual Eligible Special Needs Plans and Contracts With States (§ 422.107)

We proposed changes in § 422.107 to more clearly articulate the requirements of the contract between the D–SNP and the state Medicaid agency, while also incorporating the changes required by the Bipartisan Budget Act of 2018. In summary, we proposed to make the following specific changes:

- Delete language in paragraph (b) that is extraneous and duplicative of the proposed definition of a D–SNP in § 422.2;
- Make clarifying edits in paragraphs (c)(1) through (c)(3), which govern the minimum requirements of the contract between the D–SNP and the state Medicaid agency;
- Redesignate paragraph (d) as paragraph (e), which relates to compliance dates; and
- Establish a revised paragraph (d) that describes the new minimum contracting requirement under the Bipartisan Budget Act of 2018 that the newly designated paragraph (e)(2) would make effective January 1, 2021.

Section 50311(b) of the Bipartisan Budget Act of 2018 amended section 1859(f) of the Act by creating a new paragraph (8)(D)(i)(I) to require that the Secretary establish additional requirements for D–SNPs' contracts with state Medicaid agencies. In the proposed rule preamble, we discussed how this provision requires a D–SNP to have a state Medicaid agency contract that includes additional coordination requirements (subsection (f)(8)(D)(i)(I) of the Act); be a FIDE SNP or HIDE SNP (subsection (f)(8)(D)(i)(II) of the Act); or have exclusively aligned enrollment and have its parent organization accept full clinical and financial responsibility for all Medicare and Medicaid covered services (subsection (f)(8)(D)(i)(III) of the Act), depending on the state's election.

We proposed to implement subsection (f)(8)(D)(i)(I) of the Act by establishing at § 422.107(d) that any D–SNP that is not a FIDE SNP or HIDE SNP is subject to an additional contracting requirement. Under this proposed new contract requirement, the D–SNP would be required to notify the state Medicaid agency, or individuals or entities designated by the state Medicaid agency, of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the state Medicaid agency. We clarified in the proposed rule that this proposal would also permit the D–SNP to authorize another entity or entities (such as a D–SNP's network providers) to notify the state Medicaid agency and/or individuals or entities designated by the state Medicaid agency on its behalf, with the understanding that the D–SNP ultimately would retain responsibility for complying with this requirement. We direct readers to the proposed rule, 83 FR 54996, for a more detailed explanation of our intent and rationale for this approach.

As discussed in the proposed rule, we believe that our proposal to establish a notification requirement for D–SNPs for high-risk individuals' hospital and SNF admissions is consistent with the criteria we used to evaluate various options for the minimum contracting requirements. We considered whether a proposal would:

- Meaningfully improve care coordination and care transitions, thereby improving health outcomes for dual eligible individuals;
- Minimize burden on plans and states relative to the improvements in care coordination and transitions;
- Provide flexibility to state Medicaid agencies;
- Enable CMS to assess compliance with minimal burden on CMS, plans, and providers; and
- Be consistent with the statutory amendments made by the Bipartisan Budget Act of 2018.

We solicited comment on whether our proposal satisfied these criteria to a greater extent than the more prescriptive or alternative proposals we described in the proposed rule;[19] whether our reasoning for why our proposal was preferable to the more prescriptive or alternative proposals was sound; whether there were other minimum contacting requirements that we did not consider that were superior to our proposal; and whether our proposal provided sufficient incentives for plans and states to pursue greater levels of integration. Specifically, we considered and sought comment on the following alternatives:

- Proposing that notice requirements apply for all full-benefit dual eligible individuals' hospital and SNF admissions.
- Proposing a minimum size for the state-selected high-risk population.
- Requiring a notification for every emergency department visit, as mentioned in section 1859(f)(8)(D)(i)(I) of the Act.
- Proposing that the notification occur not later than 48 hours after the D–SNP learns of the admission or discharge.
- Requiring each D–SNP to take affirmative steps to schedule its individual health risk assessments at the same time as similar outreach is conducted by the Medicaid managed care plan, to use a combined or aligned assessment instrument, or take other steps that would minimize the burden on enrollees or providers. As we noted in the proposed rule, we continue to hear of scenarios where a D–SNP enrollee is assessed separately by the D–SNP and then again by their Medicaid MCO, even though there may be a high degree of overlap in what each organization is assessing and ultimately what each organization is requesting of the enrollee. We solicited comment on how pervasive this issue is and the extent of overlap in the assessment instruments and degree of burden on providers and beneficiaries, including a specific request for feedback on the extent to which the requirements that we proposed do not accomplish enough or should be modified to address this issue.
- Requiring D–SNPs to identify any enrollees who are in need of LTSS and behavioral health services and transmitting such information to the state Medicaid agency.
- Requiring D–SNPs to train plan staff and their network providers on the availability of LTSS and behavioral health services covered by Medicaid.
- Requiring D–SNPs to solicit state input on the plan's model of care (which is currently required and submitted to CMS pursuant to § 422.101(f)), health risk assessment instrument, and beneficiary communication materials. We sought comment regarding state burden and on compelling reasons why additional contracting requirements in this area may be necessary.
- The merits of requiring D–SNPs to share data with state Medicaid agencies or entities designated by state Medicaid

[19] We direct readers to the proposed rule, 83 FR 54997–98, for a more detailed discussion of these alternatives.

agencies that would benefit the coordination of Medicare and Medicaid items and services, as described in section 1859(f)(8)(D)(i)(I) of the Act as an example for implementing that provision. We solicited comment on whether there should be additional regulatory requirements around data sharing.

We requested feedback on our notification proposal at § 422.107(d), including the ways that state Medicaid agencies and plans would fulfill this requirement, and the additional contracting requirements we considered in the proposed rule preamble.

In addition to the new requirement for contracts between the state and MA organization at proposed § 422.107(d) for D–SNPs that are not FIDE SNPs or HIDE SNPs, we proposed to include additional specifications in the regulations governing D–SNP contracts with state Medicaid agencies at § 422.107 by amending paragraph (b) and several provisions in paragraph (c). As stated in the preamble to the proposed rule, we do not believe that these specifications materially alter these agreements; however, we proposed them in response to questions raised since the state Medicaid agency contracting requirements were promulgated in the September 2008 interim final rule (73 FR 54226). We also believed that these changes aligned with the integration requirements for D–SNPs in the Bipartisan Budget Act of 2018.

We proposed modifying the general rule for contracts with D–SNPs at § 422.107(b) to strike ''The MA organization retains responsibility under the contract for providing benefits, or arranging for benefits to be provided, for individuals entitled to receive medical assistance under Title XIX. Such benefits may include long-term care services consistent with State policy, . . .'' As discussed in the proposed rule, we believed this proposed change would be consistent with the coordination requirements in our proposed definition at § 422.2 of ''D–SNP.''

We proposed to revise the contracting requirement at § 422.107(c)(1), which currently requires the contract to document the MA organization's responsibility, including financial obligations, to provide or arrange for Medicaid benefits, to specify instead that the contract must document the MA organization's responsibility to provide, as applicable, and coordinate the delivery of Medicaid benefits, including LTSS and behavioral health services, for individuals who are eligible for such services. We solicited comment on whether our proposed amendments to this section fully communicated what we intend to require of D–SNPs or whether there were additional revisions we ought to consider to express our intent more clearly for D–SNPs, state Medicaid agencies, and other stakeholders.

In § 422.107(c)(2), we proposed to revise the current requirement that the contract between the D–SNP and the state Medicaid agency document the categories of dual eligible individuals who are eligible to enroll in the D–SNP. We proposed to revise this requirement to specify not only the categories of eligibility but also any additional criteria of eligibility to account for such conditions of eligibility under Medicaid as nursing home level of care and age. We clarified that these criteria could also include a requirement for D–SNP enrollees to enroll in a companion Medicaid plan to receive their Medicaid services.

Finally, at § 422.107(c)(3), we proposed that the contract between the D–SNP and the state Medicaid agency document the Medicaid services the D–SNP is responsible for covering in accordance with a capitated contract with the D–SNP directly or through a risk contract, defined at § 438.2, with the companion Medicaid managed care organization operated by the D–SNP's parent organization. As discussed in the proposed rule, we believe this proposed change would reduce burden on D–SNPs and would enable us to identify the particular Medicaid services that are covered under a capitated contract for FIDE SNPs and HIDE SNPs but would not limit or contravene other requirements for D–SNPs to approach their obligations to coordinate the delivery of all Medicare and Medicaid benefits. We sought comment on whether the regulatory change fully communicates what we wish to require.

We received the following comments on these proposed definitions:

Comment: We received a number of comments in support of our proposal to establish a notification requirement for any D–SNP that is not a FIDE SNP or HIDE SNP. One commenter believed the proposed requirement is consistent with the intent and language of the Bipartisan Budget Act of 2018. Several commenters supported the flexibility to allow state Medicaid agencies to build on notification processes already in place. A commenter noted that minimum contract requirements are more practical to implement than more prescriptive requirements due to variation in state capabilities and current data-sharing methods. Another commenter appreciated the flexibility states have to implement the requirement based on their needs and readiness. Another commenter believed that the notification requirement will facilitate care transitions for dual eligible individuals in instances where they are not enrolled in an aligned D–SNP and provides a framework upon which states can advance Medicare and Medicaid benefit integration in the future.

Response: We thank commenters for their support of our proposed notification requirement. We agree that the requirement is consistent with the statutory amendments made by the Bipartisan Budget Act of 2018. We intend for this notification requirement to be a catalyst for increasing care coordination during transitions of care, while minimizing plan and state burden and preserving state flexibility to develop solutions that build upon current integration efforts.

Comment: Several commenters supported our proposed notification requirement but believed that it represents a transitional step and that our integration efforts should be scaled up over time, with one commenter requesting that CMS establish timelines and benchmarks for states and plans. One commenter believed that the new statutory amendments to the Act made by the Bipartisan Budget Act of 2018 not only permit, but require, the notification requirement to be scaled up over time. A few commenters recommended that the notification requirement be broadened to include more enrollees.

Response: As we discussed in the proposed rule, our intent in establishing this notification requirement is for states and D–SNPs to begin on the path toward greater integration on a smaller scale. Not every state is similarly positioned to move towards greater integration. We note that, as processes and infrastructure mature, a state Medicaid agency may choose through its contracts with D–SNPs to scale up this notification to include additional subpopulations of full-benefit dual eligible individuals. As we gain experience with implementing the integration requirements in this final rule, we will evaluate whether further rulemaking is necessary to build on the notification requirement.

Comment: Some commenters expressed concern that CMS's proposed notification requirement will not meet the goal of promoting greater integration of Medicare and Medicaid benefits, creates unnecessary burden, or may not be the most appropriate requirement in all states. MedPAC noted that states are currently able to require D–SNPs to provide this information through their state Medicaid agency contracts, but

since few states do, states were unlikely to use this information to improve care coordination. Several commenters believed that many states may lack the capability to implement the contracting requirement and use the data in a meaningful way. Several commenters expressed concern that the requirement was too burdensome for states and would discourage states from pursuing or continuing to contract with D–SNPs. A few commenters noted that notifications of hospital or SNF admissions may not be the most useful or best way to incentivize coordinated transitions of care in every state and emphasized that states are in the best position to determine what requirements best fit their delivery system. One commenter noted that limiting the notification requirement to only one group of high-risk full-benefit dual eligible individuals would not meaningfully advance coordination efforts. Another commenter believed that the proposed requirement does not ensure both the state and D–SNP will be engaged in discharge planning in a way that ensures timely access to the most appropriate and cost effective benefits. One commenter expressed a belief that this requirement puts the state in the middle of communication between the D–SNP and enrollee's care team. Another commenter questioned whether states would utilize the information provided in the notifications. Several commenters also questioned what would happen to D–SNPs if a state was not interested in participating in the notification requirement.

Response: These commenters raise important points about our proposed notification requirement. However, we believe the requirement strikes an appropriate balance among incentivizing further integration for states and D–SNPs, limiting the administrative burdens for states and MA organizations, and ensuring flexibility in implementation to fit the needs of each state's policy environment. In addition to the notification requirement, we note that—as discussed in sections II.A.2.a.(1) and II.A.2.b.(1) of this final rule—we are also establishing through this rulemaking an explicit requirement at § 422.2 that D–SNPs coordinate dual eligible individuals' Medicare and Medicaid benefits, as well as a requirement that D–SNPs provide assistance with Medicaid appeals and grievances at § 422.562(a)(5). In implementing the statute by establishing the notification requirement, we incentivize not only D–SNPs, but also the states with which they must contract, to make incremental progress in coordinating care for dual eligible individuals. By design, the notification requirement gives the state Medicaid agency broad latitude to establish notification procedures and protocols that are within the state's capacity and consistent with the state's needs and integration goals. We believe this requirement is scalable for D–SNPs and states where no coordination activity is currently taking place. We also point to the flexibility within the notification requirement for the state to designate another individual or entity to receive the notification, therefore allowing for the timeliest action following a care transition or other significant event.

Comment: Several commenters supported the flexibility in the proposed notification requirement for the state to designate other individuals or entities to receive notification of an admission. These commenters believed that collection of this information at the state level may not be the most appropriate or useful approach. One commenter noted that Tennessee's approach, which requires D–SNPs to notify a Medicaid provider of hospitalizations and emergency department visits, better achieves the goal of improved coordination of services than a notification to the state. Another commenter requested that CMS modify the notification proposal by requiring that the beneficiary's unaligned Medicaid MCO also be notified of any admissions for beneficiaries that receive LTSS or behavioral health services.

Response: We appreciate the commenters' support for the flexibility afforded to states to designate other individuals or entities to receive notification of an admission in our proposal. We agree that in some markets, providers and other entities, such as a Medicaid MCO, may be better able to use admissions information to timely coordinate care for a beneficiary. We do not agree that CMS should finalize the regulation to require D–SNPs to notify MCOs specifically of inpatient admissions, however, but note that such delegation is already permissible under § 422.107(d). We defer to states to establish when and to whom the notification is appropriate to best achieve integration and improve outcomes for dual eligible individuals, based on how the state operates its Medicaid program.

Comment: Several commenters expressed concern that our proposed language allowing a D–SNP to authorize another entity or entities, such as the D–SNP's network providers, to notify the state Medicaid agency of inpatient admissions would create significant burden for providers. However, one commenter also acknowledged that notifications would be timelier if originated by providers. One commenter recommended removing this language from the regulatory text, while a few other commenters recommended that CMS provide guidance and provider education about the requirement. Another commenter noted that states and D–SNPs are dependent on prompt and complete claims submissions from hospitals and SNFs to achieve better care coordination and emphasized the importance of provider education about these requirements to ensure the flow of this information.

Response: In our proposed notification requirement, we provided flexibility to allow for transmission of information about hospital and SNF admissions in multiple ways because we believe the most efficient and effective processes may vary by state and evolve over time. In some cases, this might include reporting by providers and providing information to specific providers to aid in care coordination. However, our proposed requirement places the ultimate responsibility on D–SNPs and does not directly require actions by providers. When developing notification processes to meet our regulatory requirements, we expect that states and D–SNPs will consider any potential impacts on providers.

Comment: Several commenters requested that CMS provide states with technical assistance and disseminate best practices related to the notification requirement both to facilitate the contracting process and to ensure that a sufficient degree of coordination is achieved to promote successful transitions of care. These commenters' requests particularly focused on the need to develop data exchange technology, systems, and processes to achieve successful transitions of care. One commenter recommended CMS provide states with parameters for implementing the state contracting requirements to mitigate operational burden on D–SNPs while supporting implementation. Another commenter recommended CMS seek assistance from a group of plan and state stakeholders in developing this guidance and best practice models.

Response: We agree with these commenters that support for states will improve the implementation of the requirements of this final rule. As stated earlier in this final rule, the Medicare-Medicaid Coordination Office provides technical assistance to states on integration issues, including through the Integrated Care Resource Center (see

https://www.integratedcareresourcecenter.com/). We are committed to continuing our work with states to gather and disseminate best practice information and to engage stakeholders to ensure a successful implementation.

Comment: Several commenters requested that CMS establish clear guidelines and standardized formats for the proposed notification requirement, including methods, content, and timeframes for notification. One commenter requested clarification with respect to how high-risk populations should be defined. Another commenter recommended requiring that states include functional ability in their definitions of high-risk populations. A few commenters expressed concern that variation in how this requirement is implemented across states will be costly and time consuming, leading to potential problems in implementing the requirement effectively. Some commenters expressed interest in uniform requirements in order to reduce administrative burden for plans that operate in multiple states. One commenter noted that standardization of data exchange will contribute to the value of the data for benchmarking and quality improvement activities.

Response: As discussed earlier in this preamble, we intend that the proposed notification requirement provide states with discretion to develop solutions consistent with their particular policy and operational environments. We believe that a more prescriptive notification requirement would ultimately be counterproductive for both states and D–SNPs by limiting the development of solutions appropriate to each market. Regardless of the approach a state chooses to take under this final rule, our aim is to have actionable information that enables providers and payers to facilitate seamless care transitions for high-risk populations, that is, those full-benefit dual eligible individuals who are most likely to benefit from effective interventions (such as through the provision of LTSS and behavioral health services) that enable them to live independently in the setting of their choice and in a way that values their own needs and preferences. As we gain more experience with the implementation of the notification requirement in this final rule, we will share best practices and continue to provide technical assistance and guidance to states and D–SNPs.

Comment: Several commenters requested that CMS do more to establish a data-sharing system to facilitate the proposed notification requirement, citing limited ability for some states to implement data sharing mechanisms. Some commenters noted that a unified system to share data should be used by states, D–SNPs, providers, and beneficiaries. One commenter expressed support for the proposed notification requirement serving as a starting point for a robust two-way health information exchange system between D–SNPs and states to share data on dual eligible individuals' utilization of Medicare and Medicaid services. Another commenter recommended that CMS encourage states to build on current data collection and sharing efforts, such as health information exchanges (HIEs). Some commenters recommended specific data exchange solutions, such as building on the Blue Button 2.0 Framework or modifying the Transformed Medicaid Statistical Information System (T–MSIS).

Response: We believe it is most appropriate at this time to defer to state Medicaid agencies on the manner in which notification occurs and how data be exchanged. For example, in markets where there is existing infrastructure to leverage, such as a state HIE, a state may elect an approach that requires data sharing across a common platform using industry standards, including those adopted by the Office of the National Coordinator for Health IT in accordance with 45 CFR part 170, subpart B. Regardless of process, we expect that notifications occur timely in order to ensure prompt care coordination and effective care transitions. To that end, we encourage states and D–SNPs to use the most efficient notification mechanisms available, which may include the state's HIE. However, we appreciate that not every state is similarly positioned, and, therefore, if a state elected to implement this requirement on a smaller scale, targeting a small subset of high-risk beneficiaries, a solution that does not initially require automation may be more appropriate and pragmatic. We reiterate that the notification requirement we are finalizing in this rule is a first step towards improved data exchange and integration. As health information technology advances and industry standards for data exchange are established, it may be feasible to establish or leverage a standardized data-sharing system.

Comment: One commenter requested direction on how to implement the proposed notification requirement in states like Washington where high-risk dual eligible individuals are enrolled in a health home under demonstration authority.

Response: As noted previously, our final requirement at § 422.107(d) provides broad latitude to each state to determine the subset of high-risk D–SNP enrollees subject to the notification requirement. The regulation, as proposed and finalized, requires that the enrollees for which the notification must be made must be at least one group of full-benefit dual eligible and high-risk. The state is not required to specify all high-risk dual eligible individuals for this group so long as the identification of the group is consistent with the regulation's requirements.

Comment: Several commenters questioned the impact the proposed notification requirement will have on notification systems and the robust reporting requirements already in place in several states. One commenter noted that the proposed requirement would duplicate the software program currently used by Washington in which hospitals enter admissions and emergency department visit information for other providers and case managers to view. Another commenter expressed concern that the language requiring a D–SNP to notify or authorize another entity to notify a state agency may not accommodate the current Oregon Health Information Technology System, which creates a notification of admission without the D–SNP's action. This commenter recommended changing our proposed regulatory language to ensure this type of notification system meets our notification requirement such that D–SNPs would not be required to repeat a duplicate notification.

Response: We appreciate that states have different and evolving infrastructure and policies, including mandatory data sharing requirements. The notification requirement we are finalizing in this rule is not intended to impact such existing requirements, and states may continue to require additional notifications or other data sharing consistent with their state Medicaid agency contracts. We thank the commenters that raised specific operational scenarios where HIEs or other notification systems are currently in place and could be leveraged for purposes of satisfying our notification requirement. In this final rule, we are modifying the verbs used to describe the D–SNP's obligations in § 422.107(d) to clarify those responsibilities; as finalized, the D–SNP notifies or arranges for another entity to notify (instead of ''will notify or authorize another entity'' as proposed) the state Medicaid agency of hospital and SNF admissions for at least one group of high-risk full-benefit dual eligible individuals, as identified by the state Medicaid agency. We believe the phrase ''arrange for'' provides more flexibility to encompass arrangements such as those described by

the commenters. Thus, for example, a D–SNP could meet the notification requirement by arranging for another entity—for example, a hospital—to notify the state Medicaid agency or its designee when the various parties participate in an HIE or other notification system.

Comment: Several commenters raised concerns about D–SNPs' ability to fully comply with our proposed revision to § 422.107(c)(1), which codifies a requirement for D–SNPs to document their responsibility to coordinate the delivery of Medicaid benefits for their enrollees, as well as our proposed notification requirement at 422.107(d), citing potential barriers imposed by the Health Insurance Portability and Accountability Act of 1996 and 42 CFR part 2, with respect to sharing information that would allow D–SNPs to effectively coordinate and share information about behavioral health services. One commenter cited 42 CFR part 2 as preventing covered entities from effectively coordinating behavioral health services when the need for such services involves substance abuse treatment and the D–SNP cannot obtain member consent, and urged CMS to consider ways to address this issue and allow for coordinating and sharing of data without the need for written consent. Another commenter suggested that CMS work with the Office for Civil Rights and the Substance Abuse and Mental Health Services Administration on this issue.

Response: These commenters have raised important issues with respect to care coordination for individuals with substance use disorder. This final rule does not change or eliminate current requirements for D–SNPs to comply with HIPAA and 42 CFR part 2. We clarify that the requirements finalized in this rule, including the requirement codified at § 422.2 that a D–SNP coordinate Medicare and Medicaid benefits and the requirement at § 422.107(d) requiring notification of high-risk enrollee inpatient and SNF admissions, must be implemented in a way that complies with all applicable laws. As a result, we acknowledge there are limitations to D–SNPs' ability to notify states of certain inpatient admissions for high-risk enrollees with substance use disorder, as well as to their ability to coordinate these individuals' care, absent member consent for the disclosure of such information. When establishing the notification requirement in the state Medicaid agency contract, we encourage states to collaborate with D–SNPs to identify and address concerns regarding compliance with other statutes and regulations, including HIPAA and 42 CFR part 2.

Comment: Some commenters requested additional requirements for state Medicaid agency contracts between states and D–SNPs. One commenter stated that the proposed contracting requirements at § 422.107 would better meet CMS's stated goals if they were more prescriptive. Several commenters recommended additional contracting requirements to those in the proposed rule, while one commenter requested that CMS refrain from adding more contract requirements until after the implementation of the notification requirement finalized in this rulemaking. Some commenters recommended that CMS require states and D–SNPs to develop a process for coordinating Medicaid-funded services, such as LTSS and behavioral health services. One commenter recommended requiring D–SNPs to annually submit a plan for coordinating Medicaid LTSS and behavioral health services for approval by the state. A few commenters suggested requiring improved information sharing regarding Medicaid provider participation and enrollees' Medicaid and Medicare eligibility. One commenter noted that additional contracting requirements may ease administrative burdens and promote further integration and recommended that CMS clearly define minimum coordination requirements and establish uniform language and definitions.

Response: We appreciate the suggestions for modifications or additions to the state Medicaid agency contract requirements for D–SNPs currently codified at § 422.107. We are not finalizing any additional substantive changes to § 422.107 in this final rule beyond those discussed in our proposed rule. However, we will continue to evaluate D–SNPs' progress toward achieving a minimum level of integration as intended under the Bipartisan Budget Act of 2018 to determine whether additional contracting requirements might be necessary in the future. As discussed in various places in this final rule, states retain the ability to add more stringent contracting requirements in their state Medicaid agency contracts with D–SNPs in order to best achieve their specific policy goals and meet the needs of their population of dual eligible individuals.

Comments: Several commenters recommended that CMS consider new incentives that would enhance integration, such as an increase to the Federal Medical Assistance Percentage (FMAP) rate for activities related to Medicare-Medicaid integration, including for investments in state data-sharing systems and infrastructure. One commenter noted that requiring or incentivizing states to assist D–SNPs in the development of such administrative processes to assist with integration efforts would prevent states from shifting this responsibility to D–SNPs.

Response: We agree that state investments in additional data-sharing or other administrative processes may facilitate D–SNP efforts to implement the notification requirement, but also more broadly to better coordinate Medicare and Medicaid coverage. As discussed in the Collection of Information section of this final rule, we estimate that half of the cost of developing infrastructure and processes to implement the proposed notification requirement would be offset by federal financial participation for Medicaid administrative activities. However, increases to FMAP rates are beyond the scope of this rulemaking.

Comment: A few commenters supported the alternative we noted for consideration that would apply the notification requirement to all full-benefit dual eligible individuals enrolled in the D–SNP, and not just a subgroup of high-risk individuals. These commenters cited improved access to Medicaid benefits that promote care in the least restrictive environment as the reason to support the broader requirement. Another commenter requested that we establish a minimum size for the state-selected high-risk population, another alternative CMS noted for consideration in the proposed rule. This commenter noted that factors such as minimum population size impact the feasibility of implementation of this provision and would mitigate operational burden for health plans.

Response: We appreciate the commenters' requests for a broader notification requirement, but we believe that limiting the notification requirement to high-risk individuals in this final rule is preferable. Research suggests that targeting high-risk individuals is critically important to cost-effective interventions.[20] In addition, all states have some care management infrastructure for high-risk individuals in their Medicaid programs, such as through Medicaid 1915(c) HCBS waivers.[21] The notification provision at

[20] Brown, R.S., Peikes, D., Peterson, G., Schore, J. & Razafindrakoto, C.M., (2012). ''Six Features of Medicare Coordinated Care Demonstration Programs That Cut Hospital Admissions of High-risk Patients.'' *Health Affairs,* 31(6).

[21] *See: https://www.medicaid.gov/medicaid/ltss/health-homes/index.html; https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/index.html;* and *Care*

§ 422.107(d) gives state Medicaid agencies the discretion to decide which group of beneficiaries is at high risk and how large or small the group(s) may be. Providing states with such flexibility to define their population of high-risk individuals will allow them to tailor the D–SNP notification requirement to align with existing infrastructure for coordinating and managing care for high-risk individuals. Such targeting will not only limit notifications to those which are most meaningful and actionable for the state, but will also reduce administrative burden and implementation costs.

Comment: One commenter encouraged CMS to require D–SNPs to provide notification of emergency department visits for unaligned D–SNP enrollees receiving LTSS and behavioral health services from fee-for-service Medicaid or an MCO.

Response: We acknowledge the potential benefits of a real-time notification of emergency department visits, but we decline to finalize a broader requirement including notification of emergency department visits at this time. We believe the greatest opportunity to target interventions and improve outcomes is after a hospital or SNF admission where there is more time to initiate discharge planning. However, as noted in the proposed rule, so long as the requirements of § 422.107(d) are met, a state Medicaid agency could choose to require a notification for full-benefit dual eligible individuals enrolled in a D–SNP who are high utilizers of emergency departments, where there may be opportunities to address barriers to accessing primary care and unmet health care needs.

Comment: One commenter recommended that CMS improve person-centered decision making during care transitions by using protocols for communication and coordination similar to interdisciplinary team models or California's guidance for MMPs on hospital discharge planning.

Response: We appreciate the commenter's suggestion and will consider this input as we develop technical assistance and identify best practices following the implementation of this final rule.

Comment: One commenter expressed support for state flexibility in determining the timeline for the notification, while several commenters expressed concerns about the lack of a specific timeliness requirement. Several commenters requested that CMS require a specific timeframe for reporting. A few commenters believed that the 48-hour requirement discussed in our proposed rule preamble as an alternative for consideration was reasonable and synchronized well with requirements for discharge notices. One commenter suggested that CMS ensure that any timeframes imposed by states begin after the health plan has received the admissions data. A few commenters expressed concern that the notifications would not be timely and therefore would not be helpful in care coordination. One commenter requested that CMS clarify its intent for requiring states to collect this admissions information.

Response: We appreciate comments on the timing and timeliness of the notification requirement. We believe that states may choose to use the notification for a variety of purposes, including coordination of care at the point of hospital or SNF discharge. When establishing a timeframe, we encourage the states to consider the current process for how D–SNPs in their markets receive admissions information to reduce burden on D–SNPs and their provider networks. Because these processes vary by state, we are not inclined to specify timing requirements for these notifications at this time. However, we may consider a timeliness standard in future rulemaking based on our experience implementing the provisions of this final rule.

Comment: Several commenters expressed support for the alternative we noted for consideration in the proposed rule that would establish requirements for coordination of individual health needs or risk assessments between D–SNPs and Medicaid MCOs. These commenters generally recommended that CMS encourage, but not require, D–SNPs to make every effort to coordinate the assessment due to concerns about feasibility. A few commenters noted that coordination could result in delays in administering the assessment. One commenter noted that guidelines for the coordination of assessments would be more appropriate in subregulatory guidance or state contracts, rather than as a regulatory requirement. Another commenter requested that CMS consider requiring D–SNPs to share assessment findings with coordinating plans. One commenter noted this could be an area for future integrated requirements for exclusively aligned plans.

Response: We agree with commenters' concerns regarding the feasibility of coordinating individual health needs or risk assessments. We believe the pervasiveness of this issue and the extent of overlap in assessment instruments varies across state lines and requires further study. We are therefore declining to add this requirement to D–SNP state Medicaid agency contract requirements at § 422.107 at this time.

Comment: One commenter supported requiring that D–SNPs identify and notify states of enrollees in need of LTSS or behavioral health services to promote care coordination and improve outcomes.

Response: We thank the commenter. Although we considered this alternative in the proposed rule, we note that D–SNPs are already required, at § 422.101(f), to develop individualized care plans and perform health risk assessments that identify the physical, psychosocial, and functional needs of each SNP enrollee. Additionally, D–SNPs have the responsibility to coordinate the delivery of Medicare and Medicaid services consistent with the D–SNP definition at § 422.2 finalized in this rule. We do not believe the burden associated with an additional requirement to proactively identify for the state enrollees in need of LTSS or behavioral health services is advisable given the potential overlap with these existing requirements. We are therefore not modifying our proposed notification requirement to include notification of enrollees in need of LTSS or behavioral health services.

Comment: A few commenters supported the alternative CMS considered in the proposed rule that states provide input on the plan's model of care, health risk assessment instrument, and beneficiary communication materials. One commenter noted this requirement would ensure that states stay active in their role as health insurance regulators and that beneficiary materials have correct state-specific information.

Response: We thank commenters for their input, but we remain disinclined to impose such a requirement on D–SNPs that do not have exclusively aligned enrollment. We believe this requirement would create additional burden for states without capitated arrangements with D–SNPs for the provision of Medicaid services, as Medicaid agencies may not see a role for themselves in reviewing such documents. We note that state Medicaid agencies can choose to require that a D–SNP provide such documents for state input through their contracts with D–SNPs, and that—as discussed earlier in this preamble—CMS has worked with several states with integrated D–SNPs to develop more streamlined and

Coordination in Managed Long-Term Services and Supports (2015, July), prepared for AARP by Truven Health Analytics. Retrieved from: *https://www.aarp.org/content/dam/aarp/ppi/2015/care-coordination-in-managed-long-term-services-and-supports-report.pdf.*

integrated beneficiary communications materials.

Comment: A few commenters supported additional or alternative data-sharing requirements for D–SNPs to comply with the statutory requirements for integration. One commenter requested that CMS provide any existing analysis on whether the notification of an admission to a hospital or SNF is more beneficial than sharing other information, such as enrollment information and care coordination contacts.

Response: While there may be additional or different requirements that would facilitate D–SNPs' integration of Medicare and Medicaid benefits, we are choosing to initially focus on a notification requirement for hospital and SNF admissions, which we believe will lead to more immediate improvements in the care transition process, while preserving state and plan flexibility and minimizing burden. After we gain sufficient experience in implementing the notification requirement we are finalizing in this rule, we will assess whether changes are necessary to achieve additional integration.

Comment: A few commenters supported inclusion of a requirement, consistent with the example included in section 1859(f)(8)(D)(i)(I) of the Act that a D–SNP demonstrate its integration of Medicare and Medicaid benefits by assigning one primary care provider for each enrollee. One commenter requested clarification as to why this specific requirement was not included in the proposed rule, noting that the primary care provider is the coordinator of the beneficiary's entire spectrum of care and a critical liaison between the beneficiary and the plan.

Response: We agree with the commenter's statement about the importance of a primary care provider, but we decline to require D–SNPs to assign a primary care provider for each enrollee as a minimum standard for integration. We considered the value of such a requirement but were unable to determine how meaningfully it would advance integration. We also note that, consistent with § 422.112(a)(2), all MA organizations offering an MA coordinated care plan, including those offering D–SNPs, must establish a panel from which an enrollee may select a primary care provider and are permitted to assign a primary care provider in limited circumstances. We are concerned that establishing a primary care provider assignment requirement may conflict with enrollee choice provisions at § 422.112(a)(2).

Comment: One commenter supported a requirement that D–SNPs submit to the state Medicaid agency the name and contact information for their designated care coordinators.

Response: We appreciate this suggestion but decline to make this change to our regulatory requirements at this time due to the burden on D–SNPs provide and update this information and on states to meaningfully use this information. We will consider this suggestion for future rulemaking.

Comment: One commenter recommend that CMS establish data reporting requirements that address integrated care and incorporate LTSS, such as requiring reporting of quarterly care coordination and LTSS referral data.

Response: We thank the commenter and will consider this suggestion for future rulemaking.

Comment: One commenter requested clarification on whether CMS intended for the notification requirement to include discharges as well as admissions.

Response: We chose to focus on notification of admissions to allow states to initiate care coordination activities prior to discharge. Our proposal deliberately did not address discharges due to concerns that care coordination activities would not be timely if they begin after a discharge takes place. However, we note that states are not precluded from adding a notification requirement for discharges through the state Medicaid agency contracts with D–SNPs under § 422.107.

Comment: One commenter recommended that CMS stop new enrollment into D–SNPs that are not contracted by the state to provide Medicaid benefits, and that CMS also require these D–SNPs to establish meaningful and timely data exchange and coordination processes with the state or MCOs for existing beneficiaries to ensure timely access to Medicaid benefits.

Response: We believe that the commenter's recommendation goes beyond section 1859(f)(8)(D)(i)(I) of the Act, which envisions a pathway for D–SNPs to remain an option in states that do not pursue a selective contracting model, subject to additional integration requirements established by CMS in this final rule. We will, however, continue to assess opportunities to promote greater levels of aligned enrollment. We note that states may establish additional requirements for data exchange and coordination in their state Medicaid agency contracts with D–SNPs.

Comment: A few commenters requested exceptions to the notification requirement. One commenter requested clarifications on possible exemptions for some non-integrated D–SNPs. Another commenter recommended that D–SNPs providing some Medicaid services, but not providing LTSS or behavioral health services, be recognized as more integrated than plans that do not provide any Medicaid services and therefore be allowed additional flexibility on the data elements D–SNPs are required to share with the state.

Response: Section 1859(f)(8)(D)(i)(I) of the Act is clear that D–SNPs that do not (i) meet the requirements of a FIDE SNP nor (ii) enter into a capitated contract with the state Medicaid agency to provide LTSS, behavioral health services, or both, must meet additional criteria for integration; CMS is establishing those criteria in this final rule. We are therefore unable to exempt D–SNPs that do not meet the definitions of either a FIDE SNP or a HIDE SNP established in this final rule from the notification requirement. We will consider the utility of establishing additional granularity with respect to D–SNP integration levels but note that such additional granularity is not relevant to D–SNPs' compliance with the statutory provisions regarding D–SNP integration.

Comment: One commenter requested that CMS extend the proposed D–SNP notification requirements to FIDE SNPs and HIDE SNPs when the affected member is not receiving all Medicaid services through the SNP.

Response: We appreciate the commenter's suggestion to hold FIDE SNPs and HIDE SNPs to the same standard as other D–SNPs required to comply with the notification requirement for their unaligned members. However, we believe that most FIDE SNPs and HIDE SNPs already demonstrate a level of Medicare-Medicaid integration through the provision of Medicaid benefits through a capitated arrangement with the state Medicaid agency, such that exchanging admission data about specified high-risk dual eligible enrollees would have less impact relative to the costs of compliance. We decline to accept the commenter's recommendation, as we believe it would be burdensome for plans that already provide a higher level of integration than plans that provide few or no Medicaid benefits to their enrollees. As discussed in section II.A.2.a.(1) of this preamble, we note that FIDE SNPs and HIDE SNPs are also required to coordinate their coverage with their members' Medicaid benefits.

Comment: Several commenters supported our proposal at § 422.107(c)(2) that the contract between

the D–SNP and the state Medicaid agency document not only the categories of dual eligible individuals who may enroll in the D–SNP but also any additional criteria of eligibility.

Response: We appreciate the commenters' support and are finalizing this provision without modification.

Comment: Several commenters supported our proposed change to § 422.107(c)(3) that would require the contract between the D–SNP and the state Medicaid agency to document the Medicaid services the D–SNP is responsible for covering in accordance with a capitated contract with the D–SNP either directly or through a companion Medicaid managed care organization operated by the D–SNP's parent organization. One of these commenters specifically noted that the revised contract requirement may help CMS achieve greater consistency in determining whether a D–SNP is a FIDE SNP or a HIDE SNP. A few commenters recommended that the D–SNP's state Medicaid agency contract also include a list of all Medicaid covered services, but specifically identify those covered by the D–SNP. One commenter recommended that in cases where the state Medicaid agency contract encompasses all the requirements in § 422.107 as amended and already clearly distinguishes between plan covered and non-covered Medicaid benefits, a separate document duplicating this information should not be required. Another commenter requested clarification regarding the intent of this provision, citing concerns that CMS' intent could be misconstrued as requiring D–SNPs to offer Medicaid benefits under a capitated contract with the state.

Response: We thank commenters for their support of this revised contracting requirement for D–SNPs. We decline to accept the recommendation that the state Medicaid agency contract also include a list of all Medicaid-covered services, including those not covered by the D–SNP or an affiliated MCO. We believe this change to the current contracting requirement will reduce burden on D–SNPs to identify and document in the contract every Medicaid-covered service. D–SNPs often submit to CMS a list of all Medicaid services in their state Medicaid agency contracts, even those for which the D–SNP is not under a capitated contract and for which the D–SNP bears no risk. We clarify that our modified requirement does not impact current processes for state Medicaid agency contract submission and approval. We also clarify that this provision in no way precludes a D–SNP that does not provide any Medicaid services—and otherwise meets all relevant regulatory requirements—from continuing to contract with CMS to operate as a D–SNP. We are also simplifying the language at § 422.107(c)(3) to ensure all potential variations of D–SNP contracting arrangements to cover Medicaid services are documented in the state Medicaid agency contract. Specifically, we are revising the requirement such that the D–SNP must document any Medicaid benefits covered by the MA organization offering the D–SNP, whether under a capitated contract with the state Medicaid agency, by the D–SNP's parent organization, or by another entity that is owned and controlled by its parent organization.

After consideration of the comments we received, we are finalizing our proposed amendments to § 422.107(b) as proposed. We are finalizing our proposed amendments to § 422.107(c)(1), (c)(2), (c)(3), (d) and (e)(2) substantively as proposed but with some minor modifications from the proposal.

- We are making a technical, non-substantive change to replace the term ''dual-eligible'' with the term ''dual eligible'' in paragraph (a), which is consistent with the revision to the section heading for § 422.107 in the proposed and final rules.
- As discussed in section II.A.2.a.(1) of this final rule, to better align with our final definition of a D–SNP, we are finalizing the regulation with a new paragraph (c)(1)(i) to clarify that the D–SNP must document its responsibility to coordinate the delivery of Medicaid benefits for individuals who are eligible for such services, and a new paragraph (c)(1)(ii) to clarify that, to the extent a D–SNP provides coverage of Medicaid benefits—including LTSS and behavioral health services—for individuals eligible for such services, it must also document in the state Medicaid agency contract its responsibility to do so.
- As proposed with minor grammatical corrections, we are finalizing paragraph (c)(2) to require the contract to document the categories and criteria for eligibility for dual eligible individuals to be enrolled under the SNP, including as described in sections 1902(a), 1902(f), 1902(p) and 1905 of the Act.
- We are finalizing paragraph (c)(3) with revisions to clarify the requirement of the contract such that the D–SNP must document any Medicaid benefits covered under a capitated contract between the state Medicaid agency and either: (1) The MA organization offering the D–SNP; (2) the D–SNP's parent organization; or (3) the another entity that is owned and controlled by the D–SNP's parent organization.

In addition, as discussed in section II.A.2.b.(2) of this final rule, we are finalizing new text in a new paragraph (c)(9) to address the requirement under section 1859(f)(8)(C) of the Act that contracts between D–SNPs that are applicable integrated plans, defined in § 422.561, and the state Medicaid agency require the use of unified grievance and appeals procedures.

- We are finalizing paragraph (d) with modifications to the regulatory text clarifying the responsibility of a D–SNP with the phrase ''the SNP notifies or arranges for another entity or entities to notify . . .'' in place of the proposed text ''the SNP will notify or authorize for another entity or entities to notify . . .'' and making edits to clarify that states can require D–SNPs to send notification of an admission to the state, individuals or entities designated by the state, or both.
- Lastly, we are finalizing paragraph (e)(2) as proposed and with a citation to paragraph (c)(9) as well as paragraph (d) to clarify that this state Medicaid agency contracting requirement is applicable beginning January 1, 2021.

(3) Conforming and Technical Changes (§§ 422.60(g), 422.102(e), 422.107(b), and 422.111(b)(2)(iii))

In the proposed rule, we also proposed to make the following conforming changes to several sections of Part 422 that address D–SNPs by adopting consistent terminology with respect to dual eligible individuals and creating cross-references to the newly proposed definitions.

- First, at § 422.60(g), which addresses CMS authority to implement passive enrollment, we proposed to use the term ''highly integrated dual eligible special needs plan'' in place of text referring to D–SNPs that meet a high level of integration, consistent with our proposed definition in § 422.2. As discussed in the proposed rule, this technical change would not materially change the plan types that are eligible for passive enrollment; the existing rule simply refers to them as D–SNPs that meet a high standard of integration under the supplemental benefits authority at § 422.102(e).
- Second, we proposed clarifying at § 422.102(e) that not only HIDE SNPs meeting minimum quality and performance standards are eligible to offer supplemental benefits, but FIDE SNPs that similarly meet minimum quality and performance standards may do so as well.

• Third, in the general rule at § 422.107(b), we proposed to substitute a ''special needs plan serving beneficiaries eligible for both Medicare and Medicaid (dual-eligible)'' with ''dual eligible special needs plan.''

• Finally, at § 422.111(b)(2)(iii), which requires D–SNPs to provide written information to dual eligible enrollees about their eligibility for cost-sharing protections and Medicaid benefits, we proposed to use the term ''dual eligible special needs plan'' consistent with the proposed definition.

We received the following comments and our responses follow.

Comment: One commenter noted their appreciation of our proposed clarification at § 422.102(e) that both FIDE SNPs and HIDE SNPs meeting minimum quality and performance standards are eligible to offer supplemental benefits. Another commenter requested that we clarify that current flexibilities with respect to supplemental benefits will continue for all FIDE SNPs and HIDE SNPs. Several commenters requested that CMS provide additional guidance about the supplemental benefits HIDE SNPs and FIDE SNPs may offer, noting recent regulatory changes that provide flexibility in the Medicare Advantage uniformity requirements and expand the definition of ''primarily health related'' benefits, as well as new requirements in the Bipartisan Budget Act of 2018 that provide additional benefit flexibility for chronically ill enrollees.

Response: We appreciate the commenters' support for the technical change we proposed at § 422.102(e), and we clarify that this conforming change does not impact current policy related to supplemental benefits for HIDE SNPs and FIDE SNPs. While we appreciate the complexities of recent legislative and regulatory changes related to permissible Medicare Advantage supplemental benefits and the need for clear guidance that several commenters raised, those comments are outside the scope of this regulation. For more information regarding newly expanded supplemental benefit offerings and flexibilities for all MA plan types, please refer to the CY 2019 and CY 2020 Call Letters.[22] We are therefore finalizing our changes to § 422.102(e) as proposed.

After consideration of the comments we received, we are finalizing § 422.102(e) without modification. We received no comments on our proposed conforming changes to § 422.60(g), the general rule at § 422.107(b), and § 422.111(b)(2)(iii) and are also finalizing those provisions without modification.

(4) Eligibility of Partial-Benefit Dual Eligible Individuals for Dual Eligible Special Needs Plans

The preamble to our proposed rule included discussion about an alternative we considered to propose limits on the enrollment of partial-benefit dual eligible individuals in D–SNPs, since there are no Medicaid services that the D–SNP is integrating or coordinating on their behalf. While we ultimately decided against proposing any such limits on enrollment in the proposed rule, we invited comments on this topic. We received the following comments, and our responses follow.

Comment: Several commenters suggested that CMS establish prohibitions on the enrollment of partial-benefit dual eligible individuals in D–SNPs. A few commenters suggested establishing separate D–SNPs exclusively for partial-benefit dual eligible individuals whose primary focus would not be on integrating Medicare and Medicaid benefits but rather on caring for a more complex population than a traditional MA plan.

MedPAC opined that D–SNPs can do little to promote greater integration for partial-benefit dual eligible individuals and noted that, based on their analysis of person-level quality data from HEDIS, D–SNPs perform about the same as regular MA plans for this population. MedPAC noted the greater likelihood of D–SNPs offering supplemental benefits attractive to partial-benefit dual eligible individuals than other MA plans. Consistent with its June 2018 report to the Congress and at its November 2018 meeting, the Commission described two potential ways of pursuing greater levels of integration: (1) Limiting enrollment in D–SNPs to dual eligible individuals who qualify for full Medicaid benefits or (2) requiring MA plan sponsors to have separate D–SNPs (distinct plan benefit packages) for full-benefit and partial-benefit dual eligible individuals.

A number of commenters opposed any limits on the enrollment of partial-benefit dual eligible individuals in D–SNPs, however. These commenters cited various rationales for the value of these beneficiaries' enrollment in D–SNPs, including the relative medical complexity of partial-benefit dual eligible individuals compared to non-dual eligible individuals; the value of the D–SNP care model, including additional care coordination, Medicare benefits, navigation assistance, individual health risk assessments, care plans, and interdisciplinary care teams; the propensity for churn between various dual eligibility categories and the value of D–SNPs in facilitating movement to full benefit dual eligibility status; and the potential for additional value for this population through new supplemental benefits flexibilities implemented by CMS that might prevent the need for medical spend-down to full benefit dual eligibility status. Several commenters recommended that CMS defer to states on defining eligibility requirements for D–SNPs. Another commenter noted that Congress did not explicitly instruct CMS to prevent partial-benefit dual eligible individuals from accessing D–SNPs. One commenter noted the variance in eligibility requirements for partial-benefit dual eligibility across states. One commenter recommended that CMS consider administrative changes to resolve the complexities related to integration presented by this population—for example for member materials and appeals and grievances.

A few commenters requested that, to the extent CMS continues to permit the enrollment of partial-benefit dual eligible individuals in D–SNPs, D–SNPs should be required to show how they will meet the needs of these enrollees a way that is distinct from the benefits that a non-D–SNP MA plan would offer, and that CMS measure and evaluate these additional benefits. These commenters also recommended that CMS place marketing restrictions on D–SNPs so they cannot primarily target partial-benefit dual eligible individuals, who may have lower acuity and less significant health care needs than full-benefit dual eligible individuals, and to carefully monitor enrollment patterns.

Response: We thank the commenters for the feedback on this issue. As we stated in the proposed rule, we continue to question the benefit that partial-benefit dual eligible individuals derive from their enrollment in a D–SNP relative to the challenges associated with allowing such enrollment. Although we did not propose, and therefore are not finalizing, any changes to how partial-benefit dual eligible individuals may enroll in D–SNPs, we share many of the concerns articulated by some comments, including those of MedPAC. CMS may consider future rulemaking in this area.

Comment: A commenter pointed to the definition of a D–SNP in the statute as limiting enrollment to only those ''special needs individuals who are entitled to medical assistance under a State plan under XIX of the Act'' and requested confirmation from CMS that we discontinue enrollment of partial-

[22] See *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

benefit dual eligible individuals in D–SNPs when there is no Medicaid benefit they can coordinate for those enrollees.

Response: We note that neither the MA statute nor current MA regulations prohibit the enrollment of partial-benefit dual eligible individuals in D–SNPs, although states may choose to do so through their contracts with D–SNPs. We are not finalizing any change in that policy in this final rule.

Comment: A commenter recommended that CMS consider granting eligibility for Qualified Medicare Beneficiaries to enroll in MA-only D–SNPs and requested that reimbursement rates for such enrollees be structured to accurately reflect the resources needed to adequately provide care to such complex populations.

Response: We note that these comments are somewhat outside the scope of our proposed rule. Further, D–SNPs must provide Part D prescription drug coverage, pursuant to § 422.2, as part of a comprehensive Medicare benefit package; therefore, D–SNPs may not offer MA-only coverage. In response to concerns about the accuracy of the CMS-Hierarchical Condition Category (HCC) risk adjustment model for predicting costs of dual eligible individuals, CMS analyzed how well the model performs for various types of beneficiaries. As a result of this analysis, CMS implemented significant changes to the HCC model in CY 2017.

(5) Suspension of Enrollment for Non-Compliance with D–SNP Integration Standards (§ 422.752)

Section 50311(b) of the Bipartisan Budget Act of 2018 amended section 1859(f) of the Act by creating a new paragraph (8)(D)(ii) to permit the Secretary, for plan years 2021 through 2025, to impose an intermediate sanction of stopping all new enrollment into a D–SNP if the Secretary determines that the D–SNP is failing to comply with the integration requirements set forth in section 1859(f)(8)(D)(i) of the Act. We proposed to amend § 422.752 by adding a new paragraph (d) to require CMS to impose an enrollment suspension when CMS finds that the plan is non-compliant with the integration requirements during plan years 2021 through 2025, rather than initiating outright termination. We stressed in the proposed rule that we interpreted this proposal as leaving discretion for CMS, if the D–SNP does not submit an acceptable corrective action plan or fails to abide by the correction action plan, to determine that contract termination or other enforcement action or sanction could also be imposed. In addition, in the event that any harm to enrollees is imminent, we explained how we would retain authority to immediately terminate the contract. We also proposed in § 422.752(d) that the suspension of enrollment would continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. We stated that the procedures, remedies, and appeal rights available to plans subject to intermediate sanctions provided in § 422.756 apply to D–SNPs that are sanctioned under this new authority.

Comment: Several commenters supported CMS' interpretation of the statute to impose an intermediate sanction to suspend enrollment instead of an immediate contract termination for D–SNPs that fail to meet the integration standards by contract year 2021. A few commenters requested that CMS consider not penalizing D–SNPs when state decisions impede integration or the state does not have the interest and capacity to facilitate D–SNP compliance with the integration requirements. Some commenters recommended that CMS evaluate the implementation of these sanctions in order to make recommendations on how CMS should sanction D–SNPs that do not meet the integration standards beyond 2025. Another commenter provided recommendations, summarized elsewhere in final rule, on how CMS can support and incentivize states to move toward integration.

One commenter agreed with CMS' position that non-compliance with the integration standards should not lead directly to contract termination but noted that the enrollment sanction is at the discretion of CMS. The commenter recommended that CMS not immediately impose an enrollment sanction for minor compliance issues around the integration requirements and, rather, only impose an enrollment sanction for non-compliance that is a serious threat to the health and safety of Medicare beneficiaries and let lesser violations be handled through other compliance actions (notices of non-compliance, corrective action plans, and civil monetary penalties).

Response: We appreciate the overall support for our proposal to require CMS to impose an enrollment suspension when we find a D–SNP to be out of compliance with the integration requirements in the final rule during plan years 2021 through 2025. We disagree with the commenter urging us adopt a standard for imposing an intermediate sanction based only on whether a D–SNP's integration approach is a serious threat to the health and safety of its enrollees. As we discussed in the preamble to the proposed rule, by establishing statutory requirements that established a minimum level of integration of D–SNPs in section 50311 of the Bipartisan Budget Act of 2018, we believe the goal was for beneficiaries enrolled in D–SNPs to receive a greater level of integration of Medicare and Medicaid benefits than is the case under current regulations. Because the Bipartisan Budget Act of 2018 limited the applicability of the Secretary's authority to impose an intermediate sanction on plans that do not comply with the integration requirements to plan years 2021 through 2025, we believe that the intent of this provision is to offer an alternative to outright contract or plan termination for D–SNPs that fail to meet the new integration requirements during the period of 2021 through 2025. With respect to commenters' concerns about penalizing plans, we note that since the authority to impose the intermediate sanction is specific to a D–SNP's non-compliance with the Medicare and Medicaid integration standards finalized in this rule, we intend to consider whether imposition of intermediate sanctions would be most appropriate at the plan, rather than contract, level for each affected Medicare Advantage organization. We expect such determinations to be tied to the facts of each specific situation.

In addition to authorizing this lesser sanction, the statute requires a corrective action plan, which we believe strengthens our interpretation, as it illustrates a preference for ultimate compliance by D–SNPs with the integration requirements. The statute authorizes this lesser sanction but does not require that it be used, leaving it to our discretion whether an enrollment sanction combined with a corrective action plan is sufficient to achieve the goals of the statute. We believe that imposing an intermediate sanction to suspend enrollment establishes predictability for states, beneficiaries, and MA organizations by requiring its imposition for non-compliant plans in lieu of termination or other actions. CMS retains discretion—for example, if the D–SNP does not submit an acceptable corrective action plan or fails to abide by the corrective action plan—to determine that contract termination or other enforcement action or sanction is still possible. In addition, in the event circumstances warrant—for example, when any harm to beneficiaries is imminent—we retain authority to immediately terminate the contract. We

are therefore finalizing our proposal on intermediate sanctions without modification.

As discussed elsewhere in this final rule, CMS is committed to working with stakeholders and providing technical assistance and additional guidance to states and D–SNPs to facilitate compliance with the integration requirements in this final rule. We will evaluate application of our sanction authority and consider any additional changes or clarifications, including with respect to sanctions for those D–SNPs that fail to meet the integration requirements for plan years after 2025.

Comment: One commenter recommended that CMS' imposition of sanctions be delayed until 2023 to accommodate necessary contracting and systems changes. This commenter also recommended that CMS impose sanctions only in states where the state Medicaid agency has successfully integrated with other D–SNPs using the specific integration standards the state has selected. Another commenter urged CMS to consider the integration standards to be met, and an enrollment sanction not required, if the notification language requirement discussed in section II.A.2.a.(2) of this final rule is in the state Medicaid agency contract in 2021, even if not implemented until 2022.

Response: The Bipartisan Budget Act of 2018 specifically allows for the imposition of any enrollment sanctions related to non-compliance with the D–SNP integration standards established in this final rule be applied with respect to plan years 2021 through 2025. In addition, we note that the Bipartisan Budget Act of 2018 requires all D–SNP integration criteria established by CMS to be effective starting for the 2021 plan year. The timing for the publication of the provisions set forth in this final rule in the allows D–SNPs ample opportunity to negotiate with states and address issues requiring changes in the state Medicaid agency contracts prior to the start of the 2021 plan year. Therefore, solely including the notification requirement language in a D–SNP's state Medicaid agency contract without implementing the process as required by that state would render a D–SNP out of compliance with § 422.107(d).

After consideration of the comments we received, we are finalizing our proposal regarding CMS' imposition of intermediate sanctions for non-compliance with D–SNP integration standards without modification.

b. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560–562, 422.566, 422.629–634, 438.210, 438.400, and 438.402)

Section 1859(f)(8)(B) of the Act, as added by the Bipartisan Budget Act of 2018, directs the Secretary to establish new procedures that unify, to the extent feasible, Medicare and Medicaid grievance and appeals procedures for D–SNPs. This new authority provides an important opportunity to address an area of longstanding misalignment between the Medicare and Medicaid programs. Medicare and Medicaid grievance and appeal processes have developed independently and operate entirely separately. Medicare's fee-for-service appeals processes (authorized primarily under section 1869 of the Act for Part A and B claims appeals), and MA's processes (authorized under sections 1852(f) and 1852(g) of the Act for grievance and appeal processes) are subject only to federal regulation and oversight as part of the federally-administered Medicare program. Medicaid grievances and appeals are authorized under sections 1902(a)(3) and 1902(a)(5) of the Act for Medicaid programs more generally and section 1932(b)(4) of the Act for Medicaid managed care plans. Unlike Medicare and MA, Medicaid appeals and grievance procedures are subject to both federal and state regulation and are primarily subject to state oversight and administration as part of a joint federal-state financed program. Medicare Part D grievances and appeals are authorized under sections 1860D–4(f) and (g) of the Act and are outside the scope of our authority to unify grievances and appeals under new section 1859(f)(8)(B) of the Act; we note, however, that D–SNPs are all required to provide Part D prescription drug coverage pursuant to § 422.2 (in the definition of a specialized MA plan for special needs individuals), and are therefore subject to the Part D appeals requirements in connection with Part D benefits.

Both the Medicare and Medicaid grievance and appeals systems include regulations establishing procedures for the fee-for-service programs as well as regulations governing managed care plans, including processes at the plan and post-plan levels for adjudicating appeals. Medicare rules are found at 42 CFR part 405 subpart I (general) and part 422 subpart M (Medicare Advantage); Medicaid rules are at 42 CFR part 431 subpart E (general) and part 438 subpart F (managed care). Regulations for the Medicare and Medicaid programs take broadly similar approaches to managed care appeals in that both programs establish a process for resolving a dispute at the plan level initially, followed by an opportunity for post-plan review. However, these appeals systems operate independently with sometimes subtle but important differences related to notices, adjudication timeframes, availability of benefits continuing while the appeal is pending, and levels of review. Similarly, regulations for the Medicare and Medicaid programs take different approaches with respect to some processes for grievances, including filing and adjudication timeframes and the availability of an expedited grievance process.

Although comparatively few beneficiaries file grievances or appeals,[23] these processes are vital safeguards to ensure that beneficiaries' concerns and needs are met promptly. Because of Medicare and Medicaid's misalignments in this area, beneficiaries who are dually eligible for Medicare and Medicaid can face a confusing array of choices when they seek to file a grievance or appeal. They may not know whether their complaint is tied to Medicare or Medicaid, and thus may not know where to direct their grievance. They may be uncertain if the item or service they seek is covered by Medicare, by Medicaid, or potentially by both programs, and thus may not know when or where to file an appeal following the denial of a service. The issue is particularly complicated for items and services such as home health and certain durable medical equipment that are sometimes covered by both programs but under different circumstances.

This confusion for beneficiaries and for those assisting them can result in costly and inefficient duplication of effort, as beneficiaries may file grievances and appeals under both programs when only one was necessary. Health plans and federal and state agencies may incur additional burdens and costs from having to administer parallel appeals systems. Finally, these misalignments may lead to unintended harms in the form of delayed or denied access to needed services as beneficiaries expend time and energy pursuing ultimately fruitless appeals in

[23] For example, in 2016, Medicare Part C plans reported 2.93 complaints (grievances) per 1,000 enrollees per month and 19.3 reconsideration requests (appeals) per 1,000 enrollees per month. See Analysis of Calendar Year 2016 Medicare Part C Reporting Requirements Data, available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html.*

one program when they should have been pursuing them in the other.

As summarized in our proposed rule, we have made previous efforts to better align Medicare and Medicaid grievances and appeals for dual eligible individuals, including the integrated initial level of appeal in the Programs of All-inclusive Care for the Elderly (PACE). The operation of Medicare-Medicaid Plans (MMPs) in the CMS' Financial Alignment Initiative capitated model demonstrations has provided us with the most extensive experience integrating grievances and appeals for dual eligible individuals in the managed care setting. Our experience with MMPs suggests that, although implementing a new system can be challenging, once in operation, integrated grievance and appeals systems can be simpler for beneficiaries to navigate than separate systems for Medicare and Medicaid.

Under the newly enacted amendments to section 1859(f)(8)(B) of the Act, the Secretary is required to establish, not later than April 2020 and for inclusion in contracts for D–SNPs for 2021 and subsequent years, procedures unifying grievances and appeals procedures consistent with several principles:

- Under paragraph (8)(B)(ii), the new unified procedures must include provisions that are most protective for the enrollee and, to the extent feasible as determined by the Secretary, are compatible with unified timeframes and consolidated access to external review. The statute requires that the procedures take into account differences under state Medicaid plans, and be easily navigable by enrollees.
- Additionally, under paragraph (8)(B)(iii), the integrated processes implemented are required to include a single written notice that includes all relevant grievance and appeal rights; a single pathway for resolution of covered items and services; notices written in plain English and available in languages and formats that are accessible to enrollees (including in non-English languages that are prevalent in the service area of the specialized MA plan); unified timelines for processes such as filing, acknowledging, and resolving the appeal or grievance; and requirements for plans to process, track, and resolve the grievances and appeals to ensure enrollees are notified timely of decisions and can track the status of their grievance or appeal.
- Finally, under paragraph (8)(B)(iv), new grievance and appeals procedures must, with respect to all benefits under Medicare Parts A and B and Medicaid subject to appeal under such procedures, incorporate provisions under current law and implementing regulations that provide continuation of benefits pending appeal under Title XVIII and Title XIX. We address this statutory provision in section II.A.2.b.(7).

Using this statutory framework, we developed the following goals to guide development of the unified grievance and appeals provisions:

- Adopt provisions that are most protective of the enrollee;
- Reduce burden on beneficiaries (and those assisting them), plans, states, and providers; and
- Maintain state flexibility and minimize disruption by building on existing rules and policies.

These policy goals also reflect our belief that timely, efficient, accessible, and well-functioning grievance and appeals systems are critical to ensuring that beneficiaries have access to needed items and services. Such systems are especially vital for dual eligible individuals who typically lack financial resources that might enable other beneficiaries to pay out-of-pocket for needed items or services while a dispute is pending. We requested comments regarding these policy goals and the extent to which the proposed regulations are consistent with them.

Our policy goal of minimizing disruption was also informed by statutory language directing the Secretary to establish unified provisions to the extent feasible (section 1859(f)(8)(B)(i) of the Act). Consistent with this statutory standard, we primarily proposed incremental changes that are currently feasible, conform to other current law, and build upon existing systems.

Our proposals under the notice of proposed rulemaking were divided into three substantively different types:

- First, we proposed to establish requirements for all D–SNPs, relative to the role they play in assisting full-benefit dual eligible individuals, to assist with Medicaid-related coverage issues and grievances (§ 422.562(a)).
- Second, we proposed new requirements in accordance with section 1859(f)(8)(B) of the Act to create integrated grievance and appeals systems for a limited subset of D–SNPs (''applicable integrated plans''), identified using terms and concepts we propose to define in amendments to § 422.561, with the integrated processes established by proposed new regulations (§§ 422.629–422.634).
- Finally, we proposed a number of changes of a technical and conforming nature to existing provisions in parts 422 and 438 (§§ 422.560, 422.562, 422.566, 438.210, 438.400, and 438.402).

Section 1859(f)(8)(B)(i) of the Act requires the Secretary to establish unified grievance and appeals procedures for D–SNPs not later than April 2020, and section 1859(f)(8)(C) of the Act requires the use of these unified procedures in D–SNP contracts for 2021 and subsequent years. The statute does not, however, explicitly rule out the possibility of implementing such unified processes prior to 2021. As discussed in the proposed rule, we interpret the statute as permitting a state to adopt unified grievance and appeals processes for integrated D–SNPs and Medicaid plans in that state consistent with our final regulations on this topic starting as soon as the regulations establishing such procedures are final. Such a state could require establishment of unified appeals and grievance procedures consistent with CMS' regulations in its Medicaid agency contract required under § 422.107. We solicited comments on this interpretation of the statutory implementation date requirements and our proposal to make unified procedures available to states in this way before 2021.

In this final rule preamble, we summarize at a high level our specific proposals for the unified appeals and grievance processes; we direct readers to the proposed rule, 83 FR 55003 through 55013, for more detailed discussion of the proposals and our rationale for them. We received a number of comments on our proposals to implement these unified appeals and grievance procedures, both in general and with regard to specific proposals, and summarize the general comments as follows:

Comment: We received numerous comments in support of our proposal for unified plan-level appeals and grievance processes. Many commenters supported our stated policy goals and agreed that the proposed regulations were consistent with those goals. Several commenters expressed support for our policy principle of choosing the most beneficiary-friendly appeals processes and protections where there is a discrepancy between Medicare and Medicaid rules. Many commenters noted the current misalignment of administrative and operational process for beneficiaries and plans in the Medicare and Medicaid appeals processes, which confuses enrollees and reduces access to benefits, and appreciated that our proposed appeals and grievance processes begin to address some of these misalignments through a unified system that is clearer

and easier to navigate for enrollees. One commenter expressed concern that requiring D–SNPs, which typically also offer other non-D–SNP MA–PD plans, to administer two separate grievance and appeal procedures is overly burdensome. One commenter noted that it may not be possible to implement the unified appeals and grievance processes in states with consent decrees that limit plan-level appeals.

Response: We appreciate the broad support both for unified appeals and grievance processes and for the policy goals underlying our proposed process. We agree with those commenters who stated that the unified processes will be clearer and easier to navigate for enrollees. We expect the unified processes to apply to a relatively small subset of D–SNPs and states. We note that, with respect to the concern about the burden of D–SNPs administering separate grievance and appeals processes, D–SNPs that contract to provide Medicaid benefits, including applicable integrated plans that must comply with the unified appeal processes addressed in this rule, currently administer two separate processes—one for Medicare and one for Medicaid—in addition to complying with specific appeal requirements for Part D benefits. Under the unified approach we are finalizing, integrated applicable plans will only administer one process for all non-Part D benefits. Thus, while we understand that there may be some administrative burden in setting up the new system, we believe that once the system is set up, it should be more efficient for applicable integrated plans to administer than the current system. We note that drugs covered by Medicare Part D will continue to be processed under the separate Part D appeals system in 42 CFR part 423. Appeals related to non-Part D drugs covered by Medicaid for dual eligible individuals will go through the unified appeals process as outlined in this final rule for applicable integrated plans, described later in this final rule. We therefore do not believe there will be additional burden for applicable integrated plans. We also note that we will accommodate state circumstances, as needed and possible, including where a state currently operates under a consent decree.

Comment: A number of commenters noted the need for CMS to work closely with states and other stakeholders where these unified processes will be implemented to ensure a smooth implementation and transition for enrollees and set clear expectations for applicable integrated plans. Some commenters also noted the need for CMS to release additional guidance prior to the implementation date and to communicate the process clearly to enrollees. Several commenters requested that we issue subregulatory guidance specifically addressing the following topics: Allowing enrollees to raise secondary impact on health based on the financial hardship of paying for services that were not initially covered in post-service payment cases, repeat grievances, and processing prescription drug appeals in the unified processes. A commenter requested additional information on state regulations that may need to change in order for the unified processes to be implemented. Several commenters also recommended that CMS review best practices and lessons learned in the Financial Alignment Initiative to inform implementation of unified processes for D–SNPs. One commenter questioned how states will react to implementing these requirements. Another commenter noted that any new process will produce new confusion among beneficiaries.

Response: We appreciate the commenters' concerns and anticipate issuing subregulatory guidance to further clarify the unified processes. As discussed throughout this preamble, we expect to continue to engage states, plans, and other stakeholders as we implement the requirements in this final rule, including providing technical assistance to states, disseminating best practices (including from MMPs participating in the Financial Alignment Initiative), and issuing additional subregulatory guidance and model enrollee communications to ensure a smooth implementation and to reduce any potential enrollee confusion. We also note that, for most states that will be implementing this new unified process, this final rule allows CMS 18 months prior to the January 1, 2021, implementation date to work with states, plans, and other stakeholders to ensure a smooth implementation.

Comment: One comment noted the importance of provider-neutral language in the proposed rule, which is consistent with the statutory language and recognizes the important variety of providers that serve enrollees in Medicare and Medicaid.

Response: We appreciate the commenter's support of our use of the term ''provider'' in the proposed rule and note that we are maintaining the use of this term in the final rule.

Comment: One commenter observed that there is no mention of the grievance and appeals processes for network providers, noting the lack of a process for network providers under existing contract terms with managed care plans and expressing concerns about potential retaliation from managed care plans for filing appeals or complaints. The commenter urged us to develop a process for network providers to file appeals and grievances and ensure that network provider concerns are heard by states and CMS.

Response: The unified process addressed in this final rule is for coverage decisions made by the D–SNPs and the affiliated Medicaid managed care plans with exclusively aligned enrollment. As is the case under MA rules, disputes between network providers and the applicable integrated plans are governed by their contracts with plans. Some states do provide external processes for Medicaid network providers, and these processes will remain available for Medicaid-related plan-provider disputes. In addition, providers can file complaints with CMS through the Complaint Tracking Module to raise issues and concerns to CMS' attention.

Comment: One commenter requested that we include supplemental benefits and long-term services and supports (LTSS) in the unified grievance and appeals processes, similar to the current process in the Cal MediConnect Financial Alignment Initiative demonstration.

Response: We clarify that any LTSS or supplemental benefits covered by applicable integrated plans will subject to the unified grievance and appeals processes we are finalizing in this rule, with the exception that MA supplemental benefits are not subject to the continuation of benefits pending appeal process finalized at § 422.632 in this rule. Continuation of benefits pending appeal under § 422.632(b) is available only for ''benefits under Parts A and B of title XVIII and title XIX.'' Please see section II.A.2.b.(7) of the proposed and final rules for more discussion of this issue.

Comment: Several commenters requested clarification on the impact of the unified grievance and appeals processes on applicable integrated plans' Star Ratings. A commenter recommended a grace period to mitigate this impact, and another recommended that we move the measures to the display page during the transition to the new processes. Another commenter requested more information on appeals and grievance reporting processes. One commenter requested that we make timely plan-specific grievance and appeals data available to the public.

Response: These comments are not strictly within the scope of our final rule provisions establishing unified

grievances and appeals processes. We note, however, that we do not expect Star Ratings to be negatively impacted by the unified grievance and appeals processes. The Star Ratings measures focus on how timely the MA plan sends the case to the IRE when the plan upholds its initial adverse organization determination and whether the plan's decision was upheld at the IRE. Under §§ 422.590(d)(4) and 422.592, if, upon reconsideration, an MA plan upholds its initial adverse organization determination, it must submit the case file and its decision to the IRE for automatic review. Under the unified appeals process, rules governing submission of case files to the IRE when a plan upholds its initial adverse organization determination are unchanged (see § 422.634(b)). We expect that an applicable integrated plan could in fact see a reduction in cases where the IRE reverses the applicable integrated plan's integrated reconsideration determination for cases where Medicare and Medicaid benefits overlap, since the applicable integrated plan may approve the service or item under Medicaid coverage and not have to issue a denial under Medicare. The applicable integrated plans should then have fewer cases to auto-forward to the IRE, and thus fewer cases that that the IRE could overturn and negatively impact the plan's Star Ratings.

Comment: One commenter urged CMS to reconcile and align requirements across multiple proposals aimed at reducing administrative burdens on plans and beneficiaries, including those that appeared in the proposed rule and in other proposals related to MA and step therapy for Part B drugs.

Response: We appreciate this feedback and agree that internal consistency is an important consideration in reducing administrative burden and has been a priority throughout this rulemaking process.

Comment: A commenter recommended that we extend our enrollee communications requirements to integrate all member-facing materials.

Response: We appreciate the suggestion. However, the requirements of section 1859(f)(8)(B)(iii) of the Act apply only to notices required under the unified appeals and grievance processes. We are therefore not implementing requirements for other notices in this final rule. However, as discussed elsewhere in this final rule, the Medicare-Medicaid Coordination Office is working to improve and consumer test a variety of beneficiary communications materials geared toward D–SNP and MMP enrollees.

(1) Assisting With Medicaid Coverage Issues and Grievances (§ 422.562(a)(5))

As an incremental step towards improving all D–SNP enrollees' experiences with accessing Medicaid benefits, and pursuing grievances and appeals, we proposed new regulation text to require all D–SNPs to assist beneficiaries with Medicaid coverage issues and grievances, including authorizations for or appeals related to Medicaid-related services at § 422.562 by adding a new paragraph (a)(5). As discussed in the proposed rule, these new requirements are consistent with our existing guidance and expectations for D–SNPs, but we proposed regulations to define their scope and set mandatory standards to which we can hold D–SNPs accountable. We believe that all D–SNPs should assist enrollees with resolving Medicaid coverage problems, including assistance with filing grievances, requesting coverage, and requesting appeals. Such assistance is consistent with the standard we proposed as part of the definition of a D–SNP at § 422.2. As noted in section II.A.2.a.(1) of the proposed rule and this final rule, we are codifying the statutory requirement at section 1859(f)(3)(D) of the Act that D–SNPs arrange for their enrollee's Medicaid benefits as an explicit requirement that D–SNPs coordinate the delivery of Medicare and Medicaid services for individuals who are eligible for such services, whether or not the D–SNP itself contracts with the state to provide Medicaid services. We clarified in the proposed rule that the requirements at § 422.562(a)(5) were additional requirements for D–SNPs, specifically related to assisting with access to benefits, appeals, and grievances. At § 422.562(a)(5), we proposed to supplement the obligation to provide, as applicable, and coordinate Medicaid benefits by adding a requirement that when a D–SNP receives an enrollee's request for services, appeal, or grievance related to Medicaid-covered services (regardless of whether such coverage is in Medicaid fee-for-service or a Medicaid managed care plan, such as a Medicaid MCO, PIHP, or PAHP as defined in § 438.2), the D–SNP must provide a certain level of assistance to the enrollee.

In new paragraph (a)(5)(i), we proposed to describe the types of assistance we would require all D–SNPs to provide to their enrollees regarding Medicaid-related coverage issues and grievances, including authorization of services and appeals. We proposed in paragraph (a)(5)(i) to include assistance for all D–SNP enrollees, regardless of the type of Medicaid coverage in which they are enrolled.

Our proposed regulation at § 422.562(a)(5)(i) included a list of illustrative examples, at paragraphs (5)(i)(A) through (5)(i)(C), which we did not intend to be an exhaustive list of how a D–SNP would be required to comply with the assistance obligation in § 422.562(a)(5)(i).

- In paragraph (a)(5)(i)(A), we addressed explaining to a D–SNP enrollee how to request Medicaid authorization and file an appeal. Our proposed regulation text included examples of the type of assistance we expect D–SNPs to provide to their enrollees when the enrollees need information and explanations about obtaining Medicaid services. We proposed, in paragraphs (5)(i)(A)(1) through (5)(i)(A)(3), examples of the types of assistance that a D–SNP must offer, and upon acceptance or request, provide its enrollees, such as specific instructions on how to contact the entity that may cover the service (for example, the Medicaid managed care plan or a contact in the fee-for-service system), and assistance in obtaining and filling out forms necessary for the next steps in the process.
- In paragraph (a)(5)(i)(B), we proposed that D–SNPs provide assistance in the actual filing of grievances and appeals. We requested comments regarding this proposal; in particular, we requested comments regarding how D–SNPs that do not have aligned enrollment would comply with this requirement when such entities might have financial and clinical responsibility for the disputed services, potentially presenting a conflict of interest.
- In paragraph (a)(5)(i)(C), we proposed that the D–SNP assist the enrollee in obtaining documentation in support of a request for authorization or appeal.

We explained how the examples listed in proposed paragraphs (a)(5)(i)(A) through (C) were not intended to be an exhaustive list, but rather were meant to provide some leading examples of the assistance we believe any D–SNP should provide. We invited comments on this proposal, specifically whether the regulation text was clear enough that the examples are not an exhaustive list of methods of assistance that the D–SNP must offer its enrollees, as well as suggestions for other examples of assistance that we should include in regulation or address in subsequent subregulatory guidance. We also solicited suggestions for additional examples of assistance, as

well as comments on challenges D–SNPs and others envision in implementing the provisions of proposed paragraph (a)(5). In addition, we acknowledged potential challenges D–SNPs may face because Medicaid systems vary by state.

We also proposed language related to enrollees accepting the offer of assistance in proposed paragraph (a)(5)(i). In our proposal, the only obligation on D–SNPs is to offer assistance and, when a request is made or an offer of assistance is accepted, to provide it. We requested comments on whether the regulation text, as we proposed it, was the best way to achieve this goal.

In paragraph (a)(5)(ii), we proposed to specify that the D–SNP's obligation to offer assistance arises whenever the D–SNP becomes aware of an enrollee's need for a Medicaid-covered service. Our proposal included text explicitly clarifying that enrollees do not need to make a specific request to their D–SNP for assistance. As we stated in the preamble to the proposed rule, if the issue comes to the attention of the D–SNP, we would expect the plan to offer to assist the enrollee in resolving the coverage issue(s) or grievance given the D–SNP's responsibility, consistent with our proposed definition of a D–SNP at § 422.2, that such a D–SNP provide, as applicable, and coordinate the delivery of Medicare and Medicaid services for its enrollees. We requested comments on whether we should include such explicit direction to D–SNPs in the regulation to identify issues that an enrollee is having, or whether our proposed regulation text was sufficiently clear that D–SNPs will understand and meet our goal of providing assistance to an enrollee such that the enrollee can access benefits regardless of whether the benefit is covered by Medicare or Medicaid. We clarified that we were not proposing any new requirements related to assistance with Medicare covered services or services for partial-benefit dual eligible enrollees. We requested comments regarding the provisions at proposed § 422.562(a)(5)(ii) and the need for any further clarification limiting the scope of § 422.562(a)(5) to full-benefit dual eligible individuals.

In paragraph (a)(5)(iii), we proposed to provide further detail on the methods of assistance required by proposed paragraph (a)(5)(i). The methods we proposed in the regulation were intended to be examples of what a D–SNP will be required to offer and provide to enrollees and will depend, to some extent, on the needs and preferences of the enrollee. Specifically, we proposed:

- In paragraph (a)(5)(iii)(A), that a D–SNP may provide coaching to the enrollee to promote self-advocacy. We requested comments on the methods of assistance and whether further detail is needed.
- In paragraph (a)(5)(iii)(B), an explicit requirement that a D–SNP provide whatever reasonable assistance an enrollee needs in navigating the Medicaid grievance and appeals systems, such as assistance completing forms. As discussed in the proposed rule preamble, existing MA and Medicaid managed care regulations (for example, §§ 422.111(h)(1)(iii) and 438.406(a)) address the provision of interpretation services and auxiliary aids and services for enrollees who have limited English proficiency or disabilities that require accommodation. We opted not to specify the preferred technical forms of assistance that would be required under this proposal, as the evolution of technology and the increases in integration over time may change the analysis of what methods of assistance are reasonable for a D–SNP to be required to provide to its enrollees. However, because D–SNPs are already required to provide similar assistance to their enrollees in other circumstances, we stated in the proposed rule that we did not anticipate that compliance with this provision should be burdensome to plans. We requested comments on this matter, including whether and how our goals might be met with more specific regulation text.
- In paragraph (a)(5)(iv), we proposed to require that a D–SNP provide documentation to CMS upon request that demonstrates how the D–SNP is providing the assistance proposed under paragraph (a)(5)(i).
- In paragraph (a)(5)(v), we proposed to clarify that D–SNPs are not required to represent enrollees in Medicaid appeals. We requested comments regarding whether any further clarification was needed on this issue.

We received the following comments, and our responses follow.

Comment: We received a significant number of comments in support of the proposed requirement in § 422.562(a)(5) to require all D–SNPs to provide assistance to D–SNP enrollees with Medicaid coverage issues and grievances. Many commenters were supportive of our efforts to improve D–SNP enrollees' experience and require all D–SNPs to provide a minimum level of assistance to their enrollees while granting D–SNPs flexibility in complying with the proposed requirements. A subset of commenters, while supportive of our proposal, recommended that CMS provide more specificity regarding what D–SNP assistance looks like and additional guidance on how plans can work with Medicaid agencies to obtain information on the Medicaid coverage of their enrollees.

Response: We appreciate the support we received for our proposed requirement that D–SNPs provide assistance to enrollees with Medicaid coverage issues and grievances. We believe these requirements constitute an incremental, but important, step in improving all D–SNP enrollees' access to the benefits under the Medicare and Medicaid programs. We address commenters' specific requests for clarification and guidance in subsequent responses in this section.

Comment: Several commenters expressed concerns that D–SNPs do not always have sufficient insight into whether certain Medicaid benefits are covered under the state's Medicaid program if the D–SNP does not provide those benefits directly. Many commenters noted that data sharing with states is essential for D–SNPs to access information regarding enrollees' Medicaid enrollment status—for example, whether they are enrolled in Medicaid fee-for-service or a Medicaid managed care organization (MCO), and the specific MCO they are enrolled in—in order to be fully informed about enrollees' coverage. A number of commenters recommended CMS consider issuing additional guidance to facilitate state sharing of Medicaid provider and enrollment information. One commenter suggested that CMS should create a centralized enrollment database that D–SNPs can query for Medicaid plan information regarding unaligned D–SNP enrollees. Another commenter suggested that in order to streamline the process and facilitate its implementation, CMS consider partnering with states to develop standardized resource lists with critical information on key Medicaid contacts that can be shared with enrollees and D–SNPs to streamline the navigation process and mitigate operational burden.

Response: We agree with commenters that information on how D–SNP enrollees receive their Medicaid coverage is essential for effectively fulfilling both the requirement to assist with Medicaid coverage and grievance issues and the requirement we finalized in the definition of a D–SNP at § 422.2 to coordinate Medicare and Medicaid coverage that these plans do not provide directly. We also recognize that, especially for states that do not contract

with D–SNPs to deliver Medicaid benefits, providing such information may be an operational challenge that is not among these states' priorities. We agree that it would be useful to provide states with technical assistance that would facilitate the exchange of information and help D–SNPs effectively coordinate their enrollees' Medicaid coverage.

At the same time, we do not believe that the absence of such information sharing relieves D–SNPs of their responsibility to coordinate Medicaid benefits they do not directly provide, nor prevents them from providing the types of assistance with Medicaid coverage issues and grievances that we outlined in the proposed rule. While we do not intend to penalize D–SNPs for not having in place a real-time data exchange with states on D–SNP enrollees' Medicaid coverage, we emphasize that the obligation for Medicaid coordination rests on the D–SNPs, and it is therefore incumbent on D–SNPs to develop mechanisms to coordinate Medicaid coverage and assist with Medicaid appeals and grievance issues. There are other methods that D–SNP staff can use to obtain information to better assist their members with Medicaid coverage issues, appeals, and grievances. For example, many states have data systems that providers use to obtain information on patients' Medicaid coverage; D–SNP personnel may be able to similarly access information in order to better assist enrollees. In some circumstances, a plan can assist a member simply by questioning the enrollee about their Medicaid coverage, or by jointly calling Medicaid customer service to obtain coverage information. As D–SNPs implement these provisions, we will gather and share best practices to help ensure robust implementation of these requirements.

Comment: A commenter indicated that, in certain circumstances, the state Medicaid agency is the only source that can clarify or have up-to-date information for the member. The commenter stated that D–SNPs should have the ability to direct members to state Medicaid agencies as needed.

Response: We wish to clarify that our proposal would not prevent D–SNPs from directing enrollees to state Medicaid agencies. Instead, our proposal requires that the D–SNP provide reasonable assistance in identifying the specific contacts within the state Medicaid agency, and helping the enrollee find the correct contact information, when referral of an enrollee to Medicaid resources is appropriate.

Comment: A few commenters recommended that CMS modify its proposal so that D–SNPs would be responsible for assisting members with appeals and grievances and other matters related only to services available through the D–SNP and that are clearly within the purview of the plan.

Response: We disagree with these commenters. Despite the valid data-sharing challenges, we believe it is reasonable to require that D–SNPs, as plans focused on serving dual eligible individuals, take steps to assist enrollees with obtaining Medicaid covered services and resolving Medicaid grievances, consistent with the requirement codified in this final rule in § 422.2 that D–SNPs coordinate the delivery of Medicare and Medicaid services for individuals eligible for such services. This would necessarily mean that the D–SNP take steps to gain access to information about the Medicaid benefits available to the D–SNP's enrollees. Moreover, providing such assistance is often in a D–SNP's financial interest, such as when an enrollee's access to Medicaid-covered services like personal care services and other home and community based services (HCBS) could prevent a hospitalization or address an enrollee's condition before it escalates into a need for medical services.

Comment: Several commenters requested clarification of whether the proposed regulation would require a FIDE SNP to offer to assist a dual eligible individual in appealing its own reduction of Medicaid LTSS services. The commenter believed this would be burdensome and could present a conflict for the plan.

Response: We clarify that a FIDE SNP that covers the Medicaid service through a capitated contract with a state also has an obligation to assist a dual eligible individual in appealing its own reduction or denial of Medicaid services, including LTSS, under its Medicaid MCO contract. The definition at § 422.2 finalized elsewhere in this rule requires that FIDE SNPs have Medicaid MCO contracts. As a Medicaid MCO, the FIDE SNP has an obligation under § 438.406(a) to provide reasonable assistance to its members in completing forms and taking other procedural steps related to a grievance or appeal. Therefore, FIDE SNPs already have an obligation to assist with Medicaid appeals. We do not agree that there is any undue burden or conflict under either the D–SNP or Medicaid MCO requirements to assist with appeals when that assistance results in a FIDE SNP providing coverage upon adjudication of the appeal. These requirements are, in the first instance, a component of the Medicaid MCO requirements to implement an appeals process, and, in the second instance, consistent with the requirement codified elsewhere in this final rule that D–SNPs coordinate Medicaid benefits. The new requirements we are finalizing at § 422.562(a)(5) of this final rule are applicable to all D–SNPs and to all D–SNP enrollees, whether or not they are enrolled in the Medicaid MCO offered by the D–SNP, and thereby effectively extend and complement the existing MCO requirements under § 438.406(a). Further, we note that § 422.562(a)(5)(v) expressly provides that the D–SNP does not have any obligation to represent an enrollee in a Medicaid appeal.

Comment: Several commenters emphasized that other entities have an important role in providing enrollees assistance with Medicaid coverage issues and grievances. Several of the commenters stressed the important role of the state ombudsman. One commenter proposed that CMS add language to the regulation text stating that the D–SNP must make available to their enrollees specific contact information for organizations providing free legal services and for any applicable ombudsman programs. Another commenter suggested that D–SNPs be required to make a written referral for the enrollee to the state's Medicaid managed care ombudsman, particularly when the D–SNP has a financial and/or clinical responsibility for the disputed services. One commenter highlighted the fact that the ombudsman offices are specifically funded to assist beneficiaries in filing grievances and appeals, and frequently coordinate with State Health Insurance Assistance Programs (SHIPs). The same commenter stated that many community-based organizations already receive federal funding to provide coaching to promote self-advocacy, and D–SNPs should not duplicate these services.

Response: We agree with commenters that ombudsman programs, SHIPs, legal services organizations, and other community organizations have an important role in providing assistance with Medicaid coverage and grievances and believe that referrals to such organizations can be an appropriate method for D–SNPs to provide the required assistance in certain circumstances. We recognize that such organizations often have limited capacity and encourage D–SNP partnerships with such organizations to help ensure the referrals are to organizations with the capacity to help.

Comment: Several commenters proposed requiring D–SNPs to provide

assistance in a language and format needed to effectively assist enrollees and in compliance with all language and disability access provisions.

Response: The language suggested by the commenter is very similar to obligations already required of Medicaid managed care organizations at § 438.406(a), which includes obligations to provide interpreter services and auxiliary aids to assist enrollees with grievances and appeals. MA plans also have existing obligations under Title VI of the Civil Rights Act of 1964 to take reasonable steps to ensure meaningful access by individuals with limited English proficiency and under section 504 of the Rehabilitation Act of 1973 to take appropriate steps to ensure effective communication with individuals with disabilities, including the provision of auxiliary aids and services. Section 1557 of the Affordable Care Act places similar civil rights obligations on covered entities.

Comment: Several commenters requested that CMS be mindful of dual eligible individuals' choices and recommended that CMS not penalize plans for not providing assistance when enrollees decline such assistance.

Response: If an enrollee does not want the D–SNP's help in resolving an issue, then the D–SNP would not be obligated under our proposal to provide assistance.

Comment: A few commenters recommended expanding the proposal to include providing assistance with Medicaid eligibility, and one commenter noted that case managers are in a good position to help enrollees with these issues. One commenter suggested CMS should explicitly require assistance in resolving issues related to Medicaid eligibility as a fourth requirement at § 422.562(a)(5)(i).

Response: We believe this recommendation is beyond the scope of our proposed requirement, which focuses on assistance with grievance and coverage appeals and not Medicaid eligibility. However, states may choose to require assistance with eligibility issues in their state Medicaid agency contracts with D–SNPs.

Comment: Several commenters recommended that CMS provide states and D–SNPs with technical assistance on implementing these provisions. One commenter stated that CMS should consider establishing a technical expert panel to make recommendations to CMS on appropriate practices and then develop guidance that establishes guiding principles for enrollee assistance, provides examples, and identifies related issues for states and Medicaid plans to consider. Another commenter suggested that CMS consult with states and D–SNPs in developing additional guidance to help evaluate recommended pathways for specific situations. Another commenter recommended states provide clear guidance to D–SNPs operating in the state to define the level of assistance they should provide, including applicable examples.

Response: We are committed to providing technical assistance to states and to sharing best practices with D–SNPs to implement these requirements based on consultations with stakeholders and evolving practice in this area. We expect that the best approaches will be specific to the Medicaid coverage in specific states and how these states use D–SNPs to integrate coverage.

Comment: Several commenters were supportive of our proposal at § 422.562(a)(5)(i)(A) that D–SNPs provide reasonable assistance to an enrollee and explain to an enrollee how to make a request and how to file an appeal following an adverse benefit determination. Several commenters also appreciated that the D–SNP's only obligation would be to offer assistance with filing an appeal and, upon acceptance of the request, provide its enrollees such assistance in obtaining and filling out forms as necessary for the next steps in the process. Many commenters appreciated that the proposed rule recognizes that some enrollees will wish to self-advocate and can receive support from the plan for their efforts. A few commenters believed plans must empower their staff to act in the best interests of the enrollee and that D–SNPs should establish appropriate staff training and procedures to ensure that those staff provide the same reasonable assistance that the dual eligible individual might receive from a similarly charged independent assister (which enrollees could continue to work with should they choose).

Response: We appreciate the commenters' support of CMS's approach to broadly requiring D–SNPs to provide assistance to dual eligible individuals with Medicaid grievances and appeals. D–SNPs can provide assistance in many ways, including advising enrollees to call providers and the questions to ask, assisting enrollees with medical documentation requests, identifying necessary forms to file, and referring enrollees to an organization with more expertise (such as a state ombudsman and other relevant assistance programs). We do not seek to be overly prescriptive in the types of assistance a D–SNP must provide, and our examples are not intended to be exhaustive. Further, we note that the regulation, as proposed and as finalized in this rule at § 422.560(a)(5)(v), does not require the D–SNP to represent its enrollees in Medicaid matters.

Comment: Many commenters recommended that CMS clarify what constitutes ''reasonable assistance.'' A few commenters requested additional guidance on ''coaching the enrollee to promote self-advocacy.'' Some commenters noted that it is ultimately the enrollee's responsibility to ensure that they take all procedural steps and provide and submit documentation as part of the appeals process. Other commenters requested more guidance on the expectations and extent of assistance D–SNPs must offer and give their enrollees.

Response: We emphasize that our requirements describe the D–SNP's responsibility to provide assistance and do not include a requirement to resolve the coverage issue or to represent the enrollee. Not all enrollees would need significant assistance; for many enrollees, simply receiving information under paragraph (a)(5)(i) would be sufficient. Some dual eligible individuals are highly adept at advocating for themselves, and may require only modest assistance—for example, a phone number or direction to an appropriate website—or help with technical terms in explaining why they need a specific piece of equipment. Other enrollees may need encouragement and coaching to advocate for themselves, such as talking through the steps the enrollee will take to seek resolution of the issue, or role playing to practice how to talk to a representative of the Medicaid agency or a Medicaid managed care plan. We encourage D–SNPs to provide such coaching to empower dual eligible individuals to advocate for themselves when appropriate. When a D–SNP enrollee needs a higher level of assistance with the act of filing a Medicaid grievance or appeal, the D–SNP should provide that help. However, the D–SNP is not obligated to represent the enrollee in Medicaid appeals nor advocate for coverage, as stated in paragraph (a)(5)(v). Plans can provide specific contact information, explain to enrollees the roles of the Medicaid program, and generally offer different levels of assistance based on the individual's needs.

Comment: Another comment sought an explanation of the phrase, ''becomes aware of an enrollee's need for a Medicaid-covered service.''

Response: There are a number of ways in which a D–SNP could become aware of the need for assistance. A non-

exhaustive list includes: During a health risk assessment when an enrollee shows a need for more LTSS than she currently receives through Medicaid; during a request for coverage of a Medicaid-covered service made to the D–SNP; and during a call to the D–SNP's customer service line. As the above list illustrates, the offer of assistance from the D–SNP is not dependent on an enrollee's specific request for assistance.

Comment: Many commenters agreed with the proposed provision at § 422.562(a)(5)(i)(C) requiring plans to assist an enrollee in obtaining documentation to support a request for authorization of Medicaid services or a Medicaid appeal, such as medical records. One commenter requested additional clarification from CMS on the extent of responsibility that D–SNPs will assume when obtaining documentation, including the specific types of documentation that D–SNPs might be able to provide. Several commenters questioned whether CMS was imposing a requirement on D–SNPs that duplicates the existing regulations that require Medicaid MCOs to assist enrollees with grievances and appeals.

Response: CMS believes the assistance requirement for D–SNPs is commensurate with the assistance a Medicaid MCO is required to provide for appeals and grievances at § 438.406(a), which includes reasonable assistance in completing forms and taking other procedural steps related to a grievance or appeal; however, while there may be some areas of overlap, the new MA requirement at § 422.562(a)(5) is not inappropriately duplicative. Not all D–SNPs are Medicaid MCOs, PIHPs, or PAHPs subject to the requirements under § 438.406(a). Even some D–SNPs, such as FIDE SNPs, that are also Medicaid MCOs may have some members who are not also enrolled in the Medicaid MCO, or there may be Medicaid services that are carved out of the Medicaid MCO's benefits and delivered through Medicaid FFS or a separate Medicaid plan. The assistance requirement for D–SNPs that we are finalizing here is an implementation of the overriding requirement on D–SNPs under section 1859(f)(3)(D) of the Act to coordinate Medicaid benefits. To the extent the assistance in grievances actually provided by a Medicaid MCO obviates the need for any additional assistance by the D–SNP in a grievance or appeal, such assistance would no longer be required to be provided by the D–SNP. To the extent the D–SNP enrollee requires additional advice or assistance with completing forms, or seeking documentation from relevant providers, the D–SNP should offer to provide such assistance and provide it when the enrollee agrees.

Comment: Several commenters were concerned with how D–SNPs should document and report to CMS that assistance was offered and whether or not an offer of assistance was accepted. A few commenters requested additional information on the documentation and reporting requirements that CMS will establish and whether such documentation will be reviewed as part of the audit protocols for D–SNPs. One commenter requested CMS remove the requirement at § 422.562(a)(5)(iv) that requires a D–SNP to provide documentation to CMS that demonstrates how the D–SNP is providing the assistance, citing concerns with administrative burden on plans.

Response: We agree that documentation of the assistance D–SNPs provide their enrollees with Medicaid coverage and grievances should not be overly burdensome to plans. The documentation requirement (including any potential reporting to CMS) in § 422.562(a)(5)(iv) does not prescribe certain types of assistance in all cases. Particularly in the initial years of implementation, when plans are developing processes to best implement these requirements, our goal is to provide plans with flexibility on the type of assistance they provide in individual cases and to monitor compliance with this requirement at a high level. We would not, for example, require proof that a beneficiary had declined an offer of assistance. We plan to detail the scope and content of the documentation requirements in subregulatory guidance, and it is likely that the subregulatory guidance will be made available for stakeholder comment before it is finalized.

Comment: Several commenters suggested that CMS take steps to ensure that D–SNPs that provide assistance with Medicaid coverage issues are not penalized in CMS audits or in the MA Star Ratings measure that is based on beneficiary complaints (''Complaints About the Health Plan'') when the final result—the coverage decision made by a party other than the D–SNP—is not to the beneficiary's satisfaction. Another commenter recommended that CMS protect D–SNPs from ''liability'' for providing assistance with Medicaid coverage and grievances.

Response: In general, we do not believe that D–SNPs providing their enrollees with assistance navigating their Medicaid coverage will trigger an increase in beneficiary complaints. Rather, we expect D–SNP enrollees will appreciate the assistance that their D–SNP provides. Nonetheless, we will review our criteria to ensure we are capturing complaints appropriately and will consider any future changes to these criteria that may be necessary. Outside of these areas, we are unclear how providing such assistance would increase D–SNPs' ''liability.''

After considering the comments we received and for the reasons provided in the proposed rule and our responses to those comments, we are finalizing the text proposed for codification at § 422.562(a)(5) with one technical modification. At paragraph (5)(iii)(B), we are modifying the regulatory text to clarify that the requirement that D–SNPs provide reasonable assistance in completing forms and procedural steps applies specifically to Medicaid appeals and grievances. We believe the additional clarification provided by our responses to the comments in this final rule should give D–SNPs a clearer understanding of the scope of their responsibilities under the regulation and the various methods and resources D–SNPs can use to fulfill the requirements. We recognize that there will be a joint learning process with states, MA organizations, dual eligible individuals, and their advocates on the processes that can facilitate effective implementation of these requirements. We expect to provide technical assistance to states and D–SNPs to help with implementation. In addition we plan to provide subregulatory guidance as necessary, including regarding CMS oversight of D–SNP performance in this area. We note that, unlike the remainder of the appeals and grievances provisions finalized in section II.A.2.b of this final rule, the requirements at § 422.562(a)(5) will be applicable to all D–SNPs and will be applicable beginning January 1, 2020.

(2) Statutory Basis and Scope for Unifying Grievances and Appeals (§ 422.560)

In § 422.560, we proposed to add new paragraphs (a)(4) and (b)(5) to address the statutory basis and scope of our proposal to establish unified grievance and appeals processes for a subset of D–SNPs. Specifically, we proposed a new paragraph (a)(4) to cite section 1859(f)(8) of the Act and provide that the procedures under that section apply in place of otherwise applicable grievance and appeals procedures with respect to items and services provided by certain D–SNPs. We also proposed to add new paragraph (b)(5) to identify the scope of the new proposed regulations—that is, requirements for applicable integrated plans with regard to unified appeals and grievance procedures. The substance of these proposals is addressed in sections

II.A.2.b.(3) through (11) of the proposed and final rules.

We received no comments on our proposed changes to § 422.560 and are finalizing the regulation text at paragraph (b)(5) as proposed. However, we are making a non-substantive technical change to paragraph (a)(4) to clarify that the unified appeals and grievance procedures finalized in this rule are applicable beginning January 1, 2021. We are also making a technical change to correct an inadvertent omission in the proposed rule. Section 1859(f)(8)(C) of the Act states that, effective in 2021, contracts between D–SNPs and state Medicaid agencies must require the use of the unified grievance and appeals process. In order to reflect this requirement in regulation, as noted in section II.A.2.a.(2) of this final rule, we are finalizing a new paragraph at § 422.107(c)(9) that requires that contracts between D–SNPs that are applicable integrated plans, defined in § 422.561, and the state Medicaid agency require the use of unified grievance and appeals procedures.

(3) Definitions of ''Applicable Integrated Plan'', ''Integrated Appeal'', ''Integrated Grievance'', ''Integrated Organization Determination'', and ''Integrated Reconsideration,'' and General Requirements for Applicable Integrated Plans (§§ 422.561 and 422.629(a)–(k))

A central challenge to implementing unified grievance and appeals systems for D–SNPs and the Medicaid managed care organization operated by such plan's parent organization is the variety of enrollment scenarios across states. There are only a limited number of D–SNPs in which aligned enrollment, as defined in § 422.2 of this final rule, is possible—that is, a situation when a full-benefit dual eligible individual is enrolled in a D–SNP and receives coverage of Medicaid benefits from the D–SNP's MA organization or from a Medicaid managed care organization, as defined in section 1903(m) of the Act, operated by the D–SNP's parent organization or by another entity that is owned and controlled by the D–SNP's parent organization. Even fewer D–SNPs operate in states where that state Medicaid agency mandates such aligned enrollment. With exclusively aligned enrollment, all of the enrollees of the D–SNP also receive Medicaid services through the D–SNP or an affiliated Medicaid managed care organization operated by the D–SNP's parent organization.

The bulk of D–SNP enrollment, however, is not exclusively aligned. In most states, the majority of D–SNP enrollees have Medicaid coverage either through a different organization's Medicaid MCO, in a prepaid ambulatory or inpatient health plan (PAHP or PIHP), or through a state's Medicaid fee-for-service system. In these circumstances, the D–SNP has no control over the Medicaid grievance and appeals processes. Even a D–SNP that has a Medicaid managed care organization operated by such plan's parent organization available to its enrollees, but whose members may instead enroll in other Medicaid plans, can only unify the procedures for Medicaid appeals and grievances of those enrollees who are also simultaneously enrolled in the Medicaid managed care organization operated by such plan's parent organization.

We proposed to add definitions for new terms to govern the integrated grievance and appeals processes. In § 422.561 we proposed a new definition for ''applicable integrated plan,'' which is the specific type of D–SNP and affiliated Medicaid plan that would be governed by the new integrated grievance and appeals regulations. In our definition of applicable integrated plan, we proposed to include only a subset of D–SNPs, that is, only FIDE SNPs and HIDE SNPs with exclusively aligned enrollment, terms that were also proposed (see section II.A.2.a.(1) of the proposed rule) and are finalized with limited modifications elsewhere in this rule (see section II.A.2.a.(1) of this final rule). We proposed that the affiliated Medicaid plan be a Medicaid managed care organization, as defined in section 1903(m) of the Act, that is offered by: (1) The D–SNP with exclusively aligned enrollment; (2) the parent organization of such D–SNP; or (3) another entity that is owned and controlled by the parent organization of such D–SNP. Thus, as we stated in the proposed rule, our proposed unified grievance and appeals procedures would apply only to the enrollees of the subset of D–SNPs that are FIDE SNPs or HIDE SNPs with exclusively aligned enrollment and the affiliated Medicaid managed care organizations through which such enrollees receive their Medicaid services. As we noted in our discussion of the proposed definition of aligned enrollment in section II.A.2.a.(1) of the proposed rule, we would not consider a D–SNP's companion Medicaid plan to be an applicable integrated plan where it is a PIHP or PAHP in the state's Medicaid program. We solicited comments on our proposed definition of an applicable integrated plan and how it reflects which plans and entities would have to use the proposed unified grievance and appeals procedures. We sought comment on whether limiting our proposed policies to MCOs, rather than including PIHPs and PAHPs, was appropriate in light of the statute and our policy goals. We also clarified which proposed appeal and grievance procedure requirements for D–SNPs would not apply to applicable integrated plans; D–SNPs that are not applicable integrated plans would continue to establish and administer appeal and grievance systems that comply with the existing requirements for MA plans.

For the purpose of differentiating the terminology and procedures within this framework, we proposed to establish definitions for ''integrated organization determination,'' ''integrated appeal,'' ''integrated reconsideration,'' and ''integrated grievance'' and apply them exclusively to applicable integrated plans and the unified appeal and grievance procedures.

Under our proposal, integrated organization determinations would encompass both Medicare organization determinations, as described in § 422.566, and adverse benefit determinations, as defined in § 438.400(b); however, these determinations would be made by applicable integrated plans and would therefore be subject to the integrated organization determination procedures in proposed §§ 422.629, 422.631, and 422.634. These would be the first decisions made by the applicable integrated plan regarding coverage, approval, or payment for a covered service.

Similarly, we proposed that integrated reconsiderations would be the appeal of the applicable integrated plan's adverse integrated organization determination with respect to the health care services the enrollee believes he or she is entitled to receive. Under our proposal, an integrated reconsideration would be the same as an MA plan's reconsideration (in § 422.580) of an organization determination (defined in § 422.566) and the appeal (defined in § 438.400(b)) of an adverse benefit determination made by a Medicaid managed care plan. Integrated reconsiderations would encompass both Medicare reconsiderations, as described in §§ 422.578, 422.580, 422.582, and 422.584, and appeals, as defined for the Medicaid managed care context in § 438.400(b). However, these determinations would be made by applicable integrated plans and therefore subject to the integrated reconsideration procedures in proposed § 422.629 and §§ 422.632 through 422.634.

We proposed defining integrated appeals to encompass integrated reconsiderations and any additional post-plan level unified appeal processes that may be implemented in the future.

Additionally, we proposed to define an integrated grievance as a dispute or complaint that would be defined and covered, for grievances filed by an enrollee in non-applicable integrated plans, under § 422.564 or §§ 438.400 through 438.416. Integrated grievances would not include appeals procedures or QIO complaints, as described in § 422.564(b) and (c), respectively. An integrated grievance made by an enrollee in an applicable integrated plan would be subject to the integrated grievance procedures in §§ 422.629 and 422.630.

Our proposed definitions for integrated grievance, integrated organization determination, and integrated reconsideration were intended to replicate the scope and meaning of the parallel terms in parts 422 subpart M and part 438 subpart E regarding the appeals and grievance procedures required of, respectively, MA organizations and Medicaid managed care plans because we were proposing that these regulations and procedures would take the place of those part 422 and part 438 procedures for applicable integrated plans. We solicited comment on whether our proposal adequately accomplished this.

We proposed at § 422.629 to establish general requirements for applicable integrated plans, as defined in § 422.561. In the proposed rule, we generally explained how we balanced existing Medicare and Medicaid requirements, including existing state Medicaid flexibilities. In paragraphs (a) and (b), we proposed language that sets forth the scope of the requirements and general process that applicable integrated plans must implement. In paragraph (a)(1), we proposed to specify that the proposed rules apply in lieu of the general requirements for MA organizations at §§ 422.564, 422.566(c) and (d), and 422.568 through 422.596, and Medicaid managed care plans at §§ 438.404–438.424, and encompass integrated grievances, integrated organization determinations, and integrated reconsiderations. In paragraph (b), we set forth the general requirement that applicable integrated plans create integrated processes to administer these grievance and appeals requirements.

In proposed paragraph (c), we addressed an overarching question about whether a state may establish requirements that are different for the applicable integrated plan(s) using the state Medicaid agency contract with the D–SNP required under § 422.107. Specifically, we proposed to apply the flexibility offered to states under Medicaid regulations, which establish a floor for enrollee protections while offering states flexibility to impose more stringent requirements for timeframes and notices so long as they are more protective of beneficiaries. By preserving state flexibility in adopting more stringent, beneficiary-protective requirements, we believe that we were adhering to the direction set forth in sections 1859(f)(8)(B)(ii)(I) and (II) of the Act for us to take into account differences in state plans under Title XIX. Finally, in paragraph (c), we proposed to codify the opportunity for states to establish standards that differ from the standards set forth in these regulations in its state Medicaid agency contract, per § 422.107, with the applicable integrated plans. We solicited comments on our proposed approach, and specifically how we proposed to allow state flexibilities to be incorporated into the unified procedures for an applicable integrated plan.

In paragraph (d), we proposed that the applicable integrated plan provide the enrollee who is requesting the integrated reconsideration a reasonable opportunity, in writing and in person, to present evidence and testimony and make legal and factual arguments in support of their appeal. We also proposed to require that applicable integrated plans inform enrollees of the limited time available for these opportunities in cases were the timeframe is expedited, similar to § 422.586 and § 438.406(b)(4).

In paragraph (e), we proposed to require applicable integrated plans to provide reasonable assistance to the enrollee with respect to completing and submitting their integrated appeals and integrated grievances, as well as on navigating this process. This proposal would impose on applicable integrated plans a similar standard as applies to Medicaid managed care plans pursuant to § 438.406(a).

We proposed at paragraph (f) a general rule, using cross-references to the requirements in §§ 422.560, 422.561, 422.562, 422.566, and 422.592 through 422.626, to specify the regulations that apply to the applicable integrated plan for grievance and appeals processes unless otherwise noted.

We proposed at paragraph (g) to require applicable integrated plans to send the enrollee an acknowledgement of receipt in writing for all integrated grievances and integrated reconsiderations. We proposed to adopt the standard currently in § 438.406(b) for applicable integrated plans and to clarify that the acknowledgement should be in written form.

In paragraph (h), we proposed to adopt Medicaid's grievance and appeals recordkeeping requirements, as required for Medicaid managed care plans at § 438.416, to require applicable integrated plans to maintain records of integrated appeals and grievances and review them as part of their ongoing monitoring procedures.

We proposed in paragraphs (i) and (j) to incorporate similar provisions as are imposed on Medicaid managed care plans pursuant to §§ 438.410(b) and 438.414 regarding relationships between the plan and its contracted network providers. Specifically, in paragraph (i), we proposed to prohibit an applicable integrated plan from taking any punitive action against a provider for requesting an integrated organization determination or integrated reconsideration, similar to the provisions in §§ 422.570(f) and 438.410(b). We also proposed requiring, in paragraph (j), such a plan to disclose information about its appeals and grievances procedures at the time it enters into a contract with a provider or subcontractor. We proposed to include specific topics which must be covered in this information to providers, and these specific topics are the same as in existing Medicaid regulations (see § 438.414, which cites to § 438.10(g)(2)(xi) for this purpose).

In paragraph (k), we proposed regulatory standards controlling who must review an integrated organization determination. In developing our proposal, we sought to combine the MA and Medicaid managed care requirements for who must review an organization determination. In paragraph (k)(1), we proposed to include the requirement from Medicaid (§ 438.406(2)(iii)) that any individual who reviews an integrated appeal or grievance must consider all information submitted by the enrollee, regardless of whether the information was previously made available to the plan. In paragraph (k)(2), we proposed to include the requirements for reviews of Medicaid grievances (from § 438.406(b)(2)) for who can review a grievance to integrated grievances.

In paragraph (k)(3), we proposed to include the existing requirements from MA (§ 422.566) for who can review an organization determination. We also proposed language that, in accordance with current MA regulations (§ 422.566(d)), requires that physicians or other health care professionals who review integrated organization

determinations have an unrestricted license and be acting within the scope of that license.

In paragraph (k)(4) we proposed to combine existing MA and Medicaid requirements for who can review a reconsideration or adverse benefit determination since both sets of existing regulations have relevant requirements.

We explained in the proposed rule (83 FR 55003 through 55006) how we applied the direction in section 1859(f)(8)(B)(ii)(I) of the Act to adopt the existing procedures that were more protective of enrollees and explained the rationale for our specific proposals in paragraphs (a) through (k) of proposed § 422.629. Where MA and Medicaid managed care rules are similar, our proposals tracked closely to existing MA and Medicaid managed care rules. Where MA and Medicaid managed care rules differ, we considered which rule was more protective of enrollees and proposed rules that would follow the more protective approach.

We summarize the comments we received on proposed § 422.629(a) through (k) and respond to them as follows:

Comment: Many commenters agreed with our approach to limit the unified appeals and grievance processes to applicable integrated plans. A subset of commenters, while supportive of our proposal, encouraged CMS to extend the unified processes to all D–SNPs, or at least to all FIDE SNPs and HIDE SNPs that are not exclusively aligned, to cover more dual eligible individuals. Several of these commenters recommended that, if CMS is unable to extend the unified process beyond what was proposed, we should continue to review lessons learned and best practices from our implementation of the unified processes and potentially extend the processes in the future as overall integration efforts advance. A commenter recommended that, if we are not able to extend the unified processes beyond applicable integrated plans at this time, we encourage states to facilitate cooperation between D–SNPs and other entities covering benefits for the D–SNPs enrollees. A commenter suggested that, if we did not extend the unified processes to additional plans, we at least make it optional for states and plans other than applicable integrated plans. Another commenter recommended that we restrict the unified processes to exclude HIDE SNP enrollees, due to lower level of benefits integration. A few commenters requested that CMS clarify the impact of this unified process on MMPs in the Financial Alignment Initiative demonstrations.

Response: We appreciate the broad support for the unified appeals and grievance processes we proposed. While we appreciate the support for extending these requirements to additional D–SNPs and dual eligible individuals, we do not believe it is feasible at this time to implement fully unified grievance and appeals systems for D–SNPs and Medicaid managed care plans that do not have the same enrollees or where the organizations offering the D–SNPs and Medicaid plans are unaffiliated or even competitors. We note that states may include additional integration requirements in their state Medicaid agency contracts with D–SNPs. We disagree with the commenter that suggests excluding HIDE SNPs with exclusively aligned enrollment from the definition of an applicable integrated plan, because when a HIDE SNP meets the definition of exclusively aligned enrollment, as defined in § 422.2, the plan covers Medicare and Medicaid benefits (including at least some LTSS or behavioral health services) for their dual eligible enrollees. We also clarify that this rule will not impact the appeals or grievance processes for MMPs, which will continue to be governed by the demonstration three-way contracts and demonstration-specific guidance. MMPs will continue to operate within existing waivers of part 422, as outlined in the memoranda of understanding for each demonstration.

Comment: A commenter requested that CMS clarify the relationship between the terms ''aligned enrollment,'' ''exclusively aligned enrollment,'' and ''applicable integrated plan,'' specifically, the relationship between the plan-specific nature of ''aligned enrollment,'' the state policy-specific nature of ''exclusively aligned enrollment,'' and whether it is actually CMS' intent that the term ''applicable integrated plans'' be a function of state policy and not of individual plan structure. The commenter further requested clarification as to whether it is CMS' intent to use this concept of ''exclusively aligned enrollment'' as a policy benchmark for states to meet, and, if so, whether CMS intends to somehow influence states toward that goal. A commenter also recommended that CMS clarify whether a HIDE SNP or FIDE SNP operating in a state without exclusively aligned enrollment cannot or should not unify their appeals and grievances in the fashion outlined in this section.

Response: We acknowledge that exclusively aligned enrollment is directly related to state policy choices to require such alignment. Exclusively aligned enrollment, as defined in § 422.2 in this final rule, occurs when the state requires a D–SNP operating in the state to enroll only dual eligible individuals who are also enrolled in an MCO (that has an MCO contract under section 1903(m)(2) of the Act) that is offered by the D–SNP's MA organization, the D–SNP's parent organization, or by another entity that is owned and controlled by the D–SNP's parent organization. In effect, exclusively aligned enrollment means that Medicare benefits, MA supplemental benefits, and comprehensive Medicaid benefits (which are the benefits that an MCO contract covers) are provided by one entity (the D–SNP) or closely affiliated entities that share a parent organization for all members. Applicable integrated plans are the D–SNP and MCO in this exclusively aligned enrollment arrangement. Aligned enrollment—in contrast to *exclusively* aligned enrollment—occurs when some, but not all, of the D–SNP's enrollees are covered under this arrangement.

While CMS intends to continue to provide technical assistance to states on the value of integration and exclusively aligned enrollment, we believe that it is most feasible at this time to impose the unified processes only on those plans that have the ability to unify such processes for all of their members. Therefore, only applicable integrated plans are required to comply with the regulations we proposed and are finalizing, with some modifications, in this final rule. D–SNPs, including HIDE SNPs and FIDE SNPs, that do not meet the definition of an applicable integrated plan must comply with the MA appeal and grievance system requirements in §§ 422.560 through 422.626. We also note that a state may establish additional integration requirements through its state Medicaid agency contract with D–SNPs.

Comment: We received several comments supporting our proposed definitions at § 422.561, as well as a few requests for additional clarification, including whether the definition of an integrated organization determination includes prior authorizations. One commenter expressed concern that, if integrated organization determinations do include prior authorizations, the 72-hour resolution timeframes for an expedited integrated organization determination may not be a fast enough resolution timeframe in all cases.

Response: Integrated organization determinations include prior authorizations because prior

authorizations are included in the definitions of organization determinations under § 422.566, adverse benefit determinations under § 438.400(b), and actions in § 431.201. We also note that, for resolution of an expedited integrated organization determination, the timeframe requirement is that resolution must be as expeditiously as the enrollee's health condition requires, but not to exceed 72 hours; thus, 72 hours is only a maximum timeframe, and an applicable integrated plan must take each enrollee's unique circumstances into consideration in processing and deciding an integrated organization determination. This is consistent with the requirement timeframes under both MA and Medicaid (see §§ 422.572(b) and 438.210(d)(2)).

Comment: We received a number of comments on our proposed requirement at § 422.629(c) allowing states flexibility in implementing standards for timeframes or notice requirements that are more protective for the enrollee. A number of commenters supported our proposal as a way to extend enrollee protections currently available under Medicaid in some states. Some commenters opposed or expressed concerns related to allowing state flexibility. One commenter requested clarification on whether the proposed procedures would supersede or override any conflicting current Medicaid state law or rules and federal statutes and rules related to D–SNPs and under what process any of those potential conflicts could be addressed. A few commenters noted that allowing states to shorten timeframes for resolving appeals can be detrimental to a plan's ability to collect necessary information and make fully informed decisions. A few commenters expressed concern about the burden and complexity associated with requiring applicable integrated plans to implement different timeframes for entities that operate in many states. A commenter questioned how CMS would make decisions about which state flexibilities to allow and which not to allow. One commenter expressed concern that states would not be able to implement the intent of Congress and CMS without additional guidance, or that CMS would not be able to accommodate state variations without impacting or delaying the intent of the overall process to provide simplification and clarity for beneficiaries. A few commenters encouraged CMS to work with states and stakeholders, including through a stakeholder panel, to implement this requirement.

Response: We appreciate commenters' varied perspectives on this issue. As discussed earlier in this preamble, the statute requires that we take into account differences in state plans and that we implement standards most protective of enrollees (see sections 1859(f)(8)(B)(ii)(I) and (II) of the Act). Medicaid regulations governing managed care plans currently allow variation from federal regulations as long as the state policy complies with federal standards, and thus we are designing the unified process for applicable integrated plans to include similar state flexibilities. In effect, the federal regulations we proposed and are finalizing operate as the minimum requirements on unified grievance and appeals procedures; states may use the contract they have with the D–SNP under § 422.107 and the state Medicaid contract with the Medicaid managed care plan to require timeframes that are more protective of the enrollees in the applicable integrated plans. We also note that the unified process will impact a relatively small universe of states and plans. The proposed unified process will apply for enrollees in applicable integrated plans in lieu of current federal Medicare and Medicaid regulations. With respect to the burden and complexity of administering these unified processes, D–SNPs that contract to provide Medicaid benefits, including applicable integrated plans that must comply with the unified appeal processes addressed in this rule, currently administer two separate processes—one for Medicare and one for Medicaid—in addition to complying with specific appeal requirements for Part D benefits. Under the unified approach, they will only administer one process for all non-Part D benefits. Thus, though there may be some initial burden in implementing the new unified processes, in the long term we expect the administrative burden on applicable integrated plans to be reduced.

With respect to when the state flexibility will be allowed, to the extent that a state statute or rule sets a standard that is more protective of enrollees with respect to timeframes or notices than the unified rules we are establishing in this final rule, which is the standard set by Congress in the statute, then that state standard will apply under the flexibility we are finalizing at § 422.629(c) in the unified processes, as it would currently in the state's Medicaid program. With respect to how CMS will accommodate such flexibilities, the flexibilities will need to be stated in the state's contracts with the applicable integrated plan (meaning both the contract with the D–SNP under § 422.107 and the state contract with the Medicaid MCO). States will then need to ensure compliance with state-specific requirements. We expect that any state requirements that differ from the requirements as written in this rule will reflect state-specific Medicaid requirements, and will therefore ensure the same degree of protection as that afforded to all Medicaid beneficiaries in the state. CMS is committed to continuing our work with states based on their specific policy priorities following the implementation of this final rule, including any necessary changes to state regulations or processes, and we will work to ensure changes and updates are communicated to the public.

Comment: One commenter stated that our proposed requirement, at § 422.629(g), to send written acknowledgements of all integrated reconsiderations was likely to cause confusion for enrollees and increase administrative burden for applicable integrated plans.

Response: Sections 1859(f)(8)(B)(iii)(IV) and (V) of the Act, as added by section 50311(b) of the Bipartisan Budget Act of 2018, specifically call for unified timelines and procedures for acknowledgement of appeals and grievances, and procedures to ensure enrollees are notified of and can easily determine the status of the grievance or appeal. We believe that that written acknowledgement best meets these requirements and therefore decline to make any changes to the requirement that applicable integrated plans send written acknowledgment of each integrated reconsideration. We note that applicable integrated plans have flexibility to tailor the acknowledgement to the enrollee's case to improve clarity and help avoid confusion. This requirement parallels the Medicaid regulation at § 438.406(b), and we note that MA guidance also addresses written acknowledgement of oral requests for reconsideration (see Parts C & D Enrollee Grievances, Organization/Coverage Determination, and Appeals Guidance § 50.2.1).[24]

Comment: A commenter suggested that we consider ways to ensure that plans are consistently and uniformly capturing and logging beneficiary requests for appeals and grievances and that applicable integrated plans are, at a minimum, required to provide oral notification of resolutions.

[24] See *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.*

Response: We are finalizing recordkeeping requirements at § 422.629(h) to help ensure consistency in recordkeeping and documentation of integrated grievances and appeals, including the date that the applicable integrated plan notified the enrollee of the resolution at § 422.629(h)(vii), as well as other minimum data elements. We also note that applicable integrated plans are required to provide the resolution of each integrated grievance to the enrollee, per § 422.630(e), which we address in detail in section II.A.2.b.(5) of this final rule. We will monitor the need for additional guidance on this issue during and after implementation of the unified appeals and grievance processes required by this final rule.

Comment: We received several comments supporting the proposed prohibition, at § 422.629(i), on applicable integrated plans taking punitive action against providers for supporting enrollees' integrated organization determinations or integrated reconsiderations. One commenter recommended that we clarify that this prohibition extends to an applicable integrated plans' contracted and delegated entities.

Response: We appreciate commenters' support for this requirement and note that it is our expectation that applicable integrated plans will ensure that contracted and delegated entities follow this requirement, since the managed care plan must ensure that requirements are met completely by its delegated or subcontracted entity and/or individual under current Medicaid rules (§ 438.230(b)) and current MA rules (§ 422.504(i)).

Comment: One commenter noted support for our proposed requirement, at § 422.629(j), for applicable integrated plans to provide information about the integrated grievance and appeals systems to all providers and subcontractors at the time they enter into a contract, and requested that we extend the provision to require annual refresher trainings.

Response: We appreciate the commenter's support. Both Medicaid and MA have general requirements about providing information, but no specific requirements with respect to frequency (see §§ 438.414, and 422.202(b)). We decline to incorporate the commenter's suggested requirement at this time because annual refresher training is beyond what current Medicaid or MA regulations require in connection with training on appeals and grievances processes. We believe such a requirement would be unduly prescriptive and constrain plans' flexibility in informing and training their providers and subcontractors. However, we do expect that applicable integrated plans will provide information and training to providers and subcontractors as often as is necessary to ensure requirements are well understood and met by all delegated entities.

Comment: One commenter supported the proposed requirement at § 422.629(k)(3) related to the specific individuals who can review an organization determination. A commenter recommended that we strike ''nor a subordinate of any such individual'' in the requirement at § 422.629(k)(4) related to who, at the applicable integrated plan, can review integrated reconsiderations.

Response: We appreciate the commenter's support for this requirement, but we decline to make this change, since our proposed rule applied the requirement in the Medicaid managed care regulations and we do not see a reason to set a new, different standard for review under the unified appeals process. We believe that prohibiting subordinates of someone who had already made a decision in a case is appropriate, since the goal of the requirement is to help ensure a new, objective review of the case, and a subordinate may believe a conflict of interest in this respect.

After review of the comments and for the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing the definitions at § 422.561 of applicable integrated plan, integrated appeal, integrated grievance, integrated organization determination, and integrated reconsideration substantively as proposed with minor technical and grammatical modifications to the definition of an integrated organization determination to improve readability. We are finalizing the general provisions at § 422.629(a) through (k) requiring use of unified appeals and grievance processes by applicable integrated plans substantively as proposed with a minor modifications in paragraph (a) to make a non-substantive technical change to clarify that the unified appeals and grievance procedures finalized in this rule are applicable beginning January 1, 2021, and to clarify that § 422.618(a) does not apply to applicable integrated plans and to remove the designation of the single paragraph as (a)(1).

(4) Parties and Authorization for Filing Appeals (§ 422.629(l))

In proposed at § 422.629(l), we addressed who is able to request integrated grievances, integrated organization determinations, and integrated reconsiderations. Proposed § 422.629(1) used the heading ''Parties.'' Although not explicitly stated in the preamble of the proposed rule, we intended the heading to signal that such individuals would be parties to the resulting integrated grievance, integrated organization determination, and integrated reconsideration.

We also proposed in § 422.629(l)(1)(ii) to combine the MA and Medicaid requirements, such that a treating provider or authorized representative can file an appeal on behalf of an enrollee. Our proposal primarily adopted the MA rules at § 422.566(c) and § 422.582(a) that allow a treating provider to file a request for an organization determination or standard reconsideration on behalf of an enrollee without written authorization from the enrollee, but also require that the provider notify the beneficiary. In order to mitigate the risk that a provider would file an appeal against an enrollee's interest and without an enrollee's consent, particularly to take advantage of the provisions that allow a benefit to continue while the appeal is pending, we proposed that the appealing provider obtain the enrollee's written consent before requesting an integrated reconsideration if continuation of benefits is requested under § 422.632. Our proposed regulation text at § 422.629(l)(1)(ii) also incorporated the MA provision at § 422.574(b) that allows a provider to become an assignee of the enrollee and thereby become a party to the organization determination and redetermination if the provider waives any right to payment from the enrollee for the service that is the subject of the appeal.

We summarize the comments we received on proposed § 422.629(l) and respond to them as follows:

Comment: We received broad support for our approach to authorization for filing grievances, integrated organizations, and integrated reconsiderations. Most commenters agreed that our proposal presented a workable compromise between MA and Medicaid rules that should protect enrollees' rights and minimize the potential for inappropriate appeals. A few commenters expressed concern that allowing providers to pursue appeals without first obtaining enrollees' written consent would create a risk of conflicts of interest and potentially be used to manipulate negotiated rates.

Response: We thank commenters for their broad support of our approach. Because we are adopting existing MA rules for circumstances where written

consent is not required when requesting integrated reconsiderations, we believe the potential for conflicts of interest under our proposal are no greater than they are under MA. Moreover, because we believe the most significant potential for inappropriate provider-filed appeals exists when aid (that is, coverage and payment) pending integrated reconsideration is requested, requiring enrollees' written consent in these cases should mitigate these risks. Our proposal reflected this concern by limiting a provider's ability to seek benefit continuation pursuant to § 422.632 to only when the provider had received the written request of the enrollee in proposed § 422.629(l)(1)(ii); we are finalizing this specific provision in a new paragraph (l)(1)(iv).

Comment: One commenter expressed concern that requiring enrollees' written consent for provider-filed appeals requesting continuation of Medicare services would confuse enrollees and providers and raise the risk that enrollees would miss out on the opportunity to request continuation of benefits for Medicare-related appeals. Instead, the commenter recommended allowing providers to file requests for integrated reconsiderations on behalf of enrollees without enrollees' written authorization in these cases.

Response: We appreciate this concern but disagree with the recommendation. We believe the provision requiring enrollee authorization for provider-filed appeals requesting benefits pending appeal is necessary to mitigate against potential conflicts of interest. Although it may be theoretically possible to exclude Medicare-related appeals from the requirement for written enrollee consent in integrated reconsiderations, implementing such an exception would likely be more confusing for providers and enrollees in an integrated appeals system. We are therefore not adopting this suggestion, but we encourage plans, enrollees and their advocates, and providers to advise us regarding any difficulties implementing this provision.

Comment: One commenter requested that we clarify who is a party to the integrated reconsideration, similar to what currently exists in § 422.582.

Response: Proposed § 422.629(1) used the heading ''Parties'' and identified who could request an integrated grievance, integrated organization determination, and integrated reconsideration. Although not explicitly stated in the preamble, we intended the heading to be clear that such individuals would be parties to the resulting integrated grievance, integrated organization determination, and integrated reconsideration. We are finalizing the proposal with additional language clarifying, at § 422.629(l)(1), that all of the individuals listed in that paragraph are parties to the integrated grievance, integrated organization determination, and integrated reconsideration.

In addition, we are deleting the language proposed at § 422.629(l)(3) regarding which parties can request an expedited integrated organization determination and expedited integrated reconsideration. The same provisions are also at § 422.631(c)(1) for expedited integrated organization determinations and at § 422.633(e)(1) for expedited integrated reconsiderations, and including duplicative provisions at § 422.629(l)(3) created the potential for confusion.

Comment: Several commenters requested clarification regarding whether non-treating providers would be authorized to file appeals without an enrollee's written consent.

Response: Under § 422.578, only treating providers are permitted to file reconsideration requests on behalf of enrollees without obtaining the enrollees' written consent. We did not intend to broaden the ability of providers to file appeals on behalf of enrollees beyond what is permitted in MA or change the right of assignees of an enrollee to be parties to an appeal. We are therefore finalizing regulatory text in paragraph (l)(1)(ii) that an assignee of an enrollee includes a physician or provider that has furnished or intends to furnish a service to the enrollee and has waived the right to payment from the enrollee for the service. However, we are moving the provision regarding the need for physicians and providers to provide notice to the enrollee when filing a request for an integrated reconsideration on behalf on an enrollee to a new paragraph (l)(3) along with additional clarifying language. In this new paragraph (l)(3), we clarify that only treating providers may request an integrated pre-service reconsideration on behalf of enrollees without obtaining the enrollees' written consent, but must also provide notice to the enrollee of that request. Finally, for additional clarity, we are also finalizing a new paragraph (l)(1)(iv) in this final rule that explicitly states that any providers that furnish or intend to furnish a service to the enrollee may request an integrated organization determination or, subject to the requirements of paragraph (l)(3), an integrated reconsideration. This provision is similar to the MA provision at § 422.566(c)(1)(ii), and upon consideration of comments requesting clarity on the role of treating and non-treating providers, we believe it will be helpful to include this provision explicitly in this final rule. We are also moving the requirement that a provider requesting continuation of benefits on behalf of an enrollee must obtain the enrollee's written consent from proposed paragraph (l)(1)(ii) to the new paragraph (l)(1)(iv), as this new paragraph explicitly addresses the rights of treating providers in connection with integrated appeals. We are not finalizing in this new paragraph (l)(1)(iv) the requirement that was proposed at (l)(1)(ii) in the proposed rule that an authorized representative also needs to obtain written consent when requesting continuation of benefits because authorized representatives have—by definition—obtained authority to act on enrollees' behalf.

Comment: Several commenters requested clarification regarding whether our proposal for provider authorization applies both to pre-service and post-service appeals.

Response: MA rules at § 422.578 specify that the procedures permitting treating providers to request reconsiderations on an enrollee's behalf without the enrollee's consent apply only to pre-service appeals. As with the limitation to treating providers, we did not intend to broaden providers' appeal rights in this area beyond existing MA rules. We are therefore removing the regulatory text at § 422.629(l)(1)(ii) and adding to the new paragraph (l)(3) in this final rule regulatory text clarifying that the ability of providers to file for an integrated reconsideration without obtaining the enrollee's written consent applies only to pre-service integrated reconsiderations.

Comment: One commenter supported our proposal but suggested adding an explicit requirement that providers obtain enrollees' consent and provide enrollees with status updates during the appeal process. Another commenter made a related suggestion that providers requesting integrated reconsiderations on behalf of enrollees be required to sign and document that they have informed the enrollees of the filing of the appeal.

Response: We disagree that more explicit restrictions and obligations need to be part of the regulation. The final regulation at § 422.629(l)(3) states that, as under the MA regulation at § 422.578, only treating providers may request an integrated reconsideration on behalf on an enrollee without the enrollee's written consent upon providing notice to the enrollee. Pursuant to § 422.578, a treating provider may, upon providing notice to the enrollee, request a pre-service,

standard reconsideration on the enrollee's behalf; any provider acting on behalf of an enrollee may request that the standard reconsideration be expedited, and § 422.584 does not require notice to the enrollee of the request that the reconsideration be expedited. MA rules at § 422.578 do not impose additional explicit obligations on plans requiring specific documentation or monitoring of communications between providers and enrollees to establish that notice to the enrollee has been provided in these situations. Instead, MA policy provides plans with flexibility in how to ascertain whether a provider has adequately informed an enrollee of the request for reconsideration (see Parts C & D Enrollee Grievances, Organization/ Coverage Determination, and Appeals Guidance, § 50.1).[25] We believe similar flexibilities should apply to integrated reconsiderations. For example, if there are no records indicating contact between the provider and enrollee, the plan should take reasonable steps to confirm that the provider has informed the enrollee. Such steps could include asking the provider either directly or on the form used to request the reconsideration, or looking to see that the enrollee is copied on correspondence. The plan may also contact the enrollee to confirm.

Comment: One commenter requested clarification regarding whether the provider authorization rules in this section will also apply to expedited integrated reconsideration requests.

Response: As under MA rule at § 422.578, the rules regarding a provider requesting a reconsideration on an enrollee's behalf apply both to standard and expedited integrated reconsideration requests. The new paragraph § 422.629(l)(3) we are finalizing in this rule states explicitly that the rule applies to both standard and expedited integrated reconsideration requests. We note that if there is a request for benefits pending appeal, then the enrollee's written consent is required under the provision we are finalizing at § 422.629(l)(1)(iv). In such a circumstance, the provider may file the expedited request without a request for aid pending appeal in order to get the reconsideration request filed as soon as possible. The provider may then follow up with written authorization to request continuing benefits on the enrollee's behalf after securing the enrollee's consent to that request so long as the time period for requesting continuing benefits has not expired.

After consideration of the comments and for the reasons provided in the proposed rule and our responses to the comments, we are finalizing § 422.629(l) with some modifications. Specifically—

- We have revised paragraph (l)(1) to more clearly state that that the individuals and entities identified in that section are parties to the case;

We moved the provisions addressing the ability of providers to file appeals on behalf of enrollees that were proposed at paragraph (l)(1)(ii) to a new paragraph (l)(3), and we have deleted references to authorized representatives in that paragraph.

- We have added a new paragraph (l)(1)(iv) to expressly permit any treating provider to request an integrated organization determination and integrated reconsideration. We have also moved the provisions addressing the obligation of providers to obtain written consent of enrollees when requesting continuation of benefits that were proposed at paragraph (l)(1)(ii) to the new paragraph (l)(1)(iv);
- In paragraph (l)(2), which addresses the use of the term ''enrollee,'' we have replaced the words ''this section' in the proposed rule with ''§§ 422.629 through 422.634'' because our intent is that the use of the term enrollee as described in this paragraph apply to the entire integrated grievance and appeal process. As proposed, we are concerned the reference to ''this section'' was ambiguous and therefore are clarifying it; and
- We have deleted the proposed paragraph (l)(3) because that language was redundant with provisions codified in §§ 422.631 and 422.633.

(5) Integrated Grievances (§ 422.630)

At § 422.630, we proposed to largely parallel Medicare and Medicaid requirements where these requirements are the same with regard to the treatment of integrated grievances. Where MA includes a requirement that Medicaid does not, or vice versa, or where the MA and Medicaid regulations conflict, we proposed applying the requirement that best aligns with the principles and statutory requirements discussed in section II.A.2.b. of the proposed rule. For integrated grievances, we specifically proposed:

- At paragraph (a), to establish the general purpose of the regulation, similar to § 438.402(a) and § 422.564(a), by requiring that an applicable integrated plan provide meaningful procedures for timely hearing and resolving integrated grievances filed by an enrollee. We proposed to define the scope of the required procedures as being applicable to any grievances between the enrollee and the plan or any entity or individual through which the applicable integrated plan covers health care services. We proposed this requirement for the applicable integrated plan to be responsible for ensuring timely and appropriate resolution of a grievance even if the grievance pertains to an act or decision by one of the applicable integrated plan's providers of health care services. In the regulation text, we proposed that the integrated grievance procedures applied to ''grievances between enrollees and the applicable integrated plan or any other entity or individual through which the applicable integrated plan provides health care services.''
- At paragraph (b), to provide that an enrollee may file a grievance at any time, paralleling the current Medicaid regulation at § 438.402(c)(2).
- At paragraph (c), to allow grievances to be filed with the applicable integrated plan orally or in writing, in alignment with MA and Medicaid requirements; we also proposed to allow integrated grievances related to Medicaid benefits to also be filed with the state in states that have processes in place for that in accordance with § 438.402(c)(3).
- At paragraph (d), we proposed to largely parallel the MA requirements (at § 422.564(f)) to authorize an enrollee to file an expedited grievance when the complaint involves the applicable integrated plan's decision to extend the deadline for certain appeals or refusal to grant a request for an expedited integrated organization determination or expedited integrated reconsideration.
- At paragraph (e)(1), to parallel MA's maximum 30-day timeframe for resolving the grievance and MA's requirements, at § 422.564(e)(1), for how the applicable integrated plan must respond to grievances, depending on how the grievance is received and the basis upon which the enrollee filed the grievance. Although not discussed in the preamble to the proposed rule, the proposed regulation text would require the applicable integrated plan to resolve an integrated grievance as expeditiously as the case requires based on the enrollee's health status and within 30 days, which is the current requirement under Medicare (see § 422.564(e)(1)).
- At paragraph (e)(2), to include a provision, paralleling provisions in MA (§ 422.564(e)(2)) and Medicaid managed care (§ 438.408(c)(1)), permitting the applicable integrated plan to extend the time period in which a determination on an integrated grievance must be

[25] See *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.*

issued to the enrollee by up to 14 days. We proposed combining MA and Medicaid requirements, such that applicable integrated plans must notify enrollees immediately, but no later than within 2 calendar days, which we believe to be in line with the principles identified in section 1859(f)(8)(B)(iii) of the Act for timely, clear notification to enrollees.

We invited comments on these topics, specifically whether the proposed regulation text accurately incorporated the standards from the underlying part 422 or part 438 regulation that are more beneficial to the enrollee. We also solicited comment on whether we adequately captured all relevant enrollee protections currently available under MA and Medicaid. We summarize and respond to the comments on these specific proposals as follows:

Comment: Many commenters supported our proposed integrated grievance process, including provisions for an expedited grievance process, the 14-day extension period for resolving integrated grievances, the clarification that applicable integrated plans must resolve grievances involving any entity or individual through which the applicable integrated plan provides health care services, requiring responses to grievances within 30 days, and allowing enrollees to file at any time. A few commenters opposed the proposal to allow enrollees to file integrated grievances at any time, and recommending that CMS instead limit enrollees to filing integrated grievances within 60 days, to be consistent with the current MA requirement.

Response: We appreciate the support for our proposed integrated grievance requirements. We decline to establish in this final rule a timeframe for enrollees to file a grievance. While we understand the commenters' desire to be consistent with such limits in the MA program, our proposed requirements were developed consistent with the statutory requirement that we implement standards most protective of enrollees (see section 1859(f)(8)(B)(ii)(I) of the Act). The relevant Medicaid regulation (§ 438.402(c)(2)(i)) allows a grievance to be filed at any time, while the MA regulation (§ 422.564(d)(a)) limits grievance filing to within 60 days of the event at issue. Not having a time limit for enrollees to file grievances is most protective for enrollees by eliminating barriers to filing.

In addition, we note that the language as we proposed in § 422.630(a) with respect to the types of benefits for which the applicable integrated plans is responsible for resolving integrated grievances was limited to disputes involving entities that provide ''health care services,'' which is the MA rule at § 422.564(a). Our intent was that an applicable integrated plan be responsible for resolving grievances pertaining to all its contracted providers, including those that provide items and services that might not be strictly considered health care services, such as Medicaid non-emergency transportation. Using a broader term will ensure that the right to file an integrated grievance with an applicable integrated plan includes grievances that could be filed for all Medicare and Medicaid covered benefits. Therefore, we are revising § 422.630(a) to state that the applicable integrated plan is responsible for resolving grievances between enrollees and entities through which the plan provides ''covered items and services.'' We are adopting the provision as set forth in the proposed rule with this minor revision as noted.

Comment: Several commenters supported the proposal to allow enrollees to file Medicaid-related grievances with the state. A few commenters requested clarification on which integrated grievances could be filed with the state. Another commenter suggested that CMS go further and allow integrated grievances to be filed with providers and 1–800–Medicare, and a few commenters recommended that CMS ensure that there is a ''no wrong door'' policy such that if an enrollee files a grievance with the wrong entity, it is not just dismissed.

Response: We appreciate commenters' broad support for this provision. We appreciate the importance of a ''no wrong door'' policy, and we intend to work closely with states that permit enrollees to file Medicaid grievances with the state to ensure that applicable integrated plans have the guidance they need regarding policies and procedures for these instances. Further, we will consider comments about establishment of ''no wrong door'' processes for all enrollees in applicable integrated plans; we note that CMS has established an online system for Medicare beneficiaries to submit complaints and concerns about the Medicare program, including MA plans. Additionally, 1–800–Medicare currently accepts complaints related to Medicare, and CMS ensures resolution of them.

With regard to the ability to file grievances with providers, we do not believe additional regulatory provisions are needed. We expect that, as currently is the case, most enrollees will submit grievances directly to the applicable integrated plan. Under § 422.629(j), applicable integrated plans will be required to provide information about the integrated grievance and appeals system to all contracted providers (as noted in the proposed rule, this requirement already exists for Medicaid MCOs). This information should enable contracted providers to direct enrollee grievances properly to the applicable integrated plan when necessary. In addition, plans may delegate responsibility for handling grievances to provider groups consistent with existing Medicare policy (see § 422.504(i) and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, § 10.4.3 [26]). In those circumstances, the plan remains ultimately responsible for ensuring that contracted entities comply with all rules governing responding to grievances.

With regard to comments about filing grievances with the state, we clarify that the regulation is designed to provide a means for the state to address Medicaid grievances. If a grievance contains aspects related to both Medicare and Medicaid benefits, the state can review the Medicaid benefit portions, but should ensure that the Medicare benefit portions are appropriately transferred to the applicable integrated plan for review. If a grievance related to Medicaid benefits is filed with both the state and the applicable integrated plan, we expect the two entities to be in communication to ensure the grievance is resolved, as would occur now for Medicaid managed care grievances.

Comment: One commenter requested that we require all responses to grievances to be in writing. Several other commenters suggested that we not require written acknowledgement of all grievances.

Response: We do not believe that a written response to all integrated grievances is necessary; such a standard is not imposed under current requirements for MA plans or for Medicaid managed care plans. As proposed and finalized in this rule, the regulation (§ 422.630(e)(1)) requires applicable integrated plans to respond in writing to integrated grievances when: (1) The integrated grievance was filed in writing; (2) the enrollee requests a written response to an integrated grievance that was orally submitted; and (3) the integrated grievance was related to quality of care. The regulation permits applicable integrated plans to respond in writing or orally to integrated grievances that are filed orally, unless the enrollee requests a

[26] See *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.*

written response. Additionally, the applicable integrated plan must send the enrollee a written notice when it extends the timeframe for responding to the integrated grievance (consistent with § 422.630(e)(2)(ii), it may extend the timeframe by up to 14 calendar days). Consistent with § 422.629(c) as finalized, there is flexibility for states to set standards that are more protective of enrollees in connection with timeframes and notices; a state could, at its discretion, require that applicable integrated plans provide the disposition of all grievances in writing. Such a requirement would need to be specified in the state Medicaid agency contract with the D–SNP. We note that an applicable integrated plan, consistent with § 422.629(g), must send a written notice acknowledging receipt of the grievance; in this notice, a plan could also note that the grievance is considered resolved if the applicable integrated plan has previously provided the enrollee an oral resolution to clarify the status of the grievance for the enrollee. Accordingly, we are adopting without change the provision as set forth in the proposed rule.

Comment: Several commenters requested clarification on the requirement that applicable integrated plans notify enrollees within 2 calendar days when an extension is being taken.

Response: We clarify that the applicable integrated plan must notify the enrollee that an extension is being taken within two calendar days of when the applicable integrated plan, after justifying the need for the extension and documenting how the delay is in the enrollee's interest, makes the decision to extend the timeframe. We are finalizing the regulation text at § 422.630(e)(2)(ii) with additional text to clarify this timing.

Comment: A commenter suggested that we implement integrated reporting in the Complaint Tracking Module (CTM) for grievances in the CMS Health Plan Management System (HPMS) and give states access to track all grievances and resolutions for transparency and monitoring.

Response: We appreciate the comment and will consider it as we move forward with implementation. If such a step is operationally feasible, we do not believe it would require additional regulatory language.

For the reasons provided in the proposed rule and our responses to the comments, we are finalizing the requirements at § 422.630 substantively as proposed with some minor modifications as follows:

- We are revising the regulatory text at paragraph (a) by replacing ''health care services'' with ''covered items and services'' in order to ensure that grievances pertaining all Medicare and Medicaid covered benefits are included in the requirement;
- We are finalizing the regulatory text in paragraph (d) with revisions to streamline the regulation text and, at paragraph (d)(2), to clarify the terms used; and
- We are revising paragraph (e)(2)(ii) to clarify how long the plan has to notify the enrollee when it extends the time the resolve a grievance.

(6) Integrated Organization Determinations (§ 422.631)

In proposed § 422.631, we specified the procedures applicable integrated plans would follow in making integrated organization determinations. In paragraph (a), we proposed that, as part of a unified process, all requests for benefits covered by applicable integrated plans must be subject to the same integrated organization determination process.

In paragraph (b), we proposed to adopt the MA provisions at § 422.568(a) allowing an enrollee to request an integrated organization determination either orally in writing, but requiring requests for payment to be made in writing.

In paragraph (c), we proposed to articulate the standard for making an expedited organization determination. Both MA (at § 422.570(c)) and Medicaid (at § 438.210(d)(2)) have similar standards for an expedited organization determination, including who can file it (proposed in § 422.631(c)(1)) and how it should be decided (proposed in § 422.631(c)(3)). At paragraph (c)(2), we proposed that the request to expedite the appeal can be made orally or in writing.

In paragraph (d), we proposed rules regarding timeframes and notices when resolving integrated coverage determinations. In paragraph (d)(1), we proposed to require that an applicable integrated plan send a written integrated notice when the organization determination (standard or expedited) is adverse to the enrollee. We proposed to include text specifically identifying as adverse determinations requiring a notice any decision to authorize a service or item in an amount, duration, or scope that is less than the amount requested or previously requested or authorized for an ongoing course of treatment. We also proposed to include text specifying, consistent with Medicaid managed care requirements (§ 438.404(c)(5)), that the applicable integrated plan must send an integrated determination notice when the plan fails to make a timely decision because failure to make a decision within the required timeframe is a denial (and thus an adverse determination). The proposed notice would include information about the determination, as well as information about the enrollee's appeal rights under both Medicare and Medicaid. We also proposed that the notice be written in plain language and available in a language and format that is accessible to the enrollee; this proposed requirement is consistent with section 1859(f)((8)(B)(iii)(III) of the Act.

In paragraph (d)(2), we proposed timelines for sending this notice that largely align with both existing Medicare and Medicaid requirements. We proposed, in paragraph (d)(2)(i)(A), to require that applicable integrated plans send a notice of an integrated organization determination at least 10 days before the date of action if a previously authorized benefit is being reduced, suspended, or terminated, with some exceptions in accordance with §§ 431.213 and 431.214; we briefly explained the exceptions available in accordance with §§ 431.213 and 431.214 in the proposed rule (83 FR 55008). We proposed, in paragraph (d)(2)(i)(B), to require that applicable integrated plans send the notice as expeditiously as the enrollee's health condition requires but no later than 14 calendar days from receipt of the request for a standard integrated organization determination. We further proposed to permit extensions, in paragraph (d)(2)(ii), in circumstances that largely parallel those that exist in Medicare and Medicaid currently. In paragraph (d)(2)(iii), we proposed requirements for notice to be provided to the enrollee in cases of extension; these proposed requirements also largely parallel current MA and Medicaid requirements at § 422.572(b)(2) and § 438.404(c)(4)(i), respectively. Proposed § 422.631(d)(2)(iii)(A) largely parallels § 422.572(b)(2), which provides more specific direction on timing of the notice. We also proposed in paragraph (d)(2)(iii)(B) regulatory text controlling when the notice of the integrated organization determination must be sent in cases where the applicable integrated plan makes the decision to extend the timeframe.

In paragraph (d)(2)(iv)(A), we proposed the deadline for issuing notice of expedited integrated organization determinations. Both MA and Medicaid require expedited organization determinations (or adverse actions) as expeditiously as the enrollee's health condition requires but not later than within 72 hours of the request, with the possibility of extending that timeframe

by 14 calendar days. We proposed, at paragraph (d)(2)(iv)(B), to mirror the MA requirements (§ 422.570(d)), with required procedures when an applicable integrated plan denies a request for expediting an organization determination. In paragraph (d)(2)(iv)(C), we proposed to include requirements, which parallel MA requirements (§ 422.572(d)), for applicable integrated plans when obtaining necessary information from noncontract providers.

We received the following comments on the proposals at § 422.631 and our responses follow.

Comment: We received many comments related to the notice requirement in proposed § 422.631(d)(1). Several commenters supported the notice of the integrated organization determination, the required content we proposed, and the requirement that it be written in plain language and available in the language and format that is accessible to the beneficiary. Several commenters requested clarification regarding whether the existing Integrated Denial Notice used by MA plans (Form CMS–10003–NDMCP) would be used to satisfy the requirement for notice of the integrated organization determination. Several other commenters also suggested that CMS develop a model notice to serve as the integrated organization determination notice for applicable integrated plans to use. A commenter recommended that the notice only be required to be sent when there is a denial of the service or item by all coverage sources (that is, Medicare and Medicaid).

Response: We intend to develop a separate model notice that will be used exclusively for integrated organization determinations and that will be specifically tailored to contain information relevant to the unified appeals process we are finalizing in this rule. As finalized in § 422.631(d)(1), the new integrated notice will be sent in cases where a service or item is being denied under Medicare and Medicaid. In addition, as is the case with the current MA Integrated Denial Notice (Form CMS–10003–NDMCP), we will develop instructions for appropriate use of the new model notice. The instructions will also explain how plans should tailor the model notice to explain the outcome to the enrollee in situations where a notice is required. As we note in the Collection of Information section in this final rule, this model notice, and its associated requirements and burden, will be submitted to OMB for approval separately from this final rule once we develop the model and accompanying analyses. The OMB approval process will include a public comment period.

Comment: A commenter recommended that we also make the integrated organization determination notice available for use by plans other than applicable integrated plans.

Response: We decline to accept the commenter's suggestion. We intend to tailor the model notice specifically to the unified appeals process, and information and procedures relevant to that process, we are finalizing in this rule. We do not believe the model notice will be appropriate for enrollees outside the unified process and, as such, the model notice for integrated organization determinations will be specifically tailored for use by applicable integrated plans.

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing § 422.631 substantively as proposed, but with minor modifications to streamline the regulatory text at paragraph (d) as follows:

- We are finalizing proposed paragraph (d)(1) as three new paragraphs, paragraphs (d)(1)(i) through (iii) and making minor grammatical changes.
- We are renumbering proposed paragraphs (d)(1)(i) through (viii) in the final rule as paragraphs (d)(1)(iii)(A) through (H).

(7) Continuation of Benefits Pending Appeal (§ 422.632)

At § 422.632, we proposed rules to implement the provisions added to section 1859(f) of the Act by section 50311 of the Bipartisan Budget Act of 2018 pertaining to continuation of benefits pending appeal under Titles XVIII and XIX, specifically the new provision at section 1859(f)(8)(B)(iv) of the Act. We explained in detail in the proposed rule (83 FR 55008 through 55009) how we interpret this provision as requiring CMS to apply continuation of benefits to all Medicare Parts A and B and Medicaid benefits under our proposed unified appeals processes.

Based on that interpretation, we proposed that the existing Medicaid standards applicable to Medicaid managed care plans for continuation of benefits at § 438.420 apply to applicable integrated plans for Medicare benefits under Parts A and B and Medicaid benefits in our proposed integrated appeals requirements at § 422.632. Under our proposal, if an applicable integrated plan decides to stop (as a termination or suspension) or reduce a benefit that the enrollee is currently authorized to receive, the enrollee could request that the benefit continue to be provided at the currently authorized level while the enrollee's appeal is pending through the integrated reconsideration. The enrollee would be required to make a timely request for the continuation. We proposed, at paragraph (a), a definition for ''timely files.'' This proposed definition mirrored the definition at § 438.420(a), with minor revisions to make the text applicable to applicable integrated plans instead of Medicaid managed care plans.

We proposed, at paragraph (b), to require a previously authorized service covered under Medicaid or Medicare Part A or Part B, excluding supplemental benefits as defined at § 422.102, to be continued pending an appeal of a termination of those services. We proposed to require that the continuation of these services as a covered benefit would be conditioned on meeting the same five criteria listed in § 438.420:

(1) The enrollee files the request for an integrated appeal timely in accordance with § 422.633(e);

(2) The integrated appeal involves the termination, suspension, or reduction of previously authorized services;

(3) The services were ordered by an authorized provider;

(4) The period covered by the original authorization has not expired; and

(5) The enrollee timely files for continuation of benefits.

Because proposed paragraph (b) repeated that language at section 1859(f)(8)(B)(iv) of the Act that limits the continuation of benefits to only benefits under Parts A and B of title XVIII and title XIX of the Act, we noted in the preamble to the proposed rule that MA supplemental benefits would not be subject to the proposed rule (83 FR 55009).

We proposed, at paragraph (c), to require that an applicable integrated plan continue such services pending issuance of the integrated reconsideration. We noted in the proposed rule that for Medicaid managed care plans that are not applicable integrated plans, continuation of these services after the integrated reconsideration and pending resolution of the state fair hearing is controlled by § 438.420(c). Proposed § 422.632(c)(2) provided that continuation of services would end when the applicable integrated plan issues an adverse integrated reconsideration. If the applicable integrated plan finds in favor of the enrollee, benefits would continue in accordance with the favorable integrated

reconsideration. In proposed § 422.632(c)(3), we proposed requirements for Medicaid-covered benefits to continue after the applicable integrated plan issues an adverse integrated reconsideration, mirroring the requirements currently in Medicaid managed care regulations (see § 438.420(c)(2)). The enrollee must make the request and file for a state fair hearing within 10 calendar days after the applicable integrated plan sends the notice of the integrated reconsideration. We also proposed to mirror requirements from § 438.420 for how long Medicaid-covered benefits must continue by requiring that the benefits continue until the enrollee withdraws the request for the state fair hearing or until the state fair hearing decision is issued.

In proposed paragraph (d), we addressed whether an applicable integrated plan can seek recovery for the costs of services provided while an appeal is pending. We proposed not to follow Medicaid's regulations that allow states to determine whether or not a plan, or the state, can seek recovery for the costs of services provided pending appeal. We noted there is no analogous process in Medicare, as continuation of benefits pending appeal is very limited in Medicare and generally only available in cases involving QIO review of inpatient discharges. Instead, drawing in part on the experience of a number of Financial Alignment Initiative demonstrations, we proposed to prohibit recovery of the costs of services provided pending the integrated reconsideration and, for Medicaid-covered benefits, any state fair hearing, to the extent that services were continued solely under § 422.632, for all applicable integrated plans and state agencies.

We solicited comment generally on our proposal regarding continuation of benefits and also requested comments on alternatives, including regarding the feasibility of treating Medicare and Medicaid benefits differently for the purpose of recovery of costs. We summarize the comments on this topic and respond to them as follows:

Comment: Most commenters supported our overall interpretation of the statute extending Medicaid's approach of providing aid pending appeal to items and services covered under Medicare Part A and Part B. One commenter, in supporting our overall approach, urged us to monitor for any unexpected cost consequences to D–SNPs resulting from the rule and encouraged us to ensure that any additional costs resulting from the policy are allowable for bid purposes. Another commenter objected to the entire approach based on concerns about potential cost implications to the integrated D–SNPs subject to the provision. One commenter disagreed with our approach, stating that we should make no changes to Medicare's coverage of items and services pending appeal, although this commenter provided no statutory basis for their perspective.

Response: We appreciate the strong support for our overall approach. As we discussed in the preamble to the proposed rule, we believe the most logical reading of the statutory language directs us to extend Medicaid's aid pending appeal procedure to Medicare Part A and B services covered by applicable integrated plans. Regarding costs, MMPs in the Financial Alignment Initiative have operated under similar rules and have not reported any significant resulting adverse impact on cost. The Regulatory Impact Analysis for our proposed rule, on which we received no comments related to this specific proposal, projected a minimal cost to plans from extending the Medicaid aid pending appeal procedure to Medicare Parts A and B services. We will provide further guidance on this topic for plans as part of the bid submission process.

Comment: We received many comments regarding our approach to recovery of the costs of services provided pending appeal. Many commenters supported our proposal as consistent with the statute, clearer to administer than alternatives, and most protective of beneficiaries. A significant number of other commenters, however, expressed concern that our approach could increase costs and recommended instead that states retain the flexibility to pursue recovery of costs at their discretion.

Response: We thank the commenters for their comments on this issue. After careful consideration of the commenters' perspectives, we are finalizing our proposal with some modifications to § 422.632(d) regarding recovery of the costs. We are finalizing the proposed regulation regarding recovery of costs at the integrated reconsideration level, which is now codified at § 422.632(d)(1). We believe it is highly desirable to have one single rule regarding recovery of costs apply to all services provided pending the issuance of the integrated reconsideration decision pursuant to section 1859(f)(8)(B)(iv) of the Act, rather than to treat Medicare-related and Medicaid-related services differently. We believe that it is simpler and more protective of beneficiaries to prohibit the recovery of the costs of all services provided by an applicable integrated plan pending an integrated reconsideration pursuant to a request filed under § 422.632. All services, both Medicare-related and Medicaid-related, provided by applicable integrated plans through the end of the integrated reconsideration process are considered to be furnished under the requirements of § 422.632 and are therefore not subject to recovery of costs.

However, we find it persuasive that, for cases where a plan's denial is ultimately affirmed, eliminating the ability of states to recover the costs of Medicaid services provided by the applicable integrated plan after the integrated reconsideration is final and pending a state fair hearing could create significant inconsistencies for state Medicaid appeal processes and potentially discourage states from pursuing exclusively aligned enrollment and thereby adopting integrated appeals. Moreover, because our entire integrated process extends only to the integrated reconsideration stage and not to the state fair hearing process, this rule limiting recovery of costs is also limited to costs incurred for continuation of services pending the integrated reconsideration stage. We are therefore designating the text in proposed paragraph (d) as (d)(1) in this final rule with revised text limiting that rule to recovery of costs for services continued pending the integrated reconsideration. We are also finalizing a new provision at paragraph (d)(2) to provide states with the flexibility to recover the costs of services continued pending the state fair hearing phase of an appeal (that is, after the date of the integrated reconsideration decision and until the decision is issued on the state fair hearing), consistent with state rules and with § 438.420(d). We believe this addition should mitigate concerns about costs to states. We also note a number of Financial Alignment Initiative demonstrations do not allow recoupment of costs and MMPs have not reported any adverse financial impact, suggesting a minimal impact on costs from limiting recovery of costs. In summary, under § 422.632(d)(1) and (d)(2), recovery of costs is not permitted for services provided pending the integrated reconsideration. If an enrollee requests a state fair hearing after an adverse integrated reconsideration, then state Medicaid procedures regarding continuation of benefits and recovery of costs will apply. We will work with states and plans to ensure that enrollees are fully informed of these rules. Finally, we note that this provision is

unrelated to the requirement at § 422.634(e) requiring a plan or state to pay the costs of benefits provided in the event a plan's initial decision is reversed at the integrated reconsideration or fair hearing stage. The obligations at § 422.634(e) are similar to those under Medicaid at § 438.424(b) governing effectuation of a decision, and apply to any services the enrollee receives while the appeal is pending, whether or not continuation of benefits was requested under § 422.632.

Comment: A commenter requested that CMS clarify whether services were required to continue pending IRE review. We received a number of comments recommending that we should require coverage of aid pending appeal for Medicare Parts A and B services to extend through the IRE level (and in some comments, through the administrative law judge (ALJ) or higher appeal levels as well), rather than stopping after the integrated reconsideration level. One commenter expressed concern that stopping before the IRE level would discourage appeals. Others encouraged continuation through the IRE level to ensure external review of all appeals before services ended.

Response: The regulation, as proposed and finalized at § 422.632(c)(2), requires integrated applicable plans to continue Medicare Part A and Part B and Medicaid benefits through the issuance of an integrated reconsideration decision under § 422.633(f)(4). If the applicable integrated plan affirms its decision at the integrated reconsideration level and the case involves Medicaid benefits, an enrollee may request a state fair hearing as described in § 422.634(b)(2). From that point forward, existing Medicaid rules apply, including § 438.420 that requires Medicaid managed care plans—regardless whether they are applicable integrated plans—to continue provision of Medicaid benefits on certain terms through the state fair hearing process. We decline at this time to require continuation of Medicare services through the IRE level, and will retain our rule as proposed that requires continuation of Medicare Parts A and B services only through the integrated reconsideration level. Section 1859(f)(8)(B)(iv) of the Act provides authority to extend benefits pending appeal in the context of the unified appeal procedures we are adopting in this rule. We are not at this time integrating IRE review into a unified appeal process; therefore, we believe we lack statutory authority to extend benefits pending to the IRE level review under the unified appeal process. In addition, most of the Financial Alignment Initiative demonstrations have not included aid pending appeal through the IRE level. As a result, we have little experience with either the operational complexities or the financial impact of such a policy. Finally, because IRE review is automatic for all adverse Medicare plan reconsiderations under § 422.592, there is not a risk that enrollees will end their appeal prior to the IRE review. We believe the more prudent course is to implement aid pending appeal for services through the integrated reconsideration level as we have proposed. We may consider the feasibility of broadening the unified appeal process to include IRE review and continuation of benefits through additional appeal levels in future rulemaking.

Comment: A few commenters recommended that continuation of benefits pending appeal also apply to supplemental benefits provided by applicable integrated plans.

Response: We decline to adopt this recommendation and believe that it is not consistent with the statute. Section 1859(f)(8)(B)(iv) of the Act, added by the Bipartisan Budget Act of 2018, authorizes continuation of benefits for integrated appeals is limited to benefits under Medicare Parts A and B as well as Medicaid, but does not include MA supplemental benefits, which are offered under Part C of the Act (specifically section 1852(a)(3) of the Act). We therefore do not have the authority to require continuation of supplemental benefits pending appeal. Plans may continue such benefits voluntarily, however, and states may include conditions affecting coverage of such benefits in their contracts with D–SNPs, so long as enrollees are made aware of any potential risk of financial liability.

Comment: A few commenters suggested that we establish an expedited process for integrated reconsiderations when continuation of benefits pending appeal is requested in order to minimize the risk of payment discrepancies.

Response: We decline to adopt this suggestion. We note that continuation of services pending appeal has long been part of Medicaid appeals and no special expedited process exists for such cases. We do not see a reason for treating integrated reconsiderations differently in this regard. In addition, applicable integrated plans may prioritize resolution of integrated reconsiderations where services are continuing, so long as these plans follow all procedural rules and ensure that enrollees have a full opportunity to present their case. Further, the requirement to expedite certain integrated reconsiderations based on the enrollee's health status (discussed in section II.A.2.b.(8) of this final rule) applies regardless whether benefits are continued under § 422.632.

Comment: A few commenters requested that we add language that would allow plans to dismiss an integrated reconsideration request if an enrollee becomes eligible for a service while the integrated reconsideration is pending.

Response: We decline to make this addition. There are no regulations in the MA program or Medicaid managed care program that address dismissals of reconsiderations or appeals in these circumstances, and we do not believe that we should create a new procedure unique to integrated reconsiderations here. We note that the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, § 50.8, does include guidance regarding dismissal of pre-service reconsideration requests when a service has been provided before the reconsideration is completed. We will consider if additional guidance is needed in this area for integrated reconsiderations when continuation of services is requested.

After considering the comments and for the reasons set forth in the proposed rule and our responses to the comments, we are finalizing § 422.632 as proposed with modifications to paragraph (d). In newly designated paragraph (d)(1), we are making technical changes to the proposed regulation text to clarify that an applicable integrated plan or a state agency may not pursue recovery of costs for services continued pending the integrated reconsideration. In new paragraph (d)(2), we are finalizing a provision that authorizes states to recover the costs of Medicaid services provided during the state fair hearing phase of an appeal (that is, after the date of the integrated reconsideration decision and until the decision is issued on the Medicaid state fair hearing), consistent with state rules and with § 438.420(d).

(8) Integrated Reconsiderations (§ 422.633)

In proposed § 422.633, we laid out our proposed provisions for an integrated reconsideration process for applicable integrated plans. As with other provisions, we compared relevant Medicare and Medicaid provisions, and where they differ, we chose to adopt the policy that is most protective of the beneficiary.

In paragraph (a), consistent with current MA and Medicaid regulations (§§ 422.590 and 438.402(b), respectively), we proposed that

applicable integrated plans may only have one plan level of appeal beyond the initial decision (the integrated organization determination).

In paragraph (b), we proposed to adopt a rule similar to § 438.402(c)(1)(i)(B) regarding the permissibility of external medical reviews: Medicaid managed care plan enrollees may be offered an opportunity to elect external medical review under a state external review process. Under our proposal, the ability to elect external medical review would apply only to Medicaid covered services that are the subject of an adverse integrated reconsideration issued by an applicable integrated plan because D–SNPs, like all MA plans, are not subject to state external review procedures.[27]

In paragraph (c), we proposed a right for each enrollee, and their representatives, to receive a copy of the enrollee's case file (including medical records and evidence considered, generated, or relied on by the integrated applicable plan in making the integrated organization determination) free of charge, consistent with the protection for Medicaid enrollees under § 438.406(b)(5).

In paragraph (d)(1), we proposed timelines for filing for a standard integrated reconsideration that, consistent with both MA (at § 422.582(b)) and Medicaid managed care (at § 438.402(c)(2)(ii)) regulations, would require that an integrated reconsideration be filed within 60 days of the date of the denial notice. We proposed, in paragraph (d)(2), that oral inquiries seeking to make an integrated reconsideration be treated as integrated reconsiderations; this is generally consistent with § 438.406(b)(3). We did not propose to include the language in § 438.406(b)(3) requiring beneficiaries to provide written confirmation of oral requests because such a requirement would be inconsistent with MA policy that directs plans that do accept oral requests for reconsideration to provide written confirmation to the beneficiary (see Parts C & D Enrollee Grievances, Organization/Coverage Determination, and Appeals Guidance, § 50.2.1). We proposed, in paragraph (d)(3), to include current requirements from MA (at § 422.582(c)) that allow for extending the timeframe for an enrollee, or a physician acting on behalf of an enrollee, to file a late reconsideration.

In paragraph (e), we proposed to address procedures for filing expedited integrated reconsiderations, consistent with current MA and Medicaid rules. The proposed language in paragraphs (e)(1) and (e)(2) aligns with § 422.584 in permitting the enrollee or health care provider to file a written or oral request for an expedited reconsideration. The proposed language in paragraph (e)(3) aligns with § 422.584 in setting the standard that the applicable integrated plan must use in deciding whether to expedite the integrated reconsideration.

In paragraph (e)(4), we proposed notice requirements related to requests for expedited integrated reconsiderations. We proposed requirements that parallel Medicaid managed care requirements for notice to the enrollee when the request for an expedited integrated reconsideration is denied (§ 438.410(c)(2))—specifically, that the plan must give prompt oral notice and written notice within 2 calendar days and transfer the matter to the standard timeframe for making an integrated reconsideration (that is, the timeframe specified in paragraph (f)(1)). We proposed to apply the MA requirements for what applicable integrated plans must include in the written notice to enrollees when the request to expedite the integrated reconsideration is denied (§ 422.584(d)(2)).

In paragraph (e)(5) we proposed to include requirements, which mirror MA requirements (§ 422.590(d)(3)), for applicable integrated plans when obtaining necessary information from noncontract providers. These requirements specify that the applicable integrated plan must reach out to a noncontract provider within 24 hours of the initial request for an expedited integrated reconsideration.

In paragraph (f), we proposed timelines and procedures for resolving an integrated reconsideration request. We proposed specific requirements for applicable integrated plans. Both MA (at § 422.590(a)) and Medicaid (at § 438.408(b)(2)) require resolution of pre-service standard appeal requests within 30 calendar days. We proposed the rules in paragraph (f)(1), that parallel MA (at § 422.590(a)) and Medicaid (at § 438.408(b)(2)) with the addition of a provision mirroring § 422.590(a)(2), that the integrated reconsideration decision be issued as expeditiously as the enrollee's health requires but no later than 30 calendar days from the date the applicable integrated plan receives the request for the integrated reconsideration.

In § 422.633(f)(1), we proposed to require that all integrated reconsiderations—pre-service and post-service—be resolved as expeditiously as the enrollee's health requires and within 30 calendar days from the date the applicable integrated plan receives the request for the integrated reconsideration. We noted that this timeframe is consistent with Medicaid managed care requirements for both pre- and post-service requests at § 438.408(b)(2) and with pre-service requests under MA at § 422.590(a). We deviated from the MA requirements for post-service cases involving denial of payment, as current MA requirements provide 60 calendar days for MA plans to resolve these cases.

In paragraph (f)(2), we proposed to establish the timeframes for expedited reconsiderations, which parallel both MA (at § 422.590(d)(1)) and Medicaid (at § 438.408(b)(3)) regulations for managed care plans in requiring the applicable integrated plan to resolve the expedited reconsideration as expeditiously as the enrollee's health requires and within 72 hours from the date the applicable integrated plan receives the request for the integrated reconsideration. We also proposed to apply the Medicaid managed care requirement (at § 438.408(d)(2)(ii)) by requiring that applicable integrated plans make reasonable efforts to give enrollees oral notice of the resolution in expedited cases, in addition to sending the written notice within 72 hours of receipt of the request.

In paragraph (f)(3)(i), we proposed criteria for an applicable integrated plan to extend the timeframe for resolving either a standard or expedited reconsideration. We proposed to adopt a standard similar to current MA and Medicaid rules, allowing 14-day extensions upon request of the enrollee (or the enrollee's representative) and generally using the standard in § 438.408(c) that the plan must show that the extension is in the enrollee's interest and that the information is necessary. We also proposed to use the MA standard that the timeframe may be extended if there is a need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request. We clarified in the preamble of the proposed rule that an applicable integrated plan could not extend the timeframe for making an integrated reconsideration in order to develop or find information to justify a denial of coverage.

In paragraph (f)(3)(ii), we proposed requirements for the notice that applicable integrated plans must send to enrollees when the plan extends the timeframe for making its determination, in accordance with the requirements in this paragraph. We proposed to require that the applicable integrated plan make reasonable efforts to give the enrollee

[27] Section 1856(b)(3) of the Act preempts state regulation of MA plans.

prompt oral notice and give the enrollee written notice within 2 calendar days. These requirements align with current Medicaid managed care regulations at § 438.408(c)(2). We also proposed that the notice of the extension include the reason for the delay and inform the enrollee of the right to file an expedited grievance if the enrollee disagrees with the decision to extend the timeframe.

In paragraph (f)(4), we proposed requirements for providing appellants with notices regarding the resolution of reconsiderations. We proposed to require that applicable integrated plans send notices within the resolution timeframes established in this section for all integrated reconsideration determinations, paralleling the current Medicaid managed care regulations which require notices of all determinations. We also proposed to include language requiring that the notice be written in plain language and available in a language and format that is accessible to the enrollee consistent with section 1859(8)(B)(iii)(III) of the Act. We also proposed, in paragraphs (f)(4)(i) and (ii), to adopt the standards similar to those governing the content of a notice found in § 438.408(e)—namely, that the plan must provide to the enrollee a notice of the integrated reconsideration for an adverse decision that includes the reason for the decision and the date of completion. We proposed in paragraph (f)(4)(ii)(A) that, for integrated notices not resolved wholly in the enrollee's favor, the notice include an explanation of the next level of appeal under both Medicare and Medicaid, and the steps the enrollee must take to further pursue the appeal. We explained our expectation that the integrated notice will enable the enrollee to understand which program covers the benefit at issue. We also proposed in paragraph (f)(4)(ii)(B) that the notice include specific information about the ability to request continuation of Medicaid-covered benefits pending appeal.

We summarize and respond to the comments on proposed § 422.633 as follows:

Comment: Many commenters supported our proposed requirements related to integrated reconsiderations, including the timeframes for applicable integrated plans to resolve integrated reconsiderations. One commenter specifically supported the inclusion of post-service appeals in the expedited integrated reconsiderations process, at § 422.633(e), noting significant financial need that may be present for dual eligible individuals. Another commenter supported the requirement at § 422.633(f)(1) to use the same timeframes and processes for pre-service and post-service appeals to simplify the process for enrollees. One commenter opposed requiring post-service appeals to follow the same decision timing as pre-service appeals, requesting that CMS instead apply the MA rules, which allow 60 days for decision in post-service appeals cases to allow applicable integrated plans more time to gather necessary information, including from enrollees, and potentially leading to fewer plan denials of integrated reconsiderations.

Response: We appreciate the support for our proposed integrated reconsideration requirements. We clarify that the post-service appeals timing applies to appeals from noncontracted providers as well as to enrollees. We understand the concern related to obtaining all necessary information to make a determination for post-service integrated reconsiderations; however, we decline to make a change to our proposed requirements. As we noted in the proposed rule (83 FR 55010–55011), Medicaid regulations at § 438.408(b)(2) do not distinguish between pre-service and post-service appeals—all appeals must be resolved within 30 calendar days. We do not believe the volume of post-service appeals, which would generally be only for payment, is high for dual eligible individuals, and we believe it is more protective of enrollees to have all integrated reconsiderations resolved in 30 calendar days, particularly given what may be significant financial needs for these individuals.

Comment: Several commenters expressed support for our proposed requirement, at § 422.633(c), that applicable integrated plans provide the enrollee or the enrollee's representative with a copy of the enrollee's case file for free, to help eliminate barriers to enrollees in obtaining this information. A few commenters suggested we establish specific timeframes for when the case file should be provided to ensure that it is provided timely, and a commenter suggested that we require the case file be sent automatically whenever an appeal is filed, arguing that such a requirement would be consistent with Medicaid rules.

Response: We decline to modify the regulation text at § 422.633(c) to establish specific timeframes for provision of the case file, since we are adopting the existing requirements related to case files for Medicaid managed care plans at § 438.406(b)(5); that Medicaid managed care regulation does not include timeframes for sending the case file but requires instead that the records and information be provided sufficiently in advance of the resolution timeframe for appeals. As proposed and finalized, § 422.633(c) uses the same standard. We believe this is sufficient and decline to establish a specific deadline for provision of these records and information. We also decline to specify that a plan send a case file for every appeal filed. Rather, we believe that making it clear to appellants that they may request the case file at no charge (for example, as part of the denial notice) will be less burdensome for all parties.

Comment: Several commenters supported the requirement at § 422.633(d)(2) for applicable integrated plans to accept oral requests without requiring written follow up from the enrollee, noting that this requirement helps eliminate barriers for enrollees in filing appeals. One commenter opposed this requirement. One commenter requested that applicable integrated plans have discretion, as MA plans currently do under guidance in the Parts & D Enrollee Grievances, Organization/ Coverage Determination, and Appeals Guidance § 50.2.1, to require written follow-up when enrollees file oral appeals because oral appeals can be difficult to define, track, and standardize.

Response: We thank the commenters for their support of this requirement, and decline to make any changes to it at this time. We assume the comment related to the guidance interpreting § 422.568(a)(1) and providing discretion to MA plans on whether to allow oral reconsiderations referred to the previous version of the CMS Medicare Managed Care Manual, Chapter 13, § 70.2, which stated that an MA plan may choose to accept an oral reconsideration. Similar guidance was published more recently (February 22, 2019) in an updated version of the Parts C & D Enrollee Grievances, Organization/Coverage Determination, and Appeals Guidance, § 50.2.1. We agree that this requirement is an important way to remove barriers to filing appeals for enrollees related to language, literacy, housing, and behavioral health concerns. We believe that requiring applicable integrated plans to allow oral appeals from enrollees without requiring the enrollee to follow up in writing is most consistent with the provision in section 1859(f)(8)(B)(ii)(I) of the Act requiring us to adopt provisions that are most protective for enrollees. In addition, we have recently proposed making a similar change for similar reasons to the Medicaid managed care rule at § 438.402(c)(3)(ii) (see Medicaid and Children's Health Insurance Program

(CHIP) Managed Care (CMS–2408–P), 83 FR 57264, 57283 (November 14, 2018)).

Comment: One commenter requested that, for expedited integrated reconsiderations, we clarify our regulations to align with current MA guidance and explicitly state that applicable integrated plans have three calendar days to mail written notification when verbal outreach to a member is successful.

Response: We decline to adopt this suggestion. Under § 422.633(f)(4), as proposed and finalized in this rule, the applicable integrated plan must send a written determination notice within the resolution timeframes regulations. For expedited integrated reconsiderations, these requirements are located at § 422.633(f)(2). In order to clarify the regulation text and conform it to the preamble of the proposed rule, we are finalizing paragraph (f)(2) with revised text stating that the applicable integrated plan must resolve the expedited integrated reconsideration as expeditiously as the enrollee's health condition requires but no later than 72 hours from the receipt of the request. Pursuant to paragraph (f)(4), this timeframe will also apply to the required written notice to the enrollee. We are also revising the language in the final rule regarding expedited integrated reconsiderations under § 422.633(f)(2) to clarify that the applicable integrated plan must make reasonable efforts to provide prompt oral notice of the determination in addition to providing the written notice, which aligns with Medicaid rules that require oral notification as a separate requirement that is not tied to the timing of the written notification (see § 438.408(d)(2)(ii)).

Comment: One commenter requested that we clarify when the timeline begins for the applicable integrated plan to notify an enrollee of the decision to extend the timeframe for deciding the integrated reconsideration.

Response: We clarify that the applicable integrated plan must notify the enrollee that an extension is being taken within two calendar days of when the applicable integrated plan, after considering the factors outlined in § 422.633(f)(3)(i), makes the decision to take an extension. We are finalizing revised regulation text at § 422.633(f)(3)(ii) to clarify this timing.

Comment: A few commenters supported the requirement at § 422.633(f)(4) that applicable integrated plans send a written determination in all cases when an integrated reconsideration is filed. They also supported the content requirements for the written determination notice. One commenter noted that this notice should include information on how to get assistance with the next level of appeal.

Response: We thank the commenters for their support of this requirement, and we agree that information on how to get assistance with the next step in the appeal process is important and useful information for the enrollee and would be beneficial to include in the notice. We are adding this content requirement to the regulation at § 422.633(f)(4)(ii)(A). This information may include the name and contact information of, for example, the State Health Insurance Assistance Program (SHIP), a state ombudsman program if one exists, or a legal aid office. State Medicaid agencies may also have appropriate local referrals.

For the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing § 422.633 substantively as proposed, but with some minor modifications from proposed text as follows:

- At paragraph (c), we are revising the last sentence to clarify that the records must be provided sufficiently in advance of the resolution timeframe for the integrated reconsideration, or subsequent appeal;
- At paragraphs (d)(1) and (d)(2), we are including headings to aid the reader;
- At paragraph (f)(1), we have modified the regulatory text to clarify that an applicable integrated plan has a maximum of 30 calendar days to resolve the integrated reconsideration, but must resolve it more quickly if the enrollee's health requires faster resolution. As finalized, this language exactly parallels the language from the MA requirement at § 422.590(a);
- At paragraph (f)(2), we have modified the regulatory text to clarify that an applicable integrated plan has a maximum of 72 hours to resolve the expedited integrated reconsideration, but must resolve it more quickly if the enrollee's health requires faster resolution. As finalized, this language exactly parallels the language from the MA requirement at § 422.590(d)(1). We also clarify in paragraph (f)(2) that an applicable integrated plan must make reasonable efforts attempt to provide prompt oral notice of the determination in addition to providing the written notice;
- At paragraph(f)(3)(ii) we clarify the timeframe for the applicable integrated plan to notify the enrollee that an extension is being taken; and
- At paragraph (f)(4), we are finalizing regulatory text as proposed with a modification to clarify that the notice of resolution the applicable integrated plan sends must be a written notice, and to add, at paragraph (f)(4)(ii)(A), a requirement that the notice of resolution contain information on how the enrollee can obtain assistance in pursuing the next level of appeal under each program.

(9) Effect (§ 422.634)

We proposed, at § 422.634(a), to use the same standard as in existing MA and Medicaid regulations related to a plan's failure to made a timely determination. If an applicable integrated plan fails to make a timely determination at any point in the appeals process (for an integrated organization determination or an integrated reconsideration), that failure would constitute an adverse determination, such that the enrollee could move forward with the next level of appeal procedures (see §§ 438.400(b)((b), 438.402(c)(1)(i)(A), 438.408(c)(3), 422.568(f), and 422.572(f)).

We proposed, at § 422.634(b), to establish the next steps in the appeals process if the enrollee receives an adverse decision from the applicable integrated plan on the integrated reconsideration. For cases involving Medicare benefits, we proposed, for applicable integrated plans at § 422.634(b)(1)(i), to codify the requirement that adverse reconsiderations be reviewed and resolved by an IRE, consistent with section 1852(g)(4) of the Act and existing § 422.592. In § 422.634(b)(1)(ii) and (iii), we proposed to mirror existing MA regulations (§ 422.590(a)(2) and (d)(4))[28] with requirements for applicable integrated plans to forward the case file to the independent entity within set timeframes for both standard and expedited integrated reconsiderations.

At § 422.634(b)(2), we proposed that for cases involving Medicaid benefits, the enrollee may initiate a state fair hearing no later than 120 calendar days from the date of the applicable integrated plan's notice of resolution. We also proposed to include the requirement that a provider who has not already obtained the written consent of an enrollee must do so before filing a request for a state fair hearing. We explained in the proposed rule how we intended the timeframe to mirror the appeal right and requirement in the Medicaid managed care regulation at § 438.408(f)(2) and (3).

We proposed, at § 422.634(c), language providing that determinations are binding on all parties unless the case

[28] In the proposed rule (83 FR 55010), we erroneously cited to § 422.590(d)(3) instead of (d)(4) and use the correct reference here.

is appealed to the next applicable level of appeal. We also proposed to specify that this means that, in the event that an enrollee pursues an appeal in multiple forums simultaneously (for example, files for an external state medical review and an integrated reconsideration with the applicable integrated plan, and the integrated reconsideration decision is not in the enrollee's favor but the external state medical review decision is), an applicable integrated plan would be bound by, and must implement, decisions favorable to the enrollee from state fair hearings, external medical reviews, and independent review entities (IRE). As we explained in the proposed rule, for Medicare benefits, the adverse integrated reconsideration would be automatically forwarded to the IRE, pursuant to § 422.634(b)(1), and thus the IRE's determination in those cases would ultimately be binding.

We proposed, at § 422.634(d), requirements for how quickly services must be put in to place for an enrollee after he or she receives a favorable decision on an integrated reconsideration or state fair hearing. In the first sentence of paragraph (d), we proposed that if an applicable integrated plan, or a state fair hearing with regard to a Medicaid benefit, reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services as expeditiously as the enrollee's condition requires but not later than 72 hours. We intended this to mean that when an integrated organization determination or integrated reconsideration decision is favorable to the enrollee for any covered services, and, for Medicaid benefits, when a state fair hearing reverses an applicable reconsideration (that is, makes a decision that is favorable to the enrollee with regard to Medicaid benefits), the same timeframe for the applicable integrated plan to provide the benefits would apply. We also proposed to cross-reference the existing MA regulations at §§ 422.618 and 422.619 that provide how and when disputed Medicare benefits must be provided when an integrated reconsideration denying benefits is reversed at the post-plan level of appeal. Finally, we also proposed in this paragraph to maintain the same effectuation timelines for reversals by the Medicare independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council as apply to other MA plans.

We proposed, at § 422.634(e), for Medicaid-covered benefits, to parallel Medicaid requirements from § 438.424(b) governing how services that were continued during the appeal must be paid for, if the final determination in the case is a decision to deny authorization of the services. For Medicare-covered services, we proposed that the applicable integrated plan will cover the cost of the benefit.

We received the following comments regarding our proposed provisions at § 422.634, and our responses follow.

Comment: A commener supported the proposed requirements at § 422.634. Another commenter requested that we align our requirement at § 422.634(b)(2) with the proposed Medicaid managed care rule to allow states to give enrollees between 90 and 120 days to file for a state fair hearing.

Response: We thank the commenter for their support. Our intent in proposed § 422.634(b)(2) was to follow the timeframes in the existing Medicaid managed care requirements. Because we have proposed a revision to the Medicaid managed care rules (see Medicaid and Children's Health Insurance Program (CHIP) Managed Care (CMS–2408–P), 83 FR 57264 (November 14, 2018)), we are revising the requirement at § 422.634(b)(2) to refer to the timeline requirements in § 438.408(f)(2) rather than stipulating those timelines in our final regulations. By finalizing this cross-reference, the timeframe for an enrollee to request a state fair hearing will be the same regardless of whether the enrollee is appealing a decision by an applicable integrated plan or a Medicaid managed care plan.

After considering the comments and for the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing § 422.634 substantively as proposed, but with some clarifying modifications at paragraphs (a), (b), and (d). In paragraph (a)(2), we are adding a citation to the parallel Medicaid managed care rule at § 438.408(f) for the timeframe for an enrollee to request a state fair hearing. In paragraph (b)(2), we have revised the text to cite to the state fair hearing in the timeframe specified in § 438.408(f)(2), rather than cite a specific timeframe, to ensure alignment with Medicaid managed care rules as described above. In paragraph (d), we are finalizing the first sentence with revisions to clarify that the applicable integrated plan's reversals—of integrated organization determinations and integrated reconsiderations, as well as of state fair hearing reversals—must be effectuated by the applicable integrated plan within 72 hours rather than the MA timeframe in § 422.618(a). The regulation text specifies that state fair hearing decisions are only with regard to Medicaid benefits. Post-plan level appeal decision on Medicare benefits (that is, by the Part C independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council) must be effectuated in accordance with §§ 422.618, and 422.619.

(10) Unifying Medicare and Medicaid Appeals Subsequent to Integrated Reconsideration

The new section 1859(f)(8)(B)(ii) of the Act directs us to include, to the extent we determine feasible, consolidated access to external review under an integrated process. We interpret ''external review'' in this statutory provision as meaning review outside the plan, including by a government agency or its designee. For MA, this includes the independent review entity (IRE) and ALJ review described in §§ 422.592 through 422.602. For Medicaid, this includes the state fair hearing process described in Part 431 Subpart E, as well as any additional external review offered under state law.

We believe that such a process could offer benefits to beneficiaries, plans, states, and the federal government. Currently, once a D–SNP or Medicaid managed care plan makes a final decision on an appeal, the federally-administered Medicare and state-administered Medicaid appeals processes are entirely separate. Although they have some common principles, such as ensuring access to an independent administrative hearing, they differ in many respects. In the proposed rule (83 FR 55012 through 55015), we detailed the considerable challenges of unifying D–SNP and Medicaid appeals subsequent to the reconsideration level.

Based on these complexities, we stated in the proposed rule our belief that it is not feasible to propose a unified post-plan appeals process (that is, adjudication of appeal subsequent to an applicable integrated plan's integrated reconsideration of an initial adverse determination) at this time. Instead, we solicited comments on viable paths forward given the constraints presented by the statutory mandates for the MA and Medicaid appeals processes and our experience gained through demonstrations. We received comments from six commenters. Overall, the commenters expressed support for continued efforts

to move forward in this area in the future. We thank these commenters for the time and effort expended on providing us with comments on the establishment of a unified post-plan appeals process in potential future rulemaking. We will take the comments into consideration as we continue work on this issue.

(11) Conforming Changes to Medicare Managed Care Regulations and Medicaid Fair Hearing Regulations (§ 422.562, § 422.566, § 438.210, § 438.400, and § 438.402)

We proposed a number of changes to Medicaid managed care, Medicaid fair hearing, and Medicaid single state agency regulations to conform with our proposed unified grievance and appeals provisions. Following is a summary of these proposed changes.

- In § 422.562(a)(1)(i) and (b), we proposed to add cross references to the proposed integrated grievance and appeals regulations along with new text describing how the provisions proposed in this rule for applicable integrated plans would apply in place of existing regulations.
- In § 422.566, we proposed to add additional language to paragraph (a) to establish that the procedures we proposed in this rule governing integrated organization determinations and integrated reconsiderations at proposed § 422.629 through § 422.634 apply to applicable integrated plans in lieu of the procedures at §§ 422.568, 422.570, and 422.572.
- In § 438.210(c) and (d)(4), we proposed to add cross references to the proposed integrated grievance and appeals regulations along with new text describing how the provisions proposed in this rule for applicable integrated plans would apply in place of existing regulations to determinations affecting dual eligible individuals who are also enrolled in a D–SNP with exclusively aligned enrollment, as those terms are defined in § 422.2. In § 438.210(f), we proposed to make these Medicaid changes applicable to applicable integrated plans no later than January 1, 2021, but, consistent with our discussion earlier on the effective dates of our proposed unified appeals and grievance procedures overall, we would not preclude states from applying them sooner.
- In § 438.400, we proposed adding a new paragraph (a)(4) to include the statutory basis for the proposed integration regulations (section 1859(f)(8) of the Act). We also proposed to amend § 438.400(c) to clarify that these Medicaid changes apply to applicable integrated plans no later than January 1, 2021, but, consistent with our discussion elsewhere in this final rule, we would not preclude states from applying them sooner.
- In § 438.402, we proposed amending paragraph (a) to allow a Medicaid managed care plan operating as part of an applicable integrated plan to the grievance and appeal requirements laid out in §§ 422.629 through 422.634 in lieu of the normally applicable Medicaid managed care requirements.

We received the following comments, and our responses follow.

Comment: We received several comments related to the effective date for the unified grievance and appeals procedures, including our statement in the proposed rule that states could require applicable integrated plans to implement such procedures prior to January 1, 2021, using the state Medicaid managed care contract and the contract with the D–SNP required under § 422.107. Some commenters objected to earlier implementation, noting the many processes that applicable integrated plans will need to complete, such as systems changes, staff training, policy and procedure development and implementation, and developing enrollee communication materials, as well as the need for CMS to release further guidance prior to the effective date. One commenter noted that applicable integrated plans need all final guidance from CMS one year prior to implementation. Another commenter supported early implementation, provided such early implementation would be on a trial basis only, and plans would not be subject to intermediate sanctions, penalties, or audits.

Response: We understand the commenters' concerns about the need for sufficient time to implement the unified grievance and appeals processes we are finalizing in this rule. As we stated in the proposed rule, these processes will apply to a relatively small subset of states and plans, and while early implementation at state option is possible, we do not anticipate many states implementing the processes earlier than required (that is, beginning January 1, 2021) for many of the reasons cited by these commenters. However, CMS will work closely with any state interested in early implementation to ensure that impacted applicable integrated plans have the guidance they need.

For the reasons explained in the proposed rule and our responses to comments, we are finalizing substantively as proposed the conforming changes to §§ 422.562, 422.566, 438.210, 438.400, and 438.402. We are making the following additional non-substantive changes to the noted regulations:

- We are modifying the regulatory text at § 422.562(a)(1)(i), (b)(1), (b)(2), (b)(3), (b)(4)(i), and (b)(4)(ii), and at § 422.566(a), to clarify that the effective date of the unified appeals and grievance processes finalized in this rule is January 1, 2021. We are also making a minor grammatical change to § 422.566(a) to make the language addressing applicable integrated plans a separate sentence.
- We are changing ''MA plans'' to ''Medicare Advantage plans'' in § 438.400(a)(4) because the term ''MA plans'' is not defined Part 438.
- We are finalizing § 438.402 substantively as proposed, but with some modifications to clarify that, for post-plan appeals of Medicaid benefits, state fair hearing processes and requests are subject to § 438.408(f).
- We are changing ''section'' to ''part'' in § 438.400(c)(2) to clarify that the provisions affecting applicable integrated plans throughout Part 438 are applicable no later than January 1, 2021.

3. Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153)

a. Background

This final rule sets forth the manner in which CMS will implement section 50354 of the Bipartisan Budget Act of 2018 (BBA), Public Law 115–123, enacted on February 9, 2018. Section 50354 amends section 1860D–4(c) of the Social Security Act by adding a new paragraph (6) entitled ''Providing Prescription Drug Plans with Parts A and B Claims Data to Promote the Appropriate Use of Medications and Improve Health Outcomes''. Specifically, section 1860D–4(c)(6)(A), as added by section 50354 of the BBA, provides that the Secretary shall establish a process under which the sponsor of a Prescription Drug Plan (PDP) that provides prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare claims data about its plan enrollees. Such extracts would contain a subset of Medicare Parts A and B claims data as determined by the Secretary. In defining the specific data elements and time frames for the Parts A and B claims data included in such extracts, hereinafter referred to as ''Medicare claims data,'' the Secretary is instructed, at section 1860D–4(c)(6)(D) of the Social Security

Act, to include data ''as current as practicable.''

Section 1860D–4(c)(6)(B) of the Act, as added by section 50354 of the BBA, further specifies that PDP sponsors receiving such Medicare claims data for their corresponding PDP plan enrollees may use the data for: (i) Optimizing therapeutic outcomes through improved medication use; (ii) improving care coordination so as to prevent adverse healthcare outcomes, such as preventable emergency department visits and hospital readmissions; and (iii) for any other purposes determined appropriate by the Secretary. Finally, section 1860D–4(c)(6)(C) states that the PDP sponsor may not use the data: (i) To inform coverage determinations under Part D; (ii) to conduct retroactive reviews of medically accepted conditions; (iii) to facilitate enrollment changes to a different PDP or a MA–PD plan offered by the same parent organization; (iv) to inform marketing of benefits; or (v) for any other purpose the Secretary determines is necessary to include in order to protect the identity of individuals entitled to or enrolled in Medicare, and to protect the security of personal health information.

b. Provisions of the Proposed Rule

To implement the new statutory provision at section 1860D–4(c)(6) of the Act, as added by section 50354 of the BBA, we proposed to add a new paragraph (g) at § 423.153. We summarize our proposals and comments received and provide our responses and final decisions.

c. Purposes and Limitations on the Use of Data

In accordance with section 1860D–4(c)(6)(B) of the Act we proposed to limit the purposes for which PDP sponsors are permitted to use the Medicare claims data. Consistent with the statute, we proposed at § 423.153(g)(3) that PDP sponsors would be permitted to use Medicare claims data to optimize therapeutic outcomes through improved medication use, and to improve care coordination so as to prevent adverse health outcomes. In addition, we proposed to permit PDP sponsors to use Medicare claims data for the purposes described in the first or second paragraph of ''health care operations'' under 45 CFR 164.501, or that qualify as ''fraud and abuse detection or compliance activities'' under 45 CFR 164.506(c)(4). We also proposed to permit disclosures that qualify as a ''required by law'' disclosure as defined at 45 CFR 164.103.

In accordance with section 1860D–4(c)(6)(C) of the Act, we proposed specific limitations on how Medicare claims data provided to the PDP sponsors may be used. Consistent with statutory limitations, we proposed that PDP sponsors must not use Medicare claims data provided by CMS under this subsection for any of the following purposes: (1) To inform coverage determinations under Part D; (2) to conduct retroactive reviews of medically accepted indications determinations; (3) to facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization; or (4) to inform marketing of benefits.

Section 1860D–4(c)(6)(C)(v) of the Act provides that the Secretary may place additional limitations on the use of Medicare claims data as necessary to protect the identity of individuals entitled to, or enrolled in, benefits under Part D, and to protect the security of personal health information. Therefore, we also proposed to require that the PDP sponsor contractually bind its Contractors that will be given access to Medicare claims data, and to require those contractors to contractually bind any further downstream data recipients, to the terms and conditions imposed on the PDP Sponsor. In addition, we proposed to allow CMS to refuse future releases of Medicare claims data if it determines or has a reasonable belief that the PDP sponsor has made unauthorized uses, reuses, or disclosures of prior data received under this provision. We also proposed that a PDP sponsor would have to complete a data attestation as part of the data request process to ensure an understanding of the purposes for which the Medicare claims data may be used and the limitations on its reuse, and redisclosure.

Comment: A commenter recommended CMS explore ways to share the same Parts A and B claims data with Medicare Advantage (MA) plans and Cost plans.

Response: We appreciate the suggestion that CMS explore ways to share the same Medicare data with MA plans and Cost plans. While we understand that this data may be helpful to MA and Cost plans, section 1860D–4(c)(6)(A) only provides that the Secretary shall establish a process for the sponsor of a Prescription Drug Plan (PDP) sponsor. We are continuing to evaluate additional pathways for data sharing and may consider data sharing with MA plans and Cost plans in the future.

Comment: A commenter requested additional clarification on how the data could be used for fraud and abuse detection purposes. Specifically, the commenter requested that CMS clarify that while PDP sponsors may not use the Parts A and B data to change individual coverage determinations decisions alone, they may review this data as part of an effective fraud and abuse detection program.

Response: We appreciate the request to clarify the relationship between the prohibition that PDP sponsors must not use the Medicare claims data provided under this provision to change individual coverage determination decisions with the permissible use of the Medicare claims for fraud and abuse detection or compliance activities. As stated earlier, the statutory language prohibits the use of the Medicare claims data to inform coverage determinations under Part D and to conduct retroactive reviews of medically accepted determinations. There are a number of fraud and abuse detection or compliance activities that the Medicare claims data can be used for that would not impact an individual Medicare enrollee's coverage determination under Part D. For instance, the PDP sponsor could use the Medicare claims data to create algorithms that detect fraud and abuse and this information could be used to inform future policies or procedures. PDP sponsors also could use the Medicare claims data for internal and external audits or to identify fraud and abuse activities by providers and suppliers. We also encourage the PDP sponsors to refer to the current compliance and fraud, waste, and abuse programs that are in place under the Part D Sponsor compliance program and the suggested elements that CMS has provided to Part D sponsors to consider when developing these programs.

Comment: Most commenters supported CMS's proposal for the permitted uses of the data. A few commenters suggested additional permissible uses of the data. A commenter suggested that CMS allow the use of Medicare claims data for value-based contracting. Another commenter encouraged CMS to include, as a permissible use, use of the data to make favorable coverage determination decisions. Finally, a commenter suggested that CMS permit plan sponsors to use the data for any other purpose for which protected health information can be used under HIPAA, including as de-identified data.

Response: We thank commenters for their support of the proposal. When we considered expanding the permitted uses of the data provided to the PDP sponsors beyond the statutory uses, we took into account a number of factors.

First, we examined the purpose for which Medicare claims data is provided, namely to promote the appropriate use of medications and improve health outcomes. Second, we considered the statutory limitations imposed on the use of the data, specifically that the data not be used to inform coverage determinations or to conduct retroactive review of medically accepted indications. Finally, we took into account that this is a new data disclosure. Therefore, we decided to make the additional permitted uses narrow. While we will not expand the permitted uses as suggested at this time, we will continue to assess whether additional permissible uses of the data should be proposed in future rulemaking.

Comment: A commenter requested CMS release more specific guidance on how the data could potentially be used and provide for additional comment opportunities so feedback can be shared with CMS.

Response: We thank the commenter and believe that the rule provides adequate information on the limits and permissible uses of the data under this section. We will continue to assess the program to determine if additional guidance is needed and welcome stakeholders to provide additional feedback or seek clarification on program requirements. If CMS makes future changes to the regulatory requirements of this program, then stakeholders will be able to provide feedback during that rulemaking process.

Comment: A few commenters recommended that CMS not expand the permissible uses beyond what was explicitly provided for in statute. These commenters were concerned that the expanded uses conflict, or have the potential to conflict, with the directive in the statute that PDPs may not use this information ''to inform coverage determinations under Part D'' or to conduct retroactive reviews of medically accepted indications. In particular, they were concerned about the use of the data for fraud and abuse detection and compliance activities. They encouraged CMS to limit disclosures under this authority to those expressly allowed by statute, to monitor plan's use of the data, and only consider expansion after the Secretary has evaluated plans' actual use of this data as well as the agency's audit and review capacity.

Response: We thank commenters for this feedback. Section 1860D–4(c)(6)(B)(iii) of the Act states that the Secretary can determine if there are other appropriate purposes for which the data can be used. Therefore, consistent with this statutory authority, we proposed to narrowly expand on the permitted uses of the Medicare claims data based on the factors discussed earlier. In terms of concerns about the use of the data for fraud and abuse detection and compliance activities, we clarified previously that the use of the claims data would still need to comply with the statutory limitations on the use of the data at § 423.153(g)(4). These fraud and abuse activities would not focus on an individual Medicare enrollee's Part D coverage, but rather, these fraud and abuse detection and compliance activities would be aimed at plans and providers/suppliers. In addition, as discussed in the proposed rule, we believe that PDP sponsors are required to comply with the applicable HIPAA rules, so they would have extensive experience ensuring that data is only used and disclosed as permitted or required by applicable laws. We believe that PDP sponsors understand and will abide by their obligations regarding the permitted uses and limitations on the use of Medicare data provided under this provision.

Comment: A few commenters disagreed with the limitations on using these data for coverage determinations and to conduct retroactive reviews of medically accepted indications determinations. A commenter stated that with access to claims data, PDP sponsors would be better positioned to identify appropriate interventions related to medication adherence, opioid overutilization, risk adjustment and other medication management related requirements of PDP sponsors. Another commenter stated that because plan sponsors that offer standalone Part D benefits (PDP sponsors) have no contracts with prescribing providers, they currently have no mechanism for ensuring that medications are appropriate. They further asserted that access to claims data would allow PDP sponsors to validate whether prescriptions are medically supported, as well as to identify other interventions related to opioid overutilization, medication adherence, risk adjustment and other functions related to requirements for Part D sponsors.

Response: We appreciate the feedback on the limitations on the use of the data; however, the statutory language at section 1860D–4(c)(6)(C) of the Act states that PDP sponsors must not use Medicare claims data provided by CMS under this subsection for any of the following purposes: (1) To inform coverage determinations under Part D; (2) to conduct retroactive reviews of medically accepted indications determinations; (3) to facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization; or (4) to inform marketing of benefits.

Comment: A number of commenters requested clarification that the permissible uses and limitations provided in this rule only apply to the Medicare data received under this provision and not to Medicare data that is obtained through other data disclosure pathways. For instance, a commenter requested that CMS clarify that Medicare data obtained through different sources may still be used for coverage determinations and to determine medically accepted indications. Another commenter requested clarification on how the permissible and impermissible use of this claims data will be taken into account for purposes of audits and other reviews—specifically, they requested confirmation that PDP sponsors will not be penalized for failing to implement Medically Accepted Indications (MAI) and other restrictions, even if the plan sponsor has Medicare claims data on hand since PDP sponsors are explicitly prohibited from using the Medicare claims data provided under this provision to conduct retroactive reviews of medically accepted indications determinations.

Response: We appreciate the request for clarification. The limitations and permissible uses of the Medicare claims data at § 423.513(g)(3) and (4) only apply to the data received under the authority of section 1860D–4(c)(6) of the Act. Medicare claims data provided to PDP sponsors under another program or pathway are subject to those program requirements. PDP sponsors are not permitted to use the Medicare claims data provided under this provision for any of the impermissible purposes specified by the statute at section 1860D–4(c)(6)(C). Therefore, we do not see how a PDP sponsor would be held accountable for not using that Medicare claims data in a manner that conflicts with the statutory requirements.

Comment: We received several comments on the requirement that PDP sponsors complete a data attestation as part of the data request process. A few commenters questioned whether an attestation is sufficient to ensure compliance and urged CMS to monitor Part D plan sponsors' use of the data to ensure restrictions are enforced. A commenter expressed concern that PDP sponsors do not need to show with any specificity how they intend to use the data or the results that they expect. Another commenter recommended CMS

not adopt an attestation requirement given the statutory obligations on plans relating to their use of the Medicare data. Another commenter mentioned that they would provide comments on the data attestation as part of the PRA process.

Response: Section 1860D–4(c)(6)(C)(v) of the Act provides that the Secretary may place additional limitations on the use of Medicare claims data as necessary to protect the identity of individuals entitled to, or enrolled for, benefits under Part D, and to protect the security of personal health information. In proposing additional limitations on the use of the Medicare data, we sought to balance the burden on PDP plans with CMS' commitment to ensuring beneficiary-level data is protected by strict privacy and security requirements. We believe that the data attestation requirement is a means of ensuring an understanding of, and compliance with, the terms and conditions of data access and seeks an appropriate balance. In terms of monitoring, we will pursue any complaints regarding a PDP sponsor's violation of program requirements. We would emphasize that CMS may refuse to make future releases of Medicare claims data to a PDP sponsor if the Agency makes a determination or has a reasonable belief that unauthorized uses, reuses, or disclosures have taken place. We believe this approach to monitoring is sufficient since we believe that PDP sponsors are required to comply with the HIPAA rules. Therefore, they have experience ensuring that data can only be used and disclosed for specific purposes. We believe that PDP sponsors understand and will abide by their obligations regarding the permitted uses and limitations on the Medicare data under this provision. However, as this program is implemented, we will continue to monitor and assess our program compliance policies to determine if additional oversight or guidance materials are needed on the use of the data.

In terms of the PRA process, we published a stand-alone 60-day **Federal Register** notice that set out the requirements and burden associated with the request and attestation (November 30, 2018; 83 FR 61638). We are also realigning the provision with this rulemaking by setting out such requirements and burden in section III.B.4 of this final rule. In this regard we will not be publishing a stand-alone 30-day **Federal Register** notice.

Comment: A commenter requested clarification as to PDP sponsors' access to the data (for example, single point person or multiple individuals within the PDP permitted to access the data extract).

Response: As discussed earlier, we believe that PDP sponsors are required to comply with the HIPAA Rules, including Privacy, Security and Breach Notification requirements. They are accustomed to dealing with limitations on the use and disclosure of data. We expect that they will designate a data custodian as the recipient, and establish policies and procedures as to use and disclosure that will comply with all applicable law, including this program's data usage limitations, and the limits on use and disclosure under the HIPAA regulations, including the minimum necessary concept.

We are finalizing the policy as proposed.

d. Data Request

Section 1860D–4(c)(6)(A) of the Act provides that the Secretary shall establish a process under which a PDP sponsor of a prescription drug plan may submit a request for the Secretary to provide the sponsor with standardized extracts of Medicare claims data for its enrollees. Therefore, we proposed at § 423.153(g)(1) to establish a process by which a PDP sponsor may submit a request to CMS to receive standardized extracts of Medicare claims data for its enrollees. We proposed to accept data requests on an ongoing basis beginning January 1, 2020. We proposed to require that such data requests be submitted in a form and manner specified by CMS. Consistent with the discretion accorded to the Secretary under section 1860D–4(c) (6)(D) of the Act, we proposed not to allow PDP sponsors to request data for subsets of their enrolled beneficiary populations. We proposed allowing requests to be submitted without an end date, such that the request, once reviewed for completeness and approved, would remain in effect until one or more of the following occur: the PDP sponsor notifies CMS that it no longer wants to receive Medicare claims data, CMS cancels access to Medicare claims data when a PDP sponsor leaves the Part D program, or CMS concludes or has a reasonable belief, at its sole discretion, that the PDP sponsor has used, reused or disclosed the Medicare claims data in a manner that violates the requirements of section 1860D–4(c)(6) of the Act and § 425.153(g). Upon receipt of the request from the PDP sponsor and the PDP's execution of an attestation discussed earlier, and review for completeness and approval of the application by CMS or its contractor, we proposed that the PDP sponsor would be provided access to Medicare claims data. We note that access to Medicare claims data will be further subject to all other applicable laws, including, but not limited to, the part 2 regulations governing access to certain substance abuse records (42 CFR part 2).

Comment: One commenter expressed concern about providing information on the entire membership on a continuous basis regardless of whether the Part D plan needs the complete data set or membership.

Response: We believe that in order to accomplish the purposes of the statute to promote the appropriate use of medications and improve health outcomes that the PDP sponsor will need Medicare claims data for all of its enrollees. We also believe that this approach is consistent with the discretion afforded to the Secretary under section 1860D–4(c)(6)(D) of the Act.

Comment: A commenter requested that CMS clarify how this will comply with the regulations governing the disclosure of substance use disorder data and address whether PDP sponsors will be required to scrub the substance use disorder data from the extract.

Response: In compliance with the part 2 regulations governing access to certain substance abuse records (42 CFR part 2), we do not anticipate providing substance use disorder data to PDP sponsor under this program.

We are finalizing the policy as proposed.

e. Data Extract Content

Section 1860D–4(c)(6)(D) of the Act provides the Secretary with the discretion to determine the time frame and claims data under Parts A and B to be included in the standardized extracts provide to PDP sponsors. To develop a proposed data set to include in the standardized extracts of Medicare claims data, we first considered what Medicare claims data PDP sponsors might require if they were to undertake the activities expressly permitted by section 1860D- 4(c)(6)(B) of the Act. In doing so, we attempted to limit the data set to the minimum data that we believe PDP sponsors would need to carry out those statutory activities and the additional activities we proposed to permit under § 423.153(g)(3). That is, we sought to establish data access limits that would comport with the HIPAA Privacy Rule's minimum necessary concept at 45 CFR 164.502(b) and 164.514(d), and CMS' policy-driven data release policies.

We proposed that data from all seven claim types, including inpatient, outpatient, carrier, durable medical equipment, hospice, home health, and skilled nursing facility data, would be

required to carry out the permitted uses of the data under section 1860D–4(c)(6)(B) of the Act and the proposed provision at § 423.153(g)(3). Because section 1860D–4(c)(6) of the Act focuses on providing Medicare claims data to promote the appropriate use of medications and improve health outcomes, we proposed to initially include the following Medicare Parts A and B claims data elements (fields) in the standardized extract: An enrollee identifier, diagnosis and procedure codes (for example, ICD–10 diagnosis and Healthcare Common Procedure Coding System (HCPCS) codes); dates of service; place of service; provider numbers (for example, NPI); and claim processing and linking identifiers/codes (for example, claim ID, and claim type code). We proposed that CMS would continue to evaluate the data elements provided to PDP sponsors to determine if data elements should be added or removed based on the information needed to carry out the permitted uses of the data. Any proposed changes would be established through rulemaking.

We next considered the beneficiary population for which we should draw the identified data elements, and what time span of data would best serve PDP sponsors while honoring the requirement at section 1860D–4(c)(6)(D) of the Act that the data should be as current as practicable. Therefore, because only the most timely data is needed for care coordination purposes, we proposed at § 423.153(g)(2) to draw the standardized extracts of Medicare claims data for items and services furnished under Medicare Parts A and B to beneficiaries who are enrolled in a Part D plan offered by the Part D sponsor at the time of the disclosure. We proposed to make standardized data extracts available to eligible PDP sponsors at least quarterly, as described earlier, but only on a specified release date that would be applicable to all eligible PDP sponsors. We also anticipate that Medicare claims data would be provided at least quarterly with approximately a 3-month lag from the last day of the last month of the prior quarter. In addition, given the permitted uses of the data, we proposed to use a standard format to deliver the resulting data to each PDP sponsor with standard format extracts, meaning that CMS would not customize the extracts for a PDP sponsor. We believe that these standardized data extracts would provide PDP sponsors with the minimum data necessary to carry out the permitted uses specified in section 1860D–4(c)(6)(B) of the Act and as proposed at § 423.153 (g)(3). We solicited comments about the proposed frequency and contents of the standardized data extracts.

Comment: We received a few comments seeking clarification on the standardized data extract. A commenter requested clarification about the inclusion of Part A and B data furnished by MA plans. Another commenter requested clarification that the data feed includes enrollees who may not be new to Medicare coverage, but are new to the health or PDP sponsor. A commenter requested the inclusion of Part D claims data for lives enrolled in or attributed to MA Plans and ENHANCED Track ACOs.

Response: We appreciate commenters' request for clarification. We proposed at § 423.153(g)(2) to draw the standardized extracts of Medicare claims data for items and services furnished under Medicare Parts A and B to beneficiaries who are enrolled in a Part D plan offered by the Part D sponsor at the time of the disclosure. The standardized data extract only includes Parts A and B claims data furnished under Medicare as there are no Part A and B data for MA plans. The standardized extract also does not include Part D data. We would also clarify that the standardized data extract will include all enrollees for a PDP sponsor at the time of the disclosure. Therefore, if an enrollee is new to the PDP sponsor, but not to Medicare, that enrollee will be included in the standardized extract.

Comment: A commenter recommended that CMS provide itself flexibility to not have to amend the rules every time it changes the data elements included in the data extract.

Response: We appreciate the commenter's suggestion, however, CMS believes that it is necessary to provide stakeholders with the opportunity to comment on any proposed data variables to ensure they are necessary to carry out the statutory activities and the additional activities that are proposed to be permitted under § 423.153(g)(3).

Comment: Several commenters were supportive of the data elements that were proposed. However, a commenter suggested that Hierarchical Condition Category (HCC) and Prescription Drug Hierarchical Condition Category (RxHCC), which are risk adjustment scores, would also be beneficial as they could be used to assess the degree of morbidity and potential morality associated with a beneficiary to determine whether there is a need for outreach or interventions, which would improve medication outcomes, and for identifying potential fraud and abuse.

Another commenter suggested the inclusion of national drug codes (NDC), lab results, and patient reported outcomes to support the evaluation of effectiveness of value-based contracts.

Response: We appreciate the suggested additions to the data variables. We do not believe that the HCC and RxHCC risk scores that are used to set payment rates are consistently informative for the purposes for which data is made available under this regulation, namely to provide PDPs with information that allows them to optimize therapeutic outcomes through improved medication use, and to improve care coordination so as to prevent adverse health outcomes. The claims data that will be provided under this regulation will provide a comprehensive clinical picture of each member, including utilization, cost, and diagnostic information. We do not believe that risk scores would provide significant information above and beyond what the claims data will provide. Further, risk scores for a year are not finalized until after that year is complete, and therefore, to the extent they theoretically could be pertinent for some aspect of care coordination, would not be complete until after treatment decisions have been made. We also note that if a PDP sponsor were to want the risk score of their members, they receive their Part D risk scores monthly, along with a report of the specific HCCs that contribute to those scores. If they believe that Part C risk scores would be helpful—that is, risk scores that predicted relative expected expenditures for Part A and B services—they would have the data available to them to calculate these risk scores with the claims data. With respect to the NDC, Part A claims data do not include NDC, and only very rarely is the NDC included on the Part B claims data. The statute instructs the Secretary to provide claims data, in which NCDs are generally not available. Therefore, we do not have the authority under this program to supplement the claims data made available under this provision. Finally, CMS also does not have access to lab results or patient reported outcomes in parts A and B claims data, and therefore would be unable to provide that information.

Comment: One commenter suggested adopting an existing standard format for Parts A and B data after soliciting and considering stakeholder feedback.

Response: We anticipate that the data will be provided in standard data format. CMS will publish the standard format publicly once it is finalized. As this provision is implemented, we will continue to seek feedback on the data format.

Comment: A number of commenters urged CMS to make data available as real-time and with as short of a lag time as possible, for instance on a monthly basis.

Response: We recognize that more timely data with a shorter lag time would be helpful to PDP sponsors in achieving the goals of this program. Currently, our infrastructure only supports delivery of quarterly data extracts that have roughly a five-month lag time. Our goal is to provide the Medicare data as timely and with as little of a lag in the claims data as possible and are striving to meet this goal.

Comment: A few commenters suggested providing historical data for enrollees. A commenter suggested providing historical data as it is critical to support the execution of value-based contracts and suggested a look back period of at least a year, similar to the Enhanced Medication Therapy Management (EMTM) program. Another commenter suggested providing historical data for the creation of value-based care tools to avoid counter indications. Another commenter recommended a 14-month look back similar to the Bundled Payment for Care Improvement Initiative (BPCI).

Response: Section 1860D–4(c)(6)(D) of the Act provides that the Secretary shall make standardized extracts available to PDP sponsors with data that is the most current as practicable. While we understand that historical data may assist PDP sponsors, we must adhere to the statutory language. As this program matures, PDP sponsors will amass historical data.

Comment: A commenter suggested the use of an Application Programming Interface (API) given the volume of Medicare claims data that will be provided to PDP sponsors. This commenter also suggested leveraging the process established through Blue Button 2.0 to allow beneficiaries to release Parts A and B claims directly to PDP plan sponsors.

Response: We appreciate this comment and will explore leveraging an API to enhance data releases to PDP sponsors.

Comment: Another commenter requested clarification on the term ''process and ship the data extracts.''

Response: Under the current data fulfillment process, CMS receives the approved request for data. A CMS contractor then extracts the data based on the cohort criteria, validates and performs a quality check on the data extract, and ships the data on an encrypted external hard drive to PBP sponsors.

Comment: A commenter believed that the CMS Health Plan Management System (HPMS) would be an adequate delivery system for the data extracts.

Response: We would clarify that the Medicare claims data extracts will be shipped to PDP sponsors, however, we are exploring the use of the CMS HPMS for submission of the data request by PDP sponsors.

We are finalizing the policies as proposed.

B. Improving Program Quality and Accessibility

1. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i) and 423.186(i))

a. Introduction

Last year, in the April 2018 final rule, CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 83 FR 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 83 FR 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and advance notice regarding enhancements to the Part C and D Star Ratings program. Going forward CMS must propose through rulemaking any changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes. The April 2018 final rule included mechanisms for the removal of measures for specific reasons (low statistical reliability and when the clinical guidelines associated with the specifications of measures change such that the specifications are no longer believed to align with positive health outcomes) but, generally, removal of a measure for other reasons would occur through rulemaking.

Commenters to the November 2017 proposed rule (82 FR 56336) expressed overall support for the use of the hierarchical clustering algorithm which is the methodology used for determining the non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measure-specific cut points. The cut points are used to separate a measure-specific distribution of scores into distinct, non-overlapping groups, or star categories. The cut points are determined using the hierarchical clustering algorithm based on the given year's performance data. Performance data changes from year to year based on industry performance. Therefore, the cut points can also change from year to year. While there was overall support for the use of the hierarchical clustering algorithm, the majority of commenters also recommended some enhancements be made to the proposed clustering methodology to capture the attributes that they consider important. Commenters expressed a strong preference for cut points that are stable, predictable, and free from undue influence of outliers. Further, some commenters expressed a preference for caps to limit the amount of movement in cut points from year to year. CMS did not finalize any changes in last year's rule to the clustering algorithm for the determination of the non-CAHPS cut points for the conversion of measure scores to measure-level Star Ratings, in order to allow the necessary time to simulate and examine the feasibility and impact of the suggestions provided in response to the proposed rule. In addition, CMS evaluated the degree to which the simulations captured the desired attributes identified by the commenters.

In the November 2018 proposed rule, we proposed enhancements to the cut point methodology for non-CAHPS measures. We also proposed substantive updates to the specifications for 2 measures for the 2022 Star Ratings and substantive updates to the specifications for 1 measure for the 2023 Star Ratings. We also proposed rules for calculating Star Ratings in the case of extreme and uncontrollable circumstances. Unless otherwise stated, data would be collected and performance would be measured as described in these proposed rules and regulations for the 2020 measurement period; the associated quality Star Ratings would be released prior to the annual election period held in late 2021 for the 2022 contract year and would be used to assign Quality Bonus Payment ratings for the 2023 payment year. Because of the timing of the release and use in conjunction with the annual coordinated election period, these would be the ''2022 Star Ratings.''

CMS appreciates the feedback we received on our proposals. In the sections that follow, which are arranged by topic area, we summarize the comments we received on each proposal and provide our responses. Below we summarize some comments we received related to the Star Ratings program that are not about any of the proposals outlined in the November 2018 proposed rule.

Comment: A commenter suggested that quality incentive programs should use a small set of outcomes, patient experience, and resource use measures that are not unduly burdensome to

report. Because adjusting measure results for social risk factors can mask disparities in clinical performance, Medicare should account for social risk factors by directly adjusting payment through peer grouping. Another commenter supports CMS efforts to modernize the CMS Quality Rating System by relying more heavily upon measurable improvement in patient clinical outcomes.

Response: We appreciate these comments and have been working towards using more outcome measures and increasing the weight of patient experience of care measures in the Star Ratings system. Currently, to account for social risk factors we do not directly adjust the measure scores (or resulting stars) but add the Categorical Adjustment Index to address the average within-contract disparity in performance among beneficiaries who receive a low income subsidy, are dual eligible individuals, and/or are disabled. CMS is continuing to monitor ongoing work related to socio-economic status of measure developers such as National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA) and the work of the Office of the Assistant Secretary for Planning and Evaluation (ASPE) as it works to complete its second Report to Congress as required by the Improving Medicare Post-Acute Care Transformation Act of 2014 or the IMPACT Act (Pub. L. 113–185). Changes to how CMS determines Quality Bonus Payments and the methodology for payment to MA organizations generally are out of scope for this rule.

Comment: A commenter urged CMS to develop a strategic plan that includes defined goals for the Quality Star Ratings program and creates a framework for the inclusion and retirement of measures. The commenter stated that CMS should ensure that the Quality Star Ratings are simplified, accurately reflect plan performance, and place the most emphasis on measures plans can influence and that improve beneficiaries' health. The commenter also noted that CMS should focus on data-driven measures with objective clinical relevance, rather than survey-based measures.

Response: We laid out the framework for the Star Ratings in the April 2018 final rule. We will take these comments into consideration as that framework is revised over time. As part of our efforts to put patients first, obtaining direct feedback from beneficiaries is vital in understanding the quality of care provided by plans and is an important component of the Part C and D Star Ratings program.

Comment: A commenter supported CMS's position that all substantive measure changes be proposed through rulemaking. However, this commenter requested more information about what is considered ''substantive''.

Response: The April 2018 final rule provided specific examples of substantive updates to measures. We direct readers to pages 83 FR 16534 through 16535 of the April 2018 final rule.

Comment: Several commenters offered suggestions related to adjusting for socioeconomic status (SES). A commenter suggested CMS adjust for social risk factors. Another commenter requested that Categorical Adjustment Index (CAI) adjustments be made to individual measures instead of to the overall Star Ratings, to increase the measure accuracy. A commenter made suggestions, including that CMS: Enhance the CAI by expanding the range of included measures, letting a 2 percent or greater absolute performance difference between low income subsidy/dual eligible and non-low income subsidy/dual eligible individuals be sufficient for measure inclusion; consider other methods for measuring and rewarding quality for plans with complex members; and engage with both NCQA and PQA to drive the development of adjustments for socioeconomic factors for their respective measures; and accelerate the inclusion of such adjusted measures in the Star Ratings program.

Another commenter recommended that to address D–SNPs, CMS compare D–SNPs to D–SNPs, use appropriate measures for dual eligible individuals, evaluate adjusting individual measures for social risk factors, and make improvements to the CAI to make the adjustment more effective, including additional measures and other adjusters. A commenter suggested HOS-derived measures should be included in the CAI, so that the complexities of each plan's enrollee population would be taken into account. The commenter also requested CMS use HOS samples that are larger when the plan enrollment is larger, to provide a truer representation of the member population. Another commenter expressed support for continued use of the CAI in the Star Ratings program while CMS develops a long-term solution to address disparities in plan performance associated with socio-economic status and other risk factors.

Response: CMS appreciates these comments although changes to how CMS addresses socioeconomic status (SES) are out of scope for this regulation. There continues to be additional work in the research community on both identifying the impact of social risk factors on health outcomes and how to best address the impact on clinical quality measurement such that comparisons across contracts yield accurate representations of true differences in quality as opposed to reflections of changes in the composition of beneficiaries in contracts. CMS is following the related work of the National Quality Forum (NQF) since it will have a widespread impact on quality measurement across multiple settings. The NQF has a longstanding policy prohibiting risk adjustment for SES and other demographic factors. NQF released a final report in July 2017 [29] on the findings of the 2-year trial period that temporarily lifted that prohibition. In the report, NQF recommended a 3-year initiative to further examine and consider social risk adjustment to allow evidence as to whether a change in that longstanding policy should be revised.

In addition, CMS has engaged the NCQA and PQA to review and determine if any measures are sensitive to the composition of the enrollees in a plan and whether any modifications to the specification would be appropriate.

As part of this engagement by the agency, the PQA examined their medication adherence measures, which are currently used in the Star Ratings Program, for potential risk adjustment (that is, adjustment for SES and demographic factors).[30] Based on the results of this analysis, beginning in 2018, the PQA included in the 2018 PQA Measure Manual draft recommendations on risk adjustment of the three medication adherence measures: Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension, and Medication Adherence for Cholesterol. As part of PQA's draft recommendations, they suggest that the three adherence measures be stratified by the beneficiary-level sociodemographic status characteristics listed earlier to allow health plans to identify disparities and understand how their patient population mix is affecting their measure rates.

The PQA indicated that the risk-adjusted adherence measures will be submitted through the NQF consensus

[29] NQF's Final Report can be assessed using the following link: *http://www.qualityforum.org/Publications/2017/07/Social_Risk_Trial_Final_Report.aspx.*

[30] The PQA summary can be accessed at: SDS Risk Adjustment PQA PDC CMS Part D Stars *or http://files.constantcontact.com/e9a15233201/96107f74-f6df-46f9-91e9-4a79d7e1bf0a.pdf?ver=1515729061000.*

development process for maintenance of the measures (NQF Endorsed #0541). If endorsed by NQF, CMS will consider how to implement the PQA recommendations in the future for these Star Ratings measures.

NCQA's 2019 HEDIS Volume 2 includes the additional specifications of 4 measures used in the MA Star Ratings. As discussed in the 2018 Call Letter, the additional specifications for Breast Cancer Screening, Colorectal Cancer Screening, Comprehensive Diabetes Care—Eye Exam Performed, and Plan All-Cause Readmissions [31] break out the rates by SES. While CMS continues to use specifications for the overall measure rates not broken out by SES, which are the same rates as contracts have submitted in past years, CMS is considering if and how to best incorporate the information provided by the stratified reporting in future years of the Star Ratings. In particular, CMS is considering to what extent stratified reporting helps address in a more permanent way the same issues addressed by the Categorical Adjustment Index (CAI).

The Office of the Assistant Secretary for Planning and Evaluation (ASPE), as required in the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, Pub. L. 113–185), released the first in a two-part series of Reports to Congress (RTC) in December 2016.[32] ASPE's second report is due in the fall of 2019. In the meantime, CMS continues to be in dialogue with ASPE to discuss potential options for future MA Star Ratings.

Based on stakeholders' feedback, the April 2018 final rule expanded the adjusted measure set for the determination of the CAI beginning with the 2021 Star Ratings to all measures identified as a candidate measure. A measure will be adjusted if it remains after applying the following four bases for exclusions as follows: The measure is already case-mix adjusted for SES (for example, CAHPS and HOS outcome measures); the focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue (for example, appeals, call center, Part D price accuracy measures); the measure is scheduled to be retired or revised during the Star Rating year in which the CAI is being applied; or the measure is applicable to only Special Needs Plans (SNPs) (for example, SNP Care Management, Care for Older Adults measures). HOS-outcome measures are not included in the measurement set since they are already adjusted for SES. Additionally, since HOS samples are random, increasing their size will not make them more representative.

Comment: A few commenters supported the continued prior adjustments for the lack of low-income subsidy in Puerto Rico which is part of the current CAI calculations with a commenter recommending formalizing the rules for determining the percent LIS for Puerto Rico contracts.

Response: CMS appreciates these comments. The rules for determining the percent LIS for Puerto Rico contracts were codified in the April 2018 final rule at §§ 422.166(f)(2)(vi) and (vii) and §§ 423.186(f)(2)(vi) and (vii).

Comment: A commenter suggested that CMS apply a hold harmless to both the CAI and the Reward Factor going forward. This commenter urged CMS to employ a hold harmless calculation for plan sponsors that are negatively impacted by the CAI value if it lowers a contract's Summary Ratings or Overall Ratings and to remove any negative consequences for high performing contracts related to the Reward Factor since high performing contracts are not able to achieve low variance as easily as low performing contracts.

Response: We note that this comment raises an issue that is outside of the scope of the proposals but we are explaining the current policy and regulations. The CAI values address the average within-contract disparity in performance revealed through the Star Ratings data each year among beneficiaries who receive a low income subsidy, are dual eligible individuals, and/or are disabled. The adjustment factor varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of low income subsidy/dual eligible individuals and beneficiaries with disability status. By design, the CAI values are monotonic and, thus, contracts with larger percentages of enrollees that are low income subsidy/dual eligible and/or have disability status realize larger positive adjustments. Contracts with few beneficiaries that fall in the low income subsidy/dual eligible and/or disability status categories have small negative adjustments since achieving higher ratings is easier for these contracts relative to ones with more significant percentages of vulnerable beneficiaries. Thus, CMS disagrees that contracts with low percentages of these vulnerable beneficiaries should receive a hold harmless provision. It is not clear how the commenter suggests to remove negative consequences of the Reward Factor since all of the factors are 0 or positive adjustments.

Comment: Another commenter supported both the Star Ratings methodology and past improvements that CMS has made to increase accuracy. The commenter also supported enhancements that aim to signal CMS's willingness to reward MA organizations that demonstrate excellent outcomes and enrollee experiences. Another commenter requested CMS acknowledge that outcome based measures are more challenging for plans serving complex populations.

Response: CMS appreciates these comments. The Star Ratings methodology weights the experience of enrollees and outcome measures heavily, but also includes other metrics of plan performance, as additional dimensions for holding MA and Part D plans accountable for their performance. Outcome measures such as Improving or Maintaining Physical Health and Improving or Maintaining Mental Health are adjusted for the characteristics of the enrollees, including more complex enrollees.

Comment: A commenter expressed support for retiring measures when there are 1 percentage point differences in the same direction year-over-year (for example, for 3 years).

Response: The April 2018 final rule codified rules for the retirement of measures, at §§ 422.164(e)(1) and 423.184(e)(1), which provide for retirement when a measure has low reliability and/or the clinical guidelines change such that the measure specifications are no longer believed to align with positive health outcomes. We appreciate this comment and will take it into consideration as we contemplate future enhancements to these rules.

b. Definitions

We proposed to add the following definitions for the respective subparts in part 422 and part 423, in paragraph (a) of §§ 422.162 and 423.182, respectively.

- *Absolute percentage cap* is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.
- *Cut point cap* is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut

[31] A summary of the NCQA analysis and recommendations can be accessed using the link that follows: *http://www.ncqa.org/hedis-quality-measurement/research/hedis-and-the-impact-act.*

[32] ASPE's first Report to Congress: Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs can be accessed using the link that follows: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

point. A cut point cap can restrict upward movement, downward movement, or both.

- *Guardrail* is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.
- *Mean resampling* refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. By leaving out one of the 10 groups for each run, 9 of the 10 groups, which is 90 percent of the applicable measure scores, are used for each run of the clustering algorithm. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.
- *Restricted range* is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer-fence outliers (first quartile − 3*Interquartile Range (IQR) and third quartile + 3*IQR).[33]

We proposed to specify in the definition the criteria used to identify the values that correspond to the outer fences which are used to identify extreme outliers in the data. Outer-fence outliers use established statistical criteria for the determination of the boundary values that correspond to the outer fences. The outer fences are the boundary values for an outer-fence outlier such that any measure score that either exceeds the value of the upper outer fence (third quartile + 3*IQR) or that is less than the lower outer fence (first quartile − 3*IQR) is classified as an outer fence outlier and excluded from the determination of the value of the restricted range cap.

- *Restricted range cap* is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

We received no comments on these proposed definitions in paragraph (a) of §§ 422.162 and 423.182 and are finalizing them with one non-substantive change to the mean resampling definition; we have finalized the definition with an additional sentence to clarify that by leaving out one of the 10 groups for each run, 90 percent of the measure scores are used for each run of the clustering algorithm.

c. Measure-Level Star Ratings (§§ 422.166(a), 423.186(a))

At §§ 422.166(a) and 423.186(a), we previously codified the methodology for calculating Star Ratings at the measure level in the April 2018 final rule. The methodology for non-CAHPS measures employs a hierarchical clustering algorithm to identify the gaps that exist within the distribution of the measure-specific scores to create groups (clusters) that are then used to identify the cut points. The Star Ratings categories are designed such that the scores in the same Star Ratings category are as similar as possible and the scores in different Star Ratings categories are as different as possible. The current methodology uses only data that correspond to the measurement period of the data used for the current Star Ratings program. The cut points, as implemented now, are responsive to changes in performances from one year to the next. Changes in the measure-level specific cut points across a Star Ratings year reflect lower or higher measure performance than the prior year, as well as shifts in the distribution of the scores.

In the April 2018 final rule, CMS detailed the goals of the Star Ratings program. The overarching goals of the Star Ratings program and the specific sub-goals of setting cut points serve as the rationale for any proposed changes.

The Star Ratings display quality information on Medicare Plan Finder to help beneficiaries, families, and caregivers make informed choices by being able to consider a plan's quality, cost, and coverage; to provide information for public accountability; to incentivize quality improvement; to provide information to oversee and monitor quality; and to accurately measure and calculate scores and stars to reflect true performance. In addition, pursuant to section 1853(o) of the Act and the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes Final Rule (76 FR 21485 through 21489), the Star Ratings are also used to assign Quality Bonus Payments as provided in § 422.558(d).

To separate a distribution of measure scores into distinct groups or star categories, a set of values must be identified to separate one group from another group. The set of values that break the distribution of the scores into non-overlapping groups is referred to as a set of cut points. The primary goal of any cut point methodology is to disaggregate the distribution of scores into discrete categories such that each grouping accurately reflects true performance.

The current MA Star Ratings methodology converts measure-specific scores to measure-level Star Ratings so as to categorize the most similar scores within the same measure-level Star Rating while maximizing the differences across measure-level Star Ratings. To best serve their purpose, the Star Ratings categories must capture meaningful differences in quality across the Star Ratings scale and minimize the risk of misclassification. For example, it would be considered a misclassification if a ''true'' 4-star contract were scored as a 3-star contract, or vice versa, or if nearly-identical contracts in different measure-level star categories were mistakenly identified. CMS currently employs hierarchical clustering to identify the cut points for non-CAHPS measures to ensure that the measure-level Star Ratings accurately reflect true performance and provide a signal of quality and performance on Medicare Plan Finder to empower beneficiaries, families, and caregivers to make informed choices about plans that would best align with their priorities.

We solicited comments in the 2017 proposed rule regarding the approach to convert non-CAHPS measure scores to measure-level Star Ratings (82 FR 56397 through 56399). We requested stakeholders to provide input on the desirable attributes of cut points and recommendations to achieve the suggested characteristics. In addition, we requested that commenters either suggest alternative cut point methodologies or provide feedback on several options detailed in the proposed rule, such as setting the cut points by using a moving average, using the mean of the 2 or 3 most recent years of data, or restricting the size of the change in the cut points from 1 year to the next.

The commenters identified several desirable attributes for the cut points that included stability, predictability, attenuation of the influence of outliers; restricted movement of the cut points from 1 year to the next; and either pre-announced cut points before the plan preview period or pre-determined cut points before the start of the measurement period. In the April 2018 final rule (83 FR 16567), we expressed appreciation for our stakeholders' feedback and stated our intent to use it to guide the development of an enhanced methodology. So as not to

[33] The first quartile is median of the lower half of the data; in other words, the value in the data once arranged in numerical order that divides the lower half into two equal parts. The third quartile is the median of the upper half of the data.

implement a methodology that may inordinately increase the risk of misclassification, CMS analyzed and simulated alternative options to assess the impact of any enhancements on the Star Ratings program and assess the degree to which a new methodology captures the desirable attributes that were identified by stakeholders. While CMS looked to balance the request of stakeholders to increase predictability and stability of the cut points from year to year in developing its proposal for this rulemaking, the goals of the Star Ratings program, the integrity of the methodology, and the intent of the cut point methodology remain the same. The intent of the cut point methodology is to accurately measure true performance.

A Technical Expert Panel (TEP), comprised of representatives across various stakeholder groups, convened on May 31, 2018 to provide feedback to CMS's Star Ratings contractor (currently RAND Corporation) on the Star Ratings framework, topic areas, methodology, and operational measures, including possible enhancements to the clustering methodology used to convert non-CAHPS measure scores to measure-level Star Ratings. Information about the TEP and their feedback can be found at *http://www.rand.org/star-ratings-analyses.*

In developing the proposal for modifying how cut points are set for non-CAHPS measures, CMS examined numerous alternative methodologies to minimize the influence of outliers, to restrict the upward or downward movement of cut points from one year to the next, and to simulate prediction models to allow either limited advance notice or full advance notice of cut points prior to the measurement period. As part of our analyses, we analyzed trends in performance across the Star Ratings measures. The ability to announce cut points before (full advance notice) or during (partial advance notice) the measurement period requires the use of modeling and older data to project the cut points, as well as the need for an alternative methodology for new measures introduced to the Star Ratings program. We explained in the proposed rule that modeling is challenging given differences in the performance trends over time across the Star Ratings measures; thus, a single approach for predicting all future performance does not accurately reflect performance for all measures.

We also discussed how using prediction models to establish future cut points may have unintended consequences and misalign with the underlying goals of the Star Ratings program and sub-goals of setting cut points. Predicting future cut points using older data can lead to both over or under-estimations of performance which results in a distorted signal of the Star Ratings. Over projections in the cut points will result in higher cut points and lower measure-level Star Ratings. Conversely, under projections can lead to lower cut points and higher measure-level Star Ratings. The risk of misclassification is heightened when the accuracy of the projected cut points is diminished. The use of older data for setting cut points does not allow the Star Ratings to be responsive to changes in performance in the current year. Furthermore, setting cut points in advance of the measurement year may lead to MA organizations and Part D sponsors not focusing on certain areas once they achieve a set threshold, eliminating incentives for improvement.

For example, CMS provided incentives for eligible providers to adopt certified Electronic Health Records (EHRs) and report quality measures under the Meaningful Use (MU) initiative. Consequently, there were large gains in performance for a subset of Star Ratings measures that were enabled through the EHR, which reflected a structural change among health care providers in the delivery of care. Further, an examination of performance over time of EHR-enabled measures indicates a decrease in variability of measure scores with contract performance converging toward greater uniformity. Modeling future performance using past performance from before this leveling out of performance would fail to capture the large gains in performance in the EHR-enabled measures, which would have resulted in cut points that were artificially low and measure-level Star Ratings that were higher than true performance.

We discussed in the proposed rule how pre-announced cut points for other subsets of measures in the Star Ratings would present different challenges as compared to EHR-enabled measures. Performance on new measures typically has more room to improve, and large year to year gains are possible and desirable from a quality improvement perspective. Projecting cut points using older data from periods of rapid improvement would artificially inflate future cut points which would cause artificially low measure-level Star Ratings. Measures that demonstrate very slow, consistent growth over time could have projected cut points that are artificially high. The further the projection is in advance of the measurement period, the larger the potential for unintended consequences. In addition, there exists the possibility of external factors, other than structural, that are unanticipated and unforeseen that could impact the distribution of scores for which modeling would not capture.

We listed in the proposed rule some of the challenges of full or partial advance notice:

- Older data often do not accurately reflect current performance.
- The trend in average performance is not always linear.
- External or structural factors may occur that can lead to substantial changes from period to period rather than steady, slow year-over-year improvement.
- Larger gains in performance year to year exist for relatively new measures, compared to more established measures.
- The rate of change is less likely to be linear at lower threshold levels where contracts have greater opportunities for improvement.
- Decreasing variation in measure scores reflects greater improvements in performance for lower versus higher-performing contracts—contract performance is converging over time toward greater uniformity.

These challenges are critical to consider because if we modify the current methodology to predict (or set) cut points using older data and a single model across all measures, we risk causing unintended consequences such as significantly diminishing incentives for improvement or having the Star Ratings misaligned with changes in performance that may be due to external or structural factors.

Based on stakeholder feedback and analyses of the data, we proposed two enhancements to the current hierarchical clustering methodology that is used to set cut points for non-CAHPS measure stars in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i). The first proposed enhancement was the use of mean resampling. With mean resampling, measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values. We explained in the proposed rule that mean resampling reduces the sensitivity of the clustering algorithm to outliers and reduces the random variation that contributes to fluctuations in cut points and, therefore, improves the stability of the cut points over time. Mean resampling uses the most recent

year's data for the determination of the cut points; thus, it does not require assumptions for predicting cut points over time and it continues to provide incentives for improvement in measure scores. The drawback of mean resampling alone is that it does not restrict the movement of the cut points, so the attribute of predictability is not fully captured with this methodology.

To increase the predictability of the cut points, we also proposed a second enhancement to the clustering algorithm: A guardrail for measures that have been in the Part C and D Star Ratings program for more than 3 years. We proposed a guardrail of 5 percent to be a bi-directional cap that restricts movement both above and below the prior year's cut points. A 5 percent cap restricts the movement of a cut point by imposing a rule for the maximum allowable movement per measure threshold; thus, it allows a degree of predictability. The trade-off for the predictability provided by bi-directional caps is the inability to fully keep pace with changes in performance across the industry. While cut points that change less than the cap would be unbiased and keep pace with changes in the measure score trends, changes in overall performance that are greater than the cap would not be reflected in the new cut points. A cap on upward movement may inflate the measure-level Star Ratings if true gains in performance improvements cannot be fully incorporated in the current year's ratings. Conversely, a cap on downward movement may decrease the measure-level Star Ratings since the ratings would not be adjusted fully for downward shifts in performance.

We discussed in the proposed rule that a measure-threshold-specific cap can be set multiple ways and the methodology may differ based on whether the measure is scored on a 0 to 100 scale or an alternative scale. For measures on a 0 to 100 scale, the cap can restrict the movement of the measure cut points from one year to the next by a fixed percentage, such as an absolute 5 percentage point cap. For measures not on a 0 to 100 scale, the cap can be determined for each measure by using a percentage of the measure's score distribution or a subset of the distribution, such as 5 percent of the range of the prior year scores without outer fence outliers, referred to as a restricted range cap. Alternatively, a restricted range cap can be used for all measures, regardless of scale, using a cap based on the range of the prior year scores without outliers. We proposed an absolute 5 percentage point cap for all measures scored on a 0 to 100 scale and 5 percent of the restricted range for all measures not on a 0 to 100 scale, but we explained that we were also considering alternatives to the 5 percent cap, such as using 3 percent. We noted in the proposed rule our belief that any cap larger than 5 percent would not provide the predictability requested by stakeholders that our proposal was designed to incorporate. While smaller caps provide more predictability, it is more likely that the cut points will not keep pace with changes in measure scores in the industry as the cap size gets smaller, and may require future larger one-time adjustments to reset the measure cut points. Therefore, we explained in the proposed rule that we were not sure that a smaller cap, even at a 3 percent threshold, would meet our programmatic needs and goals of providing accurate pictures of the underlying performance of each contract and its comparison to other contracts. We therefore proposed using a 5 percent cap because the use of the cap allows predictability of the cut points from year to year, but also balances the desire to continue to create incentives for contracts to focus on the quality of care of their enrollees and strive to improve performance. If the cut points are not keeping pace with the changes in the scores over time, CMS may need to propose in the future how to periodically adjust the cut points to account for significant changes in industry performance.

In summary, we proposed to amend §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to add mean resampling of the current year's data to the current clustering algorithm to attenuate the effect of outliers, and measure-specific caps in both directions to provide guardrails so that the measure-threshold-specific cut points do not increase or decrease more than the cap from one year to the next. We proposed a 5 percentage point absolute cap for measures on a 0 to 100 scale and a 5 percent restricted range cap ((0.05) * (maximum value − minimum value), where the maximum and minimum values are calculated using the prior year's measure score distributions excluding outer fence outliers). For any new measures that have been in the Part C and D Star Rating program for 3 years or less, we proposed to use the hierarchal clustering methodology with mean resampling for the first 3 years in the program in order to not cap the initial increases in performance that are seen for new measures. Under our proposal, existing provisions governing cases where multiple clusters have the same measure score value range (§§ 422.166(a)(2)(ii) and 423.186(a)(2)(ii)) and how the clustering algorithm would apply for setting cut points for the improvement score (§§ 422.166(a)(2)(iii) and 423.186(2)(iii)) remain the same. We solicited comments on this proposal, including comments on the percentage used for the cap, whether the cap should be an absolute percentage difference for measures on a 0 to 100 scale, whether the cap should be a percent of the range of prior year scores without outliers for all measures or for the subset of measures not on a 0 to 100 scale, whether the cap should be in both the upward and downward directions, and alternative methods to account for outliers.

Below we summarize the comments we received and provide our responses and final decisions.

Comment: Commenters overwhelmingly supported increasing the stability and predictability of cut points and attenuating the influence of outliers.

Response: CMS appreciates the support for increasing the stability and predictability of cut points and attenuating the influence of outliers. CMS has examined numerous alternative methodologies for setting cut points and the methodology changes we finalize in this rule are intended to make cut points more stable and predictable.

Comment: Several commenters supported implementing cut point methodology changes for contract year 2020 or as soon as possible and opposed delaying such methodology changes until 2022 Ratings.

Response: CMS appreciates the commenters' requests to implement these changes sooner but, as established in the 2018 final rule, changes to the methodology for Star Ratings go through rulemaking and are finalized prior to the relevant measurement year unless we are applying a standard in the regulation text in making the change. We proposed and are finalizing this change to how cut points for non-CAHPS measures are set for the 2020 measurement year, which is associated with the 2022 Star Ratings.

Comment: Many commenters requested more detail on the resampling methodology, including simulations of the impact of resampling and guardrails, and a couple of commenters requested an additional comment period after CMS provided more detail on the resampling methodology, but before making any changes to the cut point methodology.

Response: The reason for using the resampling approach is to increase

stability and predictability of cut points. The approach is implemented as follows. First, the current year's contract scores for a given measure are randomly divided into 10 groups or subsamples. (The current year's data means the data from the applicable performance year for the given year of Star Ratings being calculated. For example, the 2022 Star Ratings use data from the 2020 performance year.) The process can be replicated when the random number generator is given the same seed prior to each run. Then, for each of the 10 subsamples, the following steps are taken:

- Omit one subsample from the data.
- Calculate thresholds using the clustering approach on the data that combines the remaining 9 subsamples.

After those two steps are completed for each of the 10 subsamples, the resulting 10 sets of cut points are averaged.

There are two advantages of resampling. It contributes to stabilizing the cut points, which is its primary advantage over using clustering without mean resampling, and it partially addresses the sensitivity of the clustering approach to the ordering of the observations in the data set. First, each observation is included in only 90 percent of the cut point estimates that are averaged. This reduces the contribution of each observation, including outliers, to the final cut points. Second, pulling out a random 10 percent of the data prior to cut point calculation alters the order of the data. It partially accounts for the sensitivity of the clustering approach to the ordering of observations, as the tie-breaking approach of the clustering algorithm depends on the ordering of the data. Allowing for altered orders of the data reduces the effect of the tie-breaking on the final cut points. Resampling is computationally more feasible than reordering a large (for example, 1,000) number of times to search for multiple cut point combinations, given the timeline of the Star Ratings calculations. HCAHPS uses an approach that is conceptually similar. HCAHPS cut points are the average of cut points based on four segments of the data, divided by quarters, where each segment contains 25 percent of the data. Whereas this proposal is to average the cut points calculated from each of 10 segments where each segment contains 90 percent of the data.

In response to the commenters' requests, we simulated the impact of the proposed changes to the cut point methodology including mean resampling and a 5 percent guardrail on the 2018 Star Ratings. However, we note that some commenters stated that they simulated the proposed changes themselves prior to commenting on the proposed rule. All commenters could have simulated the proposed changes themselves prior to commenting on the proposed rule based on the measure data from 2018 or 2019 Star Ratings (available at *http://go.cms.gov/partcanddstarratings*). While these data do not contain contracts that terminated from the Medicare program, the available data are sufficient to simulate these methodological changes. Since the guardrail could have an effect not only on the current Star Ratings year but also on subsequent years, we accounted for this by starting our simulation of the combined mean resampling and guardrail approach with the 2016 Star Ratings data. The resulting cut points served as the reference point for applying the guardrail to the cut points obtained through applying both mean resampling and guardrails to the 2017 Star Ratings data. Finally, we simulated the 2018 Star Ratings thresholds with mean resampling and a 5 percent guardrail that referenced the simulated 2017 Star Ratings thresholds from the prior step. Overall the changes in 2018 Star Ratings under this approach were relatively modest. Six percent of MA–PD contracts would have seen their overall rating increase by half a star and five percent would have decreased by half a star. For PDP contracts, 5 percent would have increased by half a star and 7 percent would have decreased by half a star. In our simulations, there was not a disproportionally negative impact on contracts with more LIS/DE enrollees. For MA–PD contracts with LIS/DE beneficiaries of up to 50 percent, 6 percent of contracts moved up a half-star on the overall Star Ratings and 6 percent moved down by half-star. For contracts with greater than 50 percent LIS/DE beneficiaries, 7 percent moved up half-star and 2 percent moved down half-star. With regard to the request for an additional comment period, many other commenters requested CMS implement the changes as soon as possible. Further, as explained previously, some commenters conducted simulations of the proposed methodological changes themselves prior to commenting on the proposed rule. Overall, we received 47 comments on the proposed changes to the cut point methodology from the 60 day comment period. We believe the public understood the proposal and were able to submit comments effectively. Therefore, we are finalizing the proposal to implement mean resampling, because resampling will provide increased stability and predictability of cut points.

Comment: A couple commenters expressed concern that mean resampling can provide varying results depending on the number of samples used and questioned why 10 samples were chosen, and a couple commenters believed mean resampling would make the cut point methodology more complicated.

Response: We proposed and are finalizing the use of 10 samples because, as a common choice in related applications, such as cross-validation, it has proven advantages. Using 10 samples is less computationally intensive than using more samples, which is a significant advantage in light of the limited time between the availability of the measure data and the publication of Star Ratings each year. By using the ''leave-one-out approach,'' we expect improved stability in the cut point thresholds, as each data point (including outliers) will be omitted from 10 percent of the cut points that are estimated and then averaged across the ten 90 percent samples following resampling. We appreciate the commenter's concern about the complexity of mean resampling, however, we find that mean resampling is not overly complex because it is replicable, as long as the contract groupings are pre-specified.

Comment: A commenter suggested CMS provide Statistical Analysis System (SAS) programming code to run the cut points analyses.

Response: CMS provides details about how the cut points are determined, including SAS code, in the Technical Notes CMS provides for each Star Ratings year (see the Attachment regarding Individual Measure Star Assignment Process). The changes to the cut point methodology finalized in this rule will be documented in the Technical Notes for the 2022 Star Ratings. The Technical Notes can be found here: *http://go.cms.gov/partcanddstarratings.*

Comment: Several commenters supported mean resampling to address outliers.

Response: CMS appreciates the support for mean resampling. We are finalizing mean resampling as proposed.

Comment: Some commenters believed resampling would not be sufficient to address outliers or believed resampling does not directly address year to year changes in cut points. A couple commenters supported removing outliers before clustering.

Response: CMS appreciates the commenters concerns and based on these comments evaluated two options to address direct removal of outliers—trimming and Tukey outer fence outlier

deletion. We conducted simulations of the impact of each outlier deletion method combined with a cumulative 5 percent guardrail on the 2018 Star Ratings. In general, there tend to be more outliers on the lower end of measure scores. As a result, the one to two star threshold often increased in the simulations when outliers were removed compared to the thresholds when outliers were not removed, while other thresholds were not as impacted. The simulations of trimming and Tukey outlier deletion also account for the removal of the two Part D appeals measures (Appeals Auto-Forward and Appeals Upheld) and the Part C measure Adult BMI Assessment, because these measures will be removed starting with the 2022 Star Ratings, as announced in the 2020 Call Letter.

Under trimming, all contracts with scores below the 1st percentile or above the 99th percentile are removed prior to clustering. Although trimming is a simple way to remove extreme values, it removes scores below the 1st percentile or above the 99th percentile regardless of whether the scores are true outliers. In some cases, true outliers may be between the 1st and 99th percentile, and trimming will not remove these outliers, and in other cases, trimming will remove scores that are not true outliers, especially when the distribution of scores is skewed. If trimming and a 5 percent cumulative guardrail had been implemented for the 2018 Star Ratings, 2 percent of MA–PD contracts would have seen their overall Star Rating increase by half a star and 17 percent would have had it decreased by half a star. For PDP contracts, 4 percent would have increased their Part D summary Star Rating by half a star and none would have decreased.

Tukey outer fence outlier deletion is a standard statistical method for removing outliers. Under this methodology, outliers are defined as values below a certain point (first quartile − 3.0 × (third quartile − first quartile)) or above a certain point (third quartile + 3.0 × (third quartile − first quartile)). The Tukey outer fence outlier deletion will remove all outliers based on the previous definition and will not remove any cases that are not identified as outliers. As with trimming, the values identified by Tukey outer fence outlier deletion are removed prior to clustering. If Tukey outer fence outlier deletion and a 5 percent cumulative guardrail had been implemented for the 2018 Star Ratings, 2 percent of MA–PD contracts would have seen their Star Rating increase by half a star and 16 percent would have decreased by half a star. For PDP contracts, 2 percent would have increased by half a star and 18 percent would have decreased by half a star.

At this time, CMS is not finalizing a method to directly remove outliers prior to clustering. The methods to directly remove outliers resulted in some shifting of Star Ratings in the simulations, as explained previously. Further, as these methods were not included in the proposed rule, the public has not had an opportunity to comment on them specifically. CMS will continue to evaluate these and possibly other methods to directly address outliers and will consider proposing outlier deletion in future rulemaking.

Comment: A commenter opposed resampling because based on the commenter's simulations it would have little impact on cut points and could lead to cut points being raised more often than lowered.

Response: CMS appreciates the commenter's concerns that the mean resampling will not have a significant impact on cut points. However, we believe that mean resampling in conjunction with the use of the guardrails adequately addresses concerns about outliers and stability from year to year. We are finalizing mean resampling because it will lead to increased stability and predictability of cut points and will address the sensitivity of clustering to the order of the data.

Comment: A couple commenters requested CMS consider whether resampling could increase the influence of outliers on cut points.

Response: Mean resampling decreases the influence of outliers on cut points because each measure score (regardless of whether the score is an outlier) is omitted from 10 percent of the cut point estimates, which are then averaged as part of mean resampling. Based on this, any given outlier is omitted from the cut point estimates in one of the 10 runs of the clustering algorithm. When the 10 sets of cut point estimates are averaged, the influence of an outlier is less than what it would have been if resampling had not been done. Therefore, resampling will not increase the influence of outliers as a function of the methodology.

Comment: A commenter supported resampling but would like individual contract scores to be weighted by enrollment to reduce the impact of small contracts that may experience large changes in scoring from one year to the next due to small numbers.

Response: CMS appreciates the commenter's support for resampling. Giving contracts very different weights would decrease the stability of clustering and increase the role of noise in setting thresholds. The measures used in the Star Ratings program have minimum denominator criteria that must be met for a contract to be scored on a measure. As part of our usual administration of the Star Ratings system, CMS has examined changes in scores from year to year when there have been larger shifts in cut points. However, based on this comment, we again examined the data for large changes in measure scores year-over-year and found that such changes occur even for contracts with moderate or large denominators. We therefore disagree with these commenters and will not change the methodology as recommended.

Comment: A commenter opposed resampling because it does not address social disparity issues faced by some plans and outlier removal would disadvantage plans serving underserved communities by normalizing metrics towards the median. Another commenter requested CMS to consider how methodological changes may necessitate adjustments for socio-economic status (SES) factors.

Response: The purpose of resampling is to create more stability in the cut points over time. Separately, CMS in the April 2018 final rule and the 2020 Call Letter finalized a policy to expand the adjusted measures included in the Categorical Adjustment Index (CAI). Starting with the 2020 Star Ratings the CAI values will be determined using all measures in the candidate measure set for adjustment. A measure will be adjusted if it remains after applying the exclusions as follows: The measure is already case-mix adjusted for SES, the measure is a plan or provider issue, the measure is being retired or revised during the relevant Star Ratings year, or the measure only applies to Special Needs Plans. Further, the CAI for a given ratings year is developed using the same cut point methodology that will be applied in that ratings year. We believe that the CAI adequately addresses the impact of SES on the Part C and D Quality Star Ratings pending the conclusion of ASPE's second report on this issue (scheduled to be released in the fall of 2019) and steps taken by the measure stewards to further address it.

Comment: A commenter supported reordering in place of resampling, because the commenter believes resampling may not result in more stable cut points and reordering would address the sensitivity of the hierarchical clustering algorithm to the order of the data.

Response: We appreciate the commenter's concerns, but we are finalizing mean resampling as proposed. The hierarchical clustering algorithm is sensitive to the order of the data when ties occur in identifying the clusters. This means the cut points generated by the clustering algorithm can sometimes be slightly different depending on the order of the data. Mean resampling helps to address this issue, and we believe mean resampling combined with guardrails adequately addresses concerns about outliers and stability from year to year. Additionally, conducting a full-scale reordering is too computationally intensive given the time constraints of the Star Ratings calculations. Under mean resampling, each time 10 percent of the measure scores are randomly selected and removed prior to clustering the remaining 90 percent, the order of the data will be altered. We will continue to evaluate the impact of resampling on the issue identified by the commenter and consider additional enhancements to the methodology if needed.

Comment: Most commenters supported the implementation of guardrails. While about half of commenters supported setting the guardrails at 5 percent as proposed, other commenters were mixed in supporting various other options for setting guardrails, such as a 2 percent guardrail, a 3 percent guardrail, and a 5 percent restricted range guardrail for all measures.

Response: We thank commenters for their support for implementing guardrails. While we appreciate commenters' suggestions for alternatives to setting guardrails at 5 percent, we are finalizing the guardrails at 5 percent as proposed. Guardrails at 5 percent provide a balance between providing predictability in cut points while also allowing cut points to keep pace with changes in measure scores in the industry. Smaller guardrails may prevent the cut points from keeping pace with changes in measure scores in the industry, and may limit the incentive to improvement. Five percent guardrails will also allow for less frequent or possibly no future adjustments to reset the measure thresholds to keep pace with industry changes in measure scores as compared to smaller guardrails. If cut points are not keeping pace with the changes in scores over time, CMS may propose in the future how to adjust the cut points to account for significant changes in industry performance.

Comment: Some commenters requested additional information about the guardrails including simulations of the impact. Some commenters requested simulation data prior to implementation whereas other commenters requested simulations of the impact but also supported the proposed changes.

Response: We appreciate the commenters request for simulations of the impact of guardrails. We refer readers to the earlier response to comments where we provide the results of the simulations combining mean resampling and a 5 percent guardrail. Commenters could also compare cut points from prior years to see where the guardrail would go into effect to determine which cut points would be affected. Additionally, data are available to conduct a full simulation, as discussed previously.

Comment: A commenter requested CMS delay finalizing the application of a guardrail until a final cut point methodology is finalized, because guardrails should be assessed only after the final cut point methodology is determined.

Response: CMS appreciates the commenter's request but does not believe a delay is necessary or appropriate as the guardrails are a key component of how we intend the cut point methodology to provide stability and predictability from year to year, in balance with reflecting true performance. In addition, many other commenters requested CMS implement the changes as soon as possible. CMS has assessed a number of different approaches for modifying the cut point methodology and simulated the impact of the proposed modifications; therefore, we understand the impact of such changes. We discussed the results of these simulations in response to other comments earlier in this preamble. We are finalizing the guardrails as proposed, because this will lead to increased stability and predictability of cut points.

Comment: A commenter supported guardrails only above the prior year's cut points combined with not allowing cut points to decline from year to year, because the commenter believes cut points should not be allowed to decrease compared to the following year. Another commenter noted a concern for cut points getting lower from year to year since downward movement could discourage plans from making improvements to attain higher ratings.

Response: We thank the commenters for these suggestions and while we share the underlying concern about incentivizing continued improvement in performance, we do not believe restricting downward movement in cut points from year to year is appropriate. There may be instances in which industry performance declines from year to year as a result of factors that are outside of plans' control and cut points should be able to move to account for this. This is in line with our intent for the Quality Star Ratings to provide comparative information about MA and Part D plan performance.

Comment: A couple commenters were concerned about the implementation of guardrails, because it could limit the ability of the Star Ratings to respond to industry changes and make the Star Ratings a less effective comparative tool, and these commenters also suggested that guardrails would diminish incentives for improvement. A commenter was concerned about the need to rebase cut points if they did not keep up with changes in industry performance.

Response: We appreciate the commenters concern and agree the Star Ratings should be able to respond to industry changes and to reflect true performance as accurately as possible. To address this issue, we are finalizing the guardrails at 5 percent as proposed rather than a narrower guardrail. Guardrails at 5 percent provide a balance between providing predictability in cut points while also allowing cut points to keep pace with changes in measure scores in the industry. If cut points are not keeping pace with the changes in scores over time, CMS may propose in the future how to adjust the cut points to account for significant changes in industry performance.

Comment: Some commenters also supported setting guardrails for new measures.

Response: While CMS appreciates the desire for predictability of cut points, we believe setting guardrails on new measures would not allow cut points to keep pace with initial increases in performance that are typically seen for new measures and would diminish incentives for improvement. We have seen that for new measures, plans and their providers work closely to implement processes to improve performance. There is typically more room to improve for new measures and, consequently, we see large year-to-year gains in measure scores in particular for the first three or more years.

Comment: A couple commenters questioned how measures moved to display as a result of specification changes would be treated when they were returned to the Star Ratings.

Response: Measures returning to the Star Ratings after being on display as a result of substantive specification changes would be treated as new

measures. For these measures, we will use the hierarchal clustering methodology with mean resampling for the first 3 years after returning to the Star Ratings and add application of the guardrail only after that point.

Comment: A handful of commenters requested that CMS continue to work with stakeholders and other experts to improve guardrails over time and to identify alternative methodologies to increase the predictability and stability of cut points from year to year, including how to address the impact of outliers.

Response: We appreciate the commenters' suggestions to continue to obtain feedback on ways to improve the methodology over time. We will continue to solicit feedback from stakeholders on this issue, and our Star Ratings contractor will continue to obtain input from the Part C and D Star Ratings Technical Expert Panel. We are committed to continuing to analyze the impact of outliers in the data and may propose additional enhancements to specifically address this issue. We intend to consider all of this information as we develop future policies and regulations for the Part C and Part D Quality Star Ratings program.

Comment: A couple commenters supported guardrails for CAHPS measures, such as a guardrail of 0.5 to 1.00.

Response: Because cut points for CAHPS measures have relatively stable trends over time, CMS did not propose any guardrails for CAHPS measures. We will not finalize any such guardrails in this rule. The proposed narrow guardrails of 0.5 to 1.0 are below typical levels of improvement for CAHPS measures.

Comment: A commenter requested consideration of the base cut points that the guardrails are initially applied to. The commenter stated a recalculation of base cut points using new or improved methodology may be more appropriate prior to application of guardrails.

Response: We agree with the commenter. When guardrails and mean resampling are implemented for the 2022 Star Ratings, CMS will rerun the 2021 Star Ratings thresholds with mean resampling. The 2022 Star Ratings thresholds that include mean resampling will then be compared to the rerun 2021 Star Ratings thresholds in order to apply the 5 percent guardrail. Because our proposal occurred after the start of the 2019 performance period for the 2021 Star Ratings, the use of mean resampling for setting cut points is limited to setting the actual cut points for 2022 and subsequent Star Ratings. We will use the 2021 Star Ratings cut points as the starting point for applying the guardrail aspect of the new methodology, in order to allow for an apples-to-apples comparison when applying the guardrails for the 2022 Star Ratings.

Comment: A commenter believed the proposed methodology changes addressed some of the concerns raised by stakeholders and the TEP and are broadly defensible. However, the commenter believed CMS is moving further away from a standardized, uniform approach to assigning Star Ratings for the various care settings/institutions for which it issues report cards, including the Part C and D Star Ratings program and the multiple fee-for-service (FFS) Star Ratings programs for hospitals, dialysis facilities, and skilled nursing facilities. The commenter also stated the proposed methodology changes make an already complex methodology even more complex and CMS should consider the trade-offs between refining setting- or institution-specific methodologies with the pressing need for simplicity and clarity for health care consumers.

Response: CMS understands the desire to balance customization of the Star Ratings methodology for each of the different CMS programs comparing the quality of care for various types of healthcare providers, while also enhancing stability and predictability of cut points for the MA and Part D Star Ratings programs. While CMS has an overall interest and goal in aligning the various Star Ratings systems across the agency to the extent feasible, our proposal was limited to the Part C and D Star Ratings program and the needs and purposes of that program. Under section 1853(o), the Part C and D Star Ratings are used to identify MA organizations that are eligible for quality bonus payments as well as a means to provide comparative information about plan quality to Medicare beneficiaries. In other programs comparing the quality of care for healthcare providers, such as Hospital Compare for hospitals, Medicare FFS payment is not directly related to the overall Star Rating that is publicly reported. We believe the relationship between the Part C and D Star Ratings system and plan Quality Bonus Payments means that providing a measure of stability and predictability for the rated entities (in this case, MA and Part D contracts and plans), even if it means moving further away from a standardized, uniform approach to assigning Star Ratings across agency programs, is appropriate to ensure predictability and stability. Requiring the various Star Ratings systems to have a uniform methodology for setting cut points would not be consistent with the goals and uses of the separate programs and we decline to make uniformity a goal in and of itself where we see significant policy reasons to modify the cut point methodology for the Part C and D non-CAHPS measures. Simplicity and clarity for healthcare consumers would not be sacrificed by differences between methodologies between various CMS Star Ratings Systems because consumers are less likely than other stakeholders to be interested in understanding the underlying methodologies. For those who want access to more details on the methodology, the Technical Notes can be found here: *http://go.cms.gov/partcanddstarratings.* However, taking into account these differences, CMS works to ensure that the MA and Part D Star Ratings system is as closely aligned with other CMS rating systems as necessary and possible to serve the programmatic needs of each Star Rating system.

Comment: A few commenters supported distributing Quality Bonus Payments on a continuous scale.

Response: We understand the commenters' interest in alternative methods of distributing Quality Bonus Payments, however, the distribution of Quality Bonus Payments is defined in statute to be based on a Five-Star Rating system. Changes to the how Quality Bonus Payments are distributed are out of scope for this regulation.

Comment: Some commenters supported using prospectively set thresholds to create more predictability and stability, while others were opposed to setting thresholds prospectively. A commenter supported setting a predetermined cut point of 95 percent for 5 stars and stated predetermined thresholds have the ability to limit the impact of outliers and reduce the additional steps required by the cut point methodology. Another commenter supported setting fixed 5-star cut-points for measures that have stable performance among the top 25th percentile of plans over time.

Response: We understand the desire of some commenters to have pre-set thresholds. CMS had implemented pre-determined 4-star thresholds for some measures in the 2011 Star Ratings to increase transparency for organizations/sponsors and set *a priori* expectations for high performance. However, we found that pre-set thresholds created more ''noise'' or measurement error in the system and disincentivized contracts from improving once they hit the 4-star threshold. Further, while we agree that operational considerations are

important in selecting and adopting the cut point methodology, particularly as we have a limited amount of time to process the performance data and issue Star Ratings each year, CMS does not believe that those considerations should be the sole driving factor; the ease achieved by using a pre-determined cut point needs to be weighed against the drawbacks with that methodology and our overall policy goals for the Star Ratings program.

Comment: A commenter raised concerns that plans must often set unrealistic targets for physicians in order for the plan to earn incentives from CMS and supported finalizing cut point methodologies that do not impede clinical judgment.

Response: CMS does not set targets that Part C and D plans must achieve to do well in the Star Ratings program; as discussed in the prior response, CMS has moved away from the use of pre-determined cut points for Part C and D Star Ratings. Plans should not be impeding clinical judgment; physicians should be using their clinical expertise to determine how to appropriately deliver care to their patients. Further, the non-interference provision in section 1854(a)(6)(B)(iii) prohibits CMS from requiring MA organizations from having a particular price structure for payments to network providers; the Quality Star Rating system does not itself incentivize plans to compromise the delivery of medically necessary care to enrollees.

Comment: A few commenters suggested CMS use alternative clustering methodologies to address outliers, including K-means clustering with outlier removal (KMOR) and clustering with outlier removal (COR).

Response: CMS appreciates the commenters' suggestions and will consider these comments and alternatives as one of the agency's goals in administering the Quality Star Ratings program is continual improvement. CMS is exploring standard outlier removal techniques, such as Tukey outer fence outlier deletion prior to clustering, that are similar to alternatives that the commenter suggests. These approaches are available in SAS software and thus have the benefit of being accessible and transparent to stakeholders. CMS will continue to evaluate these and possibly other methods to directly address outliers and will consider proposing outlier deletion in future rulemaking.

Comment: A commenter stated cut points need to reflect meaningful differences in plan performance.

Response: CMS agrees that the cut points should provide a meaningful way to distinguish true performance. CMS believes hierarchical clustering combined with mean resampling and guardrails will result in cut points that meaningfully distinguish performance while also creating more stability and predictability. Further, CMS monitors the performance distribution for each measure in the Star Ratings program to determine if scores are tightly compressed and differences are not practically meaningful. Even small differences in scores can be meaningful. For example, Quigley, Elliott et al. (2018) established that even one point differences in CAHPS scores are meaningful. Further, CMS evaluates measures for retirement when scores are compressed and topped out such that the measure has low reliability.

Comment: A commenter supported the proposed changes as an interim step, but offered a number of suggestions for CMS to model, in particular to see the impact on plans with a high proportion of LIS/DE/disabled enrollees. The commenter's suggestions included: Stratifying cohort/peer group quintiles based on percent LIS/DE/disabled prior to applying cut point thresholds, using state as unit of analysis rather than contract, analyzing whether measures are sensitive to provider actions, assessing measures to see whether performance differs across plan benefit packages in a contract, addressing topped out measure performance by assigning thresholds for higher stars based on clinical or public health guidelines, and considering beneficiary characteristics when examining measure results.

Response: CMS appreciates the feedback and will take these suggestions into consideration as CMS makes future changes to the Star Ratings methodology. CMS continually monitors cut points and will evaluate the impact of the changes to the cut point methodology. CMS will propose additional enhancements to the cut point methodology as necessary to further the goals of providing ratings that are a true reflection of plan quality and enrollee experience, minimize the risk of misclassification, treat contracts fairly and equally, and minimize unintended consequences.

Comment: A commenter supported rounding measures scores to the next decimal place (tenths of a percent).

Response: Measure scores are already rounded to the precision indicated next to the label ''Data display'' within the detailed description of each measure in the Part C and D Star Ratings Technical Notes found at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.* Most measures are rounded to whole numbers so small differences in performance do not drive the cut points.

Comment: A couple of commenters requested additional data to validate calculations during the second plan preview and to simulate proposed enhancements.

Response: CMS will post example measure data for one Part C and one Part D measure in HPMS at the beginning of the second plan preview for contracts to check the CMS programming. Additionally, all HEDIS data from 1997 on are available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/MA-HEDIS-Public-Use-Files.html.* These data are available in September of each year and can be used to simulate and validate Ratings calculations.

Comment: A commenter questioned whether CMS has considered if measures that have shifts in cut points of 5 points should be included in the Star Ratings due to their volatility.

Response: In general, CMS believes such measures should be included in the Star Ratings. Some measures may have occasional large shifts in the performance distribution, but this does not suggest that the measure is not a reliable measure of performance. Shifts in 5 percentage points can happen occasionally since the clustering algorithm not only looks at changes in the levels of performance, but also takes into account changes in the distribution of scores across the industry. When there are more significant shifts in performance, there may be larger shifts in cut points. As finalized in this rule, the mean resampling and guardrails will prevent any very large cut point shifts.

Comment: A commenter raised concerns that the current clustering methodology is flawed since small plans with more volatility can have an outsized impact on thresholds, resulting in misclassification. Another commenter believed the proposed changes would not adequately address misclassifying nearly identical contracts into different Star Ratings levels.

Response: We appreciate the commenters' concerns about volatility and misclassification. The clustering algorithm is set up to maximize differences across star categories and minimize differences within star categories so to avoid misclassifying nearly identical contracts into different Star Ratings levels. All measures have minimum denominators to ensure that the scores included in the Star Ratings are reliable. Outliers are seen not just for small plans that may have smaller

denominators, but with larger plans with moderate or large denominators. Reducing the impact of outliers on the cut points will help to address any potential volatility. CMS is finalizing mean resampling to help address outliers. Along with guardrails, mean resampling will increase the stability and predictability of cut points. In an earlier response, CMS also presented results from simulations that looked at two ways of directly addressing outliers. CMS will continue to evaluate these and possibly other methods to directly address outliers and will consider proposing outlier deletion in future rulemaking.

Comment: A couple of commenters noted that currently plans may have a score that improves but a star that declines or a score that declines but a star that improves.

Response: Since the hierarchical clustering algorithm not only looks at changes in the levels of performance but also takes into account changes in the distribution of scores across the rated Part C and Part D contracts, scores can decline from the prior year and have a higher Star Rating and similarly scores can increase and have a lower Star Rating. The Star Ratings provide information about comparative performance and how the contracts performed compared to the other contracts. CMS is also looking into methods that directly address outliers and will consider proposing outlier deletion in future rulemaking.

Comment: A commenter requested CMS consider that more beneficiaries are enrolling in the MA program and future enhancements may be warranted to accurately reflect plan performance and not the prior care these beneficiaries received before they joined an MA plan, because quality improvement often takes longer than a year.

Response: CMS appreciates this feedback and will continue to monitor scores across the industry.

Comment: A commenter stated if methodologies are in place to restrict extreme movement of cut points, then contracts should be able to use the prior year's data to set goals and focus on improvement and reaching specific benchmarks.

Response: CMS agrees that by increasing the stability and predictability of the cut points, this methodology will assist Part C and Part D organizations in setting specific goals for improvement on Quality Star Ratings.

Comment: A commenter requested CMS reconsider the model for developing CAHPS thresholds to create meaningful differences in plan quality, because the CAHPS measure scores are clustered tightly.

Response: CMS believes that even one point differences in CAHPS scores are meaningful. See Quigley, Elliott et al. (2018). Further, the methodology for setting cut points for CAHPS measures is outside the scope of the proposal and this rulemaking.

Comment: A commenter supported a three-year rolling average of cut points to increase stability for measures that have not topped out; for topped out measures the commenter supported fixed cut points based on the most recent year when performance is categorized as topped out, and providing advance notice of thresholds for new measures for the first three Star Ratings years then move to the three-year rolling average. Additionally, the commenter stated that topped out measures should not be removed from Star Ratings if high quality is still important to maintain.

Response: Using a three-year rolling average of cut points would increase the lag used to determine cut points, which is problematic because it does not account for real improvement trends in measure performance over time. Providing an accurate reflection of the performance on measures for the applicable measurement year is a key goal of the Quality Star Ratings system. The methodology CMS proposed and is finalizing in this rule will increase stability in cut points without this limitation. As a measure is becoming topped out, the cut points already do not change much from year to year so we disagree that there would be a need to set fixed cut points. If there is no or very little variation across contracts in a measure, the measure would have low reliability and, pursuant to §§ 422.164(e) and 423.184(e), would be removed from the Star Ratings program. We will take these comments into consideration as we consider any changes for our policies regarding measures with low reliability.

Comment: A commenter recommends addressing data reliability by having measure developers review outliers and measure methodology, and set more appropriate specifications, such as increasing the minimum denominator and excluding members for which the measure may not be clinically appropriate. The commenter believes this will stabilize cut points.

Response: CMS agrees that measures used in the Part C and Part D Quality Star Rating System should be based on reliable data and provide useful information about plan performance. As discussed in the April 2018 final rule (83 FR 16521) and November 2017 proposed rule (82 FR 56336), one of the goals of the Star Ratings system is for ratings to be a true reflection of plan performance and enrollee experience and be based on data that are accurate, complete, and reliable. Measure developers have been reviewing their specifications to enhance them and CMS will encourage them to continue to review the specifications to improve their measure specifications. For example, NCQA has increased the denominator for the Plan-All Cause Readmission measure to a minimum of 150. NCQA has also been reviewing the HEDIS measures for the additional exclusion for patients with advanced illness.

Comment: A commenter suggested we consider input from the Pharmacy Quality Alliance (PQA).

Response: CMS welcomes input from all stakeholders, and considered the comments submitted by the PQA when finalizing this rule.

Comment: A commenter suggested setting a minimum number of contracts per cluster in order to address the concern that a single contract could influence a change in cut points even with guardrails.

Response: CMS believes setting a minimum number of contracts per cluster would require making a priori assumptions about the distribution of measure scores. The proposed enhancements to the cut point methodology address the commenter's concerns by moving in the direction of increasing stability and predictability of the ratings without having to make a priori assumptions. Additional outlier deletion methods may be proposed through future rulemaking will further address the commenter's concern. In an earlier response, CMS presented results from simulations that looked at two ways of directly addressing outliers. CMS will continue to evaluate these and possibly other methods to directly address outliers and will consider proposing outlier deletion in future rulemaking.

Comment: A commenter suggested that CMS communicate on Medicare Plan Finder that the decrease in stars for PDPs for the 2019 Star Ratings was due to differing cut points for PDPs versus MA–PDs and the impact of outliers on PDPs.

Response: This comment is outside the scope of our proposal for setting cut points for the 2022 and subsequent Star Ratings. The cut points for MA–PDs and PDPs have historically been set separately since performance across MA organizations that offer Part D and stand-alone PDPs may differ given the

integration of health and drug benefits under an MA–PD is very different than how a stand-alone PDP operates. CMS appreciates the comment, but the notices on Medicare Plan Finder are not designed or intended to address the intricacies of the methodology for the Star Ratings program; however, the Technical Notes for each year's Star Ratings are available publicly for those who are interested in that information and are found at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.* CMS is concerned that too much methodological detail can be overwhelming for those who use the Medicare Plan Finder website and believes that most consumers want just to see the Star Ratings, especially the overall ratings. As discussed in this final rule and responses to comments in this section, the proposed resampling and guardrails will help mitigate significant changes in the cut points from year to year.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier in this final rule, we are finalizing the methodology to determine cut points as proposed at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i). CMS is committed to incorporating feedback received from commenters about the direct removal of outliers from the calculations and will continue to evaluate the methodologies described earlier for outlier removal and possibly other methodologies. We will consider proposing outlier deletion in future rulemaking to allow all stakeholders the opportunity to comment on potential methodologies.

d. Updating Measures (§§ 422.164, 423.184)

In the April 2018 final rule (83 FR 16537), CMS stated that due to the regular updates and revisions made to measures, CMS would not codify a list of measures and specifications in regulation text; CMS adopted a final list of measures for the contract year 2019 measurement period (83 FR 16537–16546) and indicated how changes to that list—additions, updates, removals—would be done in the future, using the Advance Notice and Rate Announcement under section 1853(b) of the Act or rulemaking. The regulations at §§ 422.164 and 423.184 specify the criteria and procedure for adding, updating, and removing measures for the Star Ratings program. CMS lists the measures used for the Star Ratings each year in the Technical Notes or similar guidance document with publication of the Star Ratings. We proposed measure changes to the Star Ratings program for performance periods beginning on or after January 1, 2020 and performance periods beginning on or after January 1, 2021. For new measures and substantive updates to existing measures, as described at §§ 422.164(c) and (d)(2), and §§ 423.184(c) and (d)(2), CMS will initially announce and solicit comment through the Call Letter attachment to the announcements issued for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and will subsequently propose these measures to be added to the Star Ratings program through rulemaking. Proposals for substantive updates have been discussed in prior Call Letters (contract years 2018 and 2019). We will continue the process of announcing our intent with regard to measure updates in future Call Letters. Any measures with substantive updates must be on the display page for at least 2 years before use in the Star Ratings program. For new measures and measures with substantive updates, as described at §§ 422.166(e)(2), 423.186(e)(2) and §§ 422.164(d)(2), 423.184(d)(2), the measure will receive a weight of 1 for the first year in the Star Ratings program. In the subsequent years, the measure will be assigned the weight associated with its category.

(1) Proposed Measure Updates

(a) Controlling High Blood Pressure (Part C)

Due to the release of new hypertension treatment guidelines from the American College of Cardiology and American Heart Association,[34] NCQA implemented updates to the Controlling High Blood Pressure measure for HEDIS 2019. NCQA revised the blood pressure target to <140/90 mmHg. NCQA also made some structural changes to the measure that included allowing two outpatient encounters to identify the denominator and removing the medical record confirmation for hypertension, allowing the use of telehealth services for one of the outpatient encounters in the denominator, adding an administrative approach that utilizes CPT category II codes for the numerator, and allowing remote monitoring device readings for the numerator. Given the change to the blood pressure target and our rules for moving measures with substantive changes to the display page, this measure will be moved to the display page for the 2020 and 2021 Star Ratings. We proposed to return this measure as a measure with substantive updates by the measure steward (NCQA) to the 2022 Star Ratings using data from the 2020 measurement year with, as required by §§ 422.164(d)(2) and 422.166 (e)(2), a weight of 1 for the first year and a weight of 3 thereafter.

Below we summarize the comments we received and provide our responses and final decisions.

Comment: The majority of commenters supported our proposal.

Response: CMS appreciates receiving the support for this proposal.

Comment: A few commenters expressed support, but offered additional measure specification change suggestions. These commenters questioned whether the new standards are suitable for all populations (that is, for those with special needs, the aged, and those with multiple co-morbidities and advanced cognitive impairment populations as well as for the generally healthy elderly population). These commenters suggested adding some additional exclusions. A commenter disagreed with the new clinical standards as specified in the updated measure.

Response: NCQA is the measure steward for the Controlling High Blood Pressure measure. As codified at § 422.164(c)(1) CMS tries to include in the Star Ratings, to the extent possible, measures that are nationally endorsed and in alignment with the private sector such as the Plan All-Cause Readmissions measure developed by NCQA. Although a few commenters offered suggestions for additional changes to the measure, CMS is moving ahead to include the revised measure in the 2022 Star Ratings since we believe that this measure has been sufficiently validated by the measure steward and most commenters supported the measure updates to align with the new clinical guidelines for blood pressure control. CMS will share all suggestions, including concerns about additional exclusions and clinical disagreements with the specified updates with NCQA for their consideration as they make future enhancements to the measure.

Comment: A few commenters believe the current measure is too important to remove from the Star Ratings. Rather, they suggested keeping the legacy measure in the Star Ratings while the

[34] See Whelton P.K., Carey R.M., Aronow W.S., et al. (2018). Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Journal of the American College of Cardiology. 71(19): e127–e248. Available at *http://www.onlinejacc.org/content/71/19/e127?_ga=2.143510773.1362500146.1536262802-126396490.1536262802.*

updated measure is shown on the display pages.

Response: CMS agrees that the Controlling High Blood Pressure measure is an important measure. However, CMS believes that keeping the legacy measure in the Star Ratings while presenting the updated measure on the display pages, would create significant data collection burden on plans given the data collection complexities of the Controlling High Blood Pressure measure. Although § 422.164(d)(2) permits continued use of legacy measures when there has been a substantive update, the regulation does not require CMS to do so in all cases. Here, CMS believes that it is not appropriate.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing our proposal to return the Controlling High Blood Pressure measure, as updated by the measure steward, to the 2022 Star Ratings using data from the 2020 measurement year with a weight of 1 for the first year and a weight of 3 thereafter, as required by §§ 422.164(d)(2) and 422.166 (e)(2).

(b) MPF Price Accuracy (Part D)

Continued transparency and accuracy of sponsors' pricing data used by beneficiaries is important; therefore, we proposed to make enhancements to the MPF Price Accuracy measure to better measure the reliability of a contract's MPF advertised prices. In accordance with § 423.184(d)(2), the substantively updated measure would be a display measure for 2020 and 2021 and we proposed to use it in the 2022 Star Ratings in place of the existing MPF Price Accuracy measure, which will remain in the Star Ratings until that replacement under § 423.184(d)(2). The proposed update would measure the magnitude of difference, as well as the frequency of price differences. We proposed to implement the following changes for this measure:

• Factor both how much and how often prescription drug event (PDE) prices exceeded the prices reflected on the MPF by calculating a contract's measure score as the mean of the contract's Price Accuracy and Claim Percentage scores, based on the indexes in this rule:

++ The Price Accuracy index compares point-of-sale PDE prices to plan-reported MPF prices and determines the magnitude of differences found. Using each PDE's date of service, the price displayed on MPF is compared to the PDE price. The Price Accuracy index is computed as:

(Total amount that PDE is higher than MPF + Total PDE cost)/(Total PDE cost)

++ The Claim Percentage index measures the percentage of all PDEs that meet the inclusion criteria with a total PDE cost higher than total MPF cost to determine the frequency of differences found. The Claim Percentage index is computed as:

(Total number of claims where PDE is higher than MPF)/(Total number of claims)

++ The best possible Price Accuracy index is 1 and the best possible Claim Percentage index is 0. This indicates that a plan did not have PDE prices greater than MPF prices.

++ A contract's measure score is computed as:

—Price Accuracy Score = 100 − ((Price Accuracy Index − 1) * 100)

—Claim Percentage Score = (1 − Claim Percentage Index) * 100

—Measure Score = (0.5 * Price Accuracy Score) + (0.5 * Claim Percentage Score)

• Increase the claims included in the measure:

++ Expand the days' supply of claims included from 30 days to include claims with fills of 28–34, 60–62, or 90–100 days.

++ Identify additional retail claims using the PDE-reported Pharmacy Service Type code. Claims for pharmacies that are listed as retail in the MPF Pharmacy Cost file and also have a pharmacy service type on the PDE of either Community/Retail or Managed Care Organization (MCO) will be included.

• Round a drug's MPF cost to 2 decimal places for comparison to its PDE cost. Post-rounding, the PDE cost must exceed the MPF cost by at least one cent ($0.01) in order to be counted towards the accuracy score (previously, a PDE cost which exceeded the MPF cost by $0.005 was counted). A contract may submit an MPF unit cost up to 5 digits, but PDE cost is always specified to 2 decimal places.

Under our proposed update, PDEs priced lower than the MPF display pricing will continue to be ignored and will not have an impact on the measure score or rating. Only price increases are counted in the numerator for this measure. We proposed to add this updated measure to the 2022 Star Ratings based on the 2020 measurement year with a weight of 1.

Below we summarize the comments we received and provide our responses and final decisions.

Comment: The majority of commenters supported the measure's proposed changes, citing it is critical to provide enrollees with information they have confidence is reliable and accurate. There was strong support for price transparency, and making sure contract performance is measured in a meaningful and useful manner.

Response: CMS appreciates these commenters' support of this measure and the proposed changes, and more broadly the confirmation that beneficiaries rely on the MPF's accuracy to make critical enrollment choices. We agree that it is essential to continue this measure so that enrollees can remain confident that the data displayed on the MPF are reliable and accurate. Our Star Ratings contractor will also continue to obtain feedback on price transparency and related measure concepts as part of their TEP. CMS always values feedback on display and Star Ratings measures and will continue to identify future ideas in the 2021 Call Letter.

Comment: Several commenters opposed the addition of frequency of price differences to the measure, stating this would not be a concern to beneficiaries, or that the current Star Rating measure already includes this. They also state the frequency of pricing differences between the data available on the MPF and the price reflected in the PDE data is not due to a contract's performance, but due to established CMS timelines for MPF updates.

Response: We disagree with these commenters, and believe both the magnitude and frequency of price inaccuracies are important. A one-time discrepancy illustrates different performance by a Part D plan on this issue than multiple occasions where the price is higher than posted on the Medicare Plan Finder website; we believe both that beneficiaries appreciate such differences in performance and need to be aware of them. With the current methodology (as of the 2019 Star Ratings), a sponsor who frequently submits small inaccuracies may receive a similar score to a sponsor who submits MPF prices with very large price differences only a few times.

Comment: Some commenters criticized the overall measure because MPF files are prepared and submitted by a Part D plan according to the CMS-issued calendar and guidelines, which do not allow submissions outside the specified bi-weekly schedule. Because CMS posts files two weeks after submission which are then displayed on MPF for two weeks, the commenters state the data are typically between 19 to 31 days old.

Response: CMS understands that pricing may change much more frequently than MPF submission

windows. We have instituted a biweekly submission window to allow for a correction period (to avoid suppression of plans on MPF). This submission schedule does not dictate the schedule or frequency by which a sponsor chooses to update their own price files prior to submission to CMS. Sponsors who perform well in this measure typically update their pricing files at least every other week and typically closer to the submission dates.

Comment: A few commenters were opposed to the measure because MPF pricing data are based on a single reference/proxy NDC and are compared to an expanded list of NDCs on the PDEs. They state this is a flaw since drug costs vary by NDC, even those with the same strength or dosage form. This variability leads to unavoidable inconsistencies between a Part D plan's submitted price and the price on the claim or PDE record.

Response: For the Star Rating measure, prices that are higher on MPF as opposed to the PDE do not harm the plans' scores. CMS had expanded the list of NDCs to be compared to the MPF prices beginning with the 2011 Star Ratings in response to sponsors' requests to expand the claims studied. Previously, sponsors were only evaluated with PDEs with the same reference NDC, which limited claims, and sponsors stated, unfairly portrayed their accuracy, especially if they did not support the pricing NDC selected on the FRF. To ensure that the measure is sensitive to the accuracy of claims of NDCs beyond those on the FRF, claims for non-reference NDCs that can be linked to a reference NDC with the same brand name, generic name, strength, and dosage form are included in the measure. The inclusion of these additional claims allows for a more robust method of measuring price accuracy. We remind commenters that the average score in this measure ranged from 98–99 for PDPs and MA–PDs in the 2019 Star Ratings.

Comment: A few commenters stated a meaningful price difference to beneficiaries would be greater, and in the range $0.50–$1.00, and that the de minimis amount of $0.01 also does not account for all rounding errors.

Response: The measure's current price threshold of $0.005 was based on data analyses, and sponsor performance has been high for many years. We are raising to $0.01 to account for rounding, and thus allowing a larger variation in prices that are not counted as price increases for purposes of the measure than previously allowed. Raising the threshold level for counting a price increase to $0.50 or higher would significantly lower the usefulness of the measure as a whole, given that plans' scores have been typically clustered in the high 90s.

Comment: Some commenters were overall against CMS using the MPF Price Accuracy measure in the Star Ratings program. They state that a 100 rating in this measure does not reflect truly accurate pricing, but instead is driven primarily by the timing of the files and subsequent measure auditing of pricing. While they agree it is an important measure to ensure MAOs and PDPs are accurately representing drug pricing to plan members; the cut points require near perfection. They propose the measure instead be moved to the display page for monitoring, and that plans not be penalized by timing issues outside of plan control.

Response: CMS disagrees. The cut points are based on the clustering algorithm and reflects actual performance. CMS does not modify the cut points to require near perfection, it is that Part D sponsors generally do a good job of posting prices that are at least as high as the actual charged prices. CMS sees sponsors' frequent auditing of MPF and price adjudication files to be a beneficial result from the measure. Beneficiaries and other public stakeholders are interested in this measure as well. Knowing that they can expect accurate pricing on the MPF is extremely helpful to beneficiaries using the tool to choose their prescription drug plans.

Comment: A commenter recommended that CMS assess the additional value to beneficiaries of the MPF measure based on usage patterns for price data, etc., and weigh that against the costs to the program (through higher plan bids) that will arise from additional investments that may be required for Part D plans to comply with the revised methodology for this measure.

Response: The regulation at §§ 423.184 (c)(3) and (d)(2) requires new measures and substantively updated measures to be on the display page for at least two years prior to using the updated measure to calculate and assign Star Ratings; for the revised Part D price accuracy measure finalized here, this two year display period will be the 2020 and 2021 display page. During that period, CMS will be using the legacy measure in the Star Ratings. Additional feedback on this revised measure may be submitted during the annual Call Letter process based on experience with the revised measure on the display page. CMS does not agree that the measure's revised methodology imposes additional plan burden. Part D sponsors are required to submit accurate pricing for MPF, and adjudicate claims accurately at the point of sale.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to related comments, we are finalizing the provisions related to updating the MPF Price Accuracy measure. As proposed, we will first display the updated measure for 2020 and 2021 and then use it to replace the existing measure in the 2022 Star Ratings. Publishing the display measure for at least two years will allow Part D sponsors additional experience with contract-specific results using the new specifications.

(c) Plan All-Cause Readmissions (Part C)

NCQA is modifying the Plan All-Cause Readmissions measure for HEDIS 2020 (measurement year 2019).[35] The measure assesses the percentage of hospital discharges resulting in unplanned readmissions within 30 days of discharge. The changes made by NCQA to the measure are: Adding observation stays as hospital discharges and readmissions in the denominator and the numerator; and removing individuals with high frequency hospitalizations. These changes were implemented by the measure steward (NCQA) based on the rise in observation stays to ensure the measure better reflects patient discharge and readmission volumes. Removing individuals with high frequency hospitalizations from the measure calculation allows the readmissions rates not to be skewed by this population. To date, CMS has only included the 65+ age group in the Plan All-Cause Readmissions measure. In addition to the updates made by the measure steward, CMS proposed to combine the 18–64 and 65+ age groups as the updated measure specifications are adopted and to use NCQA's new recommendation of 150 as the minimum denominator. Given the substantive nature of the proposed updates for this measure, it would be moved to display for the 2021 and 2022 Star Ratings under our proposal and § 422.164(d)(2). We proposed to return this measure as a measure with substantive updates by the measure steward (NCQA) to the 2023 Star Ratings using data from the 2021 measurement year with, as required by §§ 422.164(d)(2) and 422.166(e)(2), a weight of 1 for the first year and a weight of 3 thereafter.

[35] HEDIS 2019, Volume2, Technical Update, Attachment C. *https://www.ncqa.org/wp-content/uploads/2018/10/HEDIS-2019-Volume-2-Technical-Update.pdf.*

Below we summarize the comments we received and provide our responses and final decisions.

Comment: The majority of commenters supported our proposal.

Response: CMS appreciates receiving the support for this proposal.

Comment: Some commenters questioned specific aspects of the measure specification, including the inclusion of observation stays in the measure's numerator and denominator and whether the measure is appropriate for high risk populations. A commenter suggested that by focusing on decreasing readmissions, mortality rates could increase. The commenter cited a 2018 JAMA Cardiology article [36] which presented data showing that the implementation of the Hospital Readmissions Reduction Program (HRRP) was temporally associated with a reduction in 30-day and 1-year readmissions but an increase in 30-day and 1-year mortality for patients discharged after heart failure among fee-for-service Medicare beneficiaries. The authors of this article suggested that this may be just a temporary association and requested additional research to confirm these results.

Response: NCQA is the measure steward for the Plan All-Cause Readmission measure. As codified at § 422.164(c)(1) CMS tries to include in the Star Ratings, to the extent possible, measures that are nationally endorsed and in alignment with the private sector such as the Plan All-Cause Readmissions measure developed by NCQA. Despite some commenters questioning specific aspects of the measures, most commenters provided support for the readmissions measure. CMS believes that this is an important outcome measure for MA contracts since the basis of the MA program is for MA contracts to coordinate the care of their enrollees. MA contracts are responsible for coordinating care following a hospitalization to ensure that their enrollees are receiving appropriate care following a hospitalization, including whether they need to be rehospitalized due to further declines in health. CMS will share all comments concerning appropriate enrollees eligible for the measure, the inclusion of observations stays, and the belief that decreasing readmissions might increase mortality with NCQA for consideration as they make future updates to the measure. Following our rules for moving measures with substantive changes to the display page, this measure will be moved to the display page for the 2021 and 2022 Star Ratings for contracts to acclimate to the new measure specifications.

Comment: A commenter suggested that when the measure is returned to the Star Ratings, the measure should have a weight of 1 for two years, not only for the first year.

Response: Using a weight of 1 for the first year of a new or newly revised MA measure is required by the regulations at §§ 422.164(d)(2) and 422.166(e)(2). Measures with substantive specification changes are treated as new measures. Changes to that policy are out of scope for this regulation. We direct readers to 83 FR 16534 for a discussion of that particular policy.

Comment: A few commenters expressed the belief that the current measure is too important to remove from the Star Ratings. Rather they suggested keeping the legacy measure in the Star Ratings, while the updated measure is on the display page for two years.

Response: CMS considered keeping the legacy measure in the Star Ratings while displaying the updated measure on the display pages, but believes that it would create a significant data collection burden for plans to submit two different sets of data that follow different specifications. This measure is relatively complex and we believe that the value gained by reporting both the legacy and updated measure would not be justified by the additional administrative burden. Although § 422.164(d)(2) permits continued uses of legacy measures when there has been a substantive update, the regulation does not require CMS to do so in all cases. Here, CMS believes that it is not appropriate.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing our proposal to return the Plan All-Cause Readmissions measure, as updated by the measure steward, to the 2023 Star Ratings with a weight of 1 for the first year and a weight of 3 thereafter, as required by §§ 422.164(d)(2) and 422.166(e)(2). Pursuant to § 422.164(d)(2), the revised measure will be collected for display only for the measurement periods of 2020 and 2021.

(d) Improvement Measures (Parts C and D)

The process for identifying eligible measures to be included in the improvement measure scores is specified as a series of steps at §§ 422.164(f)(1) and 423.184(f)(1). As part of the first step, the measures eligible to be included in the Part C and D improvement measures are identified. Only measures that have a numeric score for each of the 2 years examined are included. We proposed to add an additional rule at §§ 422.164(f)(1)(iv) and 423.184(f)(1)(iv) that would exclude any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s) used for the applicable contract. The proposed new standard would ensure that the numeric scores for each of the 2 years are unbiased. If a measure's measure-level Star Rating receives a reduction for data integrity concerns in either of the 2 years, the measure would not be eligible to be included in the improvement measure(s) for that contract.

Below we summarize the comments we received and provide our responses and final decisions.

Comment: The vast majority of commenters supported our proposal.

Response: CMS appreciates receiving the support for this proposal.

Comment: A few commenters suggested different ideas for how the improvement measures should be calculated: (1) Use a logarithmic scale rather than a linear scale; (2) calculate improvement measures for the display measures and count them in the Star Ratings improvement measures; (3) modify the hold harmless policy; and (4) weight the improvement change taking into account how well the contract performed in the prior year and the increased difficulty to improve at the higher star levels. A commenter suggested that the improvement measures be entirely dropped from the Star Ratings, stating they are unnecessary.

Response: CMS appreciates the additional feedback related to potential enhancements to the improvement measures. However, these suggestions are outside the scope of the proposed rule. CMS will consider these suggestions as we contemplate future enhancements.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the amendment to how improvement measures are identified and used as proposed for performance periods beginning on or after January 1, 2020.

[36] Gupta A et al, JAMA Cardiol. 2018; 3(1): 44–53. *https://jamanetwork.com/journals/jamacardiology/fullarticle/2663213.*

Table 2—Additions and Updates to Individual Star Rating Measures

The measure descriptions listed in the tables are high-level summaries. The Star Ratings measure specifications supporting document, *Medicare Part C & D Star Ratings Technical Notes,* provides detailed specifications for each measure. Detailed specifications include, where appropriate, the identification of a measure's: (1) Numerator; (2) denominator; (3) calculation; (4) timeframe; (5) case-mix adjustment; and (6) exclusions. The Technical Notes document is updated annually. In addition, where appropriate, the Data Source descriptions listed in this table reference the technical manuals of the measure stewards. The annual Star Ratings are produced in the fall of the prior year to assist beneficiaries in choosing their health and drug plan during the annual open enrollment. For example, Star Ratings for the year 2022 are produced in the fall of 2021.

1. If a measurement period is listed as 'the calendar year 2 years prior to the Star Ratings year' and the Star Ratings year is 2022, the measurement period is referencing the January 1, 2020 to December 31, 2020 period.

2. For CAHPS, HOS, and HEDIS/HOS measures, the measurement period is listed as 'most recent data submitted for the survey of enrollees.' See measure stewards' technical manuals, as referenced in Data Source column, for the specific measurement periods of the most recent data submitted.

TABLE 2A—UPDATES TO INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2020

Measure	Measure description	Domain	Measure category and weight	Data source	Measurement period	NQF endorsement	Statistical method for assigning star ratings	Reporting requirements (contract type)
Part C Measure								
Controlling Blood Pressure (CBP).	Percent of plan members 18–85 years of age who had a diagnosis of hypertension (HTN) and whose blood pressure was adequately controlled (<140/90).	Managing Chronic (Long Term) Conditions.	Intermediate Outcome Measure Weight of 3.	HEDIS*	The calendar year 2 years prior to the Star Ratings year.	#0018	Clustering	MA-PD and MA-only.
Part D Measure								
MPF Price Accuracy.	A score comparing the prices members actually pay for their drugs to the drug prices the plan provided for the Medicare Plan Finder website.	Drug Safety and Accuracy of Drug Pricing.	Process Measure Weight of 1.	PDE data, MPF Pricing Files.	The calendar year 2 years prior to the Star Ratings year.	Not Applicable	Clustering	MA-PD and PDP.

*NCQA HEDIS Technical Specifications, Volume 2.

TABLE 2B—UPDATES TO INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2021

Measure	Measure description	Domain	Measure category and weight	Data source	Measurement period	NQF endorsement	Statistical method for assigning star ratings	Reporting requirements (contract type)
Part C Measure								
Plan All-Cause Readmissions (PCR).	Percent of acute inpatient stays that were followed by an unplanned acute readmission or an observation stay for any diagnosis within 30 days, for members ages 18 and over. Rates are risk-adjusted.	Managing Chronic (Long Term) Conditions.	Intermediate Outcome Measure Weight of 3.	HEDIS*	The calendar year 2 years prior to the Star Ratings year.	#1768	Clustering	MA-PD and MA-only, except for 1876 Cost Plans.

*NCQA HEDIS Technical Specifications, Volume 2.

Below we summarize additional comments CMS received on measures that were not part of the proposed rule and provide our responses. CMS appreciates the additional feedback related to potential enhancements to measures and will take this feedback into consideration as we make future measure enhancements.

Comment: Commenters requested measure updates for and possible removal of the following measures: Annual Flu Vaccine, Osteoporosis Management in Women who had a Fracture, and Rheumatoid Arthritis Management. CMS also received requests for updates to the following measures: Getting Needed Care, Getting Appointments and Care Quickly, and Members Choosing to Leave the Plan. Some of the comments indicated these measures need additional specifications and exclusions, especially for the Puerto Rican population. Another commenter further suggested the need for measures specifically designed for the advanced illness populations.

Response: These comments are outside of the scope of the proposed and final rules. Where appropriate CMS will share all measure specification suggestions, including concerns about additional measure exclusions and the design of measures specifically for the advanced illness populations, with the appropriate measure stewards.

Comment: A commenter suggested that for the Part D Appeals Auto-Forward measure the minimum enrollment size for a plan to be eligible for this measure be raised or that plans having fewer than two auto-forwards be exempted from reporting. Another commenter suggested that CMS combine the call center sampling for the Part C and Part D Call Center Foreign Language Interpreter and TTY Availability measures.

Response: These suggestions are outside the scope of the proposed and final rules; however, we will take them into consideration as we contemplate future enhancements.

Comment: For the measures Complaints about Health/Drug Plans, a commenter stated these measures should be modified due to complaints arising from restricting beneficiaries' access to opioids.

Response: This suggestion is outside the scope of the proposed and final rules; however, we will take it into consideration as we contemplate future enhancements. In addition, prior to use in the Star Ratings, complaints are reviewed for resolution by plans' and CMS Regional caseworkers. If necessary, a complaint may be labeled as a CMS issue, and thus excluded from the Complaints Star Rating measure. Please note however that not all opioid related complaints should be considered to be ''CMS issues''; for example, a complaint that a plan did not properly implement opioid safety edits, or did not follow Part D requirements for coverage determinations/appeals would remain included in a plan's complaints measure data.

Comment: A few commenters suggested the measure weights for both the CAHPS and HOS measures should be reduced.

Response: In the April 2018 final rule, CMS codified, at §§ 422.166(e)(1) and 423.186(e)(1), the general rules for assigning measures the weight associated with their category. Changes to that policy are out of scope for the proposed and final rules.

Comment: A few commenters suggested electronic survey administration and electronic submission of hybrid measures to reduce provider burden and paperwork.

Response: These comments are outside of the scope of the proposed and final rules. CMS also supports the move to more electronic modes of data collection. CMS will be soliciting comment in an OMB Paperwork Reduction Act (PRA) package as CMS plans to test the web mode of survey administration across various CMS surveys. NCQA has also developed HEDIS Electronic Clinical Data Systems (ECDS) to support obtaining information that is currently available in electronic clinical datasets for HEDIS quality measures.

Comment: A commenter suggested that given the changes with the implementation of section 17006 of the Cures Act, CMS should begin to consider one or more ESRD quality measures specific to ESRD beneficiaries, home dialysis, and/or education about home dialysis.

Response: These comments are outside of the scope of the proposed and final rules. CMS has begun to consider what measures will potentially be relevant for ESRD beneficiaries. We are following the work NCQA will be doing with the National Kidney Foundation to develop a provider-level measure focused on screening for nephropathy in patients with diabetes. This work may inform potential updates/changes for the plan-level measure in HEDIS. We are also following the quality measurement work in the Comprehensive ESRD Care (CEC) Model test to see if any of those measures will be relevant. We are open to suggestions for additional measures.

Comment: A commenter suggested developing measures that reflect care for under-65 populations who are Medicare-eligible due to disability and that, while also being consistent with the Medicare Star Ratings methodology, the measures also reflect complex medical conditions that these individuals have. To bolster the ability of states and others to analyze data across various factors and programs, the commenter also requested CMS provide access to data at levels below the contract and disaggregated.

Response: These comments are outside of the scope of the proposed and final rules. CMS appreciates the importance of measuring plan performance in serving the under-65 population and the comment explaining why. To allow comparisons below the level of the contract and/or disaggregated in other ways may be challenging, since valid and reliable comparisons at those levels could be very burdensome to plans or may not be possible. However, CMS has and will continue to explore ways to address the needs of states and others to assess care for subpopulations.

Comment: A commenter suggested CMS focus more on outcome measures than on process measures.

Response: These comments are outside of the scope of the proposed and final rules. CMS agrees with the importance of focusing on outcome measures and welcomes all suggestions for potential outcome measures as additions to the Star Ratings.

Comment: CMS received a request for additional discussions of how MA and FFS/ACO regulations can be similarly constructed to streamline provider compliance and beneficiary understanding. CMS received a request to publicly post measure guides (for example, Patient Safety Report User Guides) in addition to the Star Ratings Technical Notes. The commenter referenced as an example CMS's use of member months in the Statin Use in Persons with Diabetes (SUPD) measure which differs from the PQA measure specifications, and that additional information would help improve consistency in sponsors' quality improvement efforts. Currently, more detailed information is included in the Patient Safety Report User Guides compared to the Star Ratings Technical Notes.

Response: CMS appreciates suggestions for standardizing measures and regulations across programs. CMS is currently working to ensure consistency of measure specifications across programs where applicable. CMS will consider these suggestions as we contemplate future enhancements.

CMS also agrees about the importance of transparency in CMS's calculation of Star Ratings. Sponsors and their authorized users may access the Patient Safety User Guides through the Patient Safety Analysis website set up by CMS for Part D sponsors to have access to monthly Patient Safety Reports to compare their performance to overall averages and monitor their progress in improving the prescription drug patient safety measures. We will consider options to either publicly post the Patient Safety Report User Guides or incorporate additional details in the Star Ratings Technical Notes. The commenter's reference of CMS using member months in the SUPD measure is an example of a modification necessary to fairly evaluate performance of Part D sponsors. The member-years of enrollment adjustment is used to account for beneficiaries who are enrolled for only part of the contract year. The measure is weighted based on enrollment since beneficiaries with longer enrollment episodes account for more member-years and therefore have a larger impact on a contract's rates. Each episode of enrollment is considered separately.

Comment: A commenter suggested CMS use the Net Promoter Score (NPS) rather than CAHPS measures.

Response: These comments are outside of the scope of the proposed and final rules. CMS disagrees that the NPS

should replace the CAHPS measures. NPS was developed to measure customer loyalty and does not provide information about why a customer may recommend a brand or product. Unless an organization is collecting supplemental information, NPS scores will not help drive quality improvement. Among proponents of the NPS score, there is agreement that additional feedback needs to be collected from customers.[37] This score alone is not sufficient. MA and Part D contracts can collect for their own purposes a limited number of supplemental survey items on the CAHPS surveys if they add them to the end of the survey. Some contracts do add similar questions to the NPS item to the current CAHPS surveys for their own internal purposes. There are multiple concerns about using the NPS score instead of CAHPS, including that the score may mask important differences in performance between organizations and the score is more volatile and less reliable than a composite measure that includes multiple survey questions.

Summary of Regulatory Changes

No changes are being finalized based on these comments that are out of scope of the proposed rule.

(5) Data Integrity (§§ 422.164(g), 423.184(g))

In the April 2018 final rule (83 FR 16562), CMS codified, at §§ 422.164(g)(1)(iii) and 423.184(g)(1)(ii), a policy to make scaled reductions to the Star Ratings for a contract's Part C or Part D appeals measures because the relevant Independent Review Entity (IRE) data are not complete based on the Timeliness Monitoring Project (TMP) or audit information. The reduction is applied to the measure-level Star Ratings for the applicable appeals measures. We proposed to add a provision at §§ 422.164(g)(1)(iii)(O) and 423.184(g)(1)(ii)(M) that would assign a 1-star rating to the applicable appeals measure(s) if a contract fails to submit TMP data for CMS's review to ensure the completeness of their IRE data. We explained in the proposed rule that we believe it is appropriate to assume that there is an issue related to performance when the MA organization or Part D plan sponsor has refused to provide information for the purposes of our oversight of the compliance with the appeals requirements. We also explained how our proposal to modify measure-specific ratings due to data integrity issues is separate from any CMS compliance or enforcement actions related to a sponsor's deficiencies; these rating reductions are necessary to avoid falsely assigning a high star to a contract, especially when the MA organization or Part D sponsor has refused to submit data for us to evaluate performance in this area and to ensure that the data submitted to the IRE are complete.

Below we summarize the comments we received and provide our responses and final decisions.

Comment: Most commenters supported the downgrade to one star if a contract fails to submit TMP data for CMS's review to ensure the completeness of the IRE data. A commenter suggested that a reduction should only occur when there is a complete failure to submit TMP data for CMS review.

Response: CMS appreciates the support of the data integrity policies. To fully assess the completeness of the appeals data, the TMP data need to be complete and submitted in a timely manner. The data integrity policies align with our commitment to data quality and preserve the integrity of the Star Ratings. CMS designed the data integrity policies to distinguish between occasional errors and systematic issues. This policy and these rating reductions are necessary to avoid falsely assigning a high Star Rating to a contract, especially when deficiencies have been identified that show CMS cannot objectively evaluate a sponsoring organization's performance in an area.

Comment: A commenter questioned whether the proposal is only referring to the Appeals Auto-Forward measure as the Part D appeals measure.

Response: The data assignment of one star is for both the appeals timeliness and upheld measures for Part C and Part D. If a contract does not submit the TMP data for the Part C measures, Plan Makes Timely Decision about Appeals (Part C) and the Reviewing Appeals Decisions (Part C), both will receive reductions. The same policy applies to the two Part D appeals measures, Appeals Auto-Forward (Part D) and Appeals Upheld (Part D).

Comment: Many commenters generally opposed scaled reductions, characterizing them as ''data integrity penalties'' using TMP and audit data, and a commenter supported use of audits and TMP data for scaled reductions. The commenters that were opposed stated these data integrity findings are not a reflection of the plan's quality. Others stated that the TMP is burdensome due to an additional requirement that they need to budget for and manage. A commenter opposed use of audits because they believe there could be auditor subjectivity (varying interpretation of the same issue) and changes in the audit process. Many commenters gave recommendations for the TMP or requested clarifications on the process of scaled reductions. A couple of commenters recommend consolidating auditing and/or TMP efforts with other requirements and offered suggestions such as eliminating the TMP and modifying the Part D reporting requirements and Technical Specifications for Coverage Determinations and Redeterminations reports to collect the same or similar data to confirm the accuracy of IRE data. A commenter recommended applying the requirements of Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs to fulfill the Star Ratings integrity goal, be operationally less burdensome for plan sponsors, and also save CMS and the Part D program the amount it paid for the TMP audit in 2017 and 2018. A commenter requested that CMS provide its methodology for determining which cases are in scope for scaled reductions. Another commenter requested CMS wait a minimum of 2 calendar years to use the findings in a ''punitive'' manner to allow the plans to adapt to the process. And a commenter suggested CMS examine methods to simplify appeals administration language and address areas of subjectivity identified within the guidelines that result in differing interpretations.

Response: As explained in the proposed rule, the use of the data downgrade is not a penalty or punitive but a necessary measure to reflect how the data underlying the measure are not reliable and to avoid false high ratings on these measures where the sponsoring organization has failed to provide the data necessary to ensure that performance is accurately reflected on these measures. As we explained in the April 2018 final rule at 83 FR 16562, all measures and the associated data for the Star Ratings have multiple levels of quality assurance checks. Our longstanding policy has been to reduce a contract's measure rating if we determine that a contract's data are incomplete, inaccurate, or biased. If there are data issues, we cannot accurately measure quality and performance. The data downgrade policy was adopted not as a penalty but to address instances when the data that will be used for specific measures are not reliable for measuring performance

[37] *https://aishealth.com/medicare-and-medicaid/nps-is-viewed-as-useful-but-not-best-as-sole-satisfaction-measure-for-ma-plans/.*

due to their incompleteness or biased/erroneous nature. For instances where the integrity of the data is compromised because of the action or inaction of the sponsoring organization (or its subcontractors or agents), this policy reflects the underlying fault of the sponsor and without it sponsoring organizations could ''game'' the Star Ratings and merely fail to submit data that illustrate poor performance. Not only is accepting biased data from a sponsor not fair to other organizations that follow rules and have procedures in place to properly handle appeals, but it is also not fair to beneficiaries, as they would receive inaccurate information on the plan's performance regarding its handling of appeals. The use of TMP data for scaled reductions of the appeals measures was finalized in the April 2018 final rule. In this CY2020 rulemaking, CMS only proposed a reduction to one star for the applicable appeals measures for the contracts that do not submit any TMP data but did not reopen for comment the entire provision regarding use of TMP data or scaled reductions as a whole. Therefore, while CMS appreciates this feedback related to the TMP and scaled reductions in general, these comments are outside the scope of the proposed rule; CMS will consider these suggestions as we make future enhancements.

Comment: A commenter stated the additional change modifies the appeals measures from a timeliness measure to a timeliness and data integrity measure.

Response: CMS disagrees with this assertion. The proposed addition to the scaled reductions for not submitting TMP data is not a modification to the appeals measures but a mechanism to ensure that the data used for evaluating performance on a measure are accurate, complete, and unbiased. If a contract does not submit TMP data, CMS does not have information to assess the completeness of the data used for these measures. The data used for CMS's Star Ratings must be reliable, meaning that they are accurate, complete, and without bias. CMS has historically identified issues with some contracts' data and has taken steps to protect the integrity of the data and the Star Ratings; publishing Star Ratings that are not an accurate reflection of plan performance would not be consistent with CMS's statutory obligation to provide comparative information to beneficiaries under section 1851(d) of the Act or with the goals of the Quality Payment Bonus under section 1853(o) of the Act. Our longstanding policy has been to reduce a contract's measure rating if we determine that a contract's measure data are incomplete, inaccurate, or biased. Determinations that data are inaccurate or biased may result from the mishandling of data, inappropriate processing, or implementation of incorrect practices.

Comment: A few commenters noted that there is a short window for the plans to submit TMP data and that results are not shared until 9 months later. A few commenters requested that plans be provided with TMP results in advance of the first plan preview period. A commenter requested that if CMS chooses to continue the TMP process, CMS should hold the auditor accountable for providing at least a draft audit report within 30 days.

Response: CMS appreciates this feedback. As described in the December 21, 2018 HPMS memo entitled 2019 Timeliness Monitoring Project (TMP), the data collection is done in three waves beginning in January 2019. CMS receives initial TMP results at the end of Spring 2019, and then analyzes each contract's data to apply the scale reductions as required by §§ 422.164(g)(1)(iii) and 423.184(g)(1)(ii); where the applicable regulation does not require a reduction, no reduction is taken. There are no draft TMP reports. CMS will again provide TMP results and scaled reduction information in the first plan preview and sponsoring organizations may submit any questions or comments if they believe they should not have received a reduction. CMS will consider if it is operationally feasible to make these data available any earlier in future years. CMS strongly recommends sponsoring organizations being proactive in adopting policies to ensure that data are accurate, complete, and unbiased, and that the data integrity downgrades are not applicable to them.

Comment: A commenter did not support the proposal to reduce to one star for not producing the TMP data citing that CMS should ensure that the Star Ratings system is focused on improving quality of care received by beneficiaries instead of incorporating ''penalties'' on plans for compliance purposes. Another commenter supported the proposal to reduce to one star if a contract fails to submit TMP data but stated that reducing the Star Ratings for data integrity errors confuses quality measurement with compliance and audit activities. The commenter stated that a plan that is ''penalized'' through compliance audits should not be ''penalized'' a second time through the Star Ratings, which should be focused on clinical quality and beneficiary satisfaction.

Response: CMS agrees that the Star Ratings should be focused on improving the quality of care provided by health and drug plans, but in order to ensure that the Star Ratings can focus on that, the data used to measure performance in CMS's Star Ratings program must be accurate, complete, and unbiased. We reiterate that (1) the reductions required by §§ 422.164(g) and 423.184(g) are not a penalty but a means to reflect how the sponsoring organization has not produced accurate, complete, and unbiased data for purposes of performance measurement and (2) that our proposal was on the narrow issue of addressing the failure of a sponsoring organization to submit TMP data so that CMS could evaluate if the data integrity provision would require a scaled reduction in certain appeals measures. Our longstanding policy has been to reduce a contract's measure rating if we determine that a contract's data are inaccurate, incomplete, or biased. If there are data issues, we cannot accurately measure quality and performance. Public postings of the Star Ratings data use a notice that CMS has identified issues with a plan's data in lieu of the actual rating for a measure; this notice is used when CMS has determined that inaccurate, incomplete, or biased data (such as resulting from the mishandling of data, inappropriate processing, or implementation of incorrect practices) has had an impact on the measure score. The number of stars applied to the measure will be governed by §§ 422.164(g) and 423.184(g), which address scaled reductions to appeals measures based on an analysis of TMP or audit data and to one star for HEDIS measures and other measures based on NCQA audits, lack of compliance with CMS data validation policies, and other means to identify data integrity issues. The data integrity policies align with our commitment to data quality and preserve the integrity of the Star Ratings. CMS designed and finalized these data integrity policies in the April 2018 final rule to distinguish between occasional errors and systematic issues.

Comment: A commenter suggested that if the TMP is used to measure completeness of data, it should be limited to the data for just one measure, the Part D Appeals Auto-Forward measure.

Response: The TMP assess the completeness of the IRE data for all applicable appeals measures which include two Part C and two Part D appeals measures. The assignment to one star when no TMP data are submitted is also applied to the applicable appeals measures since data completeness issues impact the data used for both the timeliness and upheld

measures for Part C and Part D. If cases are missing for the timeliness measure for either Part C or Part D, it would also result in missing cases for the applicable upheld measure.

Comment: A commenter requested that CMS provide more information on the impact of cut points if a plan fails to submit their TMP audit results and the proposal to reduce the plan's rating on the appeals measures is implemented.

Response: If a contract fails to submit TMP data for CMS's review to ensure the completeness of their IRE data, the contract receives one star for the applicable appeals measure(s) under the new regulation provision we proposed and are finalizing at §§ 422.164(g)(1)(iii)(O) and 423.184(g)(1)(ii)(M). Because CMS would have determined that the data reported as performance under the applicable appeals measure(s) was inaccurate, incomplete or biased, that data are not included in the creation of cut points. We base cut points on an analysis of performance data believed to be accurate, complete, and unbiased.

Comment: A commenter questioned what happens if a sponsor submits TMP data late. Their understanding is that currently, because there is no late submission deadline for submitting TMP data, the result is a reduction to one star. They sought to understand the impact of submitting data late under this new provision, and how this provision differs from the existing one.

Response: Failure to submit data by the deadline or an extension granted by CMS is failure to submit the TMP data. Under the new regulation provision we proposed and are finalizing here at §§ 422.164(g)(1)(iii)(O) and 423.184(g)(1)(ii)(M), the assignment of one star for the applicable appeals measures will happen if a contract fails to submit any TMP data. The December 21, 2018 HPMS memo entitled 2019 Timeliness Monitoring Project (TMP) provides details about data submission, including the deadlines. Under the current practice, a sponsor can let CMS know if there is an issue meeting the submission deadline for the TMP data and CMS can work with the sponsor to determine if an alternative deadline is feasible. CMS needs adequate time to analyze the TMP data once submitted to be able to determine the completeness of the appeals data. If the data are submitted beyond the deadline or an extension granted by CMS, it is treated as a failure to submit the TMP data.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing at §§ 422.164(g)(1)(iii)(O) and 423.184(g)(1)(ii)(M) the assignment of a 1-star rating to the applicable appeals measure(s) if a contract fails to submit TMP data for CMS's review to ensure the completeness of the contract's IRE data.

(6) Review of Sponsors' Data (§§ 422.166(h), 423.186(h))

At §§ 422.164(h)(1) and 423.184(h)(1), CMS proposed to codify a policy regarding the deadlines for an MA organization or Part D plan sponsor to request the IRE or CMS to review a contract's appeals data or CMS to review a contract's Complaints Tracking Module (CTM) data. For example, information regarding the Part C and Part D appeals process is available to MA organizations and is updated daily on the IRE website. Additionally, sponsors can access the Part D Appeals Reports under the Performance Metrics pages in HPMS. To allow enough time for the IRE to make any necessary changes to ensure the accuracy of a contract's measure score, we proposed that requests for CMS or the IRE to review contract data must be received no later than June 30 of the following year in order to have time to use accurate information in the Star Ratings calculations (for example, changes to contract year 2018 appeals data must be made by June 30, 2019 for the 2020 Star Ratings). Reopenings are not taken into account under this proposed deadline for corrections to the IRE data. For purposes of the appeals measures, if a reopening occurs and is decided prior to May 1, the revised determination is used in place of the original reconsidered determination. If the revised determination occurs on or after May 1, the original reconsidered determination is used.

Similarly, we proposed that any requests for adjustments following CMS's CTM Standard Operating Procedures for the complaints measures be made by June 30 of the following year in order for the changes to be reflected in a contract's Star Ratings data (for example, changes to contract year 2018 complaints data must be made by June 30, 2019 for the 2020 Star Ratings).

Below we summarize the comments we received and provide our responses and final decisions.

Comment: Many of the commenters supported a deadline for an MA organization or Part D plan sponsor to request the IRE or CMS to review a contract's appeals or CMS to review a contract's CTM data, but they did not support the proposal of the June 30th date. They all recommended that the date should be following the first plan preview stating that the later date would allow plans to fully respond to all appeals and complaints.

Response: CMS appreciates the feedback and is finalizing our proposal with a modification that will permit CMS to set the date annually to allow flexibility each year to determine the date based on the availability of data for plans to review.

Comment: A commenter noted that the timeframes/deadlines CMS is proposing do not appear to align with the allotted timeframes CMS allows for plans and the IRE to re-open decisions. The commenter proposed CMS review the IRE reopening process and timeframes to ensure all cases submitted to the IRE, in the measurement plan year, are fully resolved by the first plan preview period. Additionally, the commenter recommended that if the IRE does not meet the IRE reconsideration timeframes, which are outlined in the MAXIMUS Federal Medicare Health Plan Reconsideration Process Manual, then plans would still be held accountable for the outcome of the reconsideration but those cases should not be included in the plan's performance scores since they were not fully resolved.

Response: Because CMS does not want to implement policies that promote reopenings, CMS will not adopt the policy the commenter recommends. Excluding cases that were reopened but do not yet have a decision would encourage organizations to reopen more cases and possibly manipulate their ratings. Therefore, if the reopening is not decided by May 1st, the original reconsideration decision is used in the measure. Reopenings are supposed to be rare. CMS appreciates the feedback about the data timeframe for reopenings and will consider this comment in the future.

Comment: A commenter did not support the data review deadline, because CMS (and its contractor, MAXIMUS) does not provide full visibility into the fields that are required to calculate compliance on an ongoing basis. For example, the commenter pointed out that there is no timeliness indicator on MAXIMUS' website and as a result, some of the data cannot be monitored on an ongoing basis for accuracy. Instead, MA plans must develop a workaround, such as monitoring case dates for accuracy. Something as simple—and predictable—as a national holiday where mail is not delivered can result in an incorrect timeliness measure.

Response: Although there are enough data provided on the MAXIMUS website for contracts to determine if a case is late, CMS has worked with MAXIMUS, the IRE, to add a late indicator on the website for Part C Appeals data to make it easier for plans to monitor the timeliness of their cases. This update will further allow plans to request adjustments to their Part C appeals, if necessary, in a timely manner before Star Ratings calculations.

Comment: A commenter supported the proposal, but requested a clarification of the application of the deadline related to CTM data, because CMS often changes the CTM case status so that cases are no longer visible and cannot be monitored for accuracy.

Response: We appreciate the support and the opportunity to clarify which CTM data are used for Star Ratings purposes. For CTM, the quarterly reports only contain CTM complaints that are used to calculate the Star Rating CTM measure. If a CTM is not in the report, the complaint is not considered a plan issue and it would not be included in the Star Ratings measure. Therefore, sponsoring organizations may wish to focus their requests for CMS review of CTM data on the data that are part of the quarterly reports.

Comment: A few commenters supported the proposal but noted that CMS should publish a schedule of the timing of all related reports, while a commenter did not support the proposal and requested similarly a schedule of reports. Additionally, a commenter stated the Part C MAXIMUS IRE reports are not published and are only made available upon request to the CMS account manager each quarter.

Response: We appreciate the support and the opportunity to clarify the timing and availability of the reports which contain data used for the Star Ratings. Part D appeals and CTM reports are posted in HPMS quarterly; approximately 2 months following the close of the quarter. Information regarding the Part C reconsideration process is available to Medicare Advantage (MA) organizations on the *www.medicareappeal.com* website. The data available on this website are updated daily; therefore, MA organizations that notice discrepancies or have questions about the data should bring these issues to the attention of the IRE as they arise. On the website, MA organizations are able to see all the cases related to a particular plan for the date range they chose and they are also able to search by case number. MAXIMUS has added a late indicator to their website to help in the review; therefore, plans should be able to fully monitor their data throughout the year.

Comment: A commenter supported the codification of deadlines for requests by an MA organization or Part D plan sponsor to review contract appeals or Complaints Tracking Module data.

Response: CMS appreciates the support.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to related comments summarized earlier, we are finalizing the provisions at §§ 422.164(h)(1) and 423.184(h)(1) related to the policy regarding the deadlines for an MA organization or Part D plan sponsor to request CMS or the IRE to review its' appeals data or CMS to review its' Complaints Tracking Module (CTM) data with a substantive modification. We are not finalizing the June 30th deadline in regulation. To provide more flexibility to set the deadline contingent on the timing of the availability of data for plans to review, we are finalizing in this regulation that an MA organization or Part D plan sponsor may request that CMS or the IRE review its' data, provided that the request is received by the annual deadline set forth by CMS for the applicable Star Ratings year. We intend to use the annual Call Letter or an HPMS memo to set the annual deadline.

e. Extreme and Uncontrollable Circumstances (§§ 422.166(i), 423.186(i))

We proposed a policy to address how extreme and uncontrollable circumstances may have a negative impact on the Quality Star Ratings of an MA or Part D plan. Extreme and uncontrollable circumstances such as natural disasters can directly affect Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide them with important medical care and prescription drug coverage. These circumstances may negatively affect the underlying operational and clinical systems that CMS relies on for accurate performance measurement in the Star Ratings program, all without fault on the part of the MA organization or Part D plan sponsor. We proposed to adjust the Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance or measurement period in a manner that would generally hold the affected contract harmless from reductions in Star Ratings. We proposed to codify a series of special rules for calculation of the Star Ratings of certain contracts in certain extreme and uncontrollable circumstances in paragraph (i) of §§ 422.166 and 423.186.

We proposed that the adjustments be tailored to the specific areas experiencing the extreme and uncontrollable circumstance in order to avoid over-adjustment or adjustments that are unnecessary. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers in specific physical locations. To ensure that the Star Ratings adjustments focus on the specific geographic areas that experienced the greatest adverse effects from the extreme and uncontrollable circumstance and are not applied to areas sustaining little or no adverse effects, our proposal targeted the adjustments to specific contracts and further specified and limited the adjustments.

Below we summarize the comments we received on the disaster adjustments in general.

Comment: Most commenters supported our proposals to adjust Star Ratings in the event of an extreme and uncontrollable circumstance.

Response: We thank the commenters for their support of the proposal, which we are finalizing with some substantive modifications in this final rule as described below.

Comment: A few commenters requested that CMS delay codifying the extreme and uncontrollable circumstances policy and continue to assess and develop the methodology in case additional modifications are needed. A commenter requested that CMS implement the policy for measurement year 2018 in order to avoid a temporary lapse in the application of the proposed policy.

Response: The policy being adopted in this final rule will apply to the 2022 Star Ratings and beyond, for extreme and uncontrollable circumstances that begin on or after January 1, 2020. If adjustments are needed to the policy, CMS will propose them through a future rulemaking or sub regulatory guidance. The 2020 Call Letter includes CMS's policy for the 2020 Star Ratings for extreme and uncontrollable circumstances that occurred in 2018. We decline to delay adoption of this policy for a future period, because similar procedures were successfully applied to the 2019 Star Ratings as a result of the multiple 2017 disasters.

(1) Identification of Affected Contracts

In paragraph (i)(1) of §§ 422.166 and 423.186, we proposed to identify MA

and Part D contracts affected by extreme and uncontrollable circumstances during the performance or measurement period that may have affected their performance on Star Ratings measures or their ability to collect the necessary measure-level data. Under our proposal, these ''affected contracts'' are the contracts eligible for the specified adjustments that take into account the effects of the extreme and uncontrollable circumstances. For an MA or Part D contract to be considered an affected contract under our proposal, the contract would need to meet all of the following criteria:

- The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Act.
- The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).
- A certain minimum percentage (25 percent for measure star adjustments or 60 percent for exclusion from cut point and Reward Factor calculations) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

We proposed to identify an area as having experienced extreme and uncontrollable circumstances if it is within an ''emergency area'' and ''emergency period'' as defined in section 1135(g) of the Act, and also is within a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act, and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s) (*https://www.phe.gov/emergency/news/healthactions/section1135/Pages/default.aspx*). Major disaster areas are identified and can be located on FEMA's website at *https://www.fema.gov/disasters.* To ensure the policy is applied to those contracts most likely to have experienced the greatest adverse effects, we proposed to narrow it to apply to contracts with a certain minimum percentage of enrollees residing in an area declared as an Individual Assistance area because of the disaster declaration. Individual Assistance includes assistance to individuals and households, crisis counseling, disaster case management, disaster unemployment assistance, disaster legal services, and the disaster Supplemental Nutrition Assistance Program. We explained that our focus on enrollees residing in counties eligible for Individual Assistance because of a major disaster was because most Star Ratings measures are based on services provided directly to beneficiaries in their local area. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers in specific physical locations. Therefore, we proposed to target the adjustments based on extreme and uncontrollable circumstances to contracts serving beneficiaries who were eligible for individual and household assistance because of the disaster declaration.

We further proposed that at least 25 percent or 60 percent of the enrollees under the contract must reside in Individual Assistance areas identified because of the extreme and uncontrollable circumstances in order for the contract to be an affected contract eligible for adjustments. We explained that this limitation would ensure that the adjustments are limited to contracts that we believe may have experienced a real impact from the extreme and uncontrollable circumstance in terms of operations or ability to serve enrollees. In calculations for the 2019 Star Ratings, we observed that contracts tend to have either very few enrollees impacted or most of their enrollees impacted due to the nature of contracts either covering a broad region or a localized area; if 1 out of 4 enrollees were impacted during the period of the year when the disaster hit, we stated our belief that there would be a small chance that scores may have been impacted. We proposed to exclude the numeric measure scores from contracts with 60 percent or more enrollees impacted by the extreme and uncontrollable circumstances from the determination of the cut points and explained it as a conservative rule that would apply only in cases where a clear majority or all of the enrollees are impacted. We also explained that using the Individual Assistance major disaster declaration as a requirement to identify contracts that would be eligible for adjustments ensures that the policy applies only when the event is extreme, meriting the use of special adjustments to the Star Ratings.

We proposed that contracts that do not meet the definition of an ''affected contract'' would not be eligible for any adjustments based on the occurrence of the extreme and uncontrollable circumstances but also noted that the criteria to be an affected contract would not be sufficient to receive all the adjustments we proposed.

Below we summarize the comments we received on the identification of affected contracts and provide our responses and final decisions.

Comment: Several commenters suggested that CMS commit to being transparent in how it has applied the regulations, such as which contracts received adjustments and the impact on the Star Ratings program. A few stated this would allow sponsors a better understanding of marketplace performance and reduce inquiries to CMS. A commenter recommended that CMS announce areas designated as disasters for the purposes of Star Ratings on a quarterly basis, and another requested greater specificity on how a plan within a given county would qualify for the exemption rules. Another commenter requested that data and analysis on affected contracts be shared with state Medicaid agencies as this information is relevant to the states, and data sharing reduces burden on the plans.

Response: Information about which areas are designated in a major disaster declaration under the Stafford Act and when the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s) are all public information we are extracting from the relevant websites. CMS published the list of relevant 2017 disasters and affected counties in the 2019 Call Letter, and state, county, and contract enrollment data are publicly available, so information about affected contracts is already available. We agree that providing additional information when the adjustments authorized under §§ 422.166(i) and 423.186(i) may be possible. To that end, CMS plans to provide information identifying contracts that meet the definition of affected contracts in §§ 422.166(i)(1) and 423.186(i)(1). We note that the definition of ''affected contract'' in these regulations is substantially similar to the definition and standards CMS used to make similar adjustments in the 2019 Star Ratings based on disasters that occurred in 2017. For the 2019 Star Ratings, which were adjusted for the disasters (Hurricanes Harvey, Irma, and Maria, and the wildfires in California) that occurred during the 2017 performance period, 77 contracts met the 25 percent threshold of beneficiaries in FEMA-designated Individual Assistance areas at the time of the disaster. Based on a similar policy to that we are now codifying in §§ 422.166(i) and 423.186(i), affected contracts reverted to the prior year's rating an average of five times for Part

C measures and three times for Part D measures. For the 2019 Star Ratings, 57 contracts met the 60 percent threshold of beneficiaries in FEMA-designated Individual Assistance areas and had their numeric values excluded from the clustering algorithm so they did not influence cut points. CMS will continue to release the list of relevant disasters and FEMA-designated Individual Assistance counties in the Call Letter each year after the performance period so contracts know in advance of the Star Ratings preview periods whether they might be considered an affected contract based on their service area.[38]

Comment: A commenter questioned whether requiring affected contracts to meet all three criteria in §§ 422.166(i)(1) and 423.186(i)(1) was too restrictive if it requires a state-level declaration of emergency and suggested that the third criteria (that is, §§ 422.166(i)(1)(iii) and 423.186(i)(1)(iii)) was most applicable.

Response: Stafford Act disaster declarations are made by state but designate specific counties that are affected. Our policy addresses contracts with service areas in FEMA-designated Individual Assistance counties. We proposed that for a contract to be considered an affected contract it would need to meet all three criteria in §§ 422.166(i)(1) and 423.186(i)(1). This ensures the extreme and uncontrollable circumstances policy is limited to contracts that may have experienced a real impact from the disaster in terms of operations or ability to serve enrollees. It also ensures that it applies only when the event is extreme, meriting the use of special adjustments to the Star Ratings.

Comment: A commenter was concerned that contracts may deliberately combine contracts with enrollment from a non-disaster area with enrollment in a disaster area in order to meet the 25 percent threshold for Star Ratings adjustments and encouraged CMS to implement safeguards to prevent abuse of the extreme and uncontrollable circumstances policy.

Response: CMS appreciates this comment and notes that the April 2018 final rule addresses contract consolidations. In particular, for consolidations approved on or after January 1, 2019 we assign Star Ratings based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) so that the ratings reflect the performance of all contracts (surviving and consumed) involved in the consolidation. Further, the scenario described by the commenter is unlikely to occur as contract consolidations are generally approved in advance; a sponsoring organization would not be able to take advantage of an extreme and uncontrollable circumstance by subsequently consolidating contracts.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the definition of an affected contract in paragraph (i)(1) of §§ 422.166 and 423.186. We are also finalizing the introductory sentence in paragraph (i) substantially as proposed to establish a rule that in the event of certain extreme and uncontrollable circumstances, CMS calculates Star Ratings for affected contracts using the rules specified in paragraphs (i)(2) through (i)(10). Those specific rules and the text in paragraphs (i)(2) through (i)(10) are addressed in sections II.B.1.e.(2) through (10). In finalizing the first sentence of paragraph (i), we are making a grammatical change to use ''calculates'' in place of ''will calculate.'' We address additional text we are also finalizing as a new last sentence in the introductory text of paragraph (i) in section II.B.1.e.(6).

(2) CAHPS Adjustments

For CAHPS, we proposed two different types of special rules for affected contracts: Exemption from having to administer the CAHPS survey or adjustments to the Star Ratings on the CAHPS measures if the affected contract must administer the CAHPS survey. CAHPS measures are based on a survey conducted early in the year in which the Star Ratings are released, that is, the year before the year to which the Star Ratings are applicable. For example, the CAHPS survey in early 2019 will be used for the 2020 Star Ratings, which are released in late 2019, before the annual coordinated election period for 2020.

We proposed at §§ 422.166(i)(2)(i) and 423.186(i)(2)(i), that an MA and Prescription Drug Plan contract, even if it is an affected contract, must administer the CAHPS survey unless the contract demonstrates to CMS that the required sample for the CAHPS survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to a FEMA-designated disaster in the prior calendar year and requests and receives a CMS approved exemption. We explained in the proposed rule our belief that displacement of a substantial number of the contract's enrollees would make it practically impossible to contact the required sample for the CAHPS survey. For an affected contract that receives the exemption from administering the CAHPS survey, we proposed at §§ 422.166(i)(2)(iii) and 423.186(i)(2)(iii) that the affected contract would receive the prior year's CAHPS measure stars (and corresponding measure scores).

We proposed that affected contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure (including the annual flu vaccine measure). For example, for the 2022 Star Ratings for affected contracts, we would take the higher of the 2021 Star Ratings or the 2022 Star Ratings for each CAHPS measure. The affected contract would receive the CAHPS measure score for the corresponding Star Rating year chosen. We proposed the 25 percent threshold to avoid including contracts with very few enrollees impacted and explained our belief that the measure-level scores should not be adjusted for contracts with very few enrollees impacted by the extreme and uncontrollable circumstances. We stated that if a small percentage of enrollees were impacted by an extreme and uncontrollable circumstance, there should not be a significant impact on measure scores. Comments received on this specific proposal in §§ 422.166(i)(2) and 423.186(i)(2) are discussed in section II.B.1.e.(6) of this final rule.

(3) HOS Adjustments

For the HOS survey, we proposed to follow similar procedures as CAHPS but due to the follow-up component of HOS, we proposed that the adjustment be to the Star Ratings for the year after the completion of the follow-up HOS survey (that is administered 2 years after the baseline HOS survey). For example, the 2022 Star Ratings are based on data collected from April through June 2020 and reflect experiences over the past 12 months. The data collected in 2021 will be used for the 2023 Star Ratings, so responses may reflect the impact of 2020 extreme and uncontrollable circumstances and thus, those circumstances may have an impact on the 2023 Star Ratings.

We proposed at § 422.166(i)(3)(i) that an MA contract, even if it is an affected contract, must administer the HOS surveys the year after the extreme and

[38] Tables 14 and 15 in the 2020 Call Letter contain a list of the section 1135 waivers that could affect the 2020 Star Ratings and Individual Assistance counties from all of the 2018 FEMA major disaster declarations. *https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/announcements-and-documents.html.*

uncontrollable circumstance unless the contract demonstrates to CMS that the required sample cannot be contacted because a substantial number of the contract's enrollees are displaced due to a FEMA-designated disaster during the measurement period and requests and receives a CMS approved exemption. For an affected contract that receives the exemption from administering the HOS survey, we proposed at paragraph (i)(3)(iii) that the affected contract would receive the prior year's HOS and HEDIS–HOS measure stars (and corresponding measure scores).

We proposed at § 422.166(i)(3)(iv) that affected contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the previous year's Star Rating or current year's Star Rating for each HOS and HEDIS–HOS measure (and corresponding measure score) for the Star Ratings 3 years after the eligible extreme and uncontrollable circumstance. As an example, we explained that for the 2023 Star Ratings for contracts affected by an extreme and uncontrollable circumstance in 2020, we would take the higher of the 2022 or 2023 Star Rating (and corresponding measure score) for each HOS and HEDIS–HOS measure in applying the proposal. Comments received on this specific proposal in § 422.166(i)(3) are discussed in section II.B.1.e.(6).

(4) HEDIS Adjustments

For HEDIS, we proposed that an MA contract, even if an affected contract, would be required to report HEDIS data to CMS unless the contract demonstrates to CMS an inability to obtain both administrative and medical record data required for HEDIS measures due to a FEMA-designated disaster in the prior calendar year and requests and receives a CMS approved exemption. We stated in the preamble of the proposed rule that all contracts in FEMA-designated disaster areas can work with NCQA to request modifications to the samples for measures that require medical record review; however, in our proposed regulation text codifying this ability, we proposed only that ''affected contracts'' without an exemption from reporting HEDIS data would be able to seek that kind of modification from NCQA. For affected contracts that have service areas with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, we proposed to take the higher of the previous year's Star Rating or current year's Star Rating (and corresponding measure score) for each HEDIS measure. For example, for the 2022 Star Ratings for affected contracts we would take the higher of the 2021 or 2022 Star Ratings for each HEDIS measure. Comments received on this specific proposal in § 422.166(i)(4) are discussed in section II.B.1.e.(6). of this final rule.

(5) New Measure Adjustments

At proposed §§ 422.166(i)(5) and 423.186(i)(3), we proposed to implement a hold harmless provision for *new* Star Ratings measures if the inclusion of all applicable new measure(s) brings down the summary and/or overall rating. That is, for affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, all the new measures would be excluded from the calculation of the summary and/or overall rating if their inclusion brings a contract's summary (or in the case of MA–PD contracts, the overall) rating down. Comments received on this specific proposal in §§ 422.166(i)(5) and 423.186(i)(3) are discussed in section II.B.1.e.(6). of this final rule.

(6) Other Star Ratings Measure Adjustments

For all other measures for affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance (that occurs during the measurement or performance period), we proposed to take the higher of the previous or current year's measure Star Rating (and then use the corresponding measure score), as described at proposed §§ 422.166(i)(6)(i) and 423.186(i)(4)(i). For example, for the 2022 Star Ratings for affected contracts, we would take the higher of the 2021 or 2022 Star Ratings. We also proposed to exclude from this adjustment policy the Part C Call Center—Foreign Language Interpreter and TTY Availability and Part D Call Center—Foreign Language Interpreter and TTY Availability measures, except for extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study. We explained the proposed exclusion by noting that these measures and the underlying performance are completely in the plan's control and we believed therefore that there should generally be no impact from the declaration of an extreme and uncontrollable circumstance on plan performance in these areas.

Below we summarize the comments we received on the proposed rules at §§ 422.166(i)(2) through (6) and 423.186(i)(2) through (4) for adjustments to CAHPS, HOS, HEDIS, new, and other measures and provide our responses and final decisions.

Comment: A few commenters requested that we clarify whether our extreme and uncontrollable circumstances policy is ''best of'' the Star Rating or measure score. A commenter proposed that we take the higher of the previous and current year's measure score if the Star Rating is the same in both years to ensure the higher score is used in the improvement calculation.

Response: We proposed, for affected contracts as described specifically in the applicable regulation text, to select the higher of the current or previous year's measure-level Star Rating and then use the measure score that corresponds with the year selected with the higher rating. We proposed this use of the ''higher Star Rating'' rule for CAHPS, new, and other measures for MA and Part D ratings, and for HOS and HEDIS measures for MA ratings. We use the Star Rating for the measure-level comparison because the measure stars are used to calculate the overall Star Rating and the measure-level cut points can change each year. We use the corresponding measure scores for improvement calculations in order to maintain consistency in the years being compared. Where the higher score does not correspond to the higher rating, we use the score from the year with the higher Star Rating for the measure nonetheless. If the Star Rating for a measure is the same in both years we use the current year's data (that is, Star Rating and score). We only revert to the previous year's measure Star Rating if it is higher. The regulation text reflects this rule by referring to the higher of the previous or current year's Star Rating (and corresponding measure score) in §§ 422.166(i)(2)(iv), 422.166(i)(3)(iv), 422.166(i)(4)(v), 422.166(i)(6)(i), 423.186(i)(2)(iv), and 423.186(i)(4)(i).

Comment: A few commenters were concerned that the 25 percent cutoff for measure-level adjustments may be inadequate, or that the policy is biased against larger contracts serving populations spread across multiple regions.

Response: CMS chose the 25 percent cutoff for measure-level adjustments because this cutoff avoids including contracts with very few enrollees impacted by extreme and uncontrollable circumstances. As explained in the

proposed rule, we do not believe it would be appropriate to provide an adjustment to the ratings when fewer than a quarter of the enrollees covered under the contract are affected by the extreme and uncontrollable circumstance. If only a small percentage of enrollees is impacted by a disaster, there should not be a significant impact on measure scores (and therefore not on Ratings). We disagree that the policy is biased against larger contracts, since it is applied the same to all contracts. Further, for contracts with smaller service areas, the declaration of an emergency and designation of a FEMA-designated Individual Assistance area in one county might be sufficient to result in 25 percent or more of the contract's enrollees being in the FEMA-designated Individual Assistance area whereas a larger contract covering the same county might only have a small portion of its overall enrollment in the FEMA-designated Individual Assistance area.

Comment: A few commenters suggested that we instead remove beneficiaries who live within impacted geographic areas from measurement calculations. Commenters stated this would ensure that all affected contracts receive an adjustment that is proportionate with the level of impact to plan performance, be consistent with other exclusion criteria used in Star Ratings measures, and ensure that Star Ratings performance is representative of performance during the measurement period.

Response: We decline to revise our policy to include this type of adjustment, either instead or in addition to the adjustments we proposed and are finalizing in §§ 422.166(i)(2) through (6) and 423.186(i)(2) through (4). For many measures, this is not operationally feasible. For example, this would require modifications to CAHPS and HOS sampling, as well as to HEDIS reporting requirements. Other measures do not have beneficiary-level data that could be adjusted.

Comment: Several commenters questioned how CMS will apply the policy for contracts impacted by disasters in consecutive years. A few suggested that CMS use the ''higher of'' the current year's Star Rating and prior year's adjusted Star Rating, or link back to the most recent year's data not affected by disasters. Another suggested using best of ratings from periods or sources: Current measurement year performance, prior year performance, parent organization average performance, or industry average performance. Other commenters were concerned about old data being pulled forward each year. A commenter stated a ''higher of'' policy would be inappropriate for consecutive disasters, and that CMS should treat multiple year-disaster contracts as new contracts, rate them on a very small set of measures, or base their rating on a small portion of their service area. A commenter suggested that that CMS drop the threshold for relief below 25 percent and 60 percent for contracts that have had two consecutive years of disaster impact. Several commenters requested that CMS extend the disaster adjustment multiple years for select regions continuing to recover from a disaster (for example, Puerto Rico that is still recovering from 2017 hurricanes).

Response: CMS appreciates these comments and acknowledges that our proposal did not address year-over-year disasters. Given the number of comments on this topic, we believe it is appropriate to address by adopting additional provisions specific to this topic. We agree with commenters that are concerned about looking back too many years for contracts affected by disasters multiple years in a row, as well as about including too many measurement periods in 1 year of Star Ratings. We also must consider operational feasibility, and using different thresholds for contracts affected by disasters in different ways would be very complicated for administration and for providing the necessary transparency to MA organizations, Part D plan sponsors, and beneficiaries who use and rely on the Star Ratings.

We must balance these concerns about using older data with concerns about using data based on performance that has been impacted by consecutive disasters. In striking a balance of these concerns, we are finalizing a policy for setting the Star Ratings for contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas that were affected by disasters that began in one year that were also affected by disasters that began in the previous year. Under the regulations we are adopting in this final rule, such multiple year-affected contracts receive the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure. For example, if a multiple year-affected contract reverted back to the 2021 Star Rating on a given measure in the 2022 Star Ratings, the 2021 Star Rating is *not* used in determining the 2023 Star Rating; rather, the 2023 Star Rating is compared to what the 2022 Star Rating would have been absent any disaster adjustments. The rule for treatment of multiple year-affected contracts then does not carry very old data forward into the Star Ratings for many years. Under this final rule, we will use the measure score associated with the year with the higher measure Star Rating regardless of whether the score is higher or lower that year. We are finalizing this policy to address when contracts are affected by separate extreme and uncontrollable circumstances that occur in successive years for the adjustments to CAHPS, HOS, HEDIS, and other measures. This rule would apply for CAHPS, HOS, HEDIS, new, and other measures. Therefore, we are adopting new provisions at §§ 422.166(i)(2)(v), 422.166(i)(3)(v), 422.166(i)(4)(vi), 422.166(i)(6)(iv), 423.186(i)(2)(v), and 423.186(i)(4)(iv) to include this rule for how ratings for these measures will be adjusted in these circumstances.

The issue about whether and how to take into account extreme and uncontrollable circumstances that occur in successive years also raises the question of how to address a specific extreme and uncontrollable circumstance that spans two years. For example, we note that while Hurricane Maria happened in 2017 and the associated declarations of emergency under section 1135 of the Act initially happened in 2017, those declarations extended for some areas into 2018. We did not propose a specific policy for addressing such situations. We are finalizing new text at the end of the introductory language of paragraph (i) of both §§ 422.166 and 423.186 to clarify that the incident start date will be used to determine which year of Star Ratings could be affected. We believe this clarification is necessary because, in some cases, the incident period end date may change, which would make it difficult operationally to determine which Star Ratings year is impacted. For example, the major disaster declaration (DR–4353) for the California wildfires was declared January 2, 2018. The incident period was originally only in December 2017, but it was subsequently extended by FEMA through January 2018. Limiting adjustments for a single extreme and uncontrollable circumstance to one year is appropriate to avoid adversely impacting operational timelines, to limit impacts on contracts not impacted by disasters, and to preserve transparency of the Star Ratings for consumers by not using data from many different measurement years. Further, as we finalized several years ago, at §§ 422.504(o) and 423.505(p), MA organizations and Part D sponsors must develop, maintain, and implement

a business continuity plan containing policies and procedures to ensure the restoration of business operations following disruptions to business operations which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. We expect that these business continuity plans will address many of the issues that would result in an impact on the performance of an affected contract where there are extreme and uncontrollable circumstances that occur in successive years or over more than one performance period.

We note that the proposed rule establishing the exemption for administering CAHPS (§§ 422.166(i)(2)(ii) and 423.186(i)(2)(ii)), administering HOS (§ 422.166(i)(3)(ii)), and reporting HEDIS (§ 422.166(i)(4)(ii)) did not specify which type of affected contract could apply for the exemption. This lack of clarity also affected the proposed rules in §§ 422.166(i)(2)(iii), 422.166(i)(3)(iii), 422.166(i)(4)(iii), and 423.186(i)(2)(iii) that address how a contract with the exemption would receive the prior year's CAHPS, HOS, or HEDIS measure Star Rating (and corresponding measure scores). We clarify here that we intended these specific rules to apply to affected contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance. In finalizing this policy, we are using the lowest threshold identified in the definition of affected contract in paragraph (i)(1)(iii). As a result, the most generous interpretation of the potential ambiguity of our proposal is being finalized.

Finally, comments about disasters that began in 2017 are out of scope of this rule as our proposal and final regulations apply to adjustments to Star Ratings to take into account extreme and uncontrollable circumstances that begin on or after January 1, 2020.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the methodology for adjustments to CAHPS measures (§§ 422.166(i)(2) and 423.186(i)(2)), HOS and HEDIS measures (§§ 422.166(i)(3) and (i)(4)), new measures (§§ 422.166(i)(5) and 423.186(i)(3)), and other Star Ratings measures (§§ 422.166(i)(6) and 423.186(i)(4)) with substantive and non-substantive revisions. The final regulation text includes the following substantive changes on measure adjustments:

- In §§ 422.166(i)(2)(ii) and 423.186(i)(2)(ii) for CAHPS measures, 422.166(i)(3)(ii) for HOS measures, and 422.166(i)(4)(ii) for HEDIS measures, we are finalizing additional text to clarify the section applies to affected contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance.
- In § 422.166(i)(4)(iv), the final regulation text clarifies that all contracts required to report HEDIS data can work with NCQA to request modifications to the samples for measures that require medical record review. While we did not receive comments on this, CMS realized that the preamble and proposed regulation inadvertently limited which contracts are eligible to request modifications to samples from NCQA. We are finalizing corrected regulation text to eliminate this inadvertent limitation.
- In §§ 422.166(i)(2)(v) and 423.186(i)(2)(v) for CAHPS measures, 422.166(i)(3)(v) for HOS measures, 422.166(i)(4)(vi) for HEDIS measures, and 422.166(i)(6)(iv) and 423.186(4)(iv) for other Star Ratings measures, we are finalizing regulation text to identify multiple year-affected contracts as contracts that have at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years. We are finalizing regulation text that a multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).
- We noted that the regulation text did not address how this policy would be applied in the event an extreme and uncontrollable circumstance occurred during two performance periods. Because in some cases the incident period end date may change, which would make it difficult operationally to determine which Star Ratings year is impacted, we are finalizing regulation text in the introductory paragraph of (i) of §§ 422.166 and 423.186 to clarify that the start date of the incident period will be used to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

In addition to these substantive changes, we are finalizing non-substantive changes in paragraphs (ii)(B) and (iii) of §§ 422.166(i)(2), 422.166(i)(3), 422.166(i)(4), and 423.186(i)(2) to replace ''exception'' with ''exemption'' and refer to the exemption ''described'' elsewhere instead of ''defined'' elsewhere. We are also making technical revisions to verb tense, and in §§ 422.166(6)(i) and 423.186(4)(i) we changed ''then use the corresponding measure score'' to ''(and corresponding measure score).'' In § 422.166(i)(3)(ii)(A) we added the word ''paragraph,'' and we simplified the description of §§ 422.166(5) and 423.186(3) for clarity.

(7) Exclusion From Improvement Measures

Contracts must have data for at least half of the measures [39] used to calculate the Part C or Part D improvement measures to be eligible to receive a rating in each improvement measure. For affected contracts that revert back to the data underlying the previous year's Star Rating for a particular measure, we proposed that measure would be excluded from both the count of measures (for the determination of whether the contract has at least half of the measures needed to calculate the relevant improvement measure) and the applicable improvement measures for the current and next year's Star Ratings as stated at proposed §§ 422.166(i)(7) and 423.186(i)(5). That is, we proposed to codify the application of our usual rule in these special circumstances: To receive a Star Rating in the improvement measures, a contract must have measure scores for both years in at least half of the required measures used to calculate the Part C improvement or Part D improvement measures; our proposal to use the data from the previous year's Star Ratings means that there is no measure score from the current year's Star Ratings, so the usual rule would eliminate the measure from consideration. As an example, for affected contracts that revert back to the 2021 Star Ratings data for a particular measure for the 2022 Star Ratings, we would exclude that measure from the count of measures and applicable improvement measures for the 2022 and 2023 Star Ratings.

Below we summarize the comments we received on the exclusion from improvement measures and provide our responses and final decisions.

[39] See §§ 422.164(f) and 423.184(f) for more information on Part C and Part D improvement measures.

Comment: A commenter was concerned that CMS's policy would permit quality improvement measures to be excluded continually when there are repeated disasters, which they stated would undermine the goals of the Star Ratings program. A couple of commenters noted that CMS's proposed policy of using prior year's measure stars (and corresponding measure scores) could influence its use in the improvement calculation.

Response: We proposed in §§ 422.166(i)(7) and 423.186(i)(5) that any measure that reverts back to the data underlying the previous year's Star Rating under the rules in paragraph (i) of §§ 422.166 or 423.186 is excluded from the improvement calculation. This would apply to multiple year-affected contracts as well. Most affected contracts should still receive improvement measure scores since contracts only need data in half of the measures used to calculate improvement to receive an improvement measure score. We also clarify in the final regulations at §§ 422.166(i)(7) and 423.186(i)(5) that contracts affected by extreme and uncontrollable circumstances do not have the option of reverting to the prior year's improvement rating. This clarification is necessary because of the new multiple year-affected contract policy. The improvement rating is based on other measure data included in the Star Ratings program, so taking the higher of the two improvement ratings would nullify the calculations and the application of the disaster policy for the other measures. The improvement measure calculates how much of the plan's performance improved or declined from the previous year to the current year. Allowing affected contracts to revert to the prior year's improvement measure rating could result in different years of data being used for the improvement scores and for the measure scores, or different time periods used for improvement calculations for different contracts. This would be difficult to operationalize and confusing to consumers. Therefore, we decline to adopt such an adjustment in this final rule.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the rule for calculating the improvement score for affected contracts at §§ 422.166(i)(7) and 423.186(i)(5) as proposed with substantive and non-substantive revisions. We are finalizing a substantive change to clarify that contracts affected by extreme and uncontrollable circumstances do not have the option of reverting to the prior year's improvement rating. We are also making a technical revision to verb tense.

(8) Missing Data

Except in cases where an exemption was granted as described earlier, we proposed that for all measures eligible for the extreme and uncontrollable circumstance adjustment, if an affected contract has missing data in either the current or previous year (for example, because of a biased rate or the contract is too new or too small), the final measure rating would come from the current year. We proposed to codify this rule at §§ 422.166(i)(8) and 423.186(i)(6). For example, if a contract affected by an eligible 2020 extreme and uncontrollable circumstance was not granted an exemption for data collection and does not have sufficient data to receive a measure-level 2022 Star Rating, it would not receive a numeric rating for that measure for the 2022 Star Ratings regardless of whether it received a numeric rating in the previous year. Similarly, if an affected contract has missing measure data in the previous year but received a numeric rating in the current year, it would receive the current year's rating for its final measure rating. In both cases, the measure would be excluded from the contract's improvement score(s) following our usual rules.

Below we summarize the comments we received on missing data and provide our responses and final decisions.

Comment: A commenter questioned how CMS will rate contracts affected by disasters that are too new to be measured.

Response: The missing data policy proposed and codified in this final rule at §§ 422.166(i)(8) and 423.186(i)(6) applies to contracts that are too new to be measured. As proposed and finalized, the regulation does not exclude new contracts from its application. We proposed that except in cases where an exemption was granted as described earlier, for all measures eligible for the extreme and uncontrollable circumstance adjustment, if an affected contract has missing data in either the current or previous year (for example, because of a biased rate or the contract is too new or too small), the final measure rating would come from the current year.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the methodology for missing data as proposed at §§ 422.166(i)(8) and 423.186(i)(6) as proposed with non-substantive revisions to replace ''will come'' with ''comes'' and ''exceptions'' with ''exemptions.''

(9) Cut Points for Non-CAHPS Measures

Currently, the Star Rating for each non-CAHPS measure is determined by applying a clustering algorithm to the measures' numeric value scores from all contracts required to submit the measure. The cut points are derived from this clustering algorithm. At proposed §§ 422.166(i)(9) and 423.186(i)(7), we proposed to exclude from this clustering algorithm the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance. We explained that the exclusion would ensure that any impact of the extreme and uncontrollable circumstance on an affected contract's measure-level scores would not have an impact on the cut points for other contracts. We also explained that, under our proposal, these cut points calculated for all other non-affected contracts would be used to assess these affected contracts' measure Star Ratings. We would compare the affected contract's previous year's measure Star Ratings to the current year's measure Star Ratings to determine which is higher, and therefore used for the affected contract's Star Ratings calculations, as previously discussed. For example, for the 2022 Star Ratings we would compare the 2021 and 2022 measure Star Ratings for affected contracts.

Below we summarize the comments we received on cut points for non-CAHPS measures and provide our responses and final decisions.

Comment: Several commenters were concerned that removing affected contracts from cut point calculations may skew the clustering methodology or adversely impact plans not affected by disasters, or that contracts in disaster areas may make less of an effort to improve on measures. A commenter requested a simulation of what the Star Ratings would be using this methodology and 2019 data. A commenter encouraged ongoing evaluation of cut points to ensure they are not unduly impacted by adjustments for disaster-stricken areas year-over-year.

Response: We proposed to exclude the performance data of affected contracts that meet the 60 percent

threshold (that is, 60 percent or more of the contract's enrollees reside in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance) from the data used to set cut points for non-CAHPS measures. We proposed to limit this rule to non-CAHPS measures because CAHPS measures use relative distribution and significance testing rather than clustering to determine Star Ratings cut points. This rule, codified at §§ 422.166(i)(9) and 423.186(i)(7), ensures that any impact of the disaster on their measure-level scores does not impact the cut points for other contracts. In our analysis, when affected contracts were removed from the distribution of measure-level scores, the distribution of the remaining contracts looked very similar, suggesting that the affected contracts are randomly distributed among the rating levels. CMS will continue to review the impact of the extreme and uncontrollable circumstances policy on the Star Ratings of affected and unaffected contracts to determine whether any enhancements need to be proposed to these regulations in the future. Finally, the extreme and uncontrollable circumstances policy applied in the 2019 Star Ratings was very similar so existing contracts have access to data on how their contracts were affected.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the methodology for cut points for non-CAHPS measures as proposed at §§ 422.166(i)(9) and 423.186(i)(7) with technical revisions to the verb tense.

(10) Reward Factor

Similarly, at §§ 422.166(i)(10) and 423.186(i)(8), we proposed that affected contracts with 60 percent or more of their enrollees impacted would also be excluded from the determination of the performance summary and variance thresholds for the Reward Factor. However, these contracts would still be eligible for the Reward Factor based on the mean and variance calculations of other contracts.

Below we summarize the comments we received on the Reward Factor and provide our responses and final decisions.

Comment: A commenter supported the 60 percent cutoff for Reward Factor calculations but was concerned that the number of contracts excluded from Reward Factor calculations could become significant if disasters become more frequent.

Response: CMS appreciates the concern about frequency of extreme and uncontrollable circumstances and will continue to monitor application of the policy to determine if enhancements are needed.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the methodology for the Reward Factor as proposed at §§ 422.166(i)(10) and 423.186(i)(8) with technical revisions to the verb tense.

2. Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§ 423.568, 423.570, and 423.572)

In the proposed rule we proposed a change to Part D adjudication timeframes related to exceptions requests in cases where a prescribing physician's or other prescriber's supporting statement has not been received by the plan sponsor. We proposed to limit the amount of time an exceptions request can be held open in a pending status while the Part D plan sponsor attempts to obtain the prescribing physician's or other prescriber's supporting statement. Due to the importance of the prescriber's supporting statement in the exceptions process, the adjudication timeframes for a coverage determination that involves an exceptions request do not begin until the prescribing physician's or other prescriber's supporting statement is received by the Part D plan. As we noted in the preamble to the proposed rule, we are seeking to balance the importance of the plan receiving the prescriber's supporting statement so that a thorough decision may be made on the request and having a standard maximum time for notifying an enrollee of an exceptions request decision. We believe greater certainty in the exceptions process will be beneficial to enrollees and plans.

We proposed to amend §§ 423.568(b), 423.570(d)(1) and 423.572(a) to state that, for an exceptions request, the plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 72 hours (or 24 hours in the case of an expedited decision) after receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first. We invited comments on this proposal and received the following comments discussed below.

Comment: Several commenters expressed support for the proposed changes to the Part D exceptions timeframes, citing increased clarity in the exceptions process, and questioned that CMS finalize the rule as proposed.

Response: We thank the commenters for their support of our proposal to add clarity to the exceptions process. We believe the timeframes we are finalizing in this rule establish clear timeframes for exceptions requests and strike a balance between timely notification of decisions to enrollees and affording plan sponsors sufficient time to obtain and review prescriber supporting statements. As explained more fully below, we are modifying the proposal based on comments we received requesting that the process clearly account for circumstances where a prescriber's supporting statement is received late in the 14 calendar day timeframe. Under this final rule, if a supporting statement is received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) from the date the supporting statement was received. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) from the end of 14 calendar days from receipt of the exceptions request. In addition to achieving the goal of greater certainty in the exceptions process, we believe this modified approach balances protection for beneficiaries with affording plan sponsors sufficient time to obtain and review prescriber supporting statements.

Comment: Several commenters supported the enhanced clarity of the proposed rule in establishing a maximum timeframe of 14 days for a plan sponsor to notify an enrollee of a decision on an exceptions request, but also believe there is some ambiguity on how to handle cases where a prescriber's supporting statement is received late in the 14 day period and questioned whether the plan sponsor would have 72 hours (24 hours for expedited) from the end of the 14 days period in which to notify an enrollee of a decision.

Response: We thank commenters for their support for more certainty in the process and for requesting additional

clarity on how to handle situations where a prescriber's supporting statement is received late in the proposed 14 calendar day period. We agree that if a prescriber's supporting statement is received late in this 14 calendar day period, the plan sponsor should have adequate time to review the clinical documentation to determine whether it is appropriate to approve the exceptions request. After consideration of these comments, we are establishing the 14 calendar day time period as the outer limit for receipt of a prescriber's supporting statement. In all cases, the plan sponsor must notify the enrollee (and prescriber, as appropriate) of its decision no later than 72 hours (24 hours for expedited cases) of the date of receipt of the supporting statement. If the supporting statement is not received by the end of the 14 calendar days, then the plan sponsor must notify the enrollee (and prescriber, as appropriate) of its decision no later than 72 hours (24 for expedited cases) from the end of the 14 calendar days from receipt of the exception request. Plan sponsors are responsible for making reasonable and diligent efforts to promptly obtain a prescriber's supporting statement if the supporting statement is not included with the request for an exception, so as to avoid the need for an exceptions request to remain in a pending status for any longer than necessary. We are finalizing this rule to reflect the policy stated previously.

Comment: A few commenters stated that they believe the proposed rule is inconsistent with recently released draft manual guidance, which recommends a 14-day timeframe to receive a supporting statement. Commenters expressed support for this approach and suggested that the final rule clearly align with the manual guidance. Commenters also requested that CMS phase-in the effective dates of the manual guidance and final rule to allow plans time to implement new procedures. Three commenters requested a January 1, 2020 compliance effective date.

Response: We agree that plan sponsors should have up to 14 calendar days in which to attempt to obtain a prescriber's supporting statement. The prescriber's supporting statement is a key component of the exceptions process. We believe that allowing up to 14 calendar days for a plan sponsor to attempt to obtain a supporting statement appropriately balances the interests of enrollees receiving a timely decision based on a thorough clinical review of the request and of plan sponsors having adequate time to review the exceptions request. In all cases, the enrollee must be notified of the decision as expeditiously as his or her health condition requires. We emphasize that it is not our expectation that plan sponsors routinely have exceptions requests in a pending status for 14 calendar days. When an exceptions request is received, the plan sponsor is responsible for promptly requesting any documentation needed to support the request. When a prescriber's supporting statement is received, the plan must notify the enrollee of its decision within 72 hours (24 hours for expedited cases) of receipt of the supporting statement.

In response to the commenters' request that there be alignment between the approach to Part D exceptions request timeframes taken in this final rule and the combined Part C & Part D appeals manual guidance, we agree and believe the modified approach taken in this final rule aligns with the guidance; however, if additional clarity is necessary, revisions will be made to the manual guidance. We also agree with commenters who requested an effective date of January 1, 2020. The requirements of the final rule are applicable January 1, 2020, and we believe this applicability date provides plan sponsors adequate time to implement this regulatory requirement. We expect plans are already making and notifying enrollees of decisions on exceptions requests under a similar reasonable timeframe and that changes to plan sponsor operations will be minimal.

Comment: A commenter recommended CMS work with prescribers to emphasize the need to submit supporting statements as expeditiously as possible.

Response: We thank the commenter for the suggestion. We do not have a direct contractual relationship with prescribers by which we could influence timely submission of supporting statements, but we will review our provider tip sheets and other provider communications to ensure relevant CMS publications convey the importance of a prescriber's supporting statement in the Part D exceptions process. We also encourage MA–PDs to communicate the importance of timely submission of supporting statements in their provider communication materials.

Comment: We received one comment suggesting we specify that in addition to notifying enrollees of appeal rights, the MA plan be required to notify enrollees that they are also entitled to submit a new exceptions request. The commenter states it would not be appropriate for an enrollee to be denied a medically necessary and appropriate exception because an arbitrary deadline has been missed.

Response: Under existing regulations, if a plan sponsor denies the request because it does not receive timely supporting clinical documentation, the enrollee (or the prescriber on the enrollee's behalf) has the opportunity to address the exceptions request on appeal by submitting documentation that demonstrates the medical necessity of an exception. The right of an enrollee to request a coverage determination (which includes an exceptions request) is not extinguished by a plan sponsor issuing a denial; however, if an exceptions request is denied, then the appropriate next step is an appeal, and the plan can review and approve the request for a formulary or tiering exception on appeal.

Comment: A commenter requested confirmation that this requirement does not impose an obligation on the plan to do outreach and obtain the prescriber's supporting documentation within the 14-day timeframe. The commenter noted that compliance with such a requirement within that timeframe would be operationally difficult.

Response: We thank the commenter for feedback on the operational challenges of outreach for the purposes of obtaining the prescriber's supporting statement within the 14 calendar day timeframe. Under existing regulatory requirements at § 423.566(a), Part D plans must have a procedure in place for making coverage decisions. This includes soliciting necessary clinical documentation. This rule does not change plan sponsors' obligation for doing outreach for necessary clinical documentation but, instead, establishes a time limit for a plan sponsor's attempts to obtain the information. When a Part D sponsor does not have all of the information it needs to make a coverage decision, the plan must make reasonable and diligent efforts to obtain all necessary information, including medical records and other pertinent documentation, from the enrollee's prescriber within the applicable adjudication timeframe. For guidance on best practices related to outreach, please see the February 22, 2017 HPMS memorandum titled ''Updated Guidance on Outreach for Information to Support Coverage.'' The memorandum can be found under ''Downloads'' at: *https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/index.html?redirect=/MedPrescriptDrugApplGriev/.*

We believe that plans will have ample time to modify, as needed, their operations related to adjudication timeframes for exceptions in order to comply with this final rule. We expect plans are already making and notifying

enrollees of decisions on exceptions requests under a similar reasonable timeframe and that changes to plan sponsor operations will be minimal.

Comment: A commenter suggested that CMS standardize the policy for 14-day tolling followed by the 72 and 24 hour(s) adjudication timelines across all exceptions requests; including exceptions related to formulary, tiering, quantity limits, and utilization management. The commenter also suggested that CMS apply tolling to other types of coverage determinations.

Response: Based on the comment, there may be some confusion regarding what types of decisions are covered by this rule. This rule covers all types of exceptions requests, including tiering and formulary exceptions (that is, requests for off-formulary drugs and exceptions to utilization management requirements applicable to formulary drugs). We appreciate the suggestion, but this rule does not apply to other types of coverage determinations that do not involve an exceptions request; for example, a coverage determination where the enrollee is seeking to satisfy a utilization management requirement, such as prior authorization.

Comment: A commenter expressed support for our efforts to expedite the decision making process for beneficiaries, but noted concern about the potential for denials because providers missed a deadline, or because the plan lacked the time to review the documentation, causing beneficiaries to rely on the appeals process. The commenter suggested CMS require plans read and incorporate documentation as long as it comes within the deadline.

Response: We appreciate the commenter's concerns about the potential for denials due to an adjudication deadline. However, we believe it is important for there to be certainty in the timeframe in which a plan has to notify an enrollee of its decision. We acknowledge that there may be circumstances where the plan has to issue a denial because supporting documentation has not been received in a timely manner, but we believe this is offset by enhancing certainty in the process by having clear adjudication timeframes. With respect to the commenter's suggestion, § 423.566(a) requires Part D plan sponsors to have procedures for making timely coverage decisions. This includes soliciting necessary clinical documentation. If a Part D plan sponsor does not have all of the information it needs to make a coverage decision, the plan must make reasonable and diligent efforts to obtain all necessary information, including medical records and other pertinent documentation, from the enrollee's provider.

Comment: A few commenters stated they support CMS providing additional clarity, stating the previous ''reasonableness'' standard may have resulted in longer wait times. However, these commenters encourage a shorter timeframe, citing a risk of significant delays in enrollees getting access to needed medication.

Response: We thank the commenters for expressing support for the proposal to provide additional clarity. While we understand the commenters' concern about the length of the timeframe for adjudicating exceptions requests, we are attempting to balance the need to provide a timely decision with affording plan sponsors sufficient time to attempt to obtain the prescriber supporting statement and perform the clinical review necessary to determine if an exception should be granted. Plans are responsible for attempting to obtain any necessary supporting documentation and for notifying an enrollee of its decision no later than 72 hours of receipt of the prescriber's supporting statement (24 hours for an expedited request). Again, it is not our intent in establishing this timeframe that all exceptions requests be in a pending status for 14 calendar days but, instead, to establish an outer limit on the time a case can be pending for receipt of the prescriber's supporting statement. We agree with the commenters who urged us to account for circumstances where the supporting statement is not received promptly following a plan's request for such information from the prescriber and to allow sufficient time for review of the supporting clinical documentation. Accordingly, we are modifying our proposal to account for circumstances where the prescriber's supporting statement is received late in the 14 calendar day period.

Comment: A commenter suggested CMS consider replacing tolling altogether in favor of fixed processing timeframes.

Response: Under this final rule, we are retaining the current regulatory requirement of the plan sponsor notifying the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) after receipt of the physician's or other prescriber's supporting statement. As explained earlier, the prescriber's supporting statement is a critical aspect of the exceptions process. Therefore, we are retaining the existing standard of tying the start of the adjudication timeframe to receipt of the supporting statement. A plan sponsor cannot adequately assess the merits of an exceptions request in the absence of the prescriber's supporting statement. However, we are establishing a maximum timeframe under which an exceptions request can be held open pending receipt of the prescriber's supporting statement. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) from the end of 14 calendar days from receipt of the exceptions request. We believe this approach achieves the goals of allowing adequate time to obtain the prescriber statement that supports the exceptions request and establishing greater certainty in the process by establishing a maximum period of time a request can be held open.

Based on several comments received, we are finalizing this provision with modification to account for circumstances where the prescriber's supporting statement is received late in the 14 calendar day period. Under this final rule, a Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination on an exceptions request as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) after receipt of the physician's or other prescriber's supporting statement. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) from the end of 14 calendar days from receipt of the exceptions request. We believe this approach achieves the goal of balancing the importance of the plan receiving the prescriber's supporting statement so that a thorough review of the request can be performed and having a maximum time for notifying an enrollee of a decision so that exceptions requests are not held in a pending status for an indefinite or unreasonable period of time.

C. Clarifying Program Integrity Policies

1. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE

a. Background

In the April 2018 final rule, we removed several provider enrollment requirements pertaining to the MA and Part D programs. One requirement, outlined in § 423.120(c)(6), stated that for a prescription to be eligible for coverage under the Part D program, the prescriber must have: (1) An approved enrollment record in the Medicare fee-for-service program; or (2) a valid opt-out affidavit on file with a Part A/Part B Medicare Administrative Contractor (A/B MAC). A second requirement, outlined in § 422.222, stated that providers furnishing health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization must be enrolled in Medicare and be in an approved status no later than January 1, 2019. (The removal of these requirements had been proposed in a proposed rule published in the **Federal Register** on November 28, 2017, titled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' (82 FR 56336) (hereafter referred to as the November 2017 proposed rule).

The overall purpose of Medicare provider enrollment is to prevent fraud, waste, and abuse, and to protect Medicare beneficiaries, by allowing CMS to carefully screen all providers and suppliers (especially those that potentially pose an elevated risk to Medicare) to confirm that they are qualified to furnish, order, certify, refer, or prescribe Medicare items, services, or drugs.

During our preparations to implement the Part D and MA enrollment provisions by the January 1, 2019 effective date, several provider organizations expressed concerns about our forthcoming requirements. The principal concern was that the burden of the enrollment process on the provider community would outweigh the program integrity benefits to the MA and Part D programs.

Given this, we stated in the April 2018 final rule our belief that the best means of reducing the burden of the Part D and MA enrollment requirements without compromising our payment safeguard objectives would be to focus on prescribers and providers that pose an elevated risk to Medicare beneficiaries and the Trust Funds. We accordingly established in the April 2018 final rule an overall policy under which: (1) Such problematic parties would be placed on a ''preclusion list''; and (2) payment for Part D drugs and MA services and items prescribed or furnished by these individuals and entities would be rejected or denied, as applicable. Among the policies we finalized in the April 2018 final rule were the following:

• In § 423.100 (for Part D) and § 422.2 (for MA), we stated that the term ''preclusion list'' means a CMS-compiled list of, as applicable, prescribers and providers that:

++ Meet all of the following requirements:

++ The individual or entity is currently revoked from the Medicare program under § 424.535.

++ The individual or entity is currently under a reenrollment bar under § 424.535(c).

++ CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

—The seriousness of the conduct underlying the individual's or entity's revocation.

—The degree to which the individual's or entity's conduct could affect the integrity of the Part D or MA program.

—Any other evidence that CMS deems relevant to its determination; or

++ Meet both of the following requirements:

++ The individual or entity has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare.

++ CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

—The seriousness of the conduct underlying the individual's or entity's revocation.

—The degree to which the individual's or entity's conduct could affect the integrity of the Part D or MA program.

—Any other evidence that CMS deems relevant to its determination.

• We revised and added various provisions in 42 CFR part 498, subpart A that permitted individuals and entities to appeal their inclusion on the preclusion list. Specifically:

++ We added a new paragraph (20) to § 498.3(b) stating that a CMS determination to include an individual or entity on the preclusion list constitutes an initial determination.

++ In § 498.5, we added a new paragraph (n) containing the following provisions:

—In paragraph (n)(1), we stated that any individual or entity dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list may request a reconsideration in accordance with § 498.22(a).

—In paragraph (n)(2), we stated that if CMS or the individual or entity under paragraph (n)(1) is dissatisfied with a reconsidered determination under paragraph (n)(1), or a revised reconsidered determination under § 498.30, CMS or the individual or entity is entitled to a hearing before an administrative law judge (ALJ).

—In paragraph (n)(3), we stated that if CMS or the individual or entity under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the individual or entity may request review by the Departmental Appeals Board (DAB) and the individual or entity may seek judicial review of the DAB's decision.

• In § 423.120(c)(6)(v) (for Part D) and § 422.222(a)(2) (for MA), we stated that CMS would send written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice would contain the reason for this inclusion and would inform the individual or entity of their appeal rights. We further stated that the affected party could appeal their inclusion on the preclusion list in accordance with Part 498.

• We stated in § 423.120(c)(6)(iv)(A) that a Part D sponsor or its Pharmacy Benefit Manager (PBM) must not reject a pharmacy claim or request for reimbursement for a Part D drug unless the sponsor has provided the written notice to the beneficiary described in § 423.120(c)(6)(iv)(B). Under paragraph (iv)(B), the Part D sponsor or its PBM must:

++ Provide an advance written notice to any beneficiary who has received a prescription from a prescriber on the preclusion list as soon as possible but to ensure that the beneficiary receives the notice no later than 30 days after the posting of the most recent preclusion list; and

++ Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice under paragraph (iv)(B).

• We stated in the preamble to the April 2018 final rule that individuals and entities would only be placed on the preclusion list upon exhausting their first level of appeal.

• In the preamble to the November 2017 proposed rule (82 FR 56446), we stated that if a beneficiary's access to a service, item, or drug is denied because of the application of the preclusion list to his or her prescriber or provider, the beneficiary would be permitted to appeal alleged errors in applying the preclusion list. In the preamble to the April 2018 final rule (83 FR 16660), however, we stated that if payment is denied because the prescriber or provider is on the preclusion list, the beneficiary would not have the right to appeal as denials due to preclusion are not coverage determinations accompanied by appeal rights.

• We stated in the preamble to the April 2018 final rule (83 FR 16642) that an unenrolled individual or entity would remain on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the individual or entity had they been enrolled in Medicare and then revoked.

We also stated in that preamble that the preclusion list provisions in the April 2018 final rule (83 FR 16440) were to become effective on January 1, 2019.

b. Proposed Changes

In CMS–4185–P, we proposed several changes to our existing preclusion list policies. These changes, for the most part, stemmed from further CMS consideration of, and stakeholder feedback on, some of the provisions we finalized in the April 2018 final rule and the need for modifications thereto. These proposed provisions, and brief explanations of the rationale for them, are summarized in this section of this final rule.

(1) Appeals Process for Individuals and Entities on the Preclusion List

As already mentioned, we stated in the preamble to the April 2018 final rule (83 FR 16662) that individuals and entities would only be placed on the preclusion list upon exhausting their first level of appeal. Upon further analysis, we became concerned that there could be a very lengthy delay before the individual or entity is actually placed on the list. This is because the individual or entity, under existing regulations, would be able to first appeal their Medicare revocation and, if unsuccessful, could then appeal their placement on the preclusion list (due to the revocation). This is inconsistent with the principal goal of the preclusion list, which is to prevent payment for Part D drugs or MA services or items prescribed or furnished, as applicable, by problematic parties. So as to shorten the timeframe before a provider is placed on the preclusion list, we proposed the following regulatory revisions:

• In § 423.120(c)(6)(v), we proposed to:

++ Consolidate the existing version of paragraph (v) into a revised § 423.120(c)(6)(v)(A).

++ Establish a new § 423.120(c)(6)(v)(B) stating that in situations where the prescriber's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535:

—The notice described in paragraph (c)(6)(v)(A) must also include notice of the revocation, the reason(s) for the revocation, and a description of the prescriber's appeal rights concerning the revocation.

—The appeals of the prescriber's inclusion on the preclusion list and the prescriber's revocation shall be filed jointly by the prescriber and, as applicable, considered jointly by CMS under 42 CFR part 498.

• In § 422.222(a)(2), we proposed to do the following:

++ Move the existing version of this paragraph into a new § 422.222(a)(2)(i).

++ Establish a new § 422.222(a)(2)(ii) stating that in situations where the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535:

—The notice described in paragraph (a)(2)(i) must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.

—The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation shall be filed jointly by the individual or entity and, as applicable, considered jointly by CMS under 42 CFR part 498.

• In § 498.5(n)(1), we proposed to:

++ Move the existing version of this paragraph to a new § 498.5(n)(1)(i).

++ Establish a new § 498.5(n)(1)(ii)(A) stating that in situations where the individual's or entity's inclusion on the preclusion list is based on a Medicare revocation under § 424.535 and the individual or entity receives contemporaneous notice of both actions, the individual or entity may request a joint reconsideration of both the preclusion list inclusion and the revocation in accordance with § 498.22(a).

++ Establish a new § 498.5(n)(1)(ii)(B) stating that the individual or entity may not submit separate reconsideration requests under paragraph (ii)(A) for inclusion on the preclusion list or a revocation if the individual or entity received contemporaneous notice of both actions.

We believed that these changes would clarify our expectations and the program procedures concerning the filing of appeals when a party's placement on the preclusion list is based on a Medicare revocation. We also stressed that our proposed appeals consolidation would not affect appeals of OIG exclusions, which are handled through a separate process outlined in the applicable OIG regulations.

(2) Timing of Addition to the Preclusion List

While, again, we stated in the preamble to the April 2018 final rule (83 FR 16662) that prescribers and providers would only be placed on the preclusion list upon exhausting their first level of appeal, we did not include this language in the regulatory text. We therefore proposed to do so in CMS–4185–P. Specifically, we proposed in new § 423.120(c)(6)(v)(C)(*1*) (for Part D) and new § 422.222(a)(3)(i) (for MA) that, respectively, a prescriber or provider would only be included on the preclusion list after the expiration of either of the following:

• If the prescriber or provider does not file a reconsideration request under § 498.5(n)(1), the prescriber or provider will be added to the preclusion list upon the expiration of the 60-day period in which the prescriber or provider may request a reconsideration.

• If the prescriber or provider files a reconsideration request under § 498.5(n)(1), the prescriber or provider will be added to the preclusion list effective on the date on which CMS, if applicable, denies the prescriber's or provider's reconsideration.[40]

Notwithstanding the above, we noted that section 1862(e) of the Act (42 U.S.C. 1395y(e)) states that no federal health care program payment may be made for any items or services furnished by an excluded individual or entity, or directed or prescribed by an excluded physician. We believed that a failure to add an excluded provider or prescriber

[40] In the April 2018 final rule, we adopted cross-references in 42 CFR parts 417 and 460 to part 422 so that our MA preclusion list provisions in that rule would also apply to, respectively, cost plans (Part 417) and PACE organizations (Part 460). Consistent with said cross-references, we proposed that our MA preclusion list provisions in the proposed rule would similarly apply to cost plans and PACE organizations.

to the preclusion list until the expiration of the applicable time periods in § 423.120(c)(6)(v)(C)(*1*) (for Part D) and § 422.222(a)(3)(i) (for MA) would be inconsistent with section 1862(e) of the Act. Accordingly, we proposed in new § 423.120(c)(6)(v)(C)(*2*) (for Part D) and § 422.222(a)(3)(ii) (for MA) that an excluded prescriber or provider would be added to the preclusion list effective on the date of the exclusion.

(3) Effective Date

We generally proposed that the preclusion list regulatory revisions and additions addressed in CMS–4185–P would become applicable to MA organizations (and cost plans and PACE organizations by virtue of cross-references in parts 417 and 460 to the MA part 422 regulation) and Part D plans on January 1, 2020, which we believed would give stakeholders adequate time to prepare for our proposed changes. We did, however, propose one exception to this, in that the effective date of our previously mentioned consolidated appeals provisions in §§ 423.120(c)(6)(v), 422.222(a)(2), and § 498.5(n)(1) would be 60 days after their publication in a final rule. This was to ensure that problematic providers and prescribers were placed on the preclusion list as soon as possible. We also solicited public comments on whether some or all of our other proposed preclusion list provisions discussed in section III.C. of the proposed rule should become effective and applicable beginning 60 days after the publication date of a final rule.

We noted that the January 1, 2019 preclusion list effective date identified in the April 2018 final rule for the provisions finalized in that rule would remain in place.

(4) Claim Denials and Beneficiary Notification

We stated in the preamble to the April 2018 final rule (83 FR 16440) that, upon CMS' publication of the first preclusion list, once a prescriber or provider is added to such initial list after the completion of their first level of appeal, claims would not be impacted for up to a 90-day period thereafter (82 FR 16667). We explained that this 90-day period would include—(1) a 30-day period for the plans and MA organizations to intake the preclusion list data; and (2) a 60-day period in which the plan or MA organization would—(a) notify the beneficiary of the prescriber's or provider's preclusion; and (b) allow time for the beneficiary to transition to a new prescriber or provider. Once this 90-day period expires, claim denials and rejections would commence. Yet for all subsequent updates (that is, all updates after the release of the initial preclusion list), we would not require the expiration of a 90-day period before claims were denied.

After additional review, we became concerned that beneficiaries whose prescribers and providers were added to subsequent updates to the preclusion list would not receive any notice of those additions nor of the consequences of placement of such providers and prescribers on the preclusion list. Consequently, we proposed in CMS–4185–P that claim denials for preclusion list updates, beginning in 2020, would occur consistent with the following timeframes:

- Upon the posting of the updated preclusion list, the Part D sponsor or MA organization would be required to send notice to the beneficiary that his or her prescriber or provider has been added to preclusion list within 30 days of the posting of the updated preclusion list.
- Beginning 60 days after sending the beneficiary notice(s) described in the previous paragraph, the plan sponsor or MA organization would deny the prescriber's or provider's prescriptions or claims. This 60-day period would give beneficiaries time to locate another prescriber or provider from whom they can receive Part D prescriptions or MA services and items.

We recognized in the proposed rule that applying this 60 to 90-day period to subsequent updates (rather than exclusively to the initially published list) could result in a precluded prescriber or provider being permitted to continue treating Part D and MA beneficiaries for up to 3 months without their Part D prescriptions or MA claims being denied. However, we believed that the prevention of potentially serious dangers to the health and safety of Medicare beneficiaries that could ensue if they are without crucial medications for an extended period must take precedence.

Although we discussed the delayed claim denial period in the preamble to the April 2018 final rule, we did not incorporate this policy into the regulatory text. In addition, while § 423.120(c)(6) contained certain provisions regarding beneficiary notification about the preclusion list, there were no such concomitant provisions for MA in § 422.222. Thus, we proposed to make the following revisions and additions, as applicable, to § 423.120(c)(6) and § 422.222 in the April 2018 final rule:

- Section 422.222 would be revised as follows:

++ Existing paragraph (a)(1) would be moved to a new paragraph (a)(1)(i) that would state: ''Except as provided in paragraph (a)(1)(ii) of this section, an MA organization must not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list, defined in § 422.2.''

++ New paragraph (a)(1)(ii) would state: ''With respect to MA providers that have been added to an updated preclusion list, the MA organization must do all of the following:''

++ New paragraph (a)(1)(ii)(A) would state: ''No later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received an MA service or item from the individual or entity added to the preclusion list in this update.''

++ New paragraph (a)(1)(ii)(B) would state: ''Must ensure that reasonable efforts are made to notify the individual or entity described in paragraph (a)(1)(ii) of this section of a beneficiary who was sent a notice under paragraph (a)(1)(ii)(A) of this section; and''

++ New paragraph (a)(1)(ii)(C) would state: ''Must not deny payment for a service or item furnished by the newly added individual or entity, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (a)(1)(ii)(A) of this section.''

We noted that, consistent with § 422.224, the prohibition against paying precluded individuals and entities would include contracted and non-contracted parties for purposes of the provisions in § 422.222(a)(1).

Consistent with our proposed changes to § 422.222(a)(1), we proposed to delete the existing structure of § 423.120(c)(6)(iv), which we cited previously, and replace it with the following:

++ A new opening paragraph of (c)(6)(iv) would state: ''With respect to Part D prescribers that have been added to an updated preclusion list, the Part D plan sponsor must do all of the following:''

++ Revised paragraph (c)(6)(iv)(A) would state: ''Subject to all other Part D rules and plan coverage requirements, and no later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received a Part D drug prescribed by a prescriber added to the preclusion list in this update.''

++ Revised paragraph (c)(6)(iv)(B) would state: ''Must ensure that reasonable efforts are made to notify the prescriber described in paragraph (c)(6)(iv) of this section of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(A) of this section; and''

++ New paragraph (c)(6)(iv)(C) would state: ''Must not reject a pharmacy claim or deny beneficiary request for reimbursement for a Part D drug prescribed by the prescriber, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (c)(6)(iv)(A) of this section.''

We mentioned that for providers and prescribers that are both on the preclusion list and excluded by the OIG, the aforementioned beneficiary notification process would not be intended to replace or supplant any existing OIG processes for notifying beneficiaries of excluded providers or prescribers.

(5) Beneficiary Appeals

We noted earlier that in the preamble to the April 2018 final rule, we stated that if payment is denied because the prescriber or provider is on the preclusion list, the affected beneficiary would not have the right to appeal that denial as denials due to preclusion are not coverage determinations accompanied by appeal rights. As we did not include accompanying regulatory text in the April 2018 final rule, we proposed in CMS–4185–P to add new § 423.120(c)(6)(viii) and § 422.222(a)(4) stating that payment denials based upon, respectively, a prescriber's or provider's inclusion on the preclusion list are not appealable by beneficiaries.

(6) Felony Convictions

We proposed in the November 2017 proposed rule to keep unenrolled prescribers and providers on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the prescriber or provider had they been enrolled and then revoked. While this policy was finalized in the April 2018 final rule, it was not included in the regulatory text. Given this, we proposed several regulatory revisions.

First, we proposed to revise the definitions of ''preclusion list'' in §§ 423.100 and 422.2. The current definitions contain two general categories of parties that could be included on the preclusion list—(1) prescribers and providers that are currently revoked from Medicare and are under a reenrollment bar; and (2) prescribers and providers that have engaged in behavior for which CMS could have revoked the prescriber or provider to the extent applicable had they been enrolled in Medicare. While these two categories encompass felony convictions, we stated in CMS–4185–P that the severity of felonious behavior warranted the establishment of a third category that is specific to felony convictions. We therefore proposed to remove felony convictions from the scope of the first two categories, with the new third category covering prescribers and providers—regardless of whether they are or were enrolled in Medicare—that have been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Recognizing that the facts of each case are different and must be judged on their own merits, we proposed that CMS would first consider the following factors before determining whether a prescriber's or provider's inclusion on the preclusion list is warranted under our new proposed third category for felony convictions: (1) The severity of the offense; (2) when the offense occurred; and (3) any other information that CMS deems relevant to its determination. In conformity with this change, we also proposed to add an ''or'' to the regulatory text immediately after the second category in the preclusion list definitions; this would clarify that a prescriber or provider need only come within the purview of one of the three categories to be included on the preclusion list.

Second, we proposed to establish new §§ 423.120(c)(6)(vii) and 422.222(a)(5) that would codify, clarify, and expand upon the previously mentioned policy concerning the length of a prescriber's or provider's inclusion on the preclusion list:

- In §§ 423.120(c)(6)(vii)(A) and 422.222(a)(5)(i), we proposed that, except as provided in §§ 423.120(c)(6)(vii)(C) and (D) and 422.222(a)(5)(iii) and (iv), revoked prescribers and providers, respectively, would be included on the preclusion list for the same length of time as the prescriber's or provider's reenrollment bar.
- In §§ 423.120(c)(6)(vii)(B) and 422.222(a)(5)(ii), we proposed that, except as provided in §§ 423.120(c)(6)(vii)(C) and (D) and 422.222(a)(5)(iii) and (iv), unenrolled prescribers and providers, respectively, would be included on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the prescriber or provider had they been enrolled and then revoked.
- In §§ 423.120(c)(6)(vii)(C) and 422.222(a)(5)(iii), we proposed that, except as provided in §§ 423.120(c)(6)(vii)(D) and 422.222(a)(5)(iv), prescribers and providers—regardless of whether they are or were enrolled in Medicare—that are included on the preclusion list because of a felony conviction would remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter time length of time is warranted. Factors that we would consider in making such a determination would be: (1) The severity of the offense; (2) when the offense occurred; and (3) any other information that CMS deems relevant to its determination.

We mentioned in CMS–4185–P that because our proposed preclusion list period for felonious prescribers and providers would begin on the date of the conviction, such parties may actually be included on the preclusion list for less than 10 years even if CMS imposes the full 10-year period.

We also explained in CMS–4185–P that the OIG in many cases excludes providers and prescribers for a period that is longer than the period permitted for a reenrollment bar under § 424.535(c). We believed that CMS should keep an excluded provider or prescriber on the preclusion list at least until the provider or prescriber has been reinstated by the OIG in order to be consistent with section 1862(e) of the Act. We thus proposed in new § 423.120(c)(6)(vii)(D) and 422.222(a)(5)(iv) that in cases where a prescriber or provider is excluded by the OIG, the prescriber or provider remains on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(7) Beneficiary Liability

Consistent with our existing authority under section 1857(e)(1) of the Act, we proposed to add a new paragraph (g)(1)(iv) to § 422.504 under which the MA organization is required to agree that the enrollee must not have any financial liability for services or items furnished to the enrollee by an MA contracted individual or entity on the preclusion list, as defined in § 422.2 and as described in § 422.222. This provision would be limited to providers under contract with the MA organization, for we believed this is consistent with the general applicability and scope of § 422.504 and the ability of the MA organization to control or

impose requirements on the health care providers that furnish covered services and items to enrollees. We stated our belief that proposed paragraph (g)(1)(iv) would help financially protect beneficiaries from problematic providers. It would also formally codify this position, which we expressed in the preamble to the April 2018 final rule but did not address in the regulatory text.

(8) Technical Correction Concerning the Term ''Individual'' in § 423.120(c)(6)

We also proposed to make technical changes to § 423.120(c)(6)(i), (ii), (iii), and (vi). These paragraphs stated as follows, respectively:

- Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the preclusion list, defined in § 423.100.
- Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary if the request pertains to a Part D drug that was prescribed by an individual who is identified by name in the request and who is included on the preclusion list, defined in § 423.100.
- A Part D plan sponsor may not submit a prescription drug event (PDE) record to CMS unless it includes on the PDE record the active and valid individual NPI of the prescriber of the drug, and the prescriber is not included on the preclusion list, defined in § 423.100, for the date of service.
- CMS has the discretion not to include a particular individual on (or if warranted, remove the individual from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to prescriptions.

Because some states permit pharmacies to prescribe medications under very specific circumstances, we believed that the use of the term ''individual'' in paragraphs (i), (ii), (iii), and (vi) was too restrictive. We therefore proposed in paragraphs (i), (ii), and (vi) to change this term to ''prescriber'' so as to clarify that the prescriber need not be an individual when these specific circumstances are met. In a similar vein, we proposed:

- In § 423.120(c)(6)(iii) to change the phrase ''individual NPI of the prescriber'' to ''NPI of the prescriber'', and
- In paragraph (2)(i) of the definition of ''Preclusion list'' in § 423.100 (and as reflected in our previously discussed proposal to revise this paragraph (see section (C)(1)(b)(6) above)) to change the phrase ''he or she'' to ''prescriber.''

c. Comments Received

We received comments concerning our proposed changes from approximately 25 commenters. The comments are summarized below, followed respectively by our responses thereto. They are organized into general categories, though we note that some comments and responses involve multiple policy areas.

(1) Claim Denials

Comment: With respect to claim denials, a commenter questioned: (1) Whether plans should deny all claim types (regardless of origin) when the claim date of service is equal to or greater than the ''claim reject date'' (for example, point of service claims; batch claims; paper claims); and (2) whether the ''claim reject date'' is the date that CMS will use to edit the PDE. In a similar vein, another comment questioned whether: (1) Part D plan sponsors should utilize the ''claim reject date'' (rather than the ''effective date'' field) as the relevant field for the date when claim rejections begin; and (2) the ''claim reject date'' is the relevant date for when CMS validates the PDE.

Response: We will be addressing operational issues in guidance as necessary and appropriate. We note, though, that PDE editing will use the ''claim reject date.'' (See HPMS memorandum, ''February 2019 Updates to the Drug Data Processing System (''DDPS''),'' dated January 8, 2019 and released January 9, 2019.)

Comment: A commenter stated that if CMS intends for each Part D plan to separately track a 60-day period after beneficiary notices have been sent before claim denials can occur, this could create non-standardized effective dates for claim denials across the industry. The commenter cited the example of one plan sponsor sending the beneficiary notice on day 10 and another sending the notice on day 20. The commenter recommended that CMS standardize the timing of the effective claim denial date so as to ensure (1) consistency within the industry and (2) that claim rejects start on the same day for precluded prescribers.

Response: We respectfully decline to adopt the commenter's suggestion as a regulatory requirement. Given that Part D plans may have different internal procedures, different numbers of beneficiaries to contact, and different operational mechanisms, we believe it is best to afford them the maximum feasible flexibility in sending out beneficiary notices. We believe this ensures that all beneficiaries are provided equal notice and time to find a new provider or prescriber. However, we do understand the commenter's concerns, and have indicated a claims denial/reject date on the preclusion file shared with both Part C and D plans. This date indicates the close of the 90-day period and the latest point at which claims must deny or reject. We will diligently monitor the preclusion list's implementation; should we determine that more uniformity may be necessary, we will consider addressing the matter in future rulemaking as appropriate.

Comment: Once a provider or prescriber has been added to the preclusion list and claims from the precluded provider or prescriber start to be denied, a commenter questioned how CMS expects a Part C organization determination or Part D coverage determination (submitted by either a provider on the preclusion list or an enrollee whose provider or prescriber is on the preclusion list) to be reviewed.

Response: We respectfully believe that this comment may reflect a misunderstanding of how a point-of-sale rejection is treated in the Part D program. A rejection of a pharmacy claim at point-of-sale does not constitute a coverage determination. If a claim is rejected because the prescriber is on the preclusion list, the appropriate action is for the enrollee to find another prescriber to prescribe the drug. Further, as finalized in § 422.222(a)(4), a beneficiary enrolled in an MA plan (or a cost plan or PACE organization under the incorporation of the MA regulation into those programs at §§ 417.478 and 460.86) will not be able to appeal a payment denial that is based on an individual or entity's placement on the preclusion list. The appeal rights available to an enrollee under 42 CFR part 422, subpart M are tied to whether a decision by the MA plan is an organization determination; because there will be no appeal rights for these denials, we do not believe it is appropriate to characterize denials that occur solely because of the preclusion list requirements as organization determinations. We believe that this policy appropriately balances the need to provide an appeal process to ensure protection of Medicare beneficiaries and their ability to challenge denials issued by an MA plan; an MA plan will not have any discretion to pay a precluded provider where this final rule prohibits payment and an appeal by an enrollee of a denial of payment to the precluded provider could never be resolved in the enrollee's favor. Therefore, this is not an issue that can be resolved through the benefit appeals process set forth at part

422, subpart M, under the regulation we are finalizing.

(2) Provider Reinstatement

Comment: Several commenters stated that CMS should explain the process and timing that will be used when a provider is no longer on the preclusion list. A commenter sought clarification as to what a provider record looks like when the provider is reinstated on the file and how this compares to the original provider record.

Response: The preclusion list file will include a reinstatement date indicating when a provider or prescriber is no longer precluded. The reinstatement date will be published upon the provider or prescriber being reinstated. Records of a provider's or prescriber's preclusion will not be removed from the file. We will clarify additional operational details pertaining to these issues in sub-regulatory guidance.

Comment: A commenter requested confirmation as to whether reinstated providers will: (1) Be removed from the preclusion list; or (2) remain in the preclusion list database with a date indicating the end of their preclusion period.

Response: As already mentioned, records of a provider's or prescriber's preclusion will not be removed from the preclusion list file. In such instances, the reinstated provider or prescriber will remain in the preclusion list database. Upon the prescriber or provider being reinstated, the reinstatement date will be indicated.

Comment: A commenter questioned whether reinstatement dates will be provided for each preclusion effective date and, if so, how far in advance of a provider being reinstated will the date be provided in the file.

Response: CMS will not provide advance notice regarding a reinstatement. However, once the provider is reinstated, CMS will populate a reinstatement date on the file.

Comment: A commenter recommended that CMS clarify: (1) That the removal of a provider who successfully appeals his or her addition to the preclusion list would not be retroactive to the date of the provider's original preclusion; (2) that the MA plan would not be required to retroactively pay claims for such a provider; and (3) how MA plans should implement such a provider's removal from the preclusion list. These suggestions stemmed from several concerns the commenter raised. First, requiring plans to pay such claims retroactively could create confusion among members, who may be urged by their precluded providers to continue to see the precluded provider during the appeals. Second, members may be liable for cost sharing associated with the re-submitted claims. Third, plans would face uncertainty in determining how to pay such claims (for example, at what payment rate), for the provider contract will likely have been terminated.

Response: We respectfully disagree with the commenter's apparent request that CMS not reinstate a provider or prescriber back to the original preclusion date. Providers or prescribers who are successful upon appeal will be reinstated back to the preclusion effective date. Once reinstated, the provider would have the option of resubmitting claims that had been denied during the preclusion period, which would be eligible for payment by an MA plan under this final rule, using the plan's rules for claims processing; we are not finalizing a requirement that an MA plan must waive any claims filing deadlines that may have elapsed in the time between the date of service and the decision to reinstate the provider. If a provider is reinstated retroactively, plans should pay claims that were rejected or denied due to the preclusion using, again, the MA plan's usual claims processing procedures; it is, however, the provider's responsibility to resubmit any rejected or denied claims. If a beneficiary paid out of pocket for a Part D drug that was rejected based on the prescriber's preclusion, the beneficiary would have to submit a request for reimbursement. We will clarify the process for reinstated providers and prescribers to resubmit claims in sub-regulatory guidance.

Comment: A commenter sought clarification as to how a beneficiary would know to resubmit a previously rejected claim for reimbursement if a precluded provider is reinstated retroactively.

Response: We intend to address this issue in sub-regulatory guidance. While this final rule does not require the Part D or MA plan to issue additional notices to enrollees about individuals or entities that have been reinstated after a successful appeal of placement on the preclusion list, we encourage plans to do so, especially in cases where placement on the preclusion list was in error.

(3) ''Reasonable Efforts''/Notification

Comment: Several commenters requested clarification as to what the term ''reasonable efforts'' means in the context of furnishing the notification to the prescriber as described in § 423.120(c)(6)(iv)(B). A commenter added that various parts of CMS' sub-regulatory guidance indicate that the ''reasonable efforts'' notification is required but elsewhere state that it is optional; the commenter recommended that CMS explain the circumstances under which it is, or may be, required.

Response: The term ''reasonable efforts'' in both § 423.120(c)(6)(iv)(B) and § 422.222(a)(1)(ii)(B) involves the plan using available contact information it has for a prescriber or provider to copy them on the notice mailed to the beneficiary. We expect that MA organizations would always have contact information for their MA-contracted providers. We acknowledge, however, that they may not have this data for non-contracted providers (unless the non-contracted provider submits a claim) and that Part D plan sponsors may not have this information concerning prescribers of drugs. Given this dilemma, and to ensure that a proper balance is attained between the importance of notification and the fact that contact data may be unavailable in certain circumstances, we are changing the timing and scope of this notification requirement. We are finalizing § 422.222(a)(1)(ii)(B) and § 423.120(c)(6)(iv)(B) with the following modifications:

++ The existing versions of these paragraphs will be incorporated into, respectively, new paragraphs §§ 422.222(a)(1)(ii)(B)(*1)* and 423.120(c)(6)(iv)(B)(*1*). The beginning of these respective new paragraphs, moreover, will state, ''Subject to paragraph (a)(1)(ii)(B)(*2*) of this section'' and ''Subject to paragraph (c)(6)(iv)(B)(*2*) of this section''.

++ In new paragraphs §§ 422.222(a)(1)(ii)(B)(*2*) and 423.120(c)(6)(iv)(B)(*2*), we will state that paragraph (B)(*1*) only applies upon receipt of a claim from, respectively, a precluded MA provider (contracted or non-contracted) or upon a prescriber writing a Part D prescription when: (i) Sufficient contact information is available; and (ii) the claim is received after the claim denial or reject date in the preclusion file.

Paragraph (B)(*2*), in effect, means that the ''reasonable efforts'' requirement in paragraph (B)(*1*) will apply only if both of the following conditions are met: (1) The MA organization or plan sponsor has enough information on file to either copy the provider or prescriber on the notification previously sent to the beneficiary or send a new notice informing the provider or prescriber that they may not see plan beneficiaries due to their preclusion status; and (2) the claim is received after the claim denial or reject date in the preclusion file. We believe this second criterion is

necessary to help clarify the timing of the notification requirement; it will also help to mitigate instances where a beneficiary mistakenly receives care from a precluded prescriber.

Comment: A number of commenters opposed the requirement under § 422.222(a)(1)(ii)(B) or § 423.120(c)(6)(iv)(B) that MA organizations and Part D sponsors ensure that ''reasonable efforts'' are made regarding provider and prescriber notification. Some stated that this activity should not be the responsibility of MA plans or Part D plan sponsors; this is because CMS already adequately notifies providers and prescribers of their placement on the preclusion list and remains, in the commenters' view, in the best position to continue doing so. The commenters believed that imposing the requirements of § 422.222(a)(1)(ii)(B) or § 423.120(c)(6)(iv)(B) on MA plans and Part D sponsors would thus: (1) Be both duplicative and a further administrative burden on MA plans and Part D sponsors, involving thousands of additional letters and unnecessary costs; (2) be inconsistent with the Patients over Paperwork initiative; and (3) lead to provider frustration and confusion because the provider would be receiving multiple notices regarding the same matter. A commenter added that precluded providers and prescribers are able to identify their impacted patients and need not receive this information from MA plans and Part D sponsors; the latter should not bear additional cost and burden in order to assist problematic providers and prescribers with managing impacted patients within their practices. Another commenter stated that with respect to MA non-contracted providers, it is possible that the services they provided were on an emergency/urgent basis, rather than for ongoing, routine care; there is, consequently, little value in MA plans furnishing additional notification under § 422.222(a)(1)(ii)(B) given the limited impact on a ''go-forward'' basis. An additional commenter stated that these notification requirements have not been imposed with respect to OIG-excluded providers.

Response: We appreciate the concerns these commenters expressed regarding the aforementioned requirement. Considering, however, the plans' role in the daily operational and logistical facilitation of the Medicare Part C and D programs and their close administrative relationship with prescribers and providers, we believe that the plans are best-positioned to communicate with prescribers and providers regarding their relationships with specific beneficiaries. We mention also that we have attempted to reduce to burden of this requirement with our aforementioned revisions to § 422.222(a)(1)(ii)(B) or § 423.120(c)(6)(iv)(B).

With respect to the final comment, we note that the OIG exclusion list and the administrative requirements pertaining thereto are separate from and non-binding on those regarding the preclusion list. Merely because the OIG regulations lack a requirement concomitant with § 422.222(a)(1)(ii)(B) or § 423.120(c)(6)(iv)(B) does not mandate that CMS eliminate these two provisions.

(4) Notification to Provider of Preclusion

Comment: A commenter recommended that CMS notify the prescriber of their inclusion on the preclusion list because having individual plan sponsors perform simultaneous outreach to providers would be inefficient and confusing.

Response: We believe that the commenter is referring to the CMS requirement that was finalized in the April 2018 final rule and codified in § 423.120(c)(6)(v). Assuming this is so, we agree with the commenter and stress that we did not propose to change this requirement in the November 1, 2018 proposed rule.

Comment: A commenter urged that the written notice to the individual or entity via letter of their inclusion on the preclusion list be sent via certified mail and that the letter be standardized across the MA and Part D programs. This, the commenter explained, would prevent instances where an individual or entity is not properly notified, the letter is lost in transit, or the letter goes to an incorrect office or staff member; it will also help ensure a proper chain of custody. The commenter also stated that standard language and uniformity in the letter's format will assist individuals and entities in distinguishing the notice and its purposes from other communications.

Response: We appreciate this comment and wish to clarify that CMS is indeed mailing these notices via certified mail. Additionally, the same letter template, including similar format and language, is used for notification to both Part C and D providers and prescribers.

(5) Relation to OIG Exclusion List

Comment: Several commenters urged CMS to treat the OIG exclusion list and the preclusion list consistently to avoid provider, beneficiary, and plan confusion. A commenter requested clarification regarding CMS' rationale for treating precluded providers differently than those on the OIG exclusion list, particularly with respect to the timing for the denial of claims. The commenter noted that, in contrast to the OIG exclusion process, claims denials will be delayed for the initial preclusion list and subsequent lists.

Response: We appreciate these comments. As explained in sub-regulatory guidance we have issued (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html*), we have attempted to conform the preclusion list policies to those concerning the OIG exclusion list as much as possible. We emphasize, however, that complete uniformity and/or full integration of the two lists is impracticable at this time for several reasons. First, the OIG exclusion list is governed by statute, consistent with the provisions of section 1128 of the Act. The OIG exclusion list (and the policies and procedures associated therewith) is operated under an entirely different set of laws and regulations. Second, the requirements for inclusion on the preclusion list and for inclusion on the OIG exclusion list are very different. For instance, revocation of Medicare enrollment (which can be based on any of the reasons identified in § 424.535(a)) and a non-health care related felony can serve as bases for adding a provider to the preclusion list, whereas these grounds are not, in and of themselves, bases for inclusion on the OIG exclusion list. The revocation reasons in § 424.535(a), moreover, are quite distinct from the reasons for imposing an OIG exclusion under section 1128 of the Act. The Medicare enrollment/revocation and OIG exclusion processes, in short, are operated by different agencies under different rules with different requirements, which prevents these lists from being uniform.

We also believe that the preclusion list will apply to a much larger provider population than that included on the OIG exclusion list. We remind commenters that the intent of the preclusion list was to create an effective alternative to enrollment. We thus concluded that it was necessary to establish criteria for a provider to be precluded that were broader than those for exclusion, such as being revoked from Medicare; otherwise, it was possible that certain problematic providers and prescribers could continue to furnish MA services and items or prescribe Part D drugs. By the same token, we have certain safeguards for the preclusion list, such as the claim denial timing, to prevent access to care

issues. We believe this properly balances the need for strong program integrity measures (as evidenced by our above-referenced, broader preclusion list criteria) and the importance of ensuring that beneficiaries receive needed health care.

Notwithstanding the above, we emphasize that the OIG list should take precedence over the preclusion list; consequently, no OIG-excluded provider shall receive payment or the 60-day period addressed in this rule. Once a provider is no longer excluded and a plan must review the preclusion list, there will be instances (based on Medicare reenrollment bars) where a provider is precluded after their reinstatement from an exclusion.

Comment: A commenter stated that administering the preclusion list differently than the OIG exclusion list increases administrative burden for plans while adding little value. The commenter instead supported terminating providers and denying claims in a timeframe consistent with the OIG exclusion process, rather than waiting for at least 60 days after release of the preclusion list, as CMS proposed. The commenter stated that there should not be a 60-day period before claim denials, for a provider would know that they are precluded and should thus not be seeing Medicare beneficiaries or prescribing drugs. The commenter added that having separate notices to the beneficiary and different claims denial timeframes could lead to beneficiary confusion. Accordingly, the commenter recommended that CMS: (1) Use one list that combines exclusions and preclusions; or (2) revise the preclusion list requirements to apply in the same manner as the OIG list, allowing plans to deny claims upon release of the preclusion list.

Response: As already explained, the differing requirements for inclusion on each list, the different legal and statutory requirements, and the different operational aspects involved do not permit us to establish any greater uniformity than that already described in the above-mentioned sub-regulatory guidance. With respect to claim denials, we recognize the validity of the commenter's concern. Considering, however, that (1) the preclusion list is a new concept, (2) plans need time to accustom themselves to the preclusion list process, and (3) some beneficiaries will need time to find new prescribers or providers, we are not in a position at this stage to require immediate claim denials upon release of the preclusion list. In time, should stakeholders (including the plan and beneficiary communities) become fully acclimated to the preclusion list process such that a period as long as 90 days is not realistically needed, CMS may revisit this issue in future rulemaking.

Regarding the commenter's concerns about plan and beneficiary burden and confusion, we will continue our educational and outreach efforts to stakeholders so as to minimize these effects.

Comment: A commenter recommended that CMS only include non-OIG excluded prescribers on the preclusion list in order to keep the preclusion and OIG exclusion lists separate. The commenter was concerned that with both programs releasing a monthly file at different times during the month, the potential exists for timing problems and confusion.

Response: We appreciate this suggestion. However, because (1) an OIG exclusion constitutes grounds for revocation under § 424.535(a) and (2) the revocation policies in § 424.535 (for example, application of a reenrollment bar) would apply in such cases, we believe it is important to include all revocation grounds and policies within the scope of the preclusion list. We will continue to work with stakeholders to minimize confusion regarding the interaction between the two lists. We are confident that, with time, affected parties will become acclimated to the different processes.

Comment: A commenter contended that including preclusion list standards on top of the existing OIG exclusion statutory requirements is unnecessary, creates numerous inconsistencies, and imposes operational complexities. For example, the commenter stated, once a provider is added to the OIG exclusion list, there is no grace period during which plans can continue to make payment. The proposed rule, however, contains such a period for the preclusion list under §§ 422.222(a)(1) and 423.120(c)(6)(iv). The commenter stated that: (1) Simultaneous compliance with both of these standards is impossible; and (2) CMS cannot create a rule that directly conflicts with the OIG exclusion provisions in the Social Security Act. The commenter added that while CMS could create exceptions to the preclusion list requirements for excluded providers or revise the preclusion list requirements to be consistent with those applicable to excluded providers, it would be administratively cleaner to simply extract excluded providers from the preclusion list.

Response: For reasons already stated, we are not in a position to separate the two lists or to make the preclusion list processes entirely consistent with those of the OIG exclusion list. We are also unable to remove OIG excluded prescribers and providers from the preclusion list, for CMS takes revocation action that is separate and apart from whatever exclusion action the OIG might take. A revocation action warrants the addition of the prescriber or provider to the preclusion list and is accompanied by a reenrollment bar, which determines the length of the preclusion. The reenrollment bar length may exceed the period for which the prescriber or provider is OIG excluded, which further prohibits the affected prescriber or provider from furnishing items and services to Medicare beneficiaries.

Notwithstanding the above, however, we have already clarified via sub-regulatory guidance that the OIG exclusion list takes precedence over the preclusion list. Thus, if a plan locates a provider on the OIG exclusion list, it need not consult the preclusion list with respect to that provider. The plan would simply follow its processes for OIG excluded providers as described at 42 CFR 422.204(b)(4), 422.224(a), and 422.752(a)(8). We mention further that providers and prescribers who are precluded due to an exclusion are not afforded the 60-day grace period, for the plan would reject the claim or deny the provider's requests for reimbursement based on the exclusion prior to determining if the provider or prescriber is precluded.

To codify the above policy in regulation, we will clarify the opening paragraphs of §§ 423.120(c)(6)(iv) and 422.222(a)(1)(ii) to state that §§ 423.120(c)(6)(iv) and 422.222(a)(1)(ii) do not apply if the prescriber or provider is currently excluded by the OIG. This means, in effect, that if a provider or prescriber is on both the OIG exclusion list and the preclusion list, the MA organization or Part D plan sponsor need not (with respect to that prescriber or provider) carry out the requirements of §§ 423.120(c)(6)(iv) and 422.222(a)(1)(ii) (for example, provide advance written notice to the beneficiary; delay payment denials). We believe this will help reduce duplicative administrative functions (such as letters to beneficiaries) and ensure compliance with the statutory payment prohibitions concerning OIG exclusions (that is, no grace period).

Comment: A commenter recommended that CMS limit the preclusion list to providers who are not on the OIG exclusion list so as to avoid conflicts between the exclusion and preclusion requirements. If CMS declines this suggestion, the commenter stated that giving plans up to 90 days to

begin denying payment would allow them to meet their obligation (under both OIG and CMS regulations) to deny claims for items and services provided by an excluded provider, while also allowing time—where permitted—for members to be notified and transition to a new provider. The commenter contended that this would be more consistent with MAOs' current obligations to provide members with 30 days' advance notice of a provider's contract termination; the commenter questioned why a provider placed on the preclusion list should continue to be paid for a longer period of time than a provider whose contract terminates for another reason.

Response: We previously outlined our rationale for declining to extract OIG-excluded parties from the preclusion list and the reasons for the 90-day delay in claim denials. As we indicated regarding the latter, though, we may in the future consider shortening this time period via rulemaking should circumstances warrant and operational considerations permit. We note that currently, pursuant to § 422.202(d)(4), if an MA plan terminates a contracted provider from the provider network for ''no cause'', the plan is required to furnish the provider with 60 days' advance notice; if an MA plan terminates a provider for cause, the provider is entitled to appeal rights under § 422.202(d)(1) through (3). Based on this, we believe that the timeframe of 60–90 days before an MA plan can deny payment to a precluded provider is similar to what is required when a provider is terminated by the plan under § 422.202(d)(4) without cause.

(6) Relationship to Medicaid

Comment: In cases where Medicaid is the primary payer for a drug for a dual-eligible individual, a commenter questioned whether the pharmacy must fill a prescription for a drug prescribed by a precluded prescriber. The commenter stated that CMS must address how the preclusion list applies to Medicaid-Medicare Plans (MMPs) with a three-way contract. Specifically, in an MMP the enrollee has one insurance card; he or she may thus be confused if the MMP rejects his or her Part D drugs (because the prescriber is precluded) but then pays for the Medicaid drug from the same prescriber.

Response: A Part D drug that is not covered because the prescriber is on the preclusion list—but is otherwise coverable by Part D—is not coverable under Medicaid, including under an MMP as the claim would not cross over once rejected by the Part D plan. In the rare circumstance that Medicaid is the primary payer for a prescription drug furnished to a Part D eligible individual, the preclusion list does not apply as the drug would be adjudicated through the Medicaid claims system.

Comment: A commenter requested that CMS collaborate with states if future consideration is given to the preclusion list's potential application to (and implementation by) state Medicaid agencies in unison with private sector health plan partners.

Response: We appreciate this comment and will make certain to collaborate with the states should the contingency the commenter mentions arises.

(7) Timeframe for Denying Claims

Comment: Noting the proposed commencement of claim denials 61–90 days following preclusion list publication, a commenter recommended a hard timeline of 90 days from file release to claim denial. The commenter believed that this would foster industry-wide consistency. Another commenter stated that if CMS intends to require plans to terminate precluded providers from their networks, CMS should: (1) Promulgate this requirement through rulemaking, not via sub-regulatory guidance; and (2) permit plans to terminate providers at any time prior to when plans must begin denying payments.

Response: We appreciate these comments. However, we do not wish to delay claim denials any longer than absolutely necessary, which is why we respectfully decline to mandate the expiration of a full 90-day period. Under § 422.222(a)(1), as amended in this final rule, an MA organization is prohibited from paying a provider who is on the preclusion list; this prohibition applies to claims with dates of service that fall 60 days or more after the MA organization has notified the enrollee that the provider has been placed on the preclusion list and that claims for services furnished by that provider will be denied. Section 422.222 does not itself require termination of any contract between the MA organization and the precluded provider. We anticipate, though, that many MA plans will take steps to terminate their contracts with precluded providers, at least for purposes of the MA plan, because of the prohibition on payments to precluded providers in connection with items and services provided to Medicare beneficiaries. Further, we do not believe that rulemaking is required regarding language in CMS' sub-regulatory guidance, which only suggests and does not require the removal of precluded providers from plan networks.

We believe that compliance with § 422.222(a)(1) by an MA plan will take slightly different forms depending on whether the precluded individual or entity has a contract with the MA plan to participate in its network. In managing their contracted networks, MA plans: (1) Must provide advance written notice to any beneficiary who received an item or service from an individual or entity added to the preclusion list no later than 30 days after the posting of the updated preclusion list; and (2) may pay the precluded provider for 60–90 days, depending on when the enrollee was notified. When an enrollee has received services from a non-network precluded provider, MA plans should notify the enrollee that the non-contract provider is precluded and the plan will not pay any claims from the precluded provider with a date of service after the expiration of the allowable payment period for that precluded provider.

Comment: A commenter agreed that the previously mentioned 60–90 day claim denial period will assist beneficiaries in transitioning to new providers.

Response: We appreciate the commenter's support.

Comment: Several commenters expressed support for the proposed application of the 90-day period before a claim is denied to all releases of the preclusion list (not merely the initial preclusion list).

Response: We appreciate the commenters' support.

Comment: A commenter stated that payment denials should be allowed to begin at any point up to 90 days after the provider is placed on the preclusion list. Any member notice requirement, the commenter contended, should be independent of the time frame for denying payments.

Response: Under § 422.222(a)(1)(ii)(C), the prohibition on payment to a precluded individual or entity is tied to expiration of a period of 60 days from issuance of the advance written notice to the enrollee. However, the MA plan may terminate a network provider under its contract, thereby removing the provider from its network of providers available to its enrollees in accordance with other procedures and requirements. The MA regulation at § 422.202(d) permits for-cause and without-cause terminations of provider participation agreements; § 422.111(e) specifies that an MA organization terminating a provider must make a good-faith effort to notify enrollees at least 30 calendar days before the provider termination date. If an enrollee is left without a primary care provider

and one is necessary in order to access coverage and benefits under the MA plan, § 422.112(a)(2) permits the MA organization to assign a primary care provider to the enrollee; further, § 422.122(b) imposes coordination of care responsibilities on MA organizations, which CMS generally believes means that an MA organization should offer to assist enrollees in locating a suitable provider and in ensuring that ongoing treatment is properly transitioned to a new health care provider. Section 422.222(a)(1)(ii)(A) requires that MA organizations notify enrollees within 30 days from when the MA plan receives notification from CMS that a provider has been placed on the preclusion list, which will start the 60-day period for when denials of payment based solely on the provider's inclusion on the preclusion must occur.

The enrollee notification of a terminated provider should inform the enrollee that the terminated precluded provider is no longer available to furnish plan services and offer to assist the enrollees in transitioning to a new network provider. For services received from a non-contracting precluded provider, the MA plan must also notify the enrollee that the non-network provider is precluded and include in that notification the date on which the plan will not pay any further claims from that precluded provider. This gives the enrollee time to transition to an alternative non-network provider if he or she chooses to do so.

While we believe it is clear that § 422.222 is equally applicable to network and non-network precluded providers, we wish to eliminate any confusion on this matter. As such, we are changing the title of § 422.222 from ''Preclusion list'' to ''Preclusion list for contracted and non-contracted individuals and entities.'' We believe this will help clarify the applicability of § 422.222,

Comment: A commenter urged CMS to allow plans up to 90 days to commence denying payments, meaning that plans would be permitted to: (1) Immediately stop paying claims (as required with OIG excluded providers); and (2) begin denials at any point within 90 days if there is no other legal requirement to act immediately. The commenter stated that requiring plans to pay claims for a period of time after the provider is placed on the preclusion list conflicts with other requirements that plans must follow and introduces multiple challenges. The commenter added that because the applicable statute prohibits plans from making payment for items and services furnished or prescribed by an excluded provider, CMS cannot impose a separate requirement that plans continue to pay claims for precluded providers (some of whom will also be on the exclusion list) for a particular period of time.

Response: As previously explained, we believe that beneficiaries should be afforded a sufficient opportunity to locate a new prescriber or provider should their current prescriber or provider be included on the preclusion list. We note also that nothing in the provisions we finalized in the April 2018 final rule or are finalizing in the present rule prohibit plans from immediately denying claims based on an OIG exclusion pursuant to the long-standing requirement to do so under the Social Security Act. Indeed, we refer the commenter to our previously mentioned changes to §§ 423.120(c)(6)(iv) and 422.222(a)(1)(ii), under which these provisions would not apply if the prescriber or provider is currently excluded by the OIG.

Comment: A commenter stated that the April 2018 final rule prohibits MAOs from paying claims from precluded providers and contains no requirement that the MAO notify the member or otherwise delay the denial of payment. The commenter also pointed out, however, that the previously mentioned HPMS Memo ''recommends'' that MAOs wait 90 days before denying payment. The commenter stated it will be impossible for MAOs to comply with both the immediate payment prohibition and the 90-day recommendation for claim denials.

Response: CMS acknowledges, in the previously mentioned HPMS memo, the failure to include in the regulatory text of the April 2018 final rule certain policies outlined in our responses to the comments therein. Due to the language in the April 2018 final rule preamble summarized above and our guidance in the HPMS memo, we believe that the 90-day approach is permissible for plans pending the applicability date of this final rule and our amendments to § 422.222(a). We clarify here that the HPMS memo simply requests that plans follow the 90-day approach and that this approach is being codified in the regulatory text of this final rule. We mention, however, with the finalization of this rule, that the above-referenced 60-day period and beneficiary notification will be required upon the final rule's effective date.

(8) Beneficiary Notification

Comment: A commenter sought clarification on how a plan should proceed (assuming a January 1, 2019 release of the initial preclusion list) if, on day 89 following the publication of the preclusion list, a beneficiary receives a service from a precluded provider for which no pharmacy claims history exists. The commenter questioned whether: (1) This beneficiary would receive notification from the plan about the provider's preclusion; (2) the 90-day clock will begin to run again for this beneficiary; and (3) a provider or prescriber identified on January 1, 2019 as meeting the requirements for preclusion could provide services to a Medicare beneficiary for close to 6 months following its preclusion. The commenter believed that if CMS releases the preclusion list on January 1, 2019, plans would have until February 1 to notify beneficiaries, at which time claims begin to be denied on April 1; if, however, a beneficiary sees a provider placed on the initial preclusion list on March 28, a new 90-day clock would begin to run, under which the plan would be given 30 days to contact the beneficiary (April 28) and claims would not be denied until June 28.

Response: First, we note that the commenter's example appears to be about the preclusion list regulation adopted in the April 2018 final rule that became applicable beginning January 1, 2019, and not about our proposed rule. CMS has addressed this topic via sub-regulatory guidance at the following link: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html.* That guidance clarifies that if no claims history exists for the previous 12-month period, the plan is not required to notify beneficiaries. If no notification is made, the 60–90 day period is not required, although plans may choose to wait to deny claims until the claim denial/reject date included on the preclusion list file.

Second, under the amended regulations we are finalizing here and in regard to the commenter's specific scenario, if a beneficiary received a service from a precluded provider on the 89th day following publication of the list, the plan would pay the claim. The provider would not receive an additional 60–90 day period and after the 89th day would thus be unable to continue furnishing MA items and services or prescribing Part D drugs for Medicare beneficiaries. If the service was provided on the 90th day, the plan would (upon receiving the claim) deny or reject the claim and notify the provider or prescriber that he/she is precluded, as we have finalized at § 422.222(a)(1)(ii)(B) and § 423.120(c)(6)(iv)(B). In this specific scenario, we are assuming the provider is granted the 60–90 day period as there

may be a claims history with at least one beneficiary. To further clarify, in situations where there is no claims history concerning the specific provider and any beneficiaries, the 60–90 day period is not required.

Comment: Citing CMS' Patients over Paperwork initiative, a commenter requested clarification of the rationale for requiring the mailing of beneficiary notices instead of permitting email. The commenter cited the situation where a beneficiary indicates that electronic communication is his or her preferred method of communication.

Response: Per the December 14, 2018 HPMS memo, CMS will not allow different modes of communication regardless of the beneficiary's preference. We recognize that some beneficiaries may prefer email. However, we believe that using mail is the surest means of making certain that the beneficiary receives the notice, a critical consideration given the importance of the information furnished therein.

Comment: Several commenters urged CMS to add language to the sample beneficiary notification letter stating that appeal rights will not apply when a claim is denied due to a precluded prescriber. Failure to do so, a commenter contended, could lead to beneficiary confusion.

Response: In the sample notification letter, we refer the beneficiary to our sub-regulatory guidance (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html*), in which we outline the lack of beneficiary appeals in the situation the commenter describes. We believe this furnishes sufficient notification to beneficiaries on the issue of appeals.

Comment: A commenter stated that the sample notification letter informs stand-alone Part D plans to insert the 1–800–Medicare number but then leaves the ''hours of operation'' configurable. The commenter questioned: (1) Whether the hours should be the standard hours for 1–800–Medicare; (2) whether the stand-alone Part D enrollees should call only if they need assistance in finding another prescriber but should call plans at the plan number for further questions regarding the status of their prescriptions; (3) whether, based on the sample notice, there should be two numbers for stand-alone Part D plans; (4) whether the 1–800-Medicare number should only be furnished if assistance is needed in finding another provider; and (5) whether plans should list their customer care phone number if there are further questions regarding the status of their prescription with the plan's customer care hours of operations.

Response: We will address these operational issues via sub-regulatory guidance.

Comment: Regarding an enrollee who did not receive a notification letter (and given the previously mentioned 90-day period), a commenter sought clarification as to: (1) The requirements concerning PDE edits; (2) whether CMS will pay for the PDE; and (3) whether a new PDE edit will be created to reject PDEs submitted for precluded providers.

Response: We assume the commenter is referring to situations, per the regulations finalized in the April 2018 rule, where the beneficiary did not receive notification that his or her provider or prescriber is precluded. PDE editing will be based on the ''claim reject date,'' regardless of beneficiary notification receipt status as the timing for claim denials and/or rejections begins upon the notice being sent by the plan. (See HPMS memorandum, ''February 2019 Updates to the Drug Data Processing System (''DDPS''),'' dated January 8, 2019 and released January 9, 2019.)

Comment: A commenter expressed concern that beneficiaries will not have had adequate experience with the preclusion list initiative before receiving the mandated 60-day notification.

Response: We understand the commenter's concern. We will work with beneficiary groups to help educate potentially affected Medicare patients about the preclusion list process.

Comment: A commenter urged that the beneficiary notification letter should state that: (1) The beneficiary cannot request any review of CMS' preclusion determination; and (2) he or she must seek a non-precluded prescriber for future prescriptions.

Response: With respect to the first part of the comment, we do not believe it is helpful for the notification letter to state what the beneficiary cannot do under these circumstances. Instead, consistent with the second part of the comment, we believe it is more helpful for the notification letter to clearly explain the actions the beneficiary can and should take to ensure future payments and coverage of benefits; that is, to find another non-precluded provider to furnish similar items or services.

(9) Pharmacies and Part B Drugs

Comment: A commenter stated that Part B pharmacy claims are included in Part C reporting. The commenter sought guidance regarding—if a plan offers both Part D and Part B pharmacy benefits to its members—the Part B pharmacy drug claims process if the provider is on the preclusion list. Specifically, the commenter questioned whether the Part D processed claims will reject but Part B drug claims will be allowed to process. The commenter stated that beneficiaries may be confused if some of their claims involving a precluded provider are denied while others are processed. Another commenter, too, sought clarification as to whether MA or MA–PD plans should deny payment of Part B pharmacy prescriptions written by a precluded provider. This commenter cited the example of a beneficiary who presents a pharmacy with two prescriptions from a precluded prescriber—one for a Part D drug and one for a Part B drug; the commenter questioned whether the pharmacy should reject one prescription (Part D) and fill the other prescription (Part B).

Response: We believe this situation is likely to be rare, provided that plans are applying the preclusion list to all claims submitted by both contracted and non-contracted providers. However, we acknowledge that such a situation could arise and, if it did, would cause confusion for beneficiaries and pharmacies. To reduce confusion, therefore,, if the prescriber or provider is precluded, the plan will be prohibited from making payment regardless of whether the drug is a Part B or D drug. After consideration of these comments, we will modify the language in § 422.222(a)(1)(i) that reads ''health care item or service furnished'' to instead state ''health care item, service, or drug that is furnished, ordered, or prescribed''. To ensure consistency with this revision, we will make similar edits to § 422.222(a)(1)(ii)(A) and (C) and to 422.504(g)(1)(iv); specifically, we will include therein, as applicable, references to ''ordered,'' ''prescribed,'' and ''drugs.''

Comment: A commenter requested that CMS clarify whether the proposed replacement of the term ''individual'' with ''prescriber'' in § 423.120(c)(6) means that: (1) Type 2 NPIs—when submitted on the PDE—can be accepted as a valid submission on claims; and (2) any valid NPI—whether Individual or Organizational—can be used to adjudicate claims.

Response: Based on comments we received regarding this proposed change, we are concerned that such a revision will cause confusion that will outweigh the proposal's objective. Indeed, we note that the policy that Part D plans submit PDEs with Type I NPIs is a long-standing one that supports an important program integrity goal. For

these reasons, we are not finalizing this proposal.

Comment: Several commenters recommended that CMS explain the scope of the Part D preclusion list, indicate whether and how it applies to pharmacies, and make any necessary regulatory revisions. A commenter requested that the regulatory text clarify whether CMS intends to add to the preclusion list those pharmacies that do not prescribe drugs to Part D members but do fill member prescriptions. The commenter contended that the applicable preclusion list regulations require the denial of payments to precluded prescribers but do not extend to pharmacies that fill member prescriptions. The commenter also requested that CMS limit the preclusion list to those pharmacies that are prescribers until the regulations are modified. The commenter stated that the inclusion of non-prescribing pharmacies on the preclusion list risks exposing plan sponsors that deny payments to such pharmacies to legal claims in light of, the commenter contended, the lack of regulatory authority for those denials.

Response: Although pharmacies are indeed on the preclusion list, the regulations at 422.222 only apply to pharmacy claims for Part A or B drugs covered under Part C and supplemental items or services furnished by the pharmacy (that is, they will not affect the pharmacy's ability to dispense Part D drugs so long as the prescription is not from a precluded prescriber). Coverage of Part D drugs, whether by an MA–PD or stand-alone Part D plan, are addressed in 423.120. As such, we decline to add this requirement to regulatory text. We note that the application of these requirements to pharmacies in Part C and not Part D is due to the supplemental pharmacy benefits offered by some Part C plans. We also clarify that Part A and B drugs are typically not dispensed by the pharmacy under Part C but are furnished by the Part C provider.

Comment: A commenter stated that in its December 14 FAQ, CMS mentions that Part D plans are expected to remove precluded pharmacies from their network. However, the commenter contended, the FAQ did not furnish additional information (including the necessary rulemaking) for such a decision to be made; the FAQ, the commenter stated, merely references ''future rulemaking'' and does not contain legal authority for such terminations.

Response: The November 2, 2018 CMS-issued HPMS memo entitled ''Preclusion List Requirements'' (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html.*) suggests that Part D plan sponsors remove precluded pharmacies from their network as soon as possible. Thus, there is no formal requirement that Part D plan sponsors do so.

(10) Implementation Timeframe

Comment: A number of commenters urged CMS to delay implementation of all of the preclusion list requirements in their entirety (including those in the April 2018 final rule) until January 1, 2020. A commenter stated that the preclusion list policies place an extreme strain on plans' resources, especially given the end-of-year testing. Other commenters stated that CMS has not furnished sufficient responses to stakeholders' questions and has not provided adequate guidance. This, they contended, leaves numerous issues open to interpretation, which will result in beneficiary and plan confusion. To efficiently implement these rules, these commenters added, a delay until January 1, 2020 is essential. Another commenter stated that while CMS has issued guidance regarding the preclusion list, a significant number of outstanding matters remain; these must be resolved before the preclusion list can be implemented. An additional commenter expressed concern that the varying effective dates (and contradictory requirements) concerning preclusion list implementation will confuse beneficiaries, providers, prescribers, and plans. This commenter and others added that such confusion, combined with a hasty implementation, could also harm beneficiaries who are unable to access medications or needed services. Other commenters suggested an effective date for all preclusion list requirements that is: (1) At least 18 months after CMS publishes the necessary technical guidance and confirmed file layouts; (2) at least 18 months after the publication date of this final rule; (3) at least 1 year after the consolidation of the issues covered in multiple CMS guidance documents; or (4) sometime after CMS engages with stakeholders to address outstanding operational and logistical challenges.

Response: We appreciate these comments and understand the sentiments raised. We must, however, respectfully decline to delay the implementation of the preclusion list as the commenters suggest. It is imperative that the preclusion list process commence as soon as possible so as to protect the Medicare program and beneficiaries from fraud, waste, and abuse. We believe that a delay until January 1, 2020 or later would be inconsistent with our obligations to safeguard the Trust Funds and to ensure that payments are made correctly. Nonetheless, we will closely monitor the preclusion list's progress throughout 2019 and continue engaging regularly with all stakeholders to facilitate as smooth an implementation as possible.

Comment: While recommending a January 1, 2020 implementation date for all of the preclusion list requirements, several commenters suggested that CMS could instead exercise enforcement discretion in 2019 against Medicare plans for good-faith efforts they make to implement the preclusion list rules finalized in the April 2018 rule. A commenter added that CMS could refrain from sanctioning plans that fall short of implementing the preclusion list requirements until CY 2020. In a similar vein, a commenter stated that CMS should not enforce the preclusion list requirements (1) before January 1, 2020 and (2) until CMS has released guidance that clarifies the outstanding operational issues.

Response: As stated, we respectfully decline to establish a January 1, 2020 effective date for all of the preclusion list provisions. We continue to believe it is imperative to implement the preclusion list requirements as soon as possible in order to protect Medicare beneficiaries and the Trust Funds.

Comment: A commenter urged CMS not to implement the provisions in the proposed rule.

Response: As explained previously, we believe that the provisions outlined in the proposed rule are necessary to ensure that the preclusion list process satisfies our program integrity objectives without unnecessarily burdening stakeholders.

Comment: Several commenters supported the January 1, 2020 effective date for the provisions in the proposed rule.

Response: We appreciate the commenters' support, though we note that our consolidated appeals provisions will become effective 60 days after the publication of this rule.

Comment: A commenter supported having all of the proposed preclusion list provisions become effective and applicable beginning 60 days after their publication in a final rule.

Response: While we appreciate this comment, we would prefer to give stakeholders until January 1, 2020 to prepare for the provisions we are finalizing in the rule (excluding the consolidated appeals policy).

(11) Beneficiary Liability

Comment: A commenter expressed concern about the potential financial liability of beneficiaries for precluded out-of-network providers. While supporting the proposed requirement that an MA contract with CMS state that a MA enrollee must not have any financial liability for items or services furnished to the beneficiary by a precluded MA-contracted individual, the commenter noted that this would not extend to out-of-network providers. In addition, the commenter stated that the proposed rule does not allow a beneficiary to appeal a payment denial based upon a provider's inclusion on the preclusion list. Coupled together, the commenter stated, a beneficiary may have financial liability but no administrative recourse. Regarding beneficiary appeals and liability, another commenter recommended that CMS either: (1) Allow a beneficiary to appeal a payment denial for precluded out-of-network providers; or (2) require language in the proposed advance written notice to the beneficiary of his or her financial liability if he or she continues to receive services from the out-of-network provider.

Response: We thank the commenter for the support for our proposal to minimize enrollee liability for payments to network providers. We are finalizing this requirement in § 422.504(g)(1)(iv) with several grammatical revisions; we are adding the language ''Ensure that'' to the beginning of the paragraph to ensure that it properly and grammatically flows from the closing wording of the opening paragraph of § 422.504(g). In addition, as previously explained, we are adding references to ''ordered,'' ''prescribed,'' and ''drugs'' to this new paragraph in the regulation.

In addition to the protection described in § 422.504(g)(1)(iv), we also proposed and are finalizing that the prohibition on payment to a precluded provider under § 422.222(a) must begin only after advance written notice to enrollees that a provider from whom the enrollee has previously received services is on the preclusion list. As finalized at § 422.222(a)(1)(ii)(A), plans are required to provide at least 60 days' notice to enrollees within 30 days of the posting of an updated list. We believe this timeframe will allow enrollees sufficient time to locate a new provider and avoid seeking further services from a precluded provider and any potential financial liability that may result. We believe that this advance written notice and delay as to when an MA plan is prohibited from paying a precluded provider will ensure appropriate protection of the beneficiary.

CMS believes most plans will remove precluded providers and prescribers from their networks upon identifying them. Therefore, as required by § 422.222(a)(1)(ii)(A) and consistent with § 422.111(e), MA plans that choose to terminate a precluded provider must make a good-faith effort to furnish enrollees with at least 30 days' advance notice of the termination of a network provider. Further, upon the expiration of the 60-day period (at which point both the provider and beneficiary have been notified of the preclusion), if the provider is terminated from the plan's network but seeks payment from the Medicare beneficiary, the provider would be in violation of section 1848(g)(4)(A) of the Act. If the provider remains in the plan's network, however, the provider is bound to the contractual requirements within the provider's contract, with the plan prohibiting the provider from seeking payment from the beneficiary in cases where the plan denies requests for reimbursement due to the provider's precluded status. Because the beneficiary's liability would be dependent on what action the plan takes in regard to the provider's MA contract (for they are not required to terminate the MA contract in order to operationalize the payment prohibition), we believe it would be inaccurate to add language to the notice regarding the beneficiary's potential liability and therefore decline to do so.

In addition, with respect to services received from a non-contracting precluded provider, the MA plan must notify the enrollee that the provider is precluded and include in that notification the date on which the plan will not pay any further claims from that precluded provider.

Comment: A commenter stated that CMS should clarify the point at which MA plans should terminate providers. The commenter explained that MA plans may need or prefer to remain contracted with a provider for a short period of time for various reasons. The commenter stated that: (1) A requirement to terminate a contract while payments are still being made would unnecessarily complicate delivery of the plan benefit; and (2) plans should be able to retain contractual protections for themselves (including contractual obligations imposed on providers and agreed-upon pricing terms) while they are still making payments. Moreover, the commenter stated that allowing termination up until denial of the claims would conform to: (1) CMS' requirement to notify members that a plan is terminating a network provider; and (2) similar state laws.

Response: Our final rule at § 422.222 does not require an MA plan to terminate a provider from its network if or when the provider is placed on the preclusion list. Provider termination is a decision for the MA plan. MA plans may, however, not pay a precluded provider for services rendered to plan enrollees after the 60–90 day beneficiary notification period has expired.

Comment: A commenter expressed concern regarding the proposal that an MAO's contract with CMS provide that a member shall not have any financial liability for services or items furnished by a contracted provider on the preclusion list. The commenter explained that this provision would confront plans with inconsistent requirements—specifically, that plans must not pay providers' claims while also requiring that they hold members harmless if the provider bills the member. If the provider indeed does the latter, the commenter continued, plans might have to pay the provider (so as to hold the member harmless); this would conflict with the requirement not to pay a claim. Alternatively, plans might have to reimburse a member who has paid the provider, effectively allowing the provider to circumvent the preclusion list. The commenter recommended that, in lieu of the ''hold harmless'' provision, CMS should either: (1) Prohibit the precluded provider from billing or otherwise seeking payment from the member; or (2) make the ''hold harmless'' obligation inapplicable (i) to services and items furnished by precluded providers after their contracts have been terminated or (ii) to claims the MAO must deny under § 422.222(a)(1).

Response: Under § 422.222(a)(1)(ii)(C), the MA plan may pay precluded providers for up to 60 days after the MA plan has notified enrollees that the provider has been precluded. We anticipate that MA organizations will also use this period to assist affected enrollees in transitioning to new providers or, if a new primary care provider is necessary for the enrollee to access plan covered services, to assign a new primary care provider to each affected enrollee. The plan's ability to pay a provider for up to 60–90 days after preclusion will not violate the MAO's contract with CMS and is an important beneficiary protection. At the conclusion of the 60-day period, the provider will no longer be eligible for payment from the plan and will be prohibited from pursuing payment from the beneficiary as stipulated by the terms of the contract between CMS and

the plan per 422.504(g)(1)(iv). Therefore, the provider would hold financial liability for furnished, ordered, or prescribed services and items after the close of the 60 day period, at which point the provider and the beneficiary would have already received notification of the preclusion. To formally incorporate this policy in regulatory text, we are also finalizing a new paragraph (g)(1)(v) in § 422.504; this paragraph requires that the MA plan's provider agreements contain a provision acknowledging the preclusion list requirements, prohibiting the precluded network provider from seeking payment from the enrollee, and providing that the provider will hold financial liability for any items, services, or drugs the provider furnishes, orders, or prescribes after the prohibition on payment begins (*i.e.,* after expiration of the 60–90 day period). This will make clear that the MA organization must agree to this requirement.

If the MA organization's participation agreement with the precluded provider is terminated, we recognize that the MA organization will not have a contractual means to prohibit the precluded provider from seeking payment directly from the enrollee. We encourage MA organizations to provide sufficient information and assistance to enrollees so that they look for new providers from whom to receive covered services. We further clarify that once the 60-day period ends and the provider's network contract has been terminated (at which point both the provider and beneficiary have been notified of the preclusion), there is no legal mechanism to apply the hold harmless provision nor would CMS or the plan be able to prohibit the provider from seeking payment from the beneficiary.

Comment: A commenter concurred with the proposal that the beneficiary be held harmless for financial liability if his or her provider is included on the preclusion list. Noting that the policy only applied to contracted providers, however, the commenter stated that members who use non-contracted providers that are included on the preclusion list are vulnerable to inappropriate demands for payments sent directly to them by unscrupulous providers. The commenter added that further communication and transparency concerning all providers on the preclusion list would help minimize inappropriate billing.

Response: We concur with the commenter and will work with stakeholders, including the plans and beneficiary groups, to consider effective means of preventing the situations that the commenter describes.

Comment: While supporting the limitation on beneficiary liability, a commenter encouraged CMS to expand this protection to non-contracted entities in the following two circumstances: (1) When the provider was a contracted individual or entity prior to their preclusion but whose contract was terminated as a result of the preclusion; and (2) when the MA is a PPO and offers out-of-network coverage.

Response: As noted in the previous response, we will work with stakeholders regarding effective methods to protect beneficiaries who, through no fault of their own, receive services from a precluded provider. We continue to believe, however, that the notification of enrollees and the period available to pay precluded providers will ensure that most MA patients of a precluded provider will have sufficient time to transition to a new qualified provider who can be paid by their MA plan. In regard to the commenter's suggestion of expanding the limitation on beneficiary liability, we note that once a provider's network contract is terminated, there is no legal mechanism to apply the hold harmless provision nor would CMS or the plan be able to prohibit the provider from seeking payment from the beneficiary.

(12) Appeals

Comment: Several commenters expressed support for the proposals to: (1) Shorten the preclusion list appeal timeframe from 9 months to 5 months; and (2) place providers and prescribers on the preclusion list after their first level of appeal. In both of these cases, a commenter stated, CMS has taken common sense steps to reduce administrative burden on MAOs and Part D plans, to ensure that precluded providers and prescribers do not continue to provide care and/or prescribe medications, and to consider the best interests of beneficiaries.

Response: We appreciate the commenters' support.

Comment: A commenter stated that notwithstanding the proposal that beneficiaries may not appeal a payment denial based on their provider's or prescriber's preclusion, CMS recently issued different guidance. Specifically, the commenter stated that in a December 14 FAQ, CMS declined to inform beneficiaries of their lack of appeal rights but stated that an enrollee may seek a coverage decision from the plan if there is a question regarding coverage for an item, service, or drug. The commenter accordingly sought clarification on a number of issues: (1) Whether enrollees will be permitted to appeal the denial of a claim (due to a provider's preclusion) during CY 2019 given that beneficiary appeals were not addressed in the April 2018 final rule applicable to CY 2019; (2) if the answer to the prior issue is yes, how CMS intends to notify beneficiaries of the change in policy for CY 2020; (3) whether, based on the language in the December 14 FAQ, the determination of a provider's preclusion constitutes a coverage decision that is subject to standard appeal rights; and (4) whether a beneficiary who did not receive notice that his or her provider was excluded and accordingly continued to use that provider could appeal the denial of the claim. Another commenter also raised the first, second, and fourth issues, while questioning whether the beneficiary can at least appeal the denial of the claim (given that he or she cannot appeal the provider's preclusion status).

Response: We clarify that the cited guidance was issued based on the April 2018 final rule. Therefore, that guidance is not fully applicable to this final rule and the amendments we are making to §§ 422.222 and 423.120.

A Part D claim that is rejected at the point-of-sale does not constitute a coverage determination; thus, there are no Part D appeal rights. As with claims from prescribers on the OIG exclusion list, a claim rejected at point-of-sale because the prescriber is on the preclusion list does not return the 569 reject code. In other words, the network pharmacy does not deliver the pharmacy notice that instructs an enrollee how to request a coverage determination. As previously noted in this preamble, a claim rejection at point-of-sale due to preclusion is not a Part D coverage determination, so the enrollee would not have appeal rights. This having always been the case, nothing has changed between CY 2019 and CY 2020. As previously stated in this preamble, we are finalizing § 422.222(a)(4) to state that a beneficiary enrolled in an MA plan (or a cost plan or PACE organization under the incorporation of the MA regulation into those programs at §§ 417.478 and 460.86) will not be able to appeal a payment denial that is based on an individual or entity's placement on the preclusion list.

Finally, we note that § 422.222(a)(1)(ii)(A), as amended by this final rule, requires an MA plan to issue a notice to affected enrollees when a provider is placed on the preclusion list. The prohibition on payment will begin the earlier of 60 days after this notice or 90 days after the provider was placed in the preclusion list. An MA plan that fails to provide the notices required by this regulation will be in violation of its responsibilities such that CMS may take necessary enforcement action.

Comment: A commenter supported making the proposed appeals process effective 60 days after publication of this final rule.

Response: We appreciate the commenter's support.

Comment: A commenter urged CMS to permit limited beneficiary appeals of denials of claims based upon a provider or prescriber's preclusion. The commenter stated that if the beneficiary notice required at § 422.222(a)(1)(ii)(A) described previously was incomplete or ineffective, the beneficiary should not be responsible for payment. The commenter added that CMS should consider mechanisms to protect beneficiaries from liability in such circumstances.

Response: Under the regulation we are finalizing at § 422.222(a)(4), denials of payment based on a provider's or prescriber's preclusion cannot be resolved through the beneficiary appeals process as outlined in Subpart M of 42 CFR part 423. If payment is denied because of the prescriber's or provider's preclusion, the enrollee should find another provider in the area to furnish these services and to contact the plan if assistance is needed. (This is explained in the beneficiary notice.) Further, a request for payment by a contract provider where an enrollee is held harmless does not constitute an organization determination.

Concerning an incomplete or ineffective notice, the provider or prescriber would still have been made aware of the preclusion. Indeed, this further supports our rationale for allowing claims to be paid without penalty for 60 days following the issuance of the notice to the beneficiary.

In regard to Part C, following the 60-day period and once a provider's network contract is terminated, there is no legal mechanism to apply the hold harmless provision nor would CMS or the plan be able to prohibit the provider from seeking payment from the beneficiary if the provider is terminated from the plan's network. However, if the provider remains in the plan's network, the provider must comply with contractual requirements prohibiting the provider from seeking payment from the beneficiary in cases where the plan denies requests for reimbursement due to the provider's precluded status.

We are finalizing our proposed changes concerning appeals with one exception. We are deleting the phrase ''by CMS'' in proposed § 422.222(a)(2)(ii)(B) and § 423.120(c)(6)(v)(B)(*2*). This is to clarify that Administrative Law Judges and the Department of Appeals Board, which, as applicable, consider the appeals in question, are not part of CMS.

(13) Miscellaneous Comments

Comment: A commenter suggested that the relevant notice provisions and payment preclusions in § 422.222(a)(1) be referenced in the PACE regulation by including an explicit cross reference in § 460.86. This would, the commenter stated, ensure that PACE organizations know where in the CFR to find more detailed requirements related to the preclusion list.

Response: We appreciate this comment and may consider it for future rulemaking. At this time, we believe that the PACE regulation is sufficient. We explained in the April 2018 final rule, in our proposed rule, and in this final rule how the requirements in § 422.222 are incorporated into the requirements for the PACE program.

Comment: A commenter supported the discretion given to plans to not include a particular prescriber on the preclusion list when CMS determines that exceptional circumstances exist regarding beneficiary access to prescriptions. The commenter recommended that CMS also provide similar discretion to MA plans when CMS determines the previously referenced exceptional circumstances exist.

Response: We clarify that only CMS has the discretion not to place a provider on the preclusion list due to access to care concerns. Plans can notify CMS if they believe there will be access to care issues by removing a particular provider from their network, and CMS will notify the plan of its determination regarding the preclusion. Nonetheless, we agree with the commenters' general rationale that an exception should be made for MA regarding access to care concerns. We are therefore adding a new paragraph (a)(6) to § 422.222 that mirrors the access to care exception provided at § 423.120(c)(6)(vi); specifically, CMS will have the discretion not to include a particular individual or entity on (or, if warranted, remove the individual from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to MA items, services, or drugs. In making a determination as to whether such circumstances exist, CMS takes into account: (i) The degree to which beneficiary access to MA services, items, or drugs would be impaired; and (ii) any other evidence that CMS deems relevant to its determination.

Comment: Concerning the 10-year period for the preclusion list, a commenter recommended that CMS set a lower default preclusion period of 3 years and use aggravating or mitigating factors to adjust the period as applicable. The commenter was concerned that under the proposed rule, any felony conviction automatically defaults to a 10-year preclusion period. Consistent with the March 1, 2016 proposed rule published in the **Federal Register** titled ''Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process'' (CMS–6058–P), the commenter stated that the 10-year period should be maximum, not mandatory, unless the party in question is excluded by the OIG for a longer period. The commenter stated that the 10-year default period is greater than the OIG mandatory exclusion of 5 years and the general default of 3 years of permissive exclusions. Moreover, the commenter stated, OIG mandatory exclusions only cover specific conduct and not all felonies. The commenter added that CMS should provide parameters regarding what types of felonies fall under this section; the commenter stated that this would be consistent with felony determinations under § 424.535(a)(3).

Response: We note that our proposed provisions do not automatically require a 10-year preclusion list period for every felony conviction. Under proposed § 423.120(c)(6)(vii), for instance, a 10-year period will be used unless CMS determines that a shorter timeframe is warranted based upon CMS' consideration of several factors. In each case, CMS will examine whether a period of less than 10 years is justified. Insofar as the types of felonies that may come within the purview of these provisions, we will consider further clarification via sub-regulatory guidance.

Comment: Several commenters stated that, according to their understanding, CMS would undertake a three-step process for implementing the preclusion list: (1) Beginning on January 1, 2019, the preclusion list will go into effect without the proposals outlined in the proposed rule; (2) 60 days following

publication of CMS–4185–F, Medicare plans will be required to implement the new consolidated appeals provisions; and (3) any other changes in the proposed rule that are eventually finalized will not become effective until January 1, 2020. The commenters expressed several concerns about this process. First, they believed that it saddles Medicare plans with managing multiple deadlines and effective dates despite long-term planning already underway. Second, the process involves changing and uncertain rules, which could confuse stakeholders (including beneficiaries) as to which policies apply at which time (for example, a beneficiary may be uncertain as to whether or when he or she has appeal rights); this, the commenters believed, could interrupt beneficiary care and cause beneficiary frustration with their Medicare plans and providers.

Response: While we appreciate the commenters' concerns, we stress that we have worked very closely with the plans and other stakeholders to: (1) Prepare them for the preclusion list's implementation; and (2) develop sub-regulatory guidance to address their questions. We are closely and diligently monitoring the progress of the implementation. We will continue regular communication with stakeholders and expeditiously address issues if or as they develop.

Comment: A commenter stated that the previously mentioned HPMS memo sought to impose requirements that go beyond the provisions of the April 2018 final rule. The commenter contended that: (1) These additional requirements must be promulgated through notice-and-comment rulemaking; and (2) CMS should withdraw the HPMS memo and/or clarify that it does not create binding requirements.

Response: We respectfully disagree. The HPMS memo focuses on operational details that are most appropriately developed and disseminated through sub-regulatory guidance.

Comment: Several commenters supported CMS' elimination of the provider enrollment requirements for MA providers and Part D prescribers.

Response: We appreciate the commenters' support.

Comment: A number of commenters supported the implementation of the preclusion list requirements as a whole.

Response: We appreciate the commenters' support.

Comment: Numerous commenters stated that CMS must work with the industry and other stakeholders to help ensure smooth execution of the preclusion list with as little disruption in beneficiary care as possible.

Response: We agree with the commenters. We have worked closely with stakeholders to ensure an effective implementation of the preclusion list and will continue to do so.

Comment: Several commenters stated that CMS must make certain that the preclusion list: (1) Is updated frequently to minimize the time between when a provider is precluded and the time that information is available to plans and providers; and (2) contains information needed to properly identify a precluded prescriber (for example, an NPI).

Response: We agree with the commenters. We are striving to ensure that preclusion list updates are appropriately made and that the preclusion list file contains sufficient identifying data.

Comment: A commenter questioned whether Medicare plans will be limited in the number of users granted access to the preclusion list. The commenter stated that PBMs that process and pay claims and others need access to this file. Although the commenter contended that CMS indicated in its December 14 sub-regulatory guidance that it will not grant access to the preclusion list to PBMs, the commenter urged CMS to reconsider this position, perhaps by making the preclusion list public.

Response: We state respectfully that CMS will not make the preclusion list public. The list contains sensitive data (such as revoked provider information), and CMS historically has not shared this information publicly. Nonetheless, CMS is exploring secure means (other than public release) to make the data available to PBMs and other plan subcontracted entities.

Comment: A commenter recommended that CMS work with plans to develop an automated process so that preclusion list requirements can be better implemented and operationalized.

Response: We are always receptive to plan feedback regarding file delivery and format. We are available to work with plans to implement enhancements that would make the process more efficient. We believe, however, that such enhancements are best considered once a baseline has been implemented by the applicable deadline.

Comment: A commenter urged CMS to encourage plans to educate beneficiaries about the preclusion list so that the latter understand the concept before they perhaps encounter it.

Response: We agree and have indeed suggested that plans educate their enrollees regarding the preclusion list for the reason the commenter states.

Comment: A commenter questioned whether there will be a link to the preclusion list or whether CMS will transmit the list to plans and MA organizations.

Response: Plans are granted access to the list via a secure website and file transfer process.

Comment: A commenter encouraged CMS to be flexible in overseeing and enforcing the preclusion list, for stakeholders have been using their best efforts to comply with the changing requirements and need time to acclimate to the new processes.

Response: We appreciate this comment and recognize that stakeholders have been making efforts to prepare for the preclusion list's implementation. We will closely monitor the progress of this implementation.

Comment: A commenter contended that the proposed changes (especially the reduced timeline for the mandatory denial of claims) will cause several difficulties without enhancing program integrity. First, they will significantly increase plan administrative costs. Second, beneficiaries could be harmed due to disruptions in their medication. Third, beneficiaries could become dissatisfied with the timeframes in which they must seek a new provider. Fourth, the proposed rule contains no protections that could mitigate the above-referenced problems. The commenter accordingly recommended that CMS retain the standards established in the April 2018 final rule and engage MAOs (and other stakeholders) in developing means of aligning preclusion list processes with those for the OIG exclusion list.

Response: While we appreciate the commenter's concerns, we believe the changes in this rule facilitate a more patient-minded approach. We reiterate that enrollees will have 60–90 days' prior notification that their provider is precluded. During that period, claims and prescriptions associated with the precluded provider can be paid by the Part C or D plan. This will give the enrollee time to transfer to a new, non-precluded provider. Indeed, we note that Part C and D plans are currently prohibited from paying for claims and prescriptions associated with excluded providers. The additional administrative burden for a plan to check the preclusion list is not, in our view, a significant new requirement. While this rule establishes a beneficiary notice timeframe, we have simultaneously streamlined the date that a plan is to reject/deny claims for each version of the monthly preclusion list, rather than require plans to track timeframes for

rejections/denials on a beneficiary basis. If plans were required to implement the preclusion list in the manner that the OIG exclusion list is operationalized, there may be no beneficiary notification period. For these reasons, we respectfully decline to adopt the commenter's suggestion.

Comment: A commenter stated that there is insufficient technical guidance for dual-eligible special needs plans (D–SNPs), their PBMs, and other delegated entities to sufficiently test and implement the preclusion list process by January 1, 2019. The commenter urged CMS to extend the first review period for D–SNPs to at least 180 days; this would enable D–SNPs and CMS to ensure that systems are appropriately configured and operational policies established prior to any payment denials.

Response: We believe that the commenter is suggesting a minimum 180-day delay in the implementation of the preclusion list as a whole. As stated previously, we respectfully decline to do so. However, we will work closely with D–SNPs concerning this implementation and will issue sub-regulatory guidance to assist D–SNPs in this regard.

Comment: A commenter questioned whether any of the fields are conditionally required (for example, whether a date of birth for businesses or an EIN is required).

Response: CMS will issue sub-regulatory guidance on this issue as soon as feasible.

Comment: A commenter questioned whether there is a communication process for questionable data records (for example, for missing required fields such as an NPI or a missing effective date).

Response: CMS has issued sub-regulatory guidance that clarifies the process for communicating questionable data records. It can be accessed at the following link: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html.*

Comment: A commenter sought clarification as to when PDE guidance will be available.

Response: We refer the commenter to the PDE guidance issued in the previously referenced HPMS memorandum, ''February 2019 Updates to the Drug Data Processing System (''DDPS''),'' dated January 8, 2019 and released January 9, 2019.

Comment: A commenter stated that the proposed rule lacks a ''look-back'' period indicating which plan members must be notified of a precluded provider. The commenter recommended that CMS revise proposed §§ 422.222(a)(1)(ii)(A) and 423.120(c)(6)(iv)(A) to clarify that plans need only notify a member who has received services from a precluded provider in the 12 months prior to the date the provider was added to the preclusion list. Codifying a ''look back'' period in regulation, rather than merely via sub-regulatory guidance, will provide clarity to plans.

Response: While we appreciate this suggestion, we respectfully decline to establish a formal look-back period in this rule. We must retain the flexibility (especially during the early stages of the preclusion list's implementation) to carefully monitor the program and to make any revisions (such as a look-back period) only after a careful deliberation.

Comment: Several commenters stated that CMS should clarify each of the provider types and specialties that will be on the list.

Response: We appreciate this comment and may consider furnishing such clarification, as needed, in subregulatory guidance.

Comment: Several commenters recommended that CMS detail the data sources used to place dentists who have never enrolled in Medicare on the preclusion list.

Response: Using CMS' internal data and systems (which includes, but is not limited to, the Provider Enrollment, Chain, and Ownership System and the National Plan and Provider Enumeration System), we will screen any prescriber or provider that could potentially prescribe Part D drugs or furnish MA services or items to a Medicare beneficiary through an MA plan.

Comment: Several commenters recommended that when CMS notifies providers that they are precluded, CMS should require those providers to inform patients that they do not accept Medicare beneficiaries and that their claims will not be processed. A commenter believed that this approach would be particularly appropriate if there is no claim history (for example, new patient or referral) and thus no ability for plans to notify beneficiaries.

Response: We appreciate this comment and may consider it for future rulemaking as appropriate.

Comment: Several commenters urged CMS to clarify whether urgent and emergency services are exempt from the requirement that MA plans and delegated entities deny claims for services furnished by precluded providers.

Response: Urgent and emergency services are not exempt from the claim denial requirements of § 422.222.

Comment: A commenter expressed support for the proposals to add language to the regulatory text concerning the following policies: (1) Beneficiaries may not appeal payment denials based on a provider's preclusion; and (2) unenrolled prescribers and providers should remain precluded for the same length of time as the reenrollment bar that CMS could have imposed had that prescriber or provider been enrolled and then revoked.

Response: We appreciate the commenter's support.

Comment: A commenter contended that CMS' proposed changes to its preclusion list policies would create additional complexities and be of limited value. The commenter added that the separately required beneficiary notices (and the claims denial deadlines triggered thereby) are inconsistent with CMS' goal of operationalizing the preclusion list in the same manner as the OIG exclusion list. Under the exclusion list process, the commenter stated, CMS makes the exclusion list public, updates it monthly, posts it 15 days prior to the exclusion effective date, and expects plans to deny claims as of the effective date. The commenter suggested that CMS make the preclusion list public and implement it similar to the exclusion list. This approach, the commenter believed, would alleviate inconsistencies and stakeholders' concerns.

Response: For reasons stated previously, CMS is unable to make the preclusion list public. Moreover, we do not believe it is possible to implement the preclusion list in a fashion that mirrors the OIG exclusion list. We believe that the preclusion list, upon full implementation, will impact a much larger provider population than the OIG exclusion list, for the intent of the preclusion list was to create an effective alternative to enrollment. The criteria for a provider to become precluded are therefore different and broader than those for exclusion. For this reason, we believe the beneficiary notice period is essential to protect beneficiaries from major disruptions of care. We note also that CMS has added data fields to the file to increase consistency between the notification period and the claims rejection/denial date.

Comment: A commenter questioned whether a provider must inform beneficiaries if they learn that another provider has been excluded. The commenter cited the example of a beneficiary who attempts to fill a prescription at a pharmacy retail location and the prescription is denied

due to the provider being excluded. The commenter sought clarification concerning the pharmacy's responsibility (if any) to notify the beneficiary of the excluded provider.

Response: We appreciate this comment but believe it is outside the scope of this rule.

Comment: Several commenters noted that in an FAQ issued December 14, 2018 (see (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html.*), CMS stated that subcontractors will not be granted access to the preclusion list and that MAOs will have to share the list with subcontractors as needed. Some subcontractors, the commenters noted, process all claims and credentialing activities, which makes direct access to the preclusion list imperative. Without such access, the commenters stated, downstream entities will have to work through MA organizations, which could delay enrollee notification. In sum, the commenters requested that: (1) Subcontractors and delegated entities be provided access to the preclusion list; and (2) the enforcement date for subcontractors to use the preclusion list be delayed until subcontractors have access to it.

Response: As explained earlier, CMS is unable to publicize preclusion data. However, CMS is exploring other secure means of making the data available to PBMs and other plan subcontracted entities. We must, however, respectfully decline to delay the implementation of the preclusion list as the commenter suggests.

d. Final Provisions

Given the foregoing, we are finalizing all of our proposed preclusion list provisions as proposed except as follows:

- Our proposed revisions to § 423.120(c)(6)(i), (ii), and (vi) that would change the term ''individual'' to ''prescriber'' will not be finalized.
- Our proposed change of the phrase ''individual NPI of the prescriber'' to ''NPI of the prescriber'' in § 423.120(c)(6)(iii) will not be finalized.
- In § 422.222(a)(1)(i), we are changing the language ''health care item or service furnished'' to ''health care item, service, or drug that is furnished, ordered, or prescribed''. We are making similar edits to § 422.222(a)(1)(ii)(A) and (C) and to § 422.504(g)(1)(iv); specifically, we will include therein, as applicable, references to ''ordered,'' ''prescribed,'' and ''drugs.''
- We are deleting the phrase ''by CMS'' in proposed § 422.222(a)(2)(ii)(B) and § 423.120(c)(6)(v)(B)(*2*). This is to clarify that Administrative Law Judges and the Department of Appeals Board (which would, applicable, consider the appeals in question jointly) are not part of CMS.
- We are clarifying the opening paragraphs of §§ 423.120(c)(6)(iv) and 422.222(a)(1)(ii) to state that §§ 423.120(c)(6)(iv) and 422.222(a)(1)(ii) do not apply if the prescriber or provider is currently excluded by the OIG.
- We are revising §§ 423.120(c)(6)(iv)(B) and 422.222(a)(1)(ii)(B) as follows:

++ The existing versions of these paragraphs will be incorporated into new paragraphs §§ 423.120(c)(6)(iv)(B)(*1*) and 422.222(a)(1)(ii)(B)(*1*), respectively. Also, we are inserting the following language at the beginning of these respective new paragraphs: ''Subject to paragraph (c)(6)(iv)(B)(*2*) of this section'' and ''Subject to paragraph (a)(1)(ii)(B)(*2*) of this section''.

++ In new paragraphs §§ 423.120(c)(6)(iv)(B)(*2*) and 422.222(a)(1)(ii)(B)(*2*), we will state that paragraph (B)(*1*) will apply only upon receipt of a claim from, respectively, a precluded provider (either contracted or non-contracted) in Medicare Part C or upon a prescriber writing a prescription in Medicare Part D when: (i) The MA organization or plan sponsor has enough information on file to either copy the provider or prescriber on the notification previously sent to the beneficiary or send a new notice informing the provider or prescriber that they may not see plan beneficiaries due to their preclusion status; and (ii) the claim is received after the claim denial or reject date in the preclusion file.

- To clarify the applicability of § 422.222, we are changing the title of this section from ''Preclusion list'' to ''Preclusion list for contracted and non-contracted individuals and entities.''
- We are adding a new paragraph (a)(6) to § 422.222 that would mirror the existing version of § 423.120(c)(6)(vi) and state as follows:

++ The opening paragraph will read: ''CMS has the discretion not to include a particular individual or entity on (or, if warranted, remove the individual or entity from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to MA items, services, or drugs. In making a determination as to whether such circumstances exist, *CMS* takes into account''

++ Paragraph (a)(6)(i) will read: ''The degree to which beneficiary access to MA items, services, or drugs would be impaired; and

++ Paragraph (a)(6)(ii) will read: ''Any other evidence that CMS deems relevant to its determination.''

++ We are adding the language ''Ensure that'' to the beginning of § 422.504(g)(1)(iv).

++ We are adding a new § 422.504(g)(1)(v) that would state as follows: ''Ensure that the plan's provider agreement contains a provision stating that after the expiration of the 60-day period specified in § 422.222:

—The provider will no longer be eligible for payment from the plan and will be prohibited from pursuing payment from the beneficiary as stipulated by the terms of the contract between CMS and the plan per § 422.504(g)(1)(iv); and

—The provider will hold financial liability for services, items, and drugs that are furnished, ordered, or prescribed after this 60-day period, at which point the provider and the beneficiary will have already received notification of the preclusion.''

D. Implementing Other Changes

1. Clarification Regarding Accreditation for Quality Improvement Programs

Section 1852(e)(4) of the Act requires the Secretary to deem that an MA organization has met all of the requirements for any one out of the six program areas listed in section 1852(e)(4)(B) of the Act if the MA organization is accredited in that area by an accrediting organization that has been approved by CMS and that uses the same (or stricter) standards than CMS uses to evaluate compliance with the applicable requirements. An amendment to the Act to revise subsection (e) made by section 722(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 appears not to have been fully incorporated into the provisions governing the authority to deem compliance with section 1852(e)(3) of the Act by an MA organization based on accreditation by an approved accreditation entity. We direct readers to the proposed rule for additional discussion (83 FR 55041). In the proposed rule, we clarified that an MA organization may be deemed to have satisfied the requirements of section 1852(e)(3) of the Act and the paragraphs of § 422.152 related to section 1852(e)(3) of the Act based on the review of an approved accreditation organization. We received one comment thanking us for the clarification. We will implement the clarified scope of the regulation going forward.

2. Delete the Reference to Quality Improvement Projects in § 422.156(b)(1)

Section 1852(e) of the Act requires each MA organization to have an ongoing Quality Improvement (QI) Program for the purpose of improving the quality of care provided to its enrollees. Our regulations at § 422.152 outline the QI Program requirements MA organizations. Section 422.152(a)(3) requires each MA organization to conduct quality improvement projects (QIPs) for its enrollees, and § 422.152(d) establishes the requirements for the QIPs. Effective January 1, 2019, CMS eliminated the requirements for QIPs in §§ 422.152(a)(3) and 422.152(d) in the April 2018 final rule (83 FR 16440). However, the reference to QIPs was not deleted in § 422.156(b)(1), which says QIPs are exempt from the process for deeming compliance based on accreditation.

We proposed a technical correction that would delete the phrase ''the quality improvement projects (QIPs) and'' from § 422.156(b)(1). We did not receive any comments on the proposal. We are finalizing the technical correction without modification in this final rule. We direct readers to the proposed rule for additional discussion (83 FR 55041).

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a ''collection of information,'' as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement (ICR) should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the November 1, 2018 (83 FR 54982) proposed rule, we solicited public comment on our proposed information collection requirements, burden, and assumptions. As discussed in section III.B.1. of this final rule, we received comments pertaining to Evidence of Coverage (EOC) notifications and provider directory requirements. Based on internal review, we have revised several cost estimates (see Wage Data). As explained in section III.B.4. of this final rule, we have also added burden related to Medicare Parts A and B claims data extracts.

A. Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2017 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 2 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. The adjusted wages are used to derive our cost estimates.

TABLE 3—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Business Operation Specialist	13–1199	$36.42	$36.42	$72.84
Lawyer	23–1011	68.22	68.22	136.44
Software Developers and Programmers	15–1130	49.27	49.27	98.54

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is a necessary rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

While we did not receive any public comments pertaining to our proposed wage estimates, based on internal review we have changed our proposed Programmer respondent type (BLS occupation code 15–1311 at $40.95/hr) to Software Developers and Programmers (BLS occupation code 15–1130 at $49.27/hr). The change adds $8.32/hr (mean) to our proposed Programmer-specific cost estimates and $16.64/hr (adjusted). The change affects sections III.B.2.a.(2), III.B.2.b.(2), and III.B.3.a.(2) of this final rule.

We have also corrected the occupation code for Business Operations Specialists from 13–000 to 13–1199. This correction adds $1.88/hr (mean) to our proposed Business Operations Specialist-specific cost estimates and $3.76/hr (adjusted). The change affects sections III.B.2.a.(2), III.B.2.b.(2), III.B.3.a.(1), and III.B.4. of this final rule.

We are not making any changes to the proposed Lawyer respondent type (BLS occupation code 23–1011 at $68.22/hr (mean) and $136.44/hr (adjusted)).

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance in section II. of this final rule.

1. ICRs Regarding the Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§ 422.135)

As described in section II.A.1. of this final rule, section 50323 of the Bipartisan Budget Act of 2018 allows MA plans the ability to provide MA additional telehealth benefits to enrollees starting in plan year 2020 and treat them as basic benefits. In this rule, we are finalizing—with slight modifications—most proposed requirements at § 422.135, which will authorize and set standards for MA plans to offer MA additional telehealth benefits. More specifically, we are finalizing our requirement that MA plans must advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange (§ 422.135(c)(2)). As discussed in section II.A.1. of this final rule, based on public comments we are not finalizing

the portion of proposed § 422.135(c)(2) that referenced the EOC document as the required vehicle for this notification. Instead, we intend to address the EOC in future sub-regulatory guidance.

MA plans will be required to make information about the coverage of additional telehealth benefits available to CMS upon request (finalized at § 422.135(c)(4)). We do not anticipate requesting this information from more than nine MA plans in a given year because historically we have not received a large number of complaints about coverage of benefits that might warrant our request for information from many plans. However, we reserve the right to ask for this information. Since we estimate fewer than 10 respondents, the information collection requirement is exempt (5 CFR 1320.3(c)) from the requirements of the PRA.

As discussed in section II.A.1. of this final rule, based on public comments we are not finalizing our proposed provider directory requirements under proposed § 422.135(c)(3). We have therefore modified our discussion of potential information collection requirements and assumptions related to provider directories, as it is no longer necessary to address them in the context of this final rule. Similar to the EOC, we intend to address the provider directory in future sub-regulatory guidance.

This final rule is consistent with our proposed rule in that neither set out any burden related to MA plans offering MA additional telehealth benefits.

2. ICRs Regarding Integration Requirements for Dual Eligible Special Needs Plans (§ 422.107)

The following requirements and burden will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

As described in section II.A.2.a. of this final rule, we are establishing new requirements in accordance with amendments to section 1859(f)(8) of the Act (made by section 50311(b) of the Bipartisan Budget Act of 2018), which stipulates that all dual eligible special needs plans (D–SNPs) meet certain new minimum criteria for Medicare and Medicaid integration for 2021 and subsequent years. We are also codifying the various forms of integrated care provided by D–SNPs that have evolved since their establishment nearly 15 years ago.

In § 422.107(d), any D–SNP that is not a fully integrated dual eligible special needs plan (FIDE SNP) or a highly integrated dual eligible special needs plan (HIDE SNP), as defined in § 422.2, will be subject to an additional contracting requirement. Under the additional contracting requirement, the D–SNP must notify the state Medicaid agency and/or individuals or entities designated by the state Medicaid agency of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the state Medicaid agency.

In addition, we are modifying existing requirements for the contract between states and D–SNPs at § 422.107(c). The modifications will include requirements that the contract between the D–SNP and the state: (1) Document the D–SNP's responsibility to coordinate the delivery of Medicaid benefits for individuals who are eligible for such services and, if applicable, to provide coverage of Medicaid services for those eligible; (2) specify the categories and criteria for eligibility for dual eligible individuals to be enrolled in the plan; and (3) specify the Medicaid benefits covered by the MA organization offering the D–SNP under a capitated contract with the State Medicaid agency or by the D–SNP's parent organization or another entity that is owned and controlled by its parent organization. We are also finalizing a new requirement that the contract between a D–SNP that is an applicable integrated plan, as defined in § 422.561, and the state document the D–SNP's use of the unified appeals and grievance procedures required under §§ 422.629 and 422.630, 438.210, 438.400, and 438.402, as finalized in this rule.

The primary burden arising from the modifications to the contracting provisions between states and D–SNPs will consist of the following:

- Burden to states to—

++ Execute D–SNP contract modifications regarding new and modified requirements under § 422.107(c) and the notification requirement at § 422.107(d), as detailed in section II.A.2.a.(2). of this final rule; and

++ Establish the terms of the notification at § 422.107(d), including its method, timing, and scope, and receive such notification from D–SNPs about high-risk enrollees' hospital and SNF admissions (if the state contracts with D–SNPs that are not FIDE SNPs or HIDE SNPs, as those terms are defined in § 422.2).

- Burden to D–SNPs to—

++ Execute a contract modification with the state Medicaid agency regarding new and modified requirements under § 422.107(c) and the notification requirement at § 422.107(d), as detailed in section II.A.2.a.(2). of this final rule; and

++ Notify the state Medicaid agency or its designee(s) about the hospital and SNF admissions for the state-identified population of high-risk enrollees (if the D–SNP is not a FIDE SNP or HIDE SNP, as those terms are defined in § 422.2).

a. Burden to States

(1) Contract Modifications With D–SNPs (§ 422.107)

For the initial year, we expect it will take 24 hours at $136.44/hr for a lawyer to update the state Medicaid agency's contract with every D–SNP in its market to address the changes to § 422.107 made by this final rule. Since half of the cost will be offset by federal financial participation for Medicaid administrative activities, we have adjusted our estimates for state agencies by 50 percent. Given the market penetration of D–SNPs in certain states relative to others, we recognize that this estimate reflects an average cost across all states and territories with D–SNPs. We expect that the state Medicaid agency will establish uniform contracting requirements for all D–SNPs operating in their market. As of June 2018, there were 42 states, plus the District of Columbia and Puerto Rico, in which D–SNPs were available to MA enrollees.[41] In aggregate, we estimate a one-time burden of 1,056 hours (44 respondents × 24 hr/response) at an adjusted cost of $72,040 (1,056 hr × $136.44/hr × 0.50). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 352 hours (1,056 hr × ⅓) at a cost of $24,013 ($72,040 × ⅓). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

In future years, we anticipate minimal burden associated with modifications to contract terms consistent with the changes we are finalizing to § 422.107(c)(1) through (3). While it is possible more states will move toward increased integration by contracting with applicable integrated plans and would therefore need to modify their state Medicaid agency contracts with D–SNPs consistent with the changes we are finalizing to § 422.107(c)(9), we are unable to reliably estimate the additional burden in subsequent years. In addition, while we recognize that, over time, states could modify the newly required contract term at

[41] Centers for Medicare & Medicaid Services (2018, June). SNP Comprehensive Report. Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

§ 422.107(d) to require notification about admissions for certain high-risk enrollees (for example, by expanding the population of high-risk full-benefit dual eligible individuals to whom this notification applies), we do not believe that such a contract change will have a material impact on time and effort and, therefore, will already be accounted for in the burden estimate for the overall contract that the state Medicaid agency has with each D–SNP.

Given the lack of material impact and the uncertainty involved in estimating state behavior, we are estimating a minimum of zero burden in subsequent years on plans. The maximum burden will be the estimated first year cost. However, we believe the maximum estimate is unlikely to be accurate since we expect any changes to contracting requirements to be iterative compared to the first year update.

We solicited public comment on our assumptions in the proposed rule and whether there are reasonable ways of modeling state behavior. We received no comments on our information collection requirements, burden estimates, and assumptions and are finalizing them without modification.

(2) Notification (§ 422.107(d))

To address differences among the states in available infrastructure, population sizes, and mix of enrollees, this rule provides broad flexibility to identify the groups for which the state Medicaid agency wishes to be notified and how the notification should take place. These flexibilities include: (1) Consideration of certain groups who experience hospital and SNF admissions; (2) protocols and timeframes for the notification; (3) data sharing and automated or manual notifications; and (4) use of a stratified approach over several years starting at a small scale and increasing to a larger scale. This final rule also allows states to determine whether to receive notifications directly from D–SNPs or to require that D–SNPs notify a state designee such as a Medicaid managed care organization, section 1915(c) waiver case management entity, area agency on aging, or some other organization.

Some states, using a rich infrastructure and a well-developed automated system, may fulfill this notification requirement with minimal burden, while states with less developed or no infrastructure or automated systems may incur greater burden. Furthermore, the burden, especially to those states starting on a small scale, may differ significantly from year to year. Because of the flexibilities provided in this final rule, we expect that states will choose strategies that are within their budget and best fit their existing or already-planned capabilities. We expect any state choosing to receive notification itself of such admissions to claim federal financial participation under Medicaid for that administrative activity.

As of June 2018, there were 42 states, plus the District of Columbia and Puerto Rico, in which D–SNPs were available to MA enrollees. We estimate that there are nine (9) states and territories with D–SNPs that are all expected to qualify as either FIDE SNPs or HIDE SNPs—Arizona, Florida, Hawaii, Idaho, Massachusetts, Minnesota, New Jersey, New Mexico, and Puerto Rico. We do not expect these states to establish a notification system under this final rule because none of their D–SNPs will be subject to the state notification requirement at § 422.107(d). We estimate that nine additional states that primarily use managed care for long-term services and supports (LTSS) (Michigan, New York, North Carolina, Ohio, Oregon, Pennsylvania, Tennessee, Texas, and Virginia) will delegate receipt of this information to their Medicaid managed care organizations. We also estimate that approximately half of the remaining 26 states (42 states—16 states, excluding the District of Columbia and Puerto Rico) or 13 states will build an automated system for receiving notification of hospital and SNF admissions consistent with this final rule.

We estimate that, on average, this work could be accomplished in a month with one software developer/programmer to build an automated system and one business operations specialist to define requirements. We estimate a one-time burden of 4,160 hours (13 states × 40 hr/week × 4 weeks × 2 FTEs). Since half of the cost will be offset by 50 percent federal financial participation for Medicaid administrative activities, we estimate an adjusted cost of $178,235 [((2,080 hr × $98.54/hr) + (2,080 hr × $72.84/hr)) × 0.50]. Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 1,386.667 hours (4,160 hr × ⅓) at a cost of $59,412 ($178,235 × ⅓). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

Because of the possible wide variability in states' approaches in implementing this requirement, we solicited comment in the proposed rule and requested suggestions for modeling state approaches and costs related to this provision. Given the uncertainty involved in estimating state behavior, we estimated a minimum of zero burden in subsequent years on plans and a maximum burden that is the estimated first-year cost. We received no comments and are finalizing our time estimates without change. Our proposed cost estimates have been revised to account for the changes discussed in section III.A. of this final rule.

b. Burden on Plans

(1) Contract Modifications With State Medicaid Agencies (§ 422.107)

For the initial year, we expect it will take 8 hours at $136.44/hr for a lawyer to update their plan's contract with the state Medicaid agency to reflect the revised and new provisions finalized in this rule at § 422.107(c)(1)–(3), (c)(9), and (d). We are unable to differentiate how these provisions impact individual D–SNP contracts due to the ways contracts are structured. For example, some contracts will include FIDE SNPs, HIDE SNPs, and other D–SNPs, while others may include only a subset of these D–SNP types. The specific requirements for the content of and scope of changes to the contract vary somewhat based on the type of D–SNP the plan is. However, it is reasonable to project that every D–SNP contract will require contract modifications with the state Medicaid agency.

There are 190 D–SNP contracts as of June 2018.[42] In aggregate, we estimate a one-time burden of 1,520 hours (190 D–SNPs × 8 hr/modification) at a cost of $207,389 (1,520 hr × $136.44/hr). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 507 hours (1,520 hr × ⅓) at a cost of $69,130 ($207,389/3). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

We believe that we have no reasonable way of estimating or illustrating burden in later years. The expected behavior among states is unknown relative to how often they will modify their contracts with D–SNPs on this particular matter. For example, state Medicaid agencies may remain satisfied with the initial year selection of high-risk groups and see no reason to modify their contracts in later years. In contrast, other state Medicaid agencies may seek to expand the notification requirement

[42] Centers for Medicare & Medicaid Services (2018, June). *SNP Comprehensive Report.* Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

to encompass additional groups of high-risk dual eligible individuals and may therefore modify their contracts on this basis. Given the uncertainty involved in estimating state behavior, we are estimating a minimum of zero burden in subsequent years on plans. The maximum burden will be the first year costs.

We received no comments on our assumptions in the proposed rule or on ways to reasonably model state behavior and are finalizing our proposed estimates without modification. However, we are finalizing our burden estimates to reflect the omission of the burden associated with §§ 422.107(c)(1) through (3) and 422.107(c)(9) in the proposed rule.

(2) Notifications to State Medicaid Agencies or Their Designees (§ 422.107(d))

We have noted previously in section II.A.2.a. of this final rule the broad flexibility in notification options for states. We also note that MA organizations are already required to have systems that are sufficient to organize, implement, control, and evaluate financial and marketing activities, the furnishing of services, the quality improvement program, and the administrative and management aspects of their organization (§ 422.503(b)(4)(ii)). Independent of the state Medicaid agency's selection of high-risk populations, protocols, and notification schedules, an MA organization's most likely method of sharing this notification will be through the use of an automated system that could identify enrollees with criteria stipulated by the states and issue electronic alerts to specified entities. We do not believe that this work is very complex. Therefore, we estimate it could be accomplished in a month with one software developer/programmer to update systems and one business operations specialist to define requirements. The burden will be at the contract, not the plan, level for a subset of D–SNP contracts that are not FIDE SNPs or HIDE SNPs and to which the notification requirements are applicable. As noted previously, there are 190 D–SNP contracts as of June 2018, of which 37 contracts, or 12.7 percent (about one-eighth), are FIDE SNPs.[43] While we do not have a precise count of D–SNPs that will likely meet the definition of a HIDE SNP, we estimate that another 12.7 percent of the 190 D–SNP contracts will be HIDE SNP contracts. Therefore, we expect that the number of contracts needing modification is 190 D–SNP contracts, less 37 FIDE SNP contracts, less 37 HIDE SNP contracts, or 116 D–SNP contracts. Accordingly, we estimate a one-time burden of 37,120 hours (116 contracts × 40 hr × 4 weeks × 2 FTEs) at a cost of $3,180,813 [(18,560 hr × $98.54/hr) + (18,560 hr × $72.84/hr)]. Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 12,373 hours (37,120 hr × ⅓) at a cost of $1,060,271 ($3,180,813 × ⅓). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

c. Summary of Burden Related to Integration Provisions for Dual Eligible Special Needs Plans

Table 4 summarizes the burden for the aforementioned provisions.

TABLE 4: ANNUAL BURDEN OF D-SNP INTEGRATION REQUIREMENTS

Item	Number of Respondents	Hours per Response	Total Hours[1]	Cost ($/hr)	Total Cost ($)
Initial update by state Medicaid agency of its contracts with D-SNPs	44	24	352	136.44	24,013
Initial establishment of system for notification of hospital and SNF admissions by state Medicaid agency	13	160	1,387	Varies	59,412
Subtotal (State Burden)	*44*	*Varies*	*1,738*	*Varies*	*83,425*
Initial update by D-SNPs of their contracts with the state Medicaid agency	190	8	506.67	136.44	69,130
Initial notification of hospital and SNF admissions by D-SNPs to state Medicaid agency	116	160	12,373	Varies	1,060,271
Subtotal (D-SNP Burden)	*190*	*Varies*	*12,881*	*Varies*	*1,129,401*
TOTAL	**234**	**Varies**	**14,619**	**Varies**	**1,212,826**

3. ICRs Regarding Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560 through 422.562, 422.566, 422.629 Through 422.634, 438.210, 438.400, and 438.402)

As described in section II.A.2.b. of this final rule, we are establishing for inclusion in contracts for applicable integrated plans, as defined in § 422.561, no later than 2021, procedures unifying Medicare and Medicaid grievances and appeals procedures in accordance with the newly enacted amendments to section 1859(f)(8)(B) and (C) of the Act. In this final rule, § 422.562(a)(5) requires that all dual eligible special needs plans (D–SNPs) provide assistance to beneficiaries with Medicaid coverage issues, appeals and grievances. When ready, the requirements and burden associated with these requirements will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

As of June 2018, our Special Needs Plan Comprehensive Report lists 190 D–SNP contracts with 412 D–SNP plans that have at least 11 members.[44] The universe of D–SNPs to which our unified grievance and appeals procedures will apply is comprised of D–SNPs that are either fully integrated dual eligible special needs plans (FIDE SNPs) or highly integrated dual eligible special needs plans (HIDE SNPs) with exclusively aligned enrollment—that is, where all of the plan's membership receives Medicare and Medicaid benefits from the same organization. Currently, exclusively aligned enrollment occurs in only eight states: Florida, Idaho, Massachusetts, Minnesota, New Jersey, New York, Tennessee, and Wisconsin. Currently, there are only 37 D–SNPs operating under 34 contracts with 150,000 enrollees that could be classified as FIDE SNPs or HIDE SNPs which operate

[43] Centers for Medicare & Medicaid Services (2018, June). *SNP Comprehensive Report.* Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

[44] See *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data-Items/SNP-Comprehensive-Report-2018-06.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending.*

in states with exclusively aligned enrollment. The 150,000 enrollment figure for contract year 2018 is projected to grow to 172,000 (150,000 x 1.145) enrollees by 2021, the first year that compliance with these provisions will be required.[45] While unifying grievance and appeals provisions will necessitate states with exclusively aligned enrollment policies to modify their Medicaid managed care plan contracts to incorporate the new requirements, it will impose this burden on fewer than 10 states, thereby falling below the threshold for PRA purposes.

We believe that our requirements at §§ 422.629, 422.630, and 422.631 related to integrated organization determinations and integrated grievances should not be altogether unfamiliar to applicable integrated plans because, in general terms, we are adopting whichever of the current MA D–SNP or Medicaid managed care plan contract requirements under part 422 subpart M (Medicare Advantage) and part 438 subpart F (Managed Care), respectively, is more protective of the rights of the beneficiary or provides the most state flexibility, consistent with the statutory requirements of section 1859(f)(8) of the Act. Furthermore, we believe that by unifying Medicare and Medicaid integrated organization determination and grievance requirements for applicable integrated plans (that is, FIDE SNPs and HIDE SNPs with exclusively aligned enrollment), we are reducing duplicative reviews and notices, thereby ultimately reducing the level of burden on these organizations. We detail the following:

- In section III.B.3.a. of this final rule, the burden associated with the implementation of our integrated organization determination and integrated grievance procedures (§§ 422.629, 422.630, and 422.631).
- In section III.B.3.b. of this final rule, that the information collection activities undertaken to administer our unified appeals procedures (§§ 422.629, 422.633, and 422.634) are exempt from the PRA.
- In section III.B.3.c. of this final rule, that the requirement for all D–SNPs to assist enrollees with Medicaid coverage issues and grievances in § 422.562(a)(5) is also exempt from the PRA.

[45] Table IV.C1, ''Private Health Enrollment'' in 2018 Trustee Report, accessible at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf.*

a. Integrated Organization Determinations and Integrated Grievances (§§ 422.629, 422.630, and 422.631)

Section 422.631 requires that each applicable integrated plan issue one integrated organization determination, so that all requests for benefits from and appeals of denials of coverage by applicable integrated plans will be subject to the same integrated organization determination process. Section 422.631(d)(1) requires that an applicable integrated plan send an integrated notice when the integrated organization determination is adverse to the enrollee. The notice must include information about the determination, as well as information about the enrollee's appeal rights for both Medicare and Medicaid covered benefits. Though integrating information on Medicare and Medicaid appeal rights will be a new requirement, we note that the requirement for a notice and the content of the notice largely align with current requirements in Medicaid (§ 438.404(b)) and MA (§ 422.572(e)). We believe that the provision will have minimal impact on plans based on our understanding of how plans that will meet the definition of an applicable integrated plan under this final rule currently handle coverage determinations for full-benefit dual eligible individuals receiving Medicare and Medicaid services through the plan. Currently, if such a plan were to deny or only partially cover a Medicaid service never covered by Medicare (like a personal care attendant or a clear request for Medicaid coverage), it will only issue a Medicaid denial (one notice). Under this final rule, it will do the same (that is, issue one notice). On the other hand, if the plan denied a service that is covered under either Medicare or Medicaid, such as home health services, we believe that the plan covering both Medicare and Medicaid benefits in most, if not all, states will issue an integrated determination notice that includes information about the application of Medicare and Medicaid coverage criteria to the requested service and how to appeal under both Medicare and Medicaid (one notice). This final rule codifies this practice for applicable integrated plans.

Also under § 422.568(d), if the plan covers a service such as durable medical equipment or home health services under Medicaid, but denies the same service under Medicare's rules, it must issue a Medicare denial even though the service was actually covered by the plan based on its Medicaid contract. Under this final rule, a plan covering both Medicare and Medicaid benefits will no longer need to issue a notice in this situation. We do not have data to estimate the number of instances in which D–SNPs currently issue denial notices related to overlap services; therefore, we are unable to reliably estimate the reduction in plan burden resulting from our unified appeals requirements. We solicited feedback on the burden imposed on integrated plans by having to send such a Medicare denial notice when the service is covered by the plan under Medicaid rules in the proposed rule. We did not receive any comment.

We are developing a model integrated denial notice form for use by applicable integrated plans. When ready, the model form and its associated requirements and burden will be submitted to OMB for approval. It will also be made available to the public for review/comment under the standard PRA process which includes the publication of 60- and 30-day **Federal Register** notices and the posting of the collection of information documents on our PRA website. Additionally, changes to the procedures for applicable integrated plans will be reflected in the current Notice of Denial of Medical Coverage form and instructions (OMB control number 0938–0892; CMS–10003), but will not impact this rule's burden estimates. As we did not finalize the necessary revisions for this notice at the time of the proposed rule's publication date, we did not set out such burden or solicit such comments. We are in the process of publishing a stand-alone 60-day **Federal Register** notice that set outs the revised form and form instructions.

Under § 422.629(g), applicable integrated plans must send a notice of acknowledgment for all integrated grievances and integrated reconsiderations. Medicaid managed care organizations are currently required to send this notice under § 438.406(b)(1), whereas MA plans are not currently required to send this notice. Under this final rule, applicable integrated plans must now send this notice for all grievances and appeals, not only those pertaining to Medicaid issues. Section 422.630(e) requires that applicable integrated plans issue a notice upon resolution of the integrated grievance, unless the integrated grievance was made orally and it did not concern quality of care, and the enrollee did not request a written response. A beneficiary's integrated grievance and the subsequent information collection activities necessitated by that grievance are exempt from the requirements of the PRA since the grievance would be submitted in response to an

administrative action against a specific individual (5 CFR 1320.4). However, the impact related to these requirements is estimated in section IV.B.3. of this final rule.

We believe this final rule will result in a reduction in the number of grievance reviews conducted by applicable integrated plans detailed under § 422.629(k)(2) due to the elimination of duplicative grievance reviews for Medicare and Medicaid overlap issues. We do not estimate this burden reduction as this information collection activity is exempt under 5 CFR 1320.4 from the requirements of the PRA since it occurs as part of an administrative action. However, the impact from changes to these activities are estimated in section IV.B.3. of this final rule.

We estimate negligible impacts on information collection activities involved in unifying grievances associated with our provisions at § 422.630. Under § 422.630(b), applicable integrated plans will be required to accept grievances filed at any time consistent with the Medicaid standard at § 438.402(c)(2)(i). This change will have the net effect of permitting enrollees to file a grievance for a Medicare-covered service outside of the current 60-day timely filing standard, as measured from the date of the event or incident that precipitated the grievance. The provision will effectively eliminate the timely filing period for Medicare-related grievances. We do not expect this requirement to increase the volume of grievances that an applicable integrated plan will be responsible for handling since we believe that the timeframes for filing Medicare grievances were designed to be consistent with current practice and were set in place only to eliminate complaint outliers.

Under § 422.630(c), enrollees of applicable integrated plans may file integrated grievances with the plan orally or in writing, in alignment with current Medicare and Medicaid requirements, or with the state, in states that have existing processes for accepting Medicaid grievances in place in accordance with § 438.402(c)(3). Because this provision simply extends an existing avenue for filing grievances, in states where it exists, for enrollees to file Medicaid benefits grievances with the state, we do not expect an increase in the volume of grievances that either states or applicable plans will be responsible for handling.

Section 422.630(d) will permit an enrollee to file an expedited grievance, which is available under current law for Medicare-covered, but not Medicaid-covered, benefits. We estimate that the availability of an expedited grievance for Medicaid benefits will have a negligible impact on information collection activities because applicable integrated plans will already have procedures in place to handle expedited grievances for Medicare-covered services, which could be leveraged for Medicaid-covered services. Furthermore, the availability of the expedited resolution pathway (where under current law there is only one resolution pathway for Medicaid-covered services) will have no impact on the volume of grievances.

Section 422.630(e)(1) will require that an applicable integrated plan resolve a standard (non-expedited) grievance within 30 days consistent with the MA standard (§ 422.564(e)); under Medicaid (§ 438.408(b)), the timeframe is established by the state but may not exceed 90 calendar days from day the plan receives the grievance. We estimate that this change in timeframe will have a negligible impact on information collection activities because applicable integrated plans already have business processes in place to comply with a 30-day timeframe under MA.

Section 422.630(e)(2) requires an applicable integrated plan, when extending the grievance resolution timeframe, to make reasonable efforts to notify the enrollee orally and send written notice of the reasons for the delay within 2 calendar days. We do not believe that this provision will have more than a negligible impact on plans since it adopts existing MA requirements for how an applicable integrated plan must notify an enrollee of an extension and the existing Medicaid managed care requirement for the timeliness standard. Thus, applicable integrated plans will already have business processes in place to comply with these requirements.

Although we do not estimate burden for applicable integrated plans related to information collection activities involved in unifying grievances associated with our provisions at §§ 422.629 and 422.630, some of the individual provisions in §§ 422.629 (general requirements), 422.630 (integrated grievances), and 422.631 (integrated organization determinations) will necessitate operational and systems changes on the part of applicable integrated plans. The following sections set out our burden estimates related to updates to policies and procedures and recordkeeping and storage.

(1) Updates to Policies and Procedures

We estimate a one-time burden for each applicable integrated plan to update its policies and procedures to reflect the new integrated organization determination and grievance procedures under §§ 422.629, 422.630 and 422.631. We anticipate this task will take a business operation specialist 8 hours at $72.84/hr. In aggregate, we estimate a one-time burden of 272 hours (8 hr × 34 contracts) at a cost of $19,812 (272 hr × $72.84/hr). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 91 hours (272 hr × ⅓) at a cost of $6,604 ($19,812 × ⅓). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

(2) Recordkeeping and Storage

D–SNPs, like other MA plans, are currently required to maintain records for grievances (§ 422.504(d)). However, § 422.629(h) will require the maintenance of specific data elements consisting of: A general description of the reason for the integrated grievance; the date of receipt; the date of each review or, if applicable, the review meeting; the resolution at each level of the integrated grievance, if applicable; the date of resolution at each level, if applicable; and the name of the enrollee for whom the integrated grievance was filed.

We estimate a one-time burden for applicable integrated plans to revise their systems for recordkeeping related to integrated grievances. We anticipate this task will take a software developer/programmer 3 hours at $98.54/hr. Three hours is consistent with the per-response time estimated in the May 2016 Medicaid Managed Care final rule (81 FR 27498). In aggregate, we estimate a one-time burden of 102 hours (3 hr × 34 contracts) at a cost of $10,051 (102 hr × $98.54/hr). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 34 hours (102 hr × ⅓) at a cost of $3,350 ($10,051 × ⅓). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

We do not expect the cost of storage to change under § 422.629(h)(3) since D–SNPs are currently required to store records under § 422.504(d), and the provision will not impose any new or revised storage requirements or burden.

We received no comments on our assumptions for estimating the burden associated with the operational and systems changes necessitated by §§ 422.629, 422.630, and 422.631.

However, we are updating our proposed burden estimates to reflect several omissions and minor modifications to two occupational codes

and corresponding adjusted hourly wages. Table 5 summarizes the burden resulting from these provisions.

b. Unified Appeals Procedures (§§ 422.629, 422.633, and 422.634)

A beneficiary's appeal of an adverse integrated coverage determination and the subsequent information collection activities necessitated by that appeal are exempt from the requirements of the PRA since the appeal would be submitted in response to an administrative action against a specific individual (5 CFR 1320.4). In the case of this final rule, the exemption covers any information collection activities undertaken after the adverse integrated organization determination by an applicable integrated plan, including: acknowledgement of integrated reconsiderations under § 422.629(g), recordkeeping related to integrated appeals at § 422.629(h), and notification of the applicable integrated plan's integrated reconsideration determination at § 422.633(f)(4).

c. Assisting With Medicaid Coverage Issues and Grievances (§ 422.562(a)(5))

We have not calculated the burden for all D–SNPs to assist enrollees with the filing of their grievance or appeal as required in § 422.562(a)(5). Since the provision of such assistance is a usual and customary business practice it is exempt from the PRA under 5 CFR 1320.3(b)(2). We believe that this function would be performed in the absence of federal regulation.

d. Summary

The burden associated with the individual components of our provisions for unified grievance and appeals procedures for applicable integrated plans are summarized in Table 5.

TABLE 5—SUMMARY OF D–SNP UNIFIED GRIEVANCE AND APPEALS PROCEDURES BURDEN

[OMB Control Number 0938–0753, CMS–R–267]

Item	Regulation	Number of respondents	Hours per respondent	Total hours [1]	Hourly wage	Total cost ($)
Updates to Policies and Procedures	422.629, 422.630, and 422.631.	34	8	91	72.84	6,604
Recordkeeping	422.629(g)	34	3	34	98.54	3,350
Total		34	Varies	125	Varies	9,954

4. ICRs Regarding Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153(g))

The following requirements and burden will be submitted to OMB for approval under control number 0938–TBD [46] (CMS–10691).

As described in section II.A.3. of this final rule, section 50354 of the Bipartisan Budget Act of 2018 requires the establishment of a process under which the sponsor of a PDP that provides prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare Parts A and B claims data about its plan enrollees. In this final rule we add a new § 423.153(g) to implement the process for requesting this data. The provision will allow the PDP sponsor to submit a request to CMS for claims data for its enrollees and to attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data that are listed in § 423.153.

At the time of the proposed rule's publication date, we did not finalize the operational aspects of this provision. Therefore, we did not set out such burden or request comment in the Collection of Information section of that rule. However, since that time, we have finalized the operational aspects and published a stand-alone 60-day **Federal Register** notice that set out the requirements and burden associated with the request and attestation (November 30, 2018; 83 FR 61638). Comments were received and are responded to below. We are also realigning the proposed provision with this final rulemaking by setting out such requirements and burden below. In this regard we will not be publishing a stand-alone 30-day **Federal Register** notice.

Section 423.153(g)(1)(i) states that beginning in plan year 2020, a PDP sponsor may submit a request to CMS for claims data on enrollees in its prescription drug plans. In addition, § 423.153(g)(5) provides that as a condition of receiving the requested data, the PDP sponsor must attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data. In the stand-alone notice we anticipated that the data request and attestation will be combined into a single submission. We continue to estimate it will take a business operations specialist 1 minute at $72.84/hr to complete the request for data and the attestation. As mentioned in section III.A. of this rule, we are updating the hourly wage associated with the business operations specialist.

Currently, there are 63 PDP sponsors and we estimate that all PDP sponsors would initially submit a request and attestation. We also estimate that each year approximately 1 to 5 PDP sponsors would start requesting CMS claims data for its enrollees. For purposes of impact estimates we assume the maximum, 5 PDP sponsors per year. We estimate it will take a business operations specialist 1 minute to complete the request for data and the attestation. We also estimate that each year approximately 1 to 5 PDP sponsors will request that CMS stop sending claims data for its enrollees. For purposes of impact estimates we assume the maximum, 5 sponsors, will request discontinuation. We estimate it will take a business operations specialist 1 minute (1/60 hr) to submit a request to CMS to stop sending claims data for its enrollees.

For first year sponsor requests we estimate a burden of 63/60 hours (1 hour and 3 minutes) (63 sponsors × 1/60 hr/response) at an aggregate cost of $76.48 (63 sponsors × 1/60 hr × $72.84/hr).

In subsequent years we estimate a burden of 10/60 hours (1/60/hr × (5 requests for data + 5 requests for discontinuation) at an aggregate cost of $12.14 (10/60 × 72.84).

The aggregate impact over 3 years is 83/60 hour (63/60 for the first year + 10/60 × 2 for the next 2 years) at a cost $100.76 ($76.48 for the first year + $12.14 × 2 for the next 2 years). When

[46] Currently, the control number is to be determined (TBD). OMB will assign the control number upon their approval of this new information collection request. Approval can be monitored at reginfo.gov without any login or password.

annualized over 3 years, the annual impact is 28/60 hr (83/60 divided by 3) at a cost of $33.59.

While we received a few comments, none of them were related to the PRA or any of our collection of information requirements or burden estimates. Nonetheless, we considered the comments since they were rule-related and have responded to them under the appropriate sections of this preamble, namely section II.A.3. of this final rule.

5. ICRs Regarding Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), 422.166(a) and 423.186(a), 422.164 and 423.184, and 422.166(i)(1) and 423.186(i)(1))

As described in section II.B.1. of this final rule, we are finalizing: Measure updates for the 2022 and 2023 Star Ratings, enhancements to the cut point methodology for non-CAHPS measures, and a policy for calculating the Part C and D Star Ratings when extreme and uncontrollable circumstances occur. The provisions will not change any respondent requirements or burden pertaining to any of CMS's Star Ratings-related PRA packages, including: OMB control number 0938–0732 for CAHPS (CMS–R–246), OMB control number 0938–0701 for HOS (CMS–10203), OMB control number 0938–1028 for HEDIS (CMS–10219), OMB control number 0938–1054 for Part C Reporting Requirements (CMS–10261), and OMB control number 0938–0992 for Part D Reporting Requirements (CMS–10185). Since the provisions will not impose any new or revised information collection requirements or burden, we are not making changes under any of the aforementioned control numbers.

6. ICRs Regarding Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§ 423.568, 423.570, and 423.572)

To establish greater certainty in the Part D exceptions process, we limited the amount of time an exception request can be held in a pending status while the Part D plan sponsor attempts to obtain the prescriber's supporting statement; specifically, that a plan must notify the enrollee (and the prescriber involved, as appropriate) of its decision on an exceptions request no later than 72 hours (24 hours for expedited) of receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first.

These provisions will not impose any new or revised information collection requirements or burden. Consequently, the provisions are not subject to the PRA. We did not receive any comments pertaining to our position that the proposed provisions are not subject to the PRA. Consequently, we are finalizing our position without change.

7. ICRs Regarding Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))

As described in section II.C.1. of this final rule, the provisions in §§ 422.222 and 423.120(c)(6) will not involve activities for plan sponsors and MA organizations outside of those described in the previously referenced April 2018 final rule (83 FR 16440). The provisions are, generally speaking, clarifications of intended policy and will not impose any new or revised information collection requirements or burden. Consequently, the provisions are not subject to the PRA.

We did not receive any comments pertaining to our position that the proposed provisions are not subject to the PRA. Consequently, we are finalizing our position without change.

C. Summary of Information Collection Requirements and Burden

TABLE 6: ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulatory Reference	OMB Control Number (CMS ID Number)	0938-0753 (CMS-R-267)	Total Number of Responses	Hours Per Response	Total Hours[2]	Wages ($/hr)	Total Cost ($)[1]
§ 422.107 (Initial update of States of their Contracts with D SNPs)	0938-0753 (CMS-R-267)	44	1	24	352	136.44	24,013
§ 422.107 (Initial notification systems for State Medicaid Agencies)	0938-0753 (CMS-R-267)	13	1	160	1387	85.69[3]	59,412
Subtotal (State Burden)		*44*	*1*	*Varies*	*1,739*	*Varies*	*83,425*
§ 422.107 (Initial updates of D-SNPs of their Contracts with the State)	0938-0753 (CMS-R-267)	190	1	8	507	136.44	69,130
§ 422.107 (Initial notification of D-SNPs to Medicaid Agencies)	0938-0753 (CMS-R-267)	116	1	160	12,373	85.69[3]	1,060,271
§§ 422.629, 422.630, and 422.631 (Updates to D-SNP policies and procedures)	0938-0753 (CMS-R-267)	34	1	8	91	72.84	6,604
§ 422.629(g) (Recordkeeping)	0938-0753 (CMS-R-267	34	1	3	34	98.54	3,350
§§ 423.153(g)(1)(i) and (g)(5) (Data requests and attestation)	0938-TBD (CMS-10691)	28	1	1 min (1/60 hr)	28/60	72.84	34
Subtotal (Private Sector)		*190*	*1*	*Varies*	*13,005*	*Varies*	*1,139,389*
Total		*Varies*	*1*	*Varies*	*14,744*	*Varies*	*1,222,814*

NOTES:

1. For state burdens, reflects 50 percent reduction to Federal Matching program.
2. Reflects division by 3 to annualize a one-time update over 3 years.
3. Average of $72.84 and $98.54, the wages of a business operations specialist and programmer working simultaneously on this task.

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule implements specific provisions of the Bipartisan Budget Act of 2018 related to MA additional telehealth benefits, MA dual eligible special needs plans (D–SNPs), and Part D sponsors' access to Medicare claims data. The rule will also improve quality and accessibility; clarify certain program integrity policies; reduce burden on providers, MA organizations, and Part D sponsors through providing additional policy clarification; and implement other technical changes regarding quality improvement. Although satisfaction with the MA and Part D programs remains high, these changes are necessary to implement certain provisions of the Bipartisan Budget Act of 2018 and are responsive to input we received from stakeholders while administering the programs, as well as through our requests for comment. We decided to modify the MA and Part D Prescription Drug Plan Quality Rating System in response to comments from the proposed rule entitled Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, The Medicare Prescription Drug Benefit Programs, and the PACE program (November 28, 2017, 82 FR 56336).

In this final rule, our policies continue to drive affordable private plan options for Medicare beneficiaries that meet their unique healthcare needs, such as supporting innovation in telehealth among MA plans to provide more options and additional benefits for MA enrollees. These provisions align with the Administration's focus on the interests and needs of beneficiaries, providers, MA plans, and Part D sponsors.

B. Overall Impact

We examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking (August 13, 2002), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

This final rule affects MA plans and Part D sponsors (North American Industry Classification System (NAICS) category 524114) with a minimum threshold for small business size of $38.5 million (*http://www.sba.gov/content/small-business-size-standards*). This final rule additionally affects hospitals (NAICS subsector 622) and a variety of provider categories, including physicians and specialists (NAICS subsector 621).

To clarify the flow of payments between these entities and the federal government, note that MA organizations submit bids (that is, proposed plan designs and projections of the revenue needed to provide those benefits, divided into three categories—basic benefits, supplemental benefits, and Part D drug benefits) in June 2019 for operation in contract year 2020. These bids project payments to hospitals, providers, and staff as well as the cost of administration and profits. These bids in turn determine the payments from the Medicare Trust Fund to the MA organizations that pay providers and other stakeholders for their provision of covered benefits to enrollees. Consequently, our analysis will focus on MA organizations.

There are various types of Medicare health plans, including MA plans, Part D sponsors, demonstrations, section 1876 cost plans, PDPs, and PACE plans. Forty-three percent of all Medicare health plan organizations are not-for-profit, and 31 percent of all MA plans and Part D sponsors are not-for-profit. (These figures were determined by examining records from the most recent year for which we have complete data, 2016.)

There are varieties of ways to assess whether MA organizations meet the $38.5 million threshold for small businesses. The assessment can be done by examining net worth, net income, cash flow from operations, and projected claims as indicated in their bids. Using projected monetary requirements and projected enrollment for 2018 from submitted bids, 32 percent of the MA organizations fell below the $38.5 million threshold for small businesses. Additionally, an analysis of 2016 data—the most recent year for which we have actual data on MA organization net worth—shows that 32 percent of all MA organizations fall below the minimum threshold for small businesses.

Executive Order 13272 requires that the Department of Health and Human Services (HHS) thoroughly review rules to assess and take appropriate account of their potential impact on small business, small governmental jurisdictions, and small organizations (as mandated by the RFA).

If a final rule may have a significant economic impact on a substantial number of small entities, then the final rule must discuss steps taken, including alternatives, to minimize burden on small entities. The RFA does not define the terms ''significant economic impact'' or ''substantial number.'' The Small Business Administration (SBA) [47] advises that this absence of statutory specificity allows what is ''significant'' or ''substantial'' to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. To ensure that a broad range of impacts are fully considered in the analysis, we consider ''substantial number'' to mean 5 percent or more of the affected small entities within an identified industry.

The 1984 HHS Handbook, On Developing Low Burden and Low Cost Regulatory Proposals, set forth the following definitional narrative for the term ''significant economic impact'' and is still applicable: A rule has a significant economic impact on the small entities it affects, if it significantly affects their total costs or revenues. If the economic impact is expected to be similar for all affected small entities and those entities have similar costs and revenues, then an average impact can be calculated. If the average annual impact on small entities is 3 to 5 percent or more, then we consider the rule has a significant economic impact on small entities.

While a significant number (more than 5 percent) of not-for-profit organizations and small businesses are affected by this final rule, the impact is not significant. To assess impact, we use the data in Table 17, which show that the raw (not discounted) net cost of this final rule over 10 years is $24.1 million. Comparing this number to the total monetary amounts projected to be needed just for 2020, based on plan submitted bids, we find that the impact

[47] The Regulatory Flexibility Act An Implementation Guide for Federal Agencies, pages 17–19. Issued by SBA's Office of Advocacy, and accessible at *www.sba.gov/advo.*

of this rule is significantly below the 3 to 5 percent threshold for significant impact. Had we compared the 2020 impact of the rule to projected 2020 monetary need, the impact would still be less.

Consequently, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities, and we have met the requirements of Executive Order 13272 and the RFA. In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any final rule under title XVIII, title XIX, or Part B of Title XI of the Act that may have significant impact on the operations of a substantial number of small rural hospitals. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any final rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This final rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of $154 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this final rule does not impose any substantial costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this final rule, then we should estimate the cost associated with regulatory review. There are currently 750 MA contracts (which also includes PDPs), 50 state Medicaid agencies, and 200 Medicaid managed care organizations (1,000 reviewers total). We assume each entity will have one designated staff member who will review the entire rule. Other assumptions are possible.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this final rule is $107.38 per hour, including fringe benefits and overhead costs (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 12.5 hours for each person to review this final rule. For each entity that reviews the rule, the estimated cost is $1,342 (12.5 hours * $107.38). Therefore, we estimate that the total cost of reviewing this final rule is $1,342,000 ($1,342 * 1,000 reviewers).

Note that this analysis assumed one reader per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers to approximately 500 (assuming approximately 250 parent organizations), and this will cut the total cost of reviewing in half. However, we believe it is likely that reviewing will be performed by contract. The argument for this is that a parent organization may have local reviewers assessing potential region-specific effects from this final rule.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget (OMB).

We received no comments on our estimates of impact on small businesses and other items mentioned in the Overall Impact section. Therefore, we are finalizing this section as without modification.

C. Anticipated Effects

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

As described in section II.A.1. of this final rule, section 50323 of the Bipartisan Budget Act of 2018 allows MA plans the ability to provide MA additional telehealth benefits to enrollees starting in plan year 2020 and treat them as basic benefits. In this rule, we are finalizing—with slight modifications—most proposed requirements at § 422.135, which will authorize and set standards for MA plans to offer MA additional telehealth benefits. Section 422.135(a) defines these benefits as Part B services that have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not in the same location as the enrollee. We are revising our proposed impact estimates based on stakeholder feedback. In the proposed rule, we set forth the following impacts.

There are two primary aspects of the MA additional telehealth benefits provision that could affect the cost and utilization of MA basic benefits, with a corresponding impact on Medicare program expenditures. The most direct effect is the reclassification of certain telehealth services covered by MA plans pre-Bipartisan Budget Act of 2018 from MA supplemental telehealth benefits to basic benefits. This change will lead to higher basic benefit bids, as the cost of MA additional telehealth benefits will be included in the basic benefit bid. The impact on the basic benefit bid may be muted due to the exclusion from the bid of capital and infrastructure costs related to MA additional telehealth benefits.

Prior to estimating the impact on the bid, we point out several other sources of impact. Many studies have argued that telehealth will increase utilization of medical services by making them more accessible. However, the increased utilization could lead to increased savings or cost. The increased utilization could lead to significant savings due to prevention of future illness. Alternatively, the increased utilization could lead to increased costs if enrollees start seeing doctors for complaints on which they did not traditionally seek medical advice. We cite studies for each possibility. Additionally, if there are more telehealth visits, providers may request more in-person visits to protect themselves from liability.

Consequently, there are four potential impacts of this provision, which we discuss in more detail later in this section. The four areas are as follows:

- Impact on the Medicare Trust Fund
- Savings for Enrollees due to Decreased Travel Time to Providers
- Savings from Illness Prevention due to Increased Access to Services
- Increased Costs if Unnecessary Medical Visits Increase

The final rule allows for differential cost sharing. We expect that enrollees would incur lower cost sharing from telehealth services than they would from in-person visits. This would result in enrollee savings. However, we have no way of estimating this savings because we lack any data experience with this differential cost sharing. Therefore, we are scoring this as a qualitative savings.

Because of the wide variability in potential impact, in the proposed rule we solicited comments on best practices in telehealth and the resulting savings. In the following sections, we summarize and respond to these comments.

a. Impact on the Medicare Trust Fund

Superficially, there appears to be no program change since the provision simply reclassifies certain benefits as basic instead of MA supplemental. Thus, the same benefits are provided. However, a closer look at the language and assumptions of the provision show that, while collectively MA additional telehealth benefits will yield a negligible change in program spending, there is a small transfer of costs (estimated to be 0.002 percent of the MA baseline) from enrollees to the Medicare Trust Fund, associated with reclassifying these benefits from MA supplemental benefits to basic benefits. MA supplemental benefits are generally paid with rebates while basic benefits are paid by a capitation rate, calculated with reference to the bid. For MA plans to provide benefits using rebates requires additional funding since the amount of rebates provided by the Medicare Trust Fund averages only $0.66 on the dollar. Thus, the effect of the rebate aspect is that the enrollee either pays a lower supplemental premium or receives richer MA supplemental benefits. In either case, whether the enrollee saves or receives richer MA supplemental benefits, the Medicare Trust Fund incurs a cost. It follows that this provision creates a cost transfer from the Medicare Trust Fund to enrollees. The direction of the cost is classified by whether the Medicare Trust Fund loses or gains. In this case, since the Medicare Trust Fund loses money, we classify the transfer as a cost. However, the transfer results in a savings to enrollees. After accounting for the exclusion of capital and infrastructure costs, and backing out the Part B premium, the extra cost to the Medicare Trust Fund is projected to be $80 million over 10 years. The calculations for these 10 years are presented in Table 7 and discussed in the narrative.

In order to estimate the 10-year impact (2020 through 2029) of the MA additional telehealth benefits provision on the Medicare Trust Fund, we considered the following six factors.

- First, we estimated the costs of MA additional telehealth benefits that are to be transferred from MA supplemental telehealth benefits to basic benefits. Using the 2019 submitted bid information, we estimated that $0.09 per member per month (PMPM) will be transferred. We computed $0.09 by examining and averaging the largest organizations' MA supplemental telehealth benefits, particularly under the category ''Web and Phone Based Technology.'' The reason for basing estimates on the largest organizations is that in past years, only the largest organizations included the category ''Web and Phone Based Technology'' as a separate line item in their bids; by contrast, the other organizations combined multiple, non-telehealth benefits in the same line as the MA supplemental telehealth benefits, and so we were not able to distinguish the costs between telehealth and non-telehealth for the smaller organizations. Information from the 2018 Medicare Trustees Report [48] shows that the applicable medical-inflation trend that should be applied to the $0.09 PMPM is 5.2 percent per year; the average trend can be derived from information in Table IV.C3 of this report.
- We applied the PMPM amounts to the projected MA enrollment for the years 2020 through 2029. The source of the projected MA enrollment is Table IV.C1 of the 2018 Medicare Trustees Report.
- We assumed that 15 percent of the MA additional telehealth benefits will be considered capital and infrastructure costs. As discussed in section II.A.1. of this final rule, these costs are excluded from the Medicare Trust Fund payments for MA additional telehealth benefits. We obtained the 15 percent assumption by subtracting the 85 percent required medical loss ratio (MLR) from 100 percent. We used the MLR as a proxy for the medical share of provider payments.
- We applied the average rebate percentage of 66 percent, which is based on the expected submitted bid information, including expected enrollment and expected average Star Ratings.
- We applied a factor of 86 percent to the calculation, which represents the exclusion or the backing out of the Part B premium.
- However, per OMB guidance, ordinary inflation should be carved out of estimates, while medical inflation, which outpaces ordinary inflation (as well as enrollment growth), may be retained. The source of the ordinary inflation is Table IV.D1 of the 2018 Medicare Trustees Report. It is 2.6 percent per year for each of the years 2020 through 2029.

TABLE 7—CALCULATIONS OF NET COSTS PER YEAR TO THE MEDICARE TRUST FUND FOR MA ADDITIONAL TELEHEALTH BENEFITS

Year	MA enrollment (in thousands)	PMPM cost	Number of months per year	Gross amount ($ in millions) (A)	Capital and infrastructure costs (%) (B)	Average rebate percentage (%) (C)	Backing out of Part B premium (%) (D)	Net cost ($ in millions) (A * (1 – B) * (1 – C) * (D)) (E)	Ordinary inflation (%) (F)	Net costs ($ in millions) (E)/(1 + (F)) ^ (year-2019)
2020	21,995	0.09	12	25.0	15	66	86	6.2	2.6	6.1
2021	22,873	0.10	12	27.3	15	66	86	6.8	2.6	6.5
2022	23,739	0.10	12	29.8	15	66	86	7.4	2.6	6.9
2023	24,584	0.11	12	32.5	15	66	86	8.1	2.6	7.3
2024	25,395	0.12	12	35.3	15	66	86	8.8	2.6	7.7
2025	26,198	0.12	12	38.4	15	66	86	9.5	2.6	8.2
2026	26,986	0.13	12	41.6	15	66	85	10.2	2.6	8.5
2027	27,737	0.14	12	44.9	15	66	85	11.0	2.6	9.0
2028	28,455	0.14	12	48.5	15	66	85	11.9	2.6	9.5
2029	29,101	0.15	12	52.2	15	66	85	12.8	2.6	9.9
Raw Total										79.6

Combining these six factors, we calculated the net costs to the Medicare Trust Fund to be $6.1 million in 2020, $6.5 million in 2021, $6.9 million in 2022, $7.3 million in 2023, and $7.7 million in 2024. We calculated the net costs to the Medicare Trust Fund for years 2025 through 2029 to be $8.2 million, $8.5 million, $9.0 million, $9.5

[48] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf.*

million, and $9.9 million, respectively. The calculations of impact for years 2020 through 2029 are summarized in Table 7. The total cost for all 10 years is found in the right-most column of Table 7, titled ''Net Costs.''

b. Savings for Enrollees Due to Decreased Travel Time to Providers

MA additional telehealth benefits will save enrollees the cost of traveling to and from providers. Currently, Medicare telehealth services are used to bring healthcare services to MA enrollees, including those in rural locations. In their comments on the proposed rule, as well as in response to specific inquiries we made in the proposed rule related to telehealth, stakeholders have informed CMS that MA enrollees benefit from the use of telehealth services to reduce travel times and have greater access to providers that may not otherwise be available. Several commenters provided specific details from their own experiences on the nature of these savings.

(1) Assumptions

Prior to our actual estimation of the savings for enrollees due to decreased travel time to providers, we discuss seven assumptions underlying our calculations.

(a) Current MA Supplemental Telehealth Benefits' Usage

Under the current MA program, MA plans may offer MA supplemental telehealth benefits in the form of telemonitoring and remote access technologies (including nursing hotlines).[49] However, the plan benefit package software does not have sufficient granularity to identify which types of MA supplemental telehealth benefits are being offered. Analyzing supporting documentation for the plan bids, the Office of the Actuary (OACT) has found an average spending of $0.09 PMPM for MA supplemental telehealth benefits among the large MA plans (smaller plans do not provide this data). OACT estimates that in 2019 there will be an average rebate of $110 PMPM. Of this $110, on average, 44 percent is applied to reduction in cost sharing (compared to cost sharing in original Medicare for Part A and B benefits), and 32 percent is applied to buying down the Part B and Part D premiums, leaving 24 percent or $27 PMPM with which to fund additional services. It follows that large MA plans use only 0.33 percent ($0.09/$27) of available rebate resources to fund MA supplemental telehealth benefits. It is reasonable that the $0.09 PMPM average for large MA plans is even less for smaller plans who may not have the resources to be as aggressive in their MA supplemental telehealth benefit designs.

These considerations—coupled with a discussion of how CMS and stakeholders expect telehealth to be used—suggest that while current MA policy theoretically allows MA supplemental telehealth benefits, they are not being significantly offered. The arguments for this are as follows:

- Telehealth Specialties and Telemonitoring: In response to our discussion and request for comments in the proposed rule, commenters enthusiastically supported the MA additional telehealth benefits proposal as a saver precisely because both telemonitoring and certain specialties—especially dermatology, cardiology, and psychiatry—will be used significantly more often under these new benefits. Commenters pointed out that there are not enough dermatologists, cardiologists, and psychiatrists to provide all needed services in rural areas. The availability of MA additional telehealth benefits will remedy a lack of access based on this lack of resources. Some commenters related their personal experience and the savings they expected to accrue. No commenter dissented whether this provision would significantly save. The tone of the comments seem to imply that these commenters believed that the final rule would allow these MA additional telehealth benefits or greatly facilitate their offering.
- Current Allowed MA Supplemental Telehealth Benefits: As discussed previously in the estimates of impact on the Medicare Trust Fund, we found that approximately $0.09 PMPM was being used for current MA supplemental telehealth benefits (telemonitoring and remote access technologies). Telehealth services are not low-cost (though they cost less than in-person visits). This $0.09 must pay for the provider review and assessment. Hence, this $0.09 reflects a significantly low utilization. The following simple hypothetical example illustrates this. Suppose in a plan, once a month, 30 enrollees in a plan with 8,300 total enrollees are using MA supplemental telehealth benefits, which costs $100/hr and takes 15 minutes to review. Then the cost to the plan is 30 enrollees $\times$ $100/hr $\times$ 0.25 hr = $750. However, the cost per enrollee is $750/8,300 = $0.09. This illustrative example with hypothetical numbers clarifies why we are inferring from the $0.09 that plan utilization is extremely low.

Although this $0.09 reflects the cost to the plan, it is legitimate to use this to estimate savings to enrollees. The logic behind this is as follows. The low cost of $0.09 indicates low utilization, and it is the low utilization which drives our assumption that few enrollees are spending travel time currently. For example, in our simple hypothetical example above, without MA additional telehealth benefits, only 30 enrollees would have to travel back and forth to a provider once a month. We are estimating that, under this final rule, there would be more usage of telehealth; we expect more than 30 enrollees to use this and we expect it to be used more than once a month. Without MA additional telehealth benefits, this would necessitate the cost of travel, while with MA additional telehealth benefits, there is no travel; hence, the estimate of savings is justified. Tables 8 and 9 indicate the frequency of utilization we expect over the next 10 years.

Despite the previous arguments, we must concede that currently some telehealth benefits are being offered as MA supplemental telehealth benefits. In the absence of further data, we are making an assumption that less than 50 percent of the telehealth services that will be furnished under this final rule are currently available. This assumption has intuitive appeal. If only $0.09 out of $27 is being used for MA supplemental telehealth benefits, while the remaining $26.91 is being used to fund non-telehealth benefits, it is very reasonable to assume that current utilization is less than 50 percent of what it is expected to become under the final rule when plans can fund these benefits from the Medicare Trust Fund without using their rebate dollars.

(b) Possible Overutilization

In the proposed rule, although we did estimate the potential savings to enrollees from reduced travel time to and from providers arising from MA additional telehealth benefits, we did not include this estimate in the summary and accounting tables (Tables 16 and 17) because there was a concern that telehealth would possibly lead to overutilization of provider visits, thus offsetting the savings. We address this concern in the following points:

- Only one article raised this concern, and the article itself listed several drawbacks to its conclusion.[50] More specifically, the article—

[49] Chapter 4 of the Managed Care Manual, Section 30.3 *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.*

[50] J. Ashwood, A. Mehrotra, D. Cowling, and L. Uscher-Pines, ''Direct to Consumer Telehealth May

++ Used data from only one telehealth company;

++ Used data on only specific medical conditions;

++ Referenced a population study that had a ''low uptake of telehealth;'' and

++ Was from an early period in telehealth.

Despite low uptake of telehealth in 2013, we have seen a significant increase in telehealth usage over the past few years. Furthermore, one article on telehealth points to the importance of patient buy-in, which is more common today.[51]

• To better understand the concern regarding overutilization, we solicited comments in the proposed rule on whether MA additional telehealth benefits would save enrollees due to reduced travel time. We received numerous comments from several sources, and the commenters were overwhelmingly supportive. The comments were not subjective but evidence-based, reflecting MA plans' first-hand experience with telehealth in some of their existing products. Some commenters specifically addressed the travel time issue. For example, a commenter indicated that virtual visits can not only reduce patient travel time, but can also potentially supplant nursing and in-home visits. In addition, the commenter referenced a virtual care experience in one particular plan which spoke to both clinician and patient time-in-transit savings. Other commenters simply echoed the travel time estimates in the proposed rule. However, many commenters discussed increased usage of telehealth services particularly in specialties such as cardiology, psychiatry, and dermatology, and especially in rural areas where there is a shortage of specialists.

Based on the previous discussion, we are including our estimates of travel savings in the summary and accounting tables (Tables 16 and 17). In making these estimates, we are assuming that the number of visits will remain the same overall but that a certain percentage of the in-person visits will be replaced by visits through electronic exchange from MA additional telehealth benefits.

(c) Telehealth Provider Utilization by Age

The available statistics discuss telehealth without adequate distinction based on age. It is very likely that a breakout by age would give more precise estimates, but unfortunately we do not have such data.

(d) Avoiding Overestimation of Telehealth Growth

In creating a 10-year estimate, there are several conflicting sources with the growth of telehealth visits. To avoid problems of overestimation, we adopted the lower growth rate estimates. We present numerical details of this approach in the section containing the actual estimates.

(e) Enrollee Savings Versus Medicare Trust Fund Impact

We explicitly clarify that the $80 million cost over 10 years, estimated in Table 7, is a cost incurred by the Medicare Trust Fund and represents a transfer from the government to enrollees, because the rebate dollars that formerly paid for MA supplemental telehealth benefits are now being freed, possibly, for additional benefits to enrollees either in the form of MA supplemental benefits or reduced cost sharing. However, the savings described are savings to enrollees.

(f) Internet Access in the 65+ Population

Our estimates of impact include a trend factor for increased general use of telehealth over the next few years. This trend factor is for the entire population. We therefore clarify that we do not believe that access to telehealth will be lower in the 65+ population because of the following:

• Telehealth does not exclusively require broadband internet capability; for example, telehealth access may also be provided through cell phones providing internet access.

• Many seniors have children or other members of their social support group who regularly visit them and could provide internet access through laptops, tablets, cell phones, or other internet-capable devices during their visits.

• There is now a large market for internet access, possibly without computers, offered by major manufacturers and targeted specifically for seniors. Current products include smart televisions allowing access without a computer, laptops specifically designed for seniors, and free or low-cost laptops provided by a number of national and local organizations in an effort to specifically encourage senior computer use.

• There are a variety of free online courses specifically targeted to seniors to facilitate familiarity with internet usage.

Therefore, we believe that the uniformity of trend for telehealth access is not an issue.

(g) Healthcare Savings

Although we are including in our impact analysis the savings to enrollees arising from reduced travel time, we are not including a quantification of healthcare savings. The commenters overwhelmingly supported the idea that telehealth would reduce healthcare spending due to increased preventive measures, consequent reduced readmissions and reduced initial hospitalizations, and greater access to certain specialties where access is currently low, such as cardiology, psychiatry, and dermatology. Furthermore, in the proposed rule, we had provided references, estimating in specific (typically one-time) settings, and the healthcare savings per inpatient enrollee. We have omitted mention of these studies in this final rule because MA additional telehealth benefits only apply to Part B services, not to inpatient services. However, commenters merged comments about savings from both inpatient telehealth and specialty telehealth such as tele-cardiology, tele-dermatology, and tele-psychiatry. In general, the commenters were enthusiastic about all aspects of telehealth saving money for both Part B and Part A services. Many of the commenters cited similar studies or their own experience. These articles and comments point to a quantitative savings in health care. Although, as mentioned previously, in the early years of telehealth there was concern for overutilization which would raise costs, this does not seem to be major issue today.

However, we are not quantifying the healthcare savings since each dollar of healthcare savings does not automatically become a dollar reduction in Medicare Trust Fund expenditures paying for plan bid estimates. As a simple example, some savings may translate to higher administrative margins (increased profits). Similarly, a portion of the healthcare savings may be allocated to increased benefits, for example, preventive benefits. We do not have a basis for quantifying these factors. Therefore, we are leaving the healthcare savings as a qualitative impact without further quantification.

Increase Access to Care but Does not Decrease Spending,'' Health Affairs 36(3), 2017, accessible at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1130.*

[51] Harry Wang, Director Health and Mobile Product Research, Parks Associates ''Virtual Health Care will revolutionize the Industry If we let it'', Forbes, 2014, accessible at *https://www.forbes.com/sites/ciocentral/2014/04/03/virtual-health-care-visits-will-revolutionize-the-industry-if-we-let-it/#4ee9a9e97c25; https://www.forbes.com/sites/ciocentral/2014/04/03/virtual-health-care-visits-will-revolutionize-the-industry-if-we-let-it/#4ee9a9e97c25.*

(2) Actual Estimation

Having completed our discussion of assumptions, we next turn to the actual estimation. We require four component estimates to estimate aggregate savings for enrollees due to decreased travel time to providers. We provide these four component estimates as follows:

(a) Average Travel Time and Average Travel Distance per Visit

While it is difficult to estimate the savings in reduced travel time quantitatively, since distances from enrollees to providers vary significantly, to estimate the travel time to providers we use a former CMS standard that providers should be located within 30 minutes or 30 miles of each enrollee. While this standard has since been replaced by a more sophisticated measurement of access, we can use it as a proxy. The former CMS standard was used because it is formulated simply in terms of time (30 minutes) and mileage (30 miles) and does not differentiate among provider types. The current standards for access involve sophisticated algorithms, which involve more than two parameters (time and mileage) and additionally differ by geographic location and provider types. Therefore, the current standards were not suitable due to their complexity. We therefore assume that the midpoint, 15 minutes or 0.25 hour, represents the typical travel time to providers per enrollee visit. We note that our estimate of 30 minutes round-trip is close to the 37-minute estimate used in one article.[52] Similarly, we believe that 15 miles (one-half of 30 miles) is the average travel distance per provider visit.

In estimating the savings in wages due to reduced travel time, we first note that the group of individual respondents varies widely by respondent age, location, years of employment, educational attainment, and working status with many people over 65 retired. To deal with this variability, we follow the OMB guidance for estimating hourly wages for enrollees using the occupational title ''All Occupations'' (occupation code 00–0000 on the BLS website), with a mean wage of $24.34/hour. This guidance reflects the OMB approach that all time should have a dollar value. However, since we believe most MA enrollees are not working, we are not adding 100 percent for overtime and fringe benefits. In other words, we are scoring the wages as $24.34/hour.

Thus, the net impact per enrollee per telehealth visit to providers would be $18.17 (15 miles * 2 (round trip) * $0.20 per mile (cost of gasoline for medical transportation [53]) + 0.25 hours travel time * 2 (round trip) * $24.34/hr). The $0.20 per mile for cost of gasoline for medical transportation reflects updated numbers by the Internal Revenue Service (IRS) for 2019. As discussed previously, we assume that at most 50 percent of expected telehealth visits are currently being offered. Therefore, we save at most $9.09 ($0.5 \times \$18.17$) per enrollee per telehealth visit. The actual percentage saved may be significantly more than 50 percent. This is summarized in Table 8.

(b) Average Number of Visits per Enrollee

In 2014, the Centers for Disease Control and Prevention (CDC) estimated that persons 65 years of age and older average 5.89 visits per person per year.[54]

(c) Number of MA Enrollees

Table IV.C1 of the 2018 Medicare Trustees Report provides the projected MA enrollment.

(d) Percent, per Year, of Provider Visits That Are Telehealth

Ideally, we would like an estimate on the number of total visits and telehealth visits for 65-year-olds. However, these data are not available. Therefore, we use the best available proportions. We proceed as follows.

The CDC website cited earlier estimates 885 million provider visits in 2014. This is an aggregate number over all age groups; the 885 million was not broken out further by age group.

Absent information on the proportion of telehealth visits among total visits by 65-year-olds to providers, we use general averages (across all age groups) with the understanding that some accuracy is lost. The Statista website suggests 22 million telehealth visits in 2014.[55] This implies that 2.49 percent (22/885) of all physician visits were telehealth visits.

Inferring growth rates from the numbers on the Statista website, the projected low and high growth rates for telehealth services are 8.9 percent and 22 percent respectively. Other websites give similar ranges. For example, Becker gives three estimates for telehealth growth rates of 14.3 percent, 16.5 percent, and 27.5 percent.[56] Because of this variability, we use the lower estimate for projected telehealth growth, which is about 8.9 percent. These numbers can be used to estimate the proportion of provider visits that will be telehealth in future years. For example, in 2015, we assume 1.089 (growth rate) * 2.49 percent (proportion of provider visits that are telehealth in 2014) = 2.71 percent of provider visits will be telehealth visits.

Multiplying these four component estimates together—average savings per visit ($9.09) * visits per enrollee (5.89) * number of MA enrollees * percent of provider visits that are telehealth (2.49 percent * 1.089 per year)—we arrive at a conservative aggregate savings estimate of $30 million, growing to $50 million in 2024, and $88 million in 2029. Had we used the higher projected visits, we would have obtained $30 million, growing to $280 million. The aggregate savings over 10 years is $557 million. The results are summarized in Table 9.

[52] J. Ashwood, A. Mehrotra, D. Cowling, and L. Uscher-Pines, ''Direct to Consumer Telehealth May Increase Access to Care but Does not Decrease Spending,'' Health Affairs 36(3), 2017, accessible at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1130.*

[53] *https://www.irs.gov/newsroom/irs-issues-standard-mileage-rates-for-2019.*

[54] *https://www.cdc.gov/nchs/products/databriefs/db292.htm; https://www.cdc.gov/nchs/products/databriefs/db292.htm.*

[55] *https://www.statista.com/statistics/820756/number-of-telehealth-visits-in-us/; https://www.statista.com/statistics/820756/number-of-telehealth-visits-in-us/.*

[56] See *https://www.beckershospitalreview.com/healthcare-information-technology/telemedicine-to-attract-7m-patient-users-by-2018-12-statistics-on-the-thriving-market.html; https://www.beckershospitalreview.com/telehealth/global-telemedicine-market-to-experience-16-5-annual-growth-rate-through-2023.html; https://www.beckershospitalreview.com/healthcare-information-technology/the-growth-of-telehealth-20-things-to-know.html; https://www.beckershospitalreview.com/telehealth/global-telemedicine-market-to-experience-16-5-annual-growth-rate-through-2023.html.*

TABLE 8—TRAVEL SAVINGS PER PROVIDER VISIT, TELEHEALTH

Label	Item	Amount	Source
(A)	One way travel to provider	0.25 hours	Prior CMS standard of provider availability within 30 minutes or 30 miles. We use the midpoint of 30 and 0 minutes, or 15 minutes/0.25 hours. An alternative approach uses the Health Affairs article of 37 minutes total.
(B)	Travel to and from provider	2	
(C)	Wages for enrollee per hour	$24.34	OMB guidance, use of occupational code 00–0000 on BLS website. OMB provided further guidance that, although it supports the idea of dollar value of time, since many enrollees are retirees, the wage estimate should not be doubled to reflect overhead and benefits.
(D)	Mileage cost per mile for medical travel	$0.20	IRS website.
(E)	Mileage	15 miles	Prior CMS standard of provider availability within 30 minutes or 30 miles. We use the midpoint of 30 and 0 miles, or 15 miles.
(F)	Wage savings per provider visit	$12.17	(A) * (B) * (C).
(G)	Mileage savings per provider visit	$6.00	(E) * (B) * (D).
(H)	Factor to be applied for current telehealth usage.	0.50	Currently, only 0.3% of rebate dollars available for supplemental benefits are spent on telehealth services. This small percentage suggests that, at most, half of all expected telehealth services are currently being offered.
	Total savings per visit	$9.09	0.5 × [(F) + (G)]

Notes: This table reflects savings based on the following two assumptions: The value of enrollee time is $24.34/hr and at most 50% of expected telehealth is being offered.

TABLE 9—TRAVEL SAVINGS PER YEAR, TELEHEALTH

Year	Total travel savings ($ in thousands) to enrollees from telehealth	MA enrollment (in thousands)	Savings per telehealth visit	Provider visits per enrollee	Percent of provider visits that use telehealth (percent)
2020	$30,903.7	23,181	$9.09	5.89	2.49
2021	34,912.4	24,062	9.09	5.89	2.71
2022	39,441.6	24,972	9.09	5.89	2.95
2023	44,440.5	25,858	9.09	5.89	3.21
2024	50,048.2	26,708	9.09	5.89	3.50
2025	56,218.7	27,549	9.09	5.89	3.81
2026	63,057.8	28,375	9.09	5.89	4.15
2027	70,572.1	29,161	9.09	5.89	4.52
2028	78,981.9	29,969	9.09	5.89	4.92
2029	88,393.9	30,799	9.09	5.89	5.36
Raw Total	556,970.9				

c. Savings From Illness Prevention Due to Increased Access to Services

Telehealth savings due to preventive telemonitoring may arise from easier or increased access to Part B services. The MA additional telehealth benefits to be included in the MA basic benefit bid stem from the Bipartisan Budget Act of 2018 amendment of section 1852 of the Act, and will likely represent a mix of replacement of pre-Bipartisan Budget Act of 2018 in-person visits and additional Part B services. We believe that increased coverage of the MA additional telehealth benefits will generally result in an aggregate reduction in use of emergency room visits and inpatient admissions because the relative increased ease of receiving healthcare services should improve health outcomes and reduce avoidable utilization that results from untreated conditions that exacerbate illness. Several studies predict that telehealth can significantly reduce illness through prevention. We mention two situations where Part B services could be provided by a physician or practitioner via MA additional telehealth benefits: (1) Comprehensive medication reviews and (2) post-discharge transitional care programs.

(1) Comprehensive Medication Reviews [57]

Telehealth can help significantly with patients who need multiple medications. Remote medication management can reduce the multiple patient visits that are often necessary to get the appropriate mix of medications. One recent meta-study on medication reviews summarizes seven studies, showing that using comprehensive medication reviews reduced hospitalizations, readmissions, drugs, and mortality.[58]

(2) Post-Discharge Transitional Care Programs

Telehealth has been used to provide transitional care for discharged hospital patients. One study found a savings of $1,333 per beneficiary, half of which

[57] Our current MA program allows telemonitoring, hospital readmission prevention programs, and post-discharge in home medication reconciliation.

[58] Evan A. DeZeeuw, PharmD; Ashley M. Coleman, PharmD; and Milap C. Nahata, PharmD, MS, ''Impact of Telephonic Comprehensive Medication Reviews on Patient Outcomes'', Am J Manag Care. 2018;24(2):e54–e58.

was due to reduced inpatient follow-up care.[59]

In the proposed rule, we solicited comments on potential savings. Numerous commenters were overwhelmingly supportive of CMS's projected savings. Furthermore, they backed their support with quantifiable details from their own experiences in their various products. Commenters particularly emphasized healthcare savings due to increased preventive care, significantly reduced hospital admissions, and increased access to specialties with insufficient providers to meet current demands (for example, tele-cardiology, tele-psychiatry, and tele-dermatology).

d. Increased Costs if Unnecessary Medical Visits Increase

We have moved the content in this section of the proposed rule to the previous section ''Possible Overutilization.'' We noted that we received overwhelming support from commenters that there should be no concern about overutilization, and the one article citing this concern is an old article in a very specific setting (the article itself cast doubt on its own findings).

We are finalizing our requirement that MA plans must advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange (§ 422.135(c)(2)). As discussed in section II.A.1. of this final rule, based on public comments, we are not finalizing the portion of proposed § 422.135(c)(2) that referenced the Evidence of Coverage (EOC) document as the required vehicle for this notification. Instead, we intend to address the EOC in future subregulatory guidance.

We received the following comments, and our responses follow.

Comment: In response to CMS's request for comments in the proposed rule on whether there would be savings to enrollees arising from reduced travel time to and from providers, several commenters expressed overwhelming support. More specifically, there were no dissenting comments that overutilization of services would reduce these enrollee savings.

Response: We appreciate the commenters' support. Although there will be no change in policy, based on these comments, we are confident in including the savings due to reduced enrollee travel time to and from providers in the summary and accounting tables (Tables 16 and 17). This will result in a $557 million savings over 10 years, making this final rule economically significant.

Comment: In response to CMS's request for comments in the proposed rule on whether telehealth would significantly reduce medical spending, a variety of commenters also expressed overwhelming support. Commenters pointed out that savings would arise from increased prevention, reduced hospital readmissions, and increased access in such areas as tele-dermatology and tele-psychiatry. Commenters frequently provided statistics based on their own experience.

Response: We thank the commenters for their support. Although it is clear that telehealth will result in healthcare savings, we do not have enough information to estimate the impact on reductions of Medicare Trust Fund payments. Consequently, we are scoring this as a qualitative savings in this final rule.

We received several comments on our estimated impacts for MA additional telehealth benefits. The comments were overwhelmingly supportive with no one dissenting to our impact estimates. After careful consideration of all comments received, and for the reasons set forth in our responses to the related comments summarized earlier, we are finalizing our impact analysis for this provision with the following modification. We are revising our proposed impact of this rule. The final rule is now expected to be an economically significant rule that will save enrollees $557 million over 10 years. The savings to enrollees are due to the MA additional telehealth benefits provision, which will reduce enrollee travel time to and from providers.

2. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

As stated in the earlier in the preamble of this final rule, starting in 2021, section 50311(b) of the Bipartisan Budget Act of 2018 establishes new Medicare and Medicaid integration standards for MA organizations seeking to offer D–SNPs and enrollment sanctions for those MA organizations that fail to comply with the new standards. We proposed to add a revised definition for ''D–SNP'' at § 422.2 and establish at § 422.107 revisions to the existing minimum state Medicaid agency contracting requirement for D–SNPs other than FIDE SNPs and HIDE SNPs, which are also defined at § 422.2.

As noted in the preamble of the proposed rule and at section II.A.2.a. of this final rule, many of the changes we proposed would unify and streamline existing requirements, which should reduce burden and are therefore not expected to have impact. For example—

- *Passive enrollment:* The reference to the definition of a HIDE SNP at § 422.2 will not materially change the plan types that are eligible for passive enrollment; rather, the existing rule simply refers to them as the D–SNPs that meet a high standard of integration under the supplemental benefit authority at § 422.102(e); and

- *Enhanced Supplemental Benefits:* We are also clarifying at § 422.102(e) that not only are HIDE SNPs that meet minimum quality and performance standards eligible to offer supplemental benefits, but FIDE SNPs that similarly meet minimum quality and performance standards may do so as well. While this amendment does not change what has occurred in practice, we believe it clarifies the types of plans that are eligible to offer enhanced supplemental benefits.

The impacts were presented in section III.B.2. of this final rule. However, the COI reduced the cost to state Medicaid agencies by 50 percent, reflecting a 50 percent Federal Financial Participation (FFP) rate; consequently, the RIA must include this 50 percent FFP rate as a cost to the federal government. Table 10 repeats the analysis summarized in Table 4 and includes transfers to the federal government. The narrative accompanying Table 4 presents our assumptions in reaching this impact as well as our assumption that there are no costs in subsequent years. As noted in section III.B.2. of this final rule, wage estimates and occupational titles were updated to reflect greater specificity as well as the latest BLS wage data.

As detailed in this section, the total first year cost is $3.9 million ($3.4 million to plans + $0.25 million to State Medicaid Agencies and $0.25 million to the federal government). The $3.9 million represents a true cost since it pays for the services of lawyers, software developers and programmers, and business operation specialists. Of this $3.9 million, $3.4 million is a cost to plans, while $0.5 million is a cost to the state Medicaid agencies which transfers $0.25 million to the federal government.

[59] Keith Kranker, Ph.D.; Linda M. Barterian, MPP; Rumin Sarwar, MS; G. Greg Peterson, Ph.D.; Boyd Gilman, Ph.D.; Laura Blue, Ph.D.; Kate Allison Stewart, Ph.D.; Sheila D. Hoag, MA; Timothy J. Day, MSHP; and Lorenzo Moreno, Ph.D. ''Rural Hospital Transitional Care Program Reduces Medicare Spending'', Am J Manag Care. 2018;24(5):256–260.

TABLE 10—FIRST YEAR COSTS OF D–SNP INTEGRATION REQUIREMENTS

Item	Number of respondents	Hours per respondent	Total hours	Cost per hour ($)	Cost to D–SNPs ($)	Cost to state Medicaid agencies ($)	Transfers to federal government ($)
Initial update by state Medicaid agency of its contracts with D–SNPs.	44 (states)	24	1,056	136.44		72,040	72,040
Initial establishment of system for notification of hospital and SNF admissions by state Medicaid agency.	13	160	2,080	98.54		102,482	102,482
	13	160	2,080	72.84		75,754	75,754
Initial update by D–SNPs of their contracts with state Medicaid agency.	190 (D–SNPs)	8	1,520	136.44	207,389		
Initial notification of hospital and SNF admissions by D–SNPs to state Medicaid agency.	116	160	18,560	98.54	1,828,902		
	116	160	18,560	72.84	111,351,910		
Total by Stakeholder					3,388,201	250,276	250,276

We received no comments on our impact estimates related to these provisions and therefore are finalizing our estimates as proposed, with modifications to reflect the omission of estimates for the impact of the contract modification at §§ 422.107(c)(1) through (3) and 422.107(c)(9) in the proposed rule, minor modifications to the occupational codes, and the corresponding adjusted hourly wages previously mentioned in this section.

3. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560 Through 422.562, 422.566, 422.629 Through 422.634, 438.210, 438.400, and 438.402)

The addition of the appeals and grievances provisions at §§ 422.629 through 422.634 focus on creating MA and Medicaid appeal and grievances processes that are unified for D–SNPs that also have comprehensive Medicaid managed care contracts (or are the subsidiary of a parent organization or share a parent organization with the entity with a comprehensive Medicaid managed care contract) and have exclusively aligned enrollment. The final rule addresses appeals at the plan level. Currently, Medicaid and MA appeals and grievance processes differ in several key ways. These differences hinder a streamlined grievance and appeals process across Medicare and Medicaid managed care sectors and create unnecessary administrative complexity for plans that cover dual eligible individuals for both Medicare and Medicaid services. These new regulations will allow enrollees in a D–SNP that is also a Medicaid managed care plan through which the enrollees get Medicaid coverage to better understand the grievance and appeals processes and generally receive a resolution of their grievances and appeals more quickly.

There are four areas where this provision will have an impact, listed here and discussed in further detail later in this section.

- Furnishing Medicare Parts A and B Services during the pendency of appeals (that is, through the integrated reconsideration);
- Updating plan grievance policies and procedures and consolidation of plan grievance notifications and reviews;
- Updating applicable integrated plan appeals policies and procedures; and
- Sending appeal files to enrollees who request them.

Following are details on these four areas of impact.

a. Furnishing Medicare Parts A and B Services During the Pendency of Appeals

One of the provisions related to appeals integration may marginally impact the ways MA sponsors bid for their D–SNPs, which could impact Medicare spending. We are finalizing as proposed that the existing standards for continuation of benefits at § 438.420 apply to applicable integrated plans for Medicare benefits under Parts A and B and Medicaid benefits in the new integrated appeals requirements at § 422.632. Under our final rule, and as is applicable to Medicaid managed care plans currently, if an applicable integrated plan decides to stop or reduce a benefit that the enrollee is currently authorized to receive, the enrollee could request that the benefit continue to be provided at the currently authorized level while the enrollee's appeal is pending through the integrated reconsideration. Currently, MA plans generally are not required to provide benefits pending appeal, whereas in Medicaid it has been a long-standing feature.

We expect that the new integrated appeals provisions will result in an increase in expenditures by applicable integrated plans for Medicare Parts A and Part B covered services because they will be required to continue coverage for services during the pendency of the reconsideration request, or first-level appeal under our final rule.

The estimate of impact of this continuation is based on calendar year 2016 appeal metrics, which are then trended to calendar year 2021. The assumptions, sources and calculations are summarized in Tables 11 and 12 in this rule and further clarified as follows.

The first step in this estimation is to determine the number of integrated reconsiderations per 1,000 beneficiaries enrolled in applicable integrated plans affected by this provision. Given the similarity of population characteristics, the reconsideration experience for the Medicare-Medicaid Plans (MMPs) participating in the Financial Alignment Initiative was used as a proxy for the applicable integrated plans. In 2016, MMP enrollees were impacted by 1,232 reconsiderations for services which were resolved adversely or partially favorably to the beneficiary. The corresponding MMP enrollment in 2016 was 368,841, which implies a rate of 3.3 reconsiderations per 1,000 in 2016.

We projected D–SNP enrollment impacted by the unified procedures to grow from 150,000 in 2018 to 172,000 (150,000 * 1.145) in 2021 based on the estimated enrollment growth for all D–SNPs during the period of 14.5 percent. Applying the MMP reconsideration rate of 3.3 per 1,000 to the projected 2021 enrollment in applicable integrated plans of 172,000 results in an estimated 568 (172,000 * 3.3/1,000) service reconsiderations for applicable integrated plans in 2020.

The next step is to determine the average level of benefit subject to the appeals. Table 1 in the report Medicare Part C QIC Reconsideration Data for

2016 [60] contains data on the number and benefit amounts by service category for the second level appeals filed in 2016. Analysis of these data resulted in an estimated per-appeal benefit value of $737 for 2016. The determination of this value took into account that some services would not be subject to the regulatory extension of coverage due to the existence of immediate review rights (inpatient hospital, skilled nursing facility, and home health), other benefits would likely have been rendered already (emergency room, and ambulance), and other services are not covered as a D–SNP basic benefit (hospice and non-Medicare benefits). Accounting for 19.5 percent inflation in per-capita Medicare spending between 2016 and 2021, and carving out the 13.38 percent consumer price index inflation in years 2016–2020 inclusive, results in an estimated per-appeal benefit value of $774 (that is, $737 * 1.195/1.1338) for 2021.

[60] *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/IRE.html.*

Taking the product of the number of applicable integrated plan service reconsiderations in 2021 (568) and average benefit value in 2021 ($774) yields an estimated cost in 2021 of $439,632 (that is, 568 * $774) due to an increase in Medicare expenditures stemming from the unified appeals procedures for applicable integrated plans. We believe that this figure represents an upper bound of the cost given that not all applicable services will be rendered during the extended period of benefit continuation in this regulation. These calculations are summarized in Table 11.

Using the 2021 estimates as a basis, estimates for 2021 through 2029 are presented in Table 12. The following assumptions were used in creating Table 12:

- As described earlier in this section, the numbers in the row for 2021 come from Table 11.
- The projected FIDE SNP enrollment for 2022 through 2029 was obtained by multiplying the estimated 2021 FIDE SNP enrollment of 172,000, using SNP enrollment growth factors inferred from Table IV.C1 in the 2018 Medicare Trustees Report.
- The projected cost per appeal for 2022 through 2029 was obtained by first multiplying the estimated 2021 cost per appeal of $774 by FFS per capita growth rates obtained from internal documentation for the Table of FFS USPCC, non-ESRD estimates in attachment II of the 2019 Rate Announcement and Call Letter (*https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf*).

As summarized in Table 12, there is an estimated true cost (reflecting purchase of goods and services) of $0.4 million in 2021 and $0.5 million in 2022 through 2025, modestly increasing to $0.6 and $0.7 million in 2026 through 2029. Eighty-six percent of this cost is transferred from the plans to the Medicare Trust Fund; the remainder of this cost is born by beneficiary cost sharing.

TABLE 11: IMPACT OF INTEGRATED APPEALS PROVISION OF FIDE SNPS

Row ID	Item Description	Number	Data Source
	MMP Appeals: 2016		
(A)	Appeals	1,232	2016 Parts C and D Reporting Requirements PUF (not incl. Part D MTM data) from https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html. Sum of service reconsiderations partially favorable and adverse for organization type "Demo"
(B)	Enrollment	368,841	2016 Parts C and D Reporting Requirements PUF (not incl. Part D MTM data) from https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html. Sum of enrollment for organization type "Demo"
(C)	MMP appeals per 1000	3.3	(C) =(A) / (B) * 1000
	FIDE SNP Appeals 2021		
(D)	Enrollment 2018	150,000	Internal CMS enrollment extract in HPMS data system for July 2018
(E)	D-SNP enrollment growth: '18-'21	14.5%	Table IV.C1, "Private Health Enrollment" in 2018 Medicare Trustees Report, accessible at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf
(F)	Enrollment 2021	172,000	(F) = (D)*(1+(E))
(G)	MMP Appeals per 1000 in 2016	3.3	Row (C)
(H)	FIDE SNP appeals 2021	568	(H) = (F)/1000 * (G)
	Cost of FIDE SNP Appeals: 2021		
(I)	Average benefit per appeal (2016)	$737	Data obtained from CMS Appeal & Grievance Contractor
(J)	Inflation: 2016 – 2021	19.5%	Ratio of 2021 and 2016 entries in table "Comparison of Current and Previous Estimates of the FFS USPCC - Non ESRD" in the 2019 Rate Announcement and Call letter accessible at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf
(K)	Carving out Ordinary Inflation 2016-2021	13.80%	Product of the urban consumer price index (CPI-U) increase factors for 2016-2020 inclusive. Data were obtained from Table V.B2 in the 2017 Medicare Trustees Report accessible at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf
(L)	Average benefit per appeal (2021)	$774	(L) = (I) * (1 + (J)) / (1+(K))
(M)	Aggregate amount of appeal (2021)	$440,000	(M) = (L) * (H)

TABLE 12—NET COST PER YEAR TO THE MEDICARE TRUST FUND FOR INTEGRATED PLAN APPEALS

Contract year	Affected FIDE SNP enrollment (A)	Appeals per 1,000 affected enrollees (B)	Number of affected appeals per year (C) = (A)/ 1000 * (B)	Cost per appeal (D)	Gross cost of appeals ($ in millions) (E) = (D) * (C)/ 1,000,000	Share of cost funded by medicare trust fund (%) (F)	Net cost of appeals to medicare trust fund ($ in millions) (F) * (E)	Net cost of appeals to beneficiaries ($ in millions) (1–F) * (E)
2021	172,000	3.3	568	$774	0.4	86%	0.4	
2022	179,000	3.3	591	791	0.5	86	0.4	0.1
2023	185,000	3.3	611	808	0.5	86	0.4	0.1
2024	191,000	3.3	630	828	0.5	86	0.4	0.1
2025	197,000	3.3	650	842	0.5	86	0.5	0.1
2026	203,000	3.3	670	861	0.6	85	0.5	0.1
2027	209,000	3.3	690	883	0.6	85	0.5	0.1
2028	215,000	3.3	710	903	0.6	85	0.5	0.1
2029	220,000	3.3	726	920	0.7	85	0.6	0.1

b. Updating Plan Grievance Policies and Procedures and Consolidation of Plan Grievance Notifications and Reviews

As detailed in section III.B.3. of this final rule, there are only 34 contracts representing 37 D–SNPs that we currently believe will be classified as a HIDE SNP or FIDE SNP and operate in states that have policies requiring exclusively aligned enrollment across MA and Medicaid managed care plans. In addition to the costs estimated in section III.B.3. of this final rule, we estimate the following impacts: (1) Sending a notice of acknowledgement; (2) sending a notice of resolution; and (3) review of integrated grievances.

(1) Sending a Notice of Acknowledgement

Under § 422.629(g), applicable integrated plans must send a notice of acknowledgment for all grievances, both those submitted orally and in writing. Medicaid managed care organizations are currently required to send this notice under § 438.406(b)(1), whereas MA plans are not currently required to send this notice. Under this final rule, applicable integrated plans must now send this notice for all grievances, not only those pertaining to Medicaid issues. In the absence of data on the types of grievances submitted, we assume half the grievances currently made to an applicable integrated plan are related to Medicare issues and half are related to Medicaid issues.

Estimates of impacts for this notice take into account overlapping Medicare and Medicaid benefits. As we do not have data on grievances for overlapping Medicare and Medicaid benefits, we assume 25 percent of all grievances are related to overlapping Medicare and Medicaid benefits. This 25 percent estimate reflects our belief that there is some (more than 0 percent) overlap, but that the majority of grievances (more than 50 percent) do not overlap. The average of 0 percent and 50 percent results in the 25 percent assumption we have made. We use the following 6 estimates to estimate the costs associated with this provision:

- As detailed in section IV.B.3.a of this final rule, we estimate that the aggregate number of enrollees in applicable integrated plans in Contract Year 2021 is 172,000. We used an average of the following two estimates for the percentage of enrollees expected to file a grievance:

++ The May 2016 Medicaid Managed Care final rule estimate of a 2 percent filing rate; and

++ The currently approved burden under OMB control number 0938–0753 (CMS–R–267) estimate of a 6.8 percent filing rate.

Thus we estimate that 4.4 percent (½ × (6.8 percent + 2 percent) of all enrollees file a grievance.

- As indicated previously, we estimate that 50 percent of all grievances are related to Medicare coverage issues and half are related to Medicaid coverage issues.
- As indicated previously, we estimate 25 percent of all grievances for applicable integrated plans are regarding overlapping Medicare and Medicaid benefits issues.
- We estimate that the time for mailing an acknowledgment notice using a standard form is 1 minute, or 1/60th of an hour.
- A business operations specialist would perform this task at an hourly wage of $72.84/hr.
- Therefore, we estimate there are 7,568 grievances (172,000 enrollees × 4.4 percent who file a grievance), of which 3,784 (7,568 grievances × 50 percent) are related to enrollees' Medicare coverage and 3,784 are related to their Medicaid coverage. We estimate that 1,892 grievances (7,568 grievances × 25 percent of grievances for overlapping benefits) are made with respect to overlapping Medicare and Medicaid issues and currently only require acknowledgment notices under Medicaid rules. It follows that the new burden arising from this provision applies to 1,892 grievances (3,784 grievances related to Medicare coverage minus the 1,892 grievances that would have resulted in notices of acknowledgement because they related to Medicaid coverage).

Thus the aggregate annual burden across all plans from this provision is 32 hours (1,892 grievances × 1/60 hr) at a cost of $2,297 (1,892 grievances × 1/60 hr × $72.84/hr).

(2) Sending a Notice of Resolution

Section 422.630(e) requires that applicable integrated plans issue a notice upon resolution of the integrated grievance, unless the grievance was made orally and: (1) Was not regarding quality of care; and (2) the enrollee did not request a written response. To estimate the savings from the reduction in the number of grievance resolution notices due to unification of grievance processes for applicable integrated plans, we first estimate the total cost of issuing such notices and then multiply by 25 percent (the estimated number of grievances that are regarding overlapping Medicare and Medicaid benefits). The resulting amount is the cost of the eliminated duplicative grievance notices under the unified procedures. We used the following 7 estimates in our calculation:

- As previously discussed regarding sending the notice of acknowledgement, we estimate that the aggregate number of enrollees in applicable integrated plans in Contract Year 2021 is 172,000.
- As previously discussed regarding sending the notice of acknowledgement, we estimate that 4.4 percent of all enrollees file a grievance.
- The currently approved burden under OMB control number 0938–0753 (CMS–R–267) estimates that 60 percent

of all those who file a grievance will file orally.

- We estimate that of those who file orally, 10 percent will request a follow up written response.
- We estimate 9.5 percent of those who file a grievance, file on quality matters.[61]
- We estimate that it will take one-quarter of an hour to prepare a written response to a grievance, reflecting the current time estimate under OMB control number 0938–0753 (CMS–R–267).
- A business operations specialist would perform this task at an hourly wage of $72.84/hr.

We use these 7 estimates to derive the following:

- We estimate there will be 7,568 grievances (172,000 enrollees × 4.4 percent who file a grievance)
- 51.13 percent of those who file a grievance require written responses, either because the grievance was on a quality issue, was submitted in writing, or was orally submitted (but not on quality issues) and the enrollee requested a written response. The 51.13 percent estimate is based on the following assumptions:

++ 9.5 percent of all grievances are on quality matters, all of which require written response;

++ 36.2 percent of all grievances are submitted in writing and not on quality issues (90.5 percent of grievances that are not on quality issues × 40 percent (100 percent − 60 percent of grievances submitted orally));

++ 5.43 percent of all grievances are orally submitted (but not on quality issues), and the enrollee requested a written response (90.5 percent of grievances that are not on quality issues × 60 percent of grievances are filed orally × 10 percent of all oral grievances request a written response).

It therefore follows that 51.13 percent of grievances (9.5 percent + 36.20 percent + 5.43 percent) require written response.

Thus, the aggregate burden associated with responding in writing to grievances is 967 hours (7,568 grievances × 51.13 percent of grievances requiring a written response × 0.25 hr to write a response) at a cost of $70,436 (967 hours × $72.84/hour wage of a business operations specialist). It follows that the savings due to reduction of duplicative notices is 242 hours (967 hours × 0.25 grievances involving an overlap of Medicare and Medicaid benefits) at an annual savings of $17,616 (172,000 enrollees × 4.4 percent of enrollees who file grievances × 51.13 percent of grievances requiring a written response × one quarter of grievances eliminated due to overlap of Medicare and Medicaid × one quarter hour × $72.84/hour).

(3) Review of Grievances

We estimate a burden adjustment from grievance reviews detailed under § 422.629(k)(2) in a manner similar to the estimates for sending notices of acknowledgement and resolution. We first estimate total cost and then estimate the savings as 25 percent of that total cost due to the elimination of duplicative grievance reviews for Medicare and Medicaid overlap issues. We assume that the review of each grievance will be done by a business operations specialist working at $72.84/hr. Based on the May 2016 Medicaid Managed Care final rule (81 FR 21498), we assume the average grievance takes 30 minutes for a business operations specialist to resolve. We estimate the aggregate annual cost for grievance review is 3,784 hours (172,000 enrollees × 0.044 × 0.5 hr) at a cost of $275,627 (3,784 hr × $72.84/hr). Therefore, the reduction in grievance reviews is 946 hours (3,784 hr × 25 percent), at an annual savings of $68,907 (3,784/h4 × $72.84).

Thus, the total annual savings associated with consolidation of applicable integrated plans' grievance notifications and reviews is $84,226 per year [($17,616 (notice of resolution) + $68,907 (grievance review) − $2,297 (notice of acknowledgement).]

Section III.B.3. of this final rule estimates a one-time cost of $29,864 ($19,812 for updating policies and procedures + $10,051 for recordkeeping). Thus, the total impact arising from updating policies and procedures and consolidation of grievance notices and reviews is a savings of $54,362 ($88,820 − $29,864) in the first year and savings of $84,226 in subsequent years.

c. Updating Applicable Integrated Plan Appeals Policies and Procedures

Applicable integrated plans' internal appeals policies and procedures must be updated to comply with the unified appeals requirements. In terms of updates, we see no reason to differentiate between the work required for grievances and appeals. Therefore, as indicated in section IV.B.3.b. of this final rule, we estimated a one-time cost of $29,864 for updating applicable integrated plans' appeals policies and procedures.

d. Sending Appeal Files to Enrollees Who Request Them

Medicaid managed care regulations under § 438.406(b)(5) currently require plans to send, for free, appeal case files to enrollees who appeal while, in contrast, the Parts C & D Enrollee Grievance, Organization/Coverage Determinations, and Appeals Guidance, § 50.5.2, requires MA plans to send such files at a reasonable cost.[62] Our final rule requires the applicable integrated plans to send such files for free. To estimate this cost, we must first estimate the cost of sending such a file.

Livanta, a Quality Improvement Organization, estimates the cost per case file as $40–$100.[63] This can be justified independently with a stricter range as follows: Assuming a typical case file has 100 pages, it would weigh about 1 pound at 6 pages per ounce. The cost of mailing a 1-pound case file by FedEx (to assure security) is $10. The cost of photocopying 100 pages at a minimum rate of $0.05 per page is $5. The $0.05 per page is likely to be an overestimate for plans that own their own photocopying equipment. Thus, the total cost of photocopying and mailing would be about $15. We assume a correspondence clerk, BLS occupation code 43–4021,[64] would take 1 hour of work, at $36.64 per hour (including 100 percent for overtime and fringe benefits) to retrieve the file, photocopy it, and prepare it for mailing. Thus we estimate the total cost at $36.64 + $10 + $5 = $51.64.

We need further estimates to complete the calculation. We assume 43.5 total appeals (favorable and unfavorable) per 1,000.[65] Based on our experience, we assume that 10 percent of all appeals would require a file sent. Finally, as indicated in section III.B.3. of this final rule, there are 37 applicable integrated plans in 34 contracts with 150,000 enrollees in 2018 projected to grow to 172,000 enrollees in 2021. Thus we estimate the total annual cost of mailing files to enrollees as $38,637 (that is, 172,000 enrollees * 4.35 percent appeals * 10 percent requesting files * $51.64 cost).

The various impacts of unified grievances and appeals are summarized in Table 13. The aggregate impact is a cost $0.4 to $0.6 million per year for the

[61] This percent estimate comes from the total percent of grievances relating to quality of care as reported by MA plans for calendar Year 2017 Medicare Part C Reporting Requirements Data.

[62] See *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.*

[63] See *https://bfccqioareal.com/recordrequests.html.*

[64] *https://www.bls.gov/oes/current/oes_nat.htm.*

[65] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html.*

next 10 years. This impact reflects both costs to the Medicare Trust Fund, costs to enrollees, costs related to first-year updates to policies and procedures, and savings due to consolidation of notifications to enrollees as a result of unified grievance procedures.

TABLE 13—SUMMARY OF COSTS FOR GRIEVANCE INTEGRATION PROVISION ($ IN MILLIONS)

[Negative numbers indicate savings]

Item	Cost to Medicare Trust Fund	Cost sharing for MA enrollees	Updating policies and procedures and consolidation of grievance notices and reviews	Updating appeal policies and procedures	Sending files to enrollees who request them	Total impact
Subsection in this Unified Grievance Section	(a)	(a)	(b)	(c)	(d)	
2020	n/a	n/a	n/a	n/a	n/a	n/a
2021	0.38	0.06	(0.05)	0.03	0.038	0.5
2022	0.4	0.07	(0.08)	0	0.038	0.4
2023	0.42	0.07	(0.08)	0	0.038	0.4
2024	0.45	0.07	(0.08)	0	0.038	0.5
2025	0.47	0.08	(0.08)	0	0.038	0.5
2026	0.49	0.09	(0.08)	0	0.038	0.5
2027	0.52	0.09	(0.08)	0	0.038	0.6
2028	0.54	0.1	(0.08)	0	0.038	0.6
2029	0.57	0.1	(0.08)	0	0.038	0.6

We note that these costs and savings are true costs and savings since they reflect payment for additional or fewer economic resources (reduced notifications and increased cost of appeals). The increased appeals costs are a cost to MA plans, which transfer this cost to enrollees and the Medicare Trust Fund (the government).

We received no comments on our estimates and therefore are finalizing them with modifications to reflect the omission of the impact associated with sending the notice of acknowledgement and to the occupational codes and corresponding adjusted hourly wages as previously mentioned in this section.

4. Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153)

As described in section II.A.3. of this final rule, section 50354 of the Bipartisan Budget Act of 2018 requires the establishment of a process under which the sponsor of a PDP that provides prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare claims data about its plan enrollees. In the proposed rule, we proposed to add a new § 423.153(g) to implement the process for requesting these data.

To estimate the impact we required a model of operationalizing this provision, without however committing to a particular operationalizing process. We outlined a process which—

- Meets all regulatory requirements; and
- Requires as little burden as possible to make and grant requests.

We solicited comments from stakeholders on this proposed operationalization.

Electronic request and transfers are superior (have less burden) than paper processes. We could therefore add functionalities to the CMS HPMS system (or other CMS systems) which would allow the following functions:

- Request of claims data for the current and future quarters for enrollees of the PDP requesting the data.
- Request to no longer receive data.
- Attestation that all regulatory requirements will be complied with. The attestation would be in the form of a screen listing all regulatory requirements; the authorized PDP HPMS user would have to electronically attest by clicking a button.

Such a process would combine request and attestation. The receipt of the submission would verify completeness of request. Furthermore, there would be no burden in request (under 1 minute of work).

The HPMS contractors estimated that there would be a one-time update costing approximately $200,000.

Besides requesting the data, data must be transmitted to the requesting sponsor. Ideally, data would be transmitted electronically but we do not yet have such an API. Instead, we would treat requested data like data requested for research. Typically, such data is downloaded onto encrypted external hard drives and mailed to requestors.

The data could come from the Chronic Condition Warehouse (CCW). We asked our contractors the cost of downloading quarterly such data and sending it out. The cost varies by sponsor size. Currently, based on CMS public data, there are 63 PDP sponsors. Their size and the quarterly cost per sponsor of providing them with data, should they request it, is summarized in Table 14.

TABLE 14—COST PER PDP SPONSOR PER QUARTER FOR TRANSMITTING CLAIMS DATA

PDP size in enrollees	Number of sponsors	Cost per quarter per sponsor for transmission of claims data
Above 5 million	1	$26,500
1 million–5 million	6	17,500
100,000–1 million	11	10,500

TABLE 14—COST PER PDP SPONSOR PER QUARTER FOR TRANSMITTING CLAIMS DATA—Continued

PDP size in enrollees	Number of sponsors	Cost per quarter per sponsor for transmission of claims data
Under 100,000	45	10,500

To complete the annual impact analysis we needed an estimate of proportions for each plan size that would request data. For example, we are certain that the 1 PDP sponsor with over 5 million enrollees will request data. Thus the annual burden for that plan size is 1 * 4 quarters × $26,500 per quarter = $106,000. Similarly, if we assume that all six PDP sponsors with enrollments between 1 and 5 million would request data then the annual burden is 6 sponsors * 4 quarters * $17,500 per quarter per sponsor = $420,000. If we assume that only three-quarters of these six sponsors request data then the annual burden would be 0.75 * $420,000 = $315,000. In the absence of any other basis for the decision, it is reasonable to assume that the proportion goes down as the size goes down. In the absence of data, we could use a descent of simple fractions (1, three-fourths, one-half, one-fourth). Note, that 50 percent of plans with under 100,000 enrollees have under 10,000 enrollees. It is very unlikely that such plans would have the resources to use the data. Thus an assumption that only 50 percent of plans under 100,000 request data is reasonable. However, we considered multiple scenarios. Table 15 presents for a variety of scenarios of proportions and their total impact. The average of the five scenarios is $1.5 million while the median is $1.3 million. The range of impacts is $0.8 million to $2.9 million. For purposes of Executive Order 13771 accounting we listed the impact as $1.5 million annually, with a $0.2 million one-time cost in the first year. We did not trend this estimate by year since the number of PDP sponsors has remained at 63 since 2015.

TABLE 15—ANNUAL BURDEN OF PROVIDING CLAIMS DATA TO PDP SPONSORS

Scenario label	Proportion of sponsors with over 5 million enrollees requesting data (%)	Proportion of sponsors with 1–5 million enrollees requesting data (%)	Proportion of sponsors with 100,000 to 1 million enrollees requesting data (%)	Proportion of sponsors with less than 100,000 enrollees requesting data (%)	Aggregate annual burden based on costs provided in Table 14 ($ in millions)
A	100	75	50	33	1.3
B	100	100	75	50	1.8
C	100	50	33	25	0.9
D	100	100	100	100	2.9
E	100	100	50	0	0.8

We did not anticipate any further burden. It is most likely that the PDP sponsor would exclusively use the data. In the event that downstream entities are shared any data they are already bound in their contracts by all Medicare regulations including the regulations of this provision.

We received no comments on this proposal and therefore are finalizing this provision without modification.

5. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i)(1) and 423.186(i)(1))

We proposed some measure specification updates. These type of changes are routine and do not have an impact on the highest ratings of contracts (that is, overall rating for MA–PDs, Part C summary rating for MA-only contracts, and Part D summary rating for stand-alone prescription drug plans). Hence, there will be no, or negligible, impact on the Medicare Trust Fund.

We also proposed some adjustments to MA and Part D Star Ratings for extreme and uncontrollable circumstances. The proposed policy will make adjustments to take into account the potential impact on contracts when there are extreme and uncontrollable circumstances affecting them. This policy is in response to the multiple disasters in 2017 and 2018, including several hurricanes and wildfires. We proposed a policy to permit an adjustment to Star Ratings when extreme and uncontrollable circumstances occur during the performance period or measurement period for MA and Part D plans.

We also proposed enhancements to the current methodology to set Star Ratings cut points. The intent of the changes is to increase the stability and predictability of cut points from year to year. This proposal is consistent with the CMS goal to increase transparency. We believe this provision would also have minimal impact on the highest ratings of contracts. Specifically, simulations of the proposed changes to the Star Ratings methodology using the 2018 Star Ratings data show that the impact on the MA Quality Bonus Payment (QBP) ratings is minimal with the QBP ratings overall increasing for less than 1 percent of MA enrollees.

We received no comments on our proposed RIA statement and, therefore, are finalizing this provision without modification.

6. Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§ 423.568, 423.570, and 423.572)

We proposed to limit the amount of time an exceptions request can be held open to 14 calendar days, meaning that there will be an outside limit to how long the request is in a pending status while the Part D plan sponsor attempts to obtain the prescribing physician's or other prescriber's supporting statement. Under current manual guidance, plan sponsors are instructed that an exceptions request should only be held open for a reasonable period of time if a supporting statement is needed. We believe that no more than 14 calendar

days is a reasonable period of time to have an exceptions request open and this rule seeks to codify that standard. Based on comments received, we are modifying the proposed approach to clearly account for circumstances where a prescriber's supporting statement is received late or not received at all within the 14 calendar day timeframe. Under this final rule, if a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) from the end of 14 calendar days from receipt of the exceptions request. We do not expect this to have any new impact on the number of pending appeals or pose a potential burden to plan sponsors, as we expect plans are already making and notifying enrollees of decisions on exceptions requests under a similar reasonable timeframe. Based on findings from plan sponsor audits, this approach is generally consistent with how plans sponsors have operationalized the current guidance that cases only be held open for a reasonable period of time pending receipt of a prescriber's supporting statement. Therefore, we do not expect that plan sponsors would need to hire more staff or adjust their operations in a manner that would affect costs. Consequently, we expect the impact of this final rule to be negligible.

We received no comments on our proposed RIA statement and therefore are finalizing this provision of the RIA statement without modification.

7. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))

We do not anticipate any additional cost or savings associated with our preclusion list provisions. As we indicated in section II.C.1 of this final rule, said provisions will not involve activities for plan sponsors and MA organizations outside of those described in the previously mentioned April 2018 final rule. The provisions are, generally speaking, clarifications of our intended policy and do not constitute new requirements. Hence, the expected impact is negligible.

We received no comments on our proposed RIA statement and are therefore finalizing it without modification.

D. Alternatives Considered

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Section 1852(m)(2)(A)(i) of the Act, as added by the Bipartisan Budget Act of 2018, defines MA additional telehealth benefits as services that are identified for the applicable year as clinically appropriate to furnish using electronic information and telecommunications technology when a physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not at the same location as the plan enrollee (which we refer to as ''through electronic exchange''). We considered various alternative definitions of ''clinically appropriate'' but decided not to finalize specific regulation text defining the term. We are finalizing our proposal to implement the statutory requirement for MA additional telehealth benefits to be provided only when ''clinically appropriate'' to align with existing CMS rules for contract provisions at § 422.504(a)(3)(iii), which requires each MA organization to agree to provide all benefits covered by Medicare ''in a manner consistent with professionally recognized standards of health care.''

The statute does not specify who or what entity identifies the services for the year. We considered various alternatives, including retaining the authority as an agency to specify what services are clinically appropriate to furnish each year. MA plans could have been required to comply with an annual list of clinically appropriate services identified by CMS. However, we rejected this alternative as too restrictive; we believe MA plans are in the best position and it is in their own interest to stay abreast of professional standards necessary to determine which services are clinically appropriate. MA plans have a vested interest in staying abreast of the current professionally recognized standards of health care. Healthcare standards and technology continuously develop as a result of new advancements in modern medicine. As healthcare standards change over time and differ from practice area to practice area, we believe our approach is flexible enough to allow plans to take those changes and differences into account. We believe that failing to allow this flexibility will result in the need for another regulation that addresses future technological changes in health care. We do not want to unduly burden MA plans with an unnecessary regulation or restrict their efforts to provide healthcare services. Thus, we are finalizing our proposal to interpret this provision broadly by not specifying the Part B services that an MA plan may offer as MA additional telehealth benefits for the applicable year, but instead allowing MA plans to independently determine which services each year are clinically appropriate to furnish in this manner. Our final definition of additional telehealth benefits at § 422.135(a)(2) provides that it is the MA plan (not CMS) that identifies the appropriate services for the applicable year.

We also considered alternatives to implement how telehealth benefits are provided through ''electronic exchange.'' CMS considered defining the specific means of ''electronic exchange.'' However, we decided to define ''electronic exchange'' at § 422.135(a) as ''electronic information and telecommunications technology,'' as the former is a concise term for the latter, which is the statutory description of the means used to provide the MA additional telehealth benefits. We did not propose specific regulation text that defines or provides examples of electronic information and telecommunications technology. We considered providing a complete list of means of providing electronic information and telecommunications technology. Although we provided examples of electronic information and telecommunications technology in the proposed rule, we did not provide a comprehensive list because the technology needed and used to provide MA additional telehealth benefits will vary based on the service being offered. CMS appreciates that health care is evolving. CMS's purpose in not providing specific regulation text that defines or provides examples of electronic information and telecommunications technology is to promote flexibility that allows plans to continue to develop methods of healthcare delivery. CMS cannot contemplate the various technological methods plans will use to deliver healthcare services. We do not believe plans will misuse this flexibility because it is in their best interest to provide healthcare services that meet the changing needs of enrollees. We also believe the more narrow approach of defining or providing examples of electronic information and telecommunications technology will cause the added burden of requiring another CMS rule.

We believe this broad approach will avoid tying the authority in the final rule to specific information formats or technologies that permit non-face-to-

face interactions for furnishing clinically appropriate services. This approach will also result in savings due to increased disease prevention among enrollees because plans will be able to develop technology that is less expensive, more predictive, and more accurate. We received no comments on our alternatives considered for this provision and are therefore finalizing our explanation of them without modification.

2. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

This final rule requires D–SNPs that—(1) do not meet the HIDE SNP or FIDE SNP integration standard; and (2) do not have a parent organization assuming clinical and financial responsibility for Medicare and Medicaid benefits to notify the state Medicaid agency or its designee when a high-risk full-benefit dual eligible individual has a hospital or skilled nursing facility admission. We considered several alternatives to this proposal, as explained in section II.A.2.a.(2). of the proposed rule, including examples provided in the Bipartisan Budget Act of 2018: Notifying the state in a timely manner of enrollees' emergency room visits and hospital or nursing home discharges; assigning each enrollee a primary care provider; and data sharing that benefits the coordination of items and services under Medicare and Medicaid. However, we believe our final rule is preferable to the alternatives when considering the degree to which it meets our criteria for establishing minimum contract criteria discussed in section II.A.2.a.(2) of the proposed and final rules. While we lack experience and data to quantify cost, these alternatives would impact a larger number of D–SNP enrollees and require additional state data-sharing infrastructure than the notification requirement we are finalizing in this rule, which we believe would result in increased administrative burden and implementation costs. We received no comments on this discussion of alternatives to the proposed rule and therefore are finalizing our discussion without modification.

3. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560, 422.562, 422.566, 422.629 Through 422.634, 438.210, 438.400, and 438.402)

We are creating unified grievance and appeals procedures for certain D–SNPs (FIDE SNPs and HIDE SNPs) with exclusively aligned enrollment, which we define as occurring when such a D–SNP limits enrollment to full-benefit dual eligible individuals whose Medicaid benefits are covered by the D–SNP itself, or by a Medicaid managed care organization that is the same organization, the D–SNP's parent organization, or another entity that is owned and controlled by the D–SNP's parent organization. Because most D–SNP enrollees are not enrolled in D–SNPs with exclusively aligned enrollment, we considered the feasibility of broadening the scope of these unified procedures to apply to more D–SNPs—that is, to D–SNPs without exclusively aligned enrollment. However, in most states, the majority of D–SNP enrollees have Medicaid coverage either through a different organization's Medicaid MCO, in a prepaid ambulatory or inpatient health plan (PAHP or PIHP), or through a state's Medicaid fee-for-service system. In these circumstances, the D–SNP has no control over the Medicaid grievance and appeals process. Even a D–SNP that has a Medicaid managed care organization operated by such plan's parent organization available to its enrollees, but whose members may instead enroll in other Medicaid plans, can only unify the procedures for Medicaid appeals and grievances of those enrollees who are also simultaneously enrolled in the Medicaid managed care organization controlled by such plan's parent organization. We lack experience and data to quantify the cost of this alternative due to the uncertainty involved in calculating the additional levels of administrative burden and cost associated with unifying grievance and appeals processes when D–SNPs and Medicaid managed care plans that do not have the same enrollees, or where the organizations offering the D–SNPs and Medicaid plans are unaffiliated or even competitors. We received no comments on this proposal and therefore are finalizing our discussion here without modification.

E. Accounting Statement and Table

The following table summarizes costs, savings, and transfers by provision.

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Table 16, we have prepared an accounting statement showing the savings, costs, and transfers associated with the provisions of this final rule for calendar years 2020 through 2029. Table 16 is based on Tables 17A, B, and C which lists savings, costs, and transfers by provision.

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The following Table 17 summarizes savings, costs, and transfers by provision and forms a basis for the accounting table. For reasons of space, Table 17 is broken into Table 17A (2020 through 2023), Table 17B (2024 through 2027), and Table 17C (2028, 2029, and totals). In these tables, all numbers are positive; positive numbers in the savings columns indicate actual dollars saved while positive numbers in the cost columns indicate actual dollars spent; and the aggregate row indicates savings less costs and does not include transfers. The transfer numbers are expressed as negative numbers to reflect the fact that the Medicare Trust Fund incurs a cost while enrollees experience a cost savings. All numbers are in millions. Tables 17A, 17B, and 17C form the basis for Table 16 and for the

TABLE 16: ACCOUNTING STATEMENT - CLASSIFICATIONS OF ESTIMATED SAVINGS, COSTS, AND TRANSFERS

For Calendar Years 2020 To 2029 ($ in millions)	Savings			Whom is Saving, Spending, or Transferring
	Discount Rate		Period	
	7%	3%	Covered	
Net Savings Per Year	49.76	51.75	2020-2029	See itemization in rows below.
Savings Per Year	52.27	54.21	2020-2029	MA enrollees save from reduced travel times to and from providers.
Costs Per Year	2.51	2.45	2020-2029	MA enrollees (cost sharing) and MA plans (that pass costs to the Medicare Trust Fund), Contractors (for claims processing), State Medicaid Agencies that transfer 50% of costs to the federal government.
Transfers Per Year	(7.73)	(7.86)	2020-2029	Medicare Trust Fund and MA enrollees (enrollees save while Medicare Trust Fund incurs cost of telehealth as a basic vs. supplemental benefit; hence the amount is listed as negative, reflecting Medicare Trust Fund cost)

calculation to the infinite horizon discounted to 2016, mentioned in the conclusion.

TABLE 17A: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2020 TO 2023

	2020 Savings	2020 Costs	2020 Transfers	2021 Savings	2021 Costs	2021 Transfers	2022 Savings	2022 Costs	2022 Transfers	2023 Savings	2023 Costs	2023 Transfers
Total Savings	30.9			35.0			39.5			44.5		
Total Costs		5.6			1.9			2.0			2.0	
Aggregate Total	25.3			33.0			37.6			42.5		
Total Transfers			(6.1)			(6.5)			(6.9)			(7.3)
Telehealth Enrollees	30.9			34.9			39.4			44.4		
Telehealth Government			(6.1)			(6.5)			(6.9)			(7.3)
D-SNP Integration, MA Plans		3.4										
D-SNP Integration, State Medicaid Agencies		0.5										
D-SNP Grievance & Appeals, Paperwork Reduction				0.1			0.1			0.1		
D-SNP Grievance & Appeals, Enrollees		0.0			0.1			0.1			0.1	
D-SNP Grievance & Appeals, Medicare Trust Fund		0.0			0.4			0.4			0.4	
Claims Data		1.7			1.5			1.5			1.5	
Star Ratings				0.0			0.0			0.0		
Preclusion				0.0			0.0			0.0		

TABLE 17B: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2024 TO 2027

	2024 Savings	2024 Costs	2024 Transfers	2025 Savings	2025 Costs	2025 Transfers	2026 Savings	2026 Costs	2026 Transfers	2027 Savings	2027 Costs	2027 Transfers
Total Savings	50.1			56.3			63.1			70.7		
Total Costs		2.0			2.1			2.1			2.1	
Aggregate Total	48.1			54.3			61.1			68.5		
Total Transfers			(7.7)			(8.2)			(8.5)			(9.0)
Telehealth Enrollees	50.0			56.2			63.1			70.6		
Telehealth Government			(7.7)			(8.2)			(8.5)			(9.0)
D-SNP Integration, MA Plans												
D-SNP Integration, State Medicaid Agencies												
D-SNP Grievance & Appeals, Paperwork Reduction	0.1			0.1			0.1			0.1		
D-SNP Grievance & Appeals, Enrollees		0.1			0.1			0.1			0.1	
D-SNP Grievance & Appeals, Medicare Trust Fund		0.5			0.5			0.5			0.5	
Claims Data		1.5			1.5			1.5			1.5	
Star Ratings	0.0			0.0			0.0			0.0		
Preclusion	0.0			0.0			0.0			0.0		

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TABLE 17C: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2028 TO 2029, AND TOTALS COLUMNS

	2028 Savings	2028 Costs	2028 Transfers	2029 Savings	2029 Costs	2029 Transfers	Raw Totals Savings	Raw Totals Costs	Raw Totals, Transfers, Costs to Medicare Trust Fund
Total Savings	79.1			88.5			557.7		
Total Costs		2.1			2.2			24.1	
Aggregate Total	76.9			86.3			533.6		
Total Transfers			(9.5)			(9.9)			(79.6)
Telehealth Enrollees	79.0			88.4			557.0		
Telehealth Government			(9.5)			(9.9)			
D-SNP Integration, MA Plans								3.4	
D-SNP Integration, State Medicaid Agencies								0.5	
D-SNP Grievance & Appeals, Paperwork Reduction	0.1			0.1			0.7		
D-SNP Grievance & Appeals, Enrollees		0.1			0.1			0.7	
D-SNP Grievance & Appeals, Medicare Trust Fund		0.5			0.6			4.2	
Claims Data		1.5			1.5			15.2	
Star Ratings							0.0		
Preclusion	0.0			0.0			0.0		

F. Conclusion

As indicated in Tables 17A through C, we estimate that this final rule generates annual cost savings of approximately $25 to $86 million per year over 2020 through 2029. The raw total net savings over 10 years is $534 million.

G. Reducing Regulation and Controlling Regulatory Costs

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.'' In line with Executive Order 13771, in Table 18 we estimate present and annualized values of costs and cost savings over an infinite time horizon. Both costs and savings are presented as positive numbers; net savings equals savings minus costs and is positive. As shown, this final rule generates level annual cost savings of $55.80 million in 2016 dollars over an infinite time horizon, discounted at 7 percent. Based on these cost savings, this final rule would be considered a deregulatory action under Executive Order 13771. Details on estimated savings is found in the preceding analyses.

TABLE 18—EXECUTIVE ORDER 13771 SUMMARY TABLE IN 2016 DOLLARS OVER AN INFINITE TIME HORIZON

[$ In millions]

Item	Primary (7%)	Primary (3%)
Present Value of Costs	27.27	68.39
Present Value of Cost Savings	824.36	2,431.69
Present Value of Net Costs	797.09	2,363.30
Annualized Costs	1.91	2.05
Annualized Cost Savings	57.71	72.95
Annualized Net Savings	55.80	70.90

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 422.2 is amended—

■ a. By adding definitions of ''Aligned enrollment'' and ''Dual eligible special needs plan'' in alphabetical order;

■ b. By revising the definition of ''Fully integrated dual eligible special needs plan'';

■ c. By adding the definition of ''Highly integrated dual eligible special needs plan'' in alphabetical order; and

■ d. In the definition of ''Preclusion list'' by revising the introductory text and paragraphs (1)(i), (2)(i), (2)(ii)(C) and adding paragraph (3).

The additions and revisions read as follows:

§ 422.2 Definitions.

* * * * *

Aligned enrollment refers to the enrollment in a dual eligible special needs plan of full-benefit dual eligible individuals whose Medicaid benefits are covered under a Medicaid managed care organization contract under section 1903(m) of the Act between the applicable State and: the dual eligible special needs plan's (D–SNP's) MA organization, the D–SNP's parent organization, or another entity that is owned and controlled by the D–SNP's parent organization. When State policy limits a D–SNP's membership to individuals with aligned enrollment, this condition is referred to as exclusively aligned enrollment.

* * * * *

Dual eligible special needs plan or D–SNP means a specialized MA plan for special needs individuals who are entitled to medical assistance under a State plan under title XIX of the Act that—

(1) Coordinates the delivery of Medicare and Medicaid services for individuals who are eligible for such services;

(2) May provide coverage of Medicaid services, including long-term services and supports and behavioral health services for individuals eligible for such services;

(3) Has a contract with the State Medicaid agency consistent with § 422.107 that meets the minimum requirements in paragraph (c) of such section; and

(4) Beginning January 1, 2021, satisfies one or more of the following criteria for the integration of Medicare and Medicaid benefits:

(i) Meets the additional requirement specified in § 422.107(d) in its contract with the State Medicaid agency.

(ii) Is a highly integrated dual eligible special needs plan.

(iii) Is a fully integrated dual eligible special needs plan.

* * * * *

Fully integrated dual eligible special needs plan means a dual eligible special needs plan—

(1) That provides dual eligible individuals access to Medicare and Medicaid benefits under a single entity that holds both an MA contract with CMS and a Medicaid managed care organization contract under section 1903(m) of the Act with the applicable State;

(2) Whose capitated contract with the State Medicaid agency provides coverage, consistent with State policy, of specified primary care, acute care, behavioral health, and long-term services and supports, and provides coverage of nursing facility services for a period of at least 180 days during the plan year;

(3) That coordinates the delivery of covered Medicare and Medicaid services using aligned care management and specialty care network methods for high-risk beneficiaries; and

(4) That employs policies and procedures approved by CMS and the State to coordinate or integrate beneficiary communication materials, enrollment, communications, grievance and appeals, and quality improvement.

* * * * *

Highly integrated dual eligible special needs plan means a dual eligible special needs plan offered by an MA organization that provides coverage, consistent with State policy, of long-term services and supports, behavioral health services, or both, under a capitated contract that meets one of the following arrangements—

(1) The capitated contract is between the MA organization and the Medicaid agency; or

(2) The capitated contract is between the MA organization's parent organization (or another entity that is owned and controlled by its parent organization) and the Medicaid agency.

* * * * *

Preclusion list means a CMS compiled list of individuals and entities that—

(1) * * *

(i) The individual or entity is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.

* * * * *

(2) * * *

(i) The individual or entity has engaged in behavior, other than that

described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare.

(ii) * * *

(C) Any other evidence that CMS deems relevant to its determination; or

(3) The individual or entity, regardless of whether they are or were enrolled in Medicare, has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph (3) are—

(i) The severity of the offense;

(ii) When the offense occurred; and

(iii) Any other information that CMS deems relevant to its determination.

* * * * *

■ 3. Section 422.60 is amended by revising paragraph (g)(2)(i) to read as follows:

§ 422.60 Election process.

* * * * *

(g) * * *

(2) * * *

(i) Operate as a fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan.

* * * * *

■ 4. Section 422.100 is amended by revising paragraphs (a) and (c)(1) to read as follows:

§ 422.100 General requirements.

(a) *Basic rule.* Subject to the conditions and limitations set forth in this subpart, an MA organization offering an MA plan must provide enrollees in that plan with coverage of the basic benefits described in paragraph (c)(1) of this section (except that additional telehealth benefits may be, but are not required to be, offered by the MA plan) and, to the extent applicable, supplemental benefits as described in paragraph (c)(2) of this section, by furnishing the benefits directly or through arrangements, or by paying for the benefits. CMS reviews these benefits subject to the requirements of this section and the requirements in subpart G of this part.

* * * * *

(c) * * *

(1) Basic benefits are all items and services (other than hospice care or coverage for organ acquisitions for kidney transplants) for which benefits are available under parts A and B of Medicare, including additional telehealth benefits offered consistent with the requirements at § 422.135.

* * * * *

■ 5. Section 422.102 is amended by revising paragraph (e) introductory text to read as follows:

§ 422.102 Supplemental benefits.

* * * * *

(e) *Supplemental benefits for certain dual eligible special needs plans.* Subject to CMS approval, fully integrated dual eligible special needs plans and highly integrated dual eligible special needs plans that meet minimum performance and quality-based standards may offer additional supplemental benefits, consistent with the requirements of this part, where CMS finds that the offering of such benefits could better integrate care for the dual eligible population provided that the special needs plan—

* * * * *

■ 6. Section 422.107 is amended by—

■ a. Revising the section heading;

■ b. By revising paragraphs (a), (b), (c)(1), (c)(2), and (c)(3);

■ c. By redesignating paragraph (d) as paragraph (e); and

■ d. Reserving paragraph (d).

The revisions and additions read as follows:

§ 422.107 Special needs plans and dual eligibles: Contract with State Medicaid Agency.

(a) *Definition.* For the purpose of this section, a contract with a State Medicaid agency means a formal written agreement between an MA organization and the State Medicaid agency documenting each entity's roles and responsibilities with regard to dual eligible individuals.

(b) *General rule.* MA organizations seeking to offer a dual eligible special needs plan must have a contract consistent with this section with the State Medicaid agency.

(c) * * *

(1) The MA organization's responsibility to—

(i) Coordinate the delivery of Medicaid benefits for individuals who are eligible for such services; and

(ii) If applicable, provide coverage of Medicaid services, including long-term services and supports and behavioral health services, for individuals eligible for such services.

(2) The category(ies) and criteria for eligibility for dual eligible individuals to be enrolled under the SNP, including as described in sections 1902(a), 1902(f), 1902(p), and 1905 of the Act.

(3) The Medicaid benefits covered under a capitated contract between the State Medicaid agency and the MA organization offering the SNP, the SNP's parent organization, or another entity that is owned and controlled by the SNP's parent organization.

* * * * *

(d) [Reserved]

■ 7. Effective January 1, 2021, § 422.107 is further amended by adding paragraphs (c)(9), (d), and (e)(2) to read as follows:

§ 422.107 Special needs plans and dual eligibles: Contract with State Medicaid Agency.

(c) * * *

* * * * *

(9) For each dual eligible special needs plan that is an applicable integrated plan as defined in § 422.561, a requirement for the use of the unified appeals and grievance procedures under §§ 422.629 through 422.634, 438.210, 438.400, and 438.402.

* * * * *

(d) *Additional minimum contract requirement.* For any dual eligible special needs plan that is not a fully integrated or highly integrated dual eligible special needs plan, the contract must also stipulate that, for the purpose of coordinating Medicare and Medicaid-covered services between settings of care, the SNP notifies, or arrange for another entity or entities to notify, the State Medicaid agency, individuals or entities designated by the State Medicaid agency, or both, of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, identified by the State Medicaid agency. The State Medicaid agency must establish the timeframe(s) and method(s) by which notice is provided. In the event that a SNP authorizes another entity or entities to perform this notification, the SNP must retain responsibility for complying with this requirement.

(e) * * *

(2) MA organizations offering a dual eligible SNP must comply with paragraphs (c)(9) and (d) of this section beginning January 1, 2021.

* * * * *

■ 8. Section 422.111 is amended by revising paragraph (b)(2)(iii) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(2) * * *

(iii) By a dual eligible special needs plan, prior to enrollment, for each prospective enrollee, a comprehensive written statement describing cost

sharing protections and benefits that the individual is entitled to under title XVIII and the State Medicaid program under title XIX.

* * * * *

■ 9. Section 422.135 is added to subpart C to read as follows:

§ 422.135 Additional telehealth benefits.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Additional telehealth benefits means services:

(1) For which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and

(2) That have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not in the same location as the enrollee.

Electronic exchange means electronic information and telecommunications technology.

(b) *General rule.* An MA plan may treat additional telehealth benefits as basic benefits covered under the original Medicare fee-for-service program for purposes of this part 422 provided that the requirements of this section are met. If the MA plan fails to comply with the requirements of this section, then the MA plan may not treat the benefits provided through electronic exchange as additional telehealth benefits, but may treat them as supplemental benefits as described in § 422.102, subject to CMS approval.

(c) *Requirements.* An MA plan furnishing additional telehealth benefits must:

(1) Furnish in-person access to the specified Part B service(s) at the election of the enrollee.

(2) Advise each enrollee that the enrollee may receive the specified Part B service(s) through an in-person visit or through electronic exchange.

(3) Comply with the provider selection and credentialing requirements provided in § 422.204, and, when providing additional telehealth benefits, ensure through its contract with the provider that the provider meet and comply with applicable State licensing requirements and other applicable laws for the State in which the enrollee is located and receiving the service.

(4) Make information about coverage of additional telehealth benefits available to CMS upon request. Information may include, but is not limited to, statistics on use or cost, manner(s) or method of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the requirements of this section.

(d) *Requirement to use contracted providers.* An MA plan furnishing additional telehealth benefits may only do so using contracted providers. Coverage of benefits furnished by a non-contracted provider through electronic exchange may only be covered as a supplemental benefit.

(e) *Bidding.* An MA plan that fully complies with this section may include additional telehealth benefits in its bid for basic benefits in accordance with § 422.254.

(f) *Cost sharing.* MA plans offering additional telehealth benefits may maintain different cost sharing for the specified Part B service(s) furnished through an in-person visit and the specified Part B service(s) furnished through electronic exchange.

§ 422.156 [Amended]

■ 10. Section 422.156 is amended in paragraph (b)(1) by removing the phrase ''the quality improvement projects (QIPs) and''.

■ 11. Section 422.162 (a) is amended by adding the definitions ''Absolute percentage cap'', ''Cut point cap'', ''Guardrail'', ''Mean resampling'', ''Restricted range'', and ''Restricted range cap'' in alphabetical order to read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) * * *

Absolute percentage cap is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

* * * * *

Cut point cap is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.

* * * * *

Guardrail is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

* * * * *

Mean resampling refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchal clustering algorithm is done 10 times, each time leaving one of the 10 groups out. By leaving out one of the 10 groups for each run, 9 of the 10 groups, which is 90 percent of the applicable measure scores, are used for each run of the clustering algorithm. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

* * * * *

Restricted range is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile −3*Interquartile Range (IQR) and third quartile + 3*IQR).

Restricted range cap is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

* * * * *

■ 12. Section 422.164 is amended by adding paragraphs (f)(1)(v), (g)(1)(iii)(O), and (h) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(f) * * *

(1) * * *

(v) CMS excludes any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s).

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(O) CMS reduces the measure rating to 1 star for the applicable appeals measure(s) if a contract fails to submit Timeliness Monitoring Project data for CMS's review to ensure the completeness of the contract's IRE data.

* * * * *

(h) *Review of sponsors' data.* (1) An MA organization may request that CMS or the IRE review its' contract's appeals data provided that the request is received by the annual deadline set by CMS.

(2) An MA organization may request that CMS review its' contract's Complaints Tracking Module (CTM) data provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

■ 13. Section 422.166 is amended by revising paragraph (a)(2)(i) and adding paragraph (i) to read as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data, and a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for three years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first three years in the program.

* * * * *

(i) *Extreme and uncontrollable circumstances.* In the event of extreme and uncontrollable circumstances that may negatively impact operational and clinical systems and contracts' abilities to conduct surveys needed for accurate performance measurement, CMS calculates the Star Ratings as specified in paragraphs (i)(2) through (10) of this section for each contract that is an affected contract during the performance period for the applicable measures. We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

(1) *Identification of affected contracts.* A contract that meets all of the following criteria is an affected contract:

(i) The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Act.

(ii) The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).

(iii) As specified in paragraphs (i)(2) through (10) of this section, a certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

(2) *CAHPS adjustments.* (i) A contract, even if an affected contract, must administer the CAHPS survey unless exempt under paragraph (i)(2)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from administering the CAHPS survey if the contract completes both of the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section in the prior calendar year.

(B) Requests and receives a CMS approved exemption.

(iii) An affected contract with an exemption described in paragraph (i)(2)(ii) of this section receives the contract's CAHPS measure stars and corresponding measure scores from the prior year.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure.

(v) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(3) *HOS adjustments.* (i) An affected contract must administer the HOS survey unless exempt under paragraph (i)(3)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from administering the HOS survey if the contract completes the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section during the measurement period.

(B) Requests and receives a CMS approved exemption.

(iii) Affected contracts with an exemption described in paragraph (i)(3)(ii) of this section receive the prior year's HOS and Healthcare Effectiveness Data and Information Set (HEDIS)-HOS measure stars and corresponding measure scores.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HOS and HEDIS–HOS measure.

(v) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(4) *HEDIS adjustments.* (i) An affected contract must report HEDIS data unless exempted under paragraph (i)(4)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from reporting HEDIS data if the contract completes the following:

(A) Demonstrates an inability to obtain both administrative and medical record data that are required for reporting HEDIS measures due to a FEMA-designated disaster in the prior calendar year.

(B) Requests and receives a CMS approved exemption.

(iii) Affected contracts with an exemption described in paragraph

(i)(4)(ii) of this section receive the prior year's HEDIS measure stars and corresponding measure scores.

(iv) Contracts that do not have an exemption defined in paragraph (i)(4)(ii) of this section may contact National Committee for Quality Assurance (NCQA) to request modifications to the samples for measures that require medical record review.

(v) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HEDIS measure.

(vi) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(5) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS holds the affected contract harmless by using the higher of the contract's summary or overall rating or both with and without including all of the applicable new measures.

(6) *Other Star Ratings measure adjustments.* (i) For all other measures except those measures identified in this paragraph (i)(6)(ii) of this section, affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance receive the higher of the previous or current year's measure Star Rating (and corresponding measure score).

(ii) CMS does not adjust the scores or Star Ratings for the following measures, unless the exemption in paragraph (i)(6)(iii) of this section applies.

(A) Part C Call Center—Foreign Language Interpreter and TTY Availability.

(B) Part D Call Center—Foreign Language Interpreter and TTY Availability.

(iii) CMS adjusts the measures listed in paragraph (i)(6)(ii) of this section using the adjustments listed in paragraph (i)(6)(i) of this section for contracts affected by extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study.

(iv) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(7) *Exclusion from improvement measures.* Any measure that reverts back to the data underlying the previous year's Star Rating due to the adjustments made in paragraph (i) of this section is excluded from both the count of measures and the applicable improvement measures for the current and next year's Star Ratings for the affected contract. Contracts affected by extreme and uncontrollable circumstances do not have the option of reverting to the prior year's improvement rating.

(8) *Missing data.* For an affected contract that has missing data in the current or previous year, the final measure rating comes from the current year unless any of the exemptions described in paragraphs (i)(2)(ii), (i)(3)(ii), and (i)(4)(ii) of this section apply.

(9) *Cut points for non-CAHPS measures.* (i) CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

(ii) The cut points calculated as described in paragraph (i)(9)(i) of this section are used to assess all affected contracts' measure Star Ratings.

(10) *Reward Factor.* (i) CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the Reward Factor described in paragraph (f)(1) of this section.

(ii) All affected contracts are eligible for the Reward Factor based on the calculations described in paragraph (i)(10)(i) of this section.

■ 14. Effective June 17, 2019, § 422.222 is amended by revising paragraph (a)(2) to read as follows:

§ 422.222 Preclusion list.

(a) * * *

(2)(i) CMS sends written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion and inform the individual or entity of their appeal rights. An individual or entity may appeal their inclusion on the preclusion list, defined in § 422.2, in accordance with part 498 of this chapter.

(ii) If the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(A) The notice described in paragraph (a)(2)(i) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.

(B) The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation must be filed jointly by the individual or entity and, as applicable, considered jointly under part 498 of this chapter.

■ 15. Section 422.222 is amended by revising the section heading and paragraph (a) to read as follows:

§ 422.222 Preclusion list for contracted and non-contracted individuals and entities.

(a)(1)(i) Except as provided in paragraph (a)(1)(ii) of this section, an MA organization must not make payment for a health care item, service, or drug that is furnished, ordered, or prescribed by an individual or entity that is included on the preclusion list, defined in § 422.2.

(ii) With respect to MA providers that have been added to an updated preclusion list but are not currently excluded by the OIG, the MA organization must do all of the following:

(A) No later than 30 days after the posting of this updated preclusion list,

must provide an advance written notice to any beneficiary who has received or been prescribed an MA service, item, or drug from or by the individual or entity added to the preclusion list in this update.

(B)(*1*) Subject to paragraph (a)(1)(ii)(B)(*2*) of this section, must ensure that reasonable efforts are made to notify the individual or entity described in paragraph (a)(1)(ii) of this section of a beneficiary who was sent a notice under paragraph (a)(1)(ii)(A) of this section.

(*2*) Paragraph (a)(1)(ii)(B)(*1*) of this section applies only upon receipt of a claim from a precluded provider in Medicare Part C when—

(*i*) The MA organization has enough information on file to either copy the provider on the notification previously sent to the beneficiary or send a new notice informing the provider that they may not see plan beneficiaries due to their preclusion status; and

(*ii*) The claim is received after the claim denial or reject date in the preclusion file.

(C) Must not deny payment for a service, item, or drug furnished, ordered, or prescribed by the newly added individual or entity, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (a)(1)(ii)(A) of this section.

(2)(i) CMS sends written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion and inform the individual or entity of their appeal rights. An individual or entity may appeal their inclusion on the preclusion list, defined in § 422.2, in accordance with part 498 of this chapter.

(ii) If the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(A) The notice described in paragraph (a)(2)(i) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.

(B) The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation must be filed jointly by the individual or entity and, as applicable, considered jointly under part 498 of this chapter.

(3)(i) Except as provided in paragraph (a)(3)(ii) of this section, an individual or entity will only be included on the preclusion list after the expiration of either of the following:

(A) If the individual or entity does not file a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list upon the expiration of the 60-day period in which the individual or entity may request a reconsideration; or

(B) If the individual or entity files a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list effective on the date on which CMS, if applicable, denies the individual's or entity's reconsideration.

(ii) An OIG excluded individual or entity is added to the preclusion list effective on the date of the exclusion.

(4) Payment denials based upon an individual's or entity's inclusion on the preclusion list are not appealable by beneficiaries.

(5)(i) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the individual's or entity's reenrollment bar.

(ii) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the individual or entity had they been enrolled and then revoked.

(iii) Except as provided in paragraph (a)(5)(iv) of this section, an individual or entity, regardless of whether they are or were enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are as follows:—

(A) The severity of the offense.

(B) When the offense occurred.

(C) Any other information that CMS deems relevant to its determination.

(iv) In cases where an individual or entity is excluded by the OIG, the individual or entity must remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(6) CMS has the discretion not to include a particular individual or entity on (or if warranted, remove the individual or entity from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to MA items, services, or drugs. In making a determination as to whether such circumstances exist, CMS takes into account:

(i) The degree to which beneficiary access to MA items, services, or drugs would be impaired; and

(ii) Any other evidence that CMS deems relevant to its determination.

* * * * *

■ 16. Section 422.252 is amended by revising the definition of ''MA monthly basic beneficiary premium'', ''MA monthly MSA premium'', ''Monthly aggregate bid amount'', ''Plan basic cost sharing'', and ''Unadjusted MA statutory non-drug monthly bid amount'' to read as follows:

§ 422.252 Terminology.

* * * * *

MA monthly basic beneficiary premium means the premium amount (if any) an MA plan (except an MSA plan) charges an enrollee for basic benefits as defined in § 422.100(c)(1), and is calculated as described at § 422.262.

MA monthly MSA premium means the amount of the plan premium for coverage of basic benefits as defined in § 422.100(c)(1) through an MSA plan, as set forth at § 422.254(e).

* * * * *

Monthly aggregate bid amount means the total monthly plan bid amount for coverage of an MA eligible beneficiary with a nationally average risk profile for the factors described in § 422.308(c), and this amount is comprised of the following:

(1) The unadjusted MA statutory non-drug monthly bid amount for coverage of basic benefits as defined in § 422.100(c)(1).

(2) The amount for coverage of basic prescription drug benefits under Part D (if any).

(3) The amount for provision of supplemental health care benefits (if any).

* * * * *

Plan basic cost sharing means cost sharing that would be charged by a plan for basic benefits as defined in § 422.100(c)(1) before any reductions resulting from mandatory supplemental benefits.

* * * * *

Unadjusted MA statutory non-drug monthly bid amount means a plan's estimate of its average monthly required revenue to provide coverage of basic benefits as defined in § 422.100(c)(1) to an MA eligible beneficiary with a nationally average risk profile for the

risk factors CMS applies to payment calculations as set forth at § 422.308(c).

■ 17. Section 422.254 is amended by—
■ a. Revising paragraph (b)(1)(i);
■ b. Adding paragraph (b)(3)(i);
■ c. Reserving paragraph (b)(3)(ii); and
■ d. Revising paragraphs (b)(4), (c)(3)(i), and (e)(2).

The revisions and addition read as follows:

§ 422.254 Submission of bids.

* * * * *

(b) * * *

(1) * * *

(i) The unadjusted MA statutory non-drug monthly bid amount, which is the MA plan's estimated average monthly required revenue for providing basic benefits as defined in § 422.100(c)(1).

* * * * *

(3) * * *

(i) MA plans offering additional telehealth benefits as defined in § 422.135(a) must exclude any capital and infrastructure costs and investments directly incurred or paid by the MA plan relating to such benefits from their bid submission for the unadjusted MA statutory non-drug monthly bid amount.

(ii) [Reserved]

(4) The bid amount is for plan payments only but must be based on plan assumptions about the amount of revenue required from enrollee cost-sharing. The estimate of plan cost-sharing for the unadjusted MA statutory non-drug monthly bid amount for coverage of basic benefits as defined in § 422.100(c)(1) must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare fee-for-service program option. The actuarially equivalent level of cost sharing reflected in a regional plan's unadjusted MA statutory non-drug monthly bid amount does not include cost sharing for out-of-network Medicare benefits, as described at § 422.101(d).

* * * * *

(c) * * *

(3) * * *

(i) The provision of basic benefits as defined in § 422.100(c)(1);

* * * * *

(e) * * *

(2) The amount of the MA monthly MSA premium for basic benefits (as defined in § 422.252);

* * * * *

■ 18. Section 422.264 is amended by revising paragraph (a) to read as follows:

§ 422.264 Calculation of savings.

(a) *Computation of risk adjusted bids and benchmarks*—(1) *The risk adjusted MA statutory non-drug monthly bid amount* is the unadjusted MA statutory non-drug monthly bid amount (defined at § 422.254(b)(1)(i)), adjusted using the factors described in paragraph (c) of this section for local plans and paragraph (e) of this section for regional plans.

(2) The *risk adjusted MA area-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of basic benefits defined in § 422.100(c)(1) by a local MA plan, adjusted using the factors described in paragraph (c) of this section.

(3) The *risk adjusted MA region-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of basic benefits defined in § 422.100(c)(1) by a regional MA plan, adjusted using the factors described in paragraph (e) of this section.

* * * * *

■ 19. Section 422.504 is amended by adding paragraphs (g)(1)(iv) and (v) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(g) * * *

(1) * * *

(iv) Ensure that the enrollee does not have any financial liability for services, items, or drugs furnished, ordered, or prescribed to the enrollee by an MA contracted individual or entity on the preclusion list, as defined in § 422.2 and as described in § 422.222.

(v) Ensure that the plan's provider agreement contains a provision stating that after the expiration of the 60-day period specified in § 422.222:

(A) The provider will no longer be eligible for payment from the plan and will be prohibited from pursuing payment from the beneficiary as stipulated by the terms of the contract between CMS and the plan per § 422.504(g)(1)(iv); and

(B) The provider will hold financial liability for services, items, and drugs that are furnished, ordered, or prescribed after this 60-day period, at which point the provider and the beneficiary will have already received notification of the preclusion.

* * * * *

■ 20. Effective January 1, 2021, § 422.560 is amended by adding paragraphs (a)(4) and (b)(5) to read as follows:

§ 422.560 Basis and scope.

(a) * * *

(4) Section 1859(f)(8) of the Act provides for, to the extent feasible, unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act for Medicare and Medicaid covered items and services provided by specialized MA plans for special needs individuals described in subsection 1859(b)(6)(B)(ii) of the Act for individuals who are eligible under titles XVIII and XIX of the Act. Beginning January 1, 2021, procedures established under section 1859(f)(8) of the Act apply in place of otherwise applicable grievances and appeals procedures with respect to Medicare and Medicaid covered items and services provided by applicable integrated plans.

(b) * * *

(5) Requirements for applicable integrated plans with respect to procedures for integrated grievances, integrated organization determinations, and integrated reconsiderations.

* * * * *

■ 21. Section 422.561 is amended by adding the definitions ''Applicable integrated plans'', ''Integrated appeal'', ''Integrated grievance'', ''Integrated organization determination'', and ''Integrated reconsideration'' in alphabetical order to read as follows:

§ 422.561 Definitions.

* * * * *

Applicable integrated plan means:

(1) A fully integrated dual eligible special needs plan with exclusively aligned enrollment or a highly integrated dual eligible special needs plan with exclusively aligned enrollment, and

(2) The Medicaid managed care organization, as defined in section 1903(m) of the Act, through which such dual eligible special needs plan, its parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization.

* * * * *

Integrated appeal means any of the procedures that deal with, or result from, adverse integrated organization determinations by an applicable integrated plan on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service. Integrated appeals cover procedures that would otherwise be defined and

covered, for non-applicable integrated plans, as an appeal defined in § 422.561 or the procedures required for appeals in accordance with §§ 438.400 through 438.424 of this chapter. Such procedures include integrated reconsiderations.

Integrated grievance means a dispute or compliant that would be defined and covered, for grievances filed by an enrollee in non-applicable integrated plans, under § 422.564 or §§ 438.400 through 438.416 of this chapter. Integrated grievances do not include appeals procedures and QIO complaints, as described in § 422.564(b) and (c). An integrated grievance made by an enrollee in an applicable integrated plan is subject to the integrated grievance procedures in §§ 422.629 and 422.630.

Integrated organization determination means an organization determination that would otherwise be defined and covered, for a non-applicable integrated plan, as an organization determination under § 422.566, an adverse benefit determination under § 438.400(b), or an action under § 431.201 of this chapter. An integrated organization determination is made by an applicable integrated plan and is subject to the integrated organization determination procedures in §§ 422.629, 422.631, and 422.634.

Integrated reconsideration means a reconsideration that would otherwise be defined and covered, for a non-applicable integrated plan, as a reconsideration under § 422.580 and appeal under § 438.400(b) of this chapter. An integrated reconsideration is made by an applicable integrated plan and is subject to the integrated reconsideration procedures in §§ 422.629 and 422.632 through 422.634.

* * * * *

■ 22. Section 422.562 is amended by—
■ a. Revising paragraph (a)(1)(i);
■ b. By adding paragraph (a)(5); and
■ c. By revising paragraphs (b)(1), (b)(2), (b)(3), (b)(4)(i), and (b)(4)(ii).

The revisions and addition read as follows:

§ 422.562 General provisions.

(a) * * *

(1) * * *

(i) A grievance procedure as described in § 422.564 or, beginning January 1, 2021, § 422.630 as applicable, for addressing issues that do not involve organization determinations;

* * * * *

(5) An MA organization that offers a dual eligible special needs plan has the following additional responsibilities:

(i) The dual eligible special needs plan must offer to assist an enrollee in that dual eligible special needs plan with obtaining Medicaid covered services and resolving grievances, including requesting authorization of Medicaid services, as applicable, and navigating Medicaid appeals and grievances in connection with the enrollee's own Medicaid coverage, regardless of whether such coverage is in Medicaid fee-for-service or a Medicaid managed care plan, such as a Medicaid MCO, PIHP, or PAHP as defined in § 438.2 of this chapter. If the enrollee accepts the offer of assistance, the plan must provide the assistance. Examples of such assistance include the following:

(A) Explaining to an enrollee how to make a request for Medicaid authorization of a service and how to file appeal following an adverse benefit determination, such as—

(*1*) Assisting the enrollee in identifying the enrollee's specific Medicaid managed care plan or fee-for-service point of contact;

(*2*) Providing specific instructions for contacting the appropriate agency in a fee-for-service setting or for contacting the enrollee's Medicaid managed care plan, regardless of whether the Medicaid managed care plan is affiliated with the enrollee's dual eligible special needs plan; and

(*3*) Assisting the enrollee in making contact with the enrollee's fee-for-service contact or Medicaid managed care plan.

(B) Assisting a beneficiary in filing a Medicaid grievance or a Medicaid appeal.

(C) Assisting an enrollee in obtaining documentation to support a request for authorization of Medicaid services or a Medicaid appeal.

(ii) The dual eligible special needs plan must offer to provide the assistance described in paragraph (a)(5)(i) of this section whenever it becomes aware of an enrollee's need for a Medicaid-covered service. Offering such assistance is not dependent on an enrollee's specific request.

(iii) The dual eligible special needs plan must offer to provide and actually provide assistance as required by paragraph (a)(5)(i) of this section using multiple methods.

(A) When an enrollee accepts the offer of assistance described in paragraph (a)(5)(i) of this section, the dual eligible special needs plan may coach the enrollee on how to self-advocate.

(B) The dual eligible special needs plan must also provide an enrollee reasonable assistance in completing forms and taking procedural steps related to Medicaid grievances and appeals.

(iv) The dual eligible special needs plan must, upon request from CMS, provide documentation demonstrating its compliance with this paragraph (a)(5).

(v) The obligation to provide assistance under paragraph (a)(5)(i) of this section does not create an obligation for a dual eligible special needs plan to represent an enrollee in a Medicaid appeal.

(b) * * *

(1) The right to have grievances between the enrollee and the MA organization heard and resolved, as described in § 422.564 or, beginning January 1, 2021, § 422.630, as applicable.

(2) The right to a timely organization determination, as provided under § 422.566 or, beginning January 1, 2021, § 422.631, as applicable.

(3) The right to request an expedited organization determination, as provided under §§ 422.570 or, beginning January 1, 2021, § 422.631(e), as applicable.

(4) * * *

(i) The right to a reconsideration of the adverse organization determination by the MA organization, as provided under § 422.578 or, beginning January 1, 2021, § 422.633, as applicable.

(ii) The right to request an expedited reconsideration, as provided under § 422.584 or, beginning January 1, 2021, § 422.633(f), as applicable.

* * * * *

■ 23. Effective January 1, 2021, § 422.566 is amended by revising paragraph (a) to read as follows:

§ 422.566 Organization determinations.

(a) *Responsibilities of the MA organization.* Each MA organization must have a procedure for making timely organization determinations (in accordance with the requirements of this subpart) regarding the benefits an enrollee is entitled to receive under an MA plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to pay for a health service. The MA organization must have a standard procedure for making determinations, in accordance with § 422.568, and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with §§ 422.570 and 422.572. For an applicable integrated plan, beginning January 1, 2021, the MA

organization must comply with §§ 422.629 through 422.634 in lieu of §§ 422.566(c) and (d), 422.568, 422.570 and 422.572 with regard to the procedures for making determinations, including integrated organization determinations and integrated reconsiderations, on a standard and expedited basis.

* * * * *

■ 24. Effective January 1, 2021, add an undesignated center heading and §§ 422.629 through 422.634 to Subpart M to read as follows:

Subpart M—Grievances, Organization Determinations and Appeals

* * * * *

Requirements Applicable to Certain Integrated Dual Eligible Special Needs Plans

Sec.

422.629 General requirements for applicable integrated plans.
422.630 Integrated grievances.
422.631 Integrated organization determinations.
422.632 Continuation of benefits while the applicable integrated plan reconsideration is pending.
422.633 Integrated reconsideration.
422.634 Effect.

Requirements Applicable to Certain Integrated Dual Eligible Special Needs Plans

§ 422.629 General requirements for applicable integrated plans.

(a) *Scope.* The provisions in this section and in §§ 422.630 through 422.634 set forth requirements for unified appeals and grievance processes with which applicable integrated plans must comply. Beginning January 1, 2021, these provisions apply to an applicable integrated plan in lieu of §§ 422.564, 422.566(c) and (d), and 422.568 through 422.590, and 422.618(a) and §§ 438.404 through 438.424 of this chapter.

(b) *General process.* An applicable integrated plan must create integrated processes for enrollees for integrated grievances, integrated organization determinations, and integrated reconsiderations.

(c) *State flexibilities.* A State may, at its discretion, implement standards for timeframes or notice requirements that are more protective for the enrollee than required by this section and §§ 422.630 through 422.634. The contract under § 422.107 must include any standards that differ from the standards set forth in this section.

(d) *Evidence.* The applicable integrated plan must provide the enrollee a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments for integrated grievances, and integrated reconsiderations. The applicable integrated plan must inform the enrollee of the limited time available for presenting evidence sufficiently in advance of the resolution timeframe for appeals as specified in this section if the case is being considered under an expedited timeframe for the integrated grievance or integrated reconsideration.

(e) *Assistance.* In addition to the requirements in § 422.562(a)(5), the applicable integrated plan must provide an enrollee reasonable assistance in completing forms and taking other procedural steps related to integrated grievances and integrated appeals.

(f) *Applicable requirements.* The requirements in §§ 422.560, 422.561, 422.562, 422.566, and 422.592 through 422.626 apply to an applicable integrated plan unless otherwise provided in this section or in §§ 422.630 through 422.634.

(g) *Acknowledgement.* The applicable integrated plan must send to the enrollee written acknowledgement of integrated grievances and integrated reconsiderations upon receiving the request.

(h) *Recordkeeping.* (1) The applicable integrated plan must maintain records of integrated grievances and integrated appeals. Each applicable integrated plan that is a Medicaid managed care organization must review the Medicaid-related information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy.

(2) The record of each integrated grievance or integrated appeal must contain, at a minimum:

(i) A general description of the reason for the integrated appeal or integrated grievance.

(ii) The date of receipt.

(iii) The date of each review or, if applicable, review meeting.

(iv) Resolution at each level of the integrated appeal or integrated grievance, if applicable.

(v) Date of resolution at each level, if applicable.

(vi) Name of the enrollee for whom the integrated appeal or integrated grievance was filed.

(vii) Date the applicable integrated plan notified the enrollee of the resolution.

(3) The record of each integrated grievance or integrated appeal must be accurately maintained in a manner accessible to the State and available upon request to CMS.

(i) *Prohibition on punitive action.* Each applicable integrated plan must ensure that no punitive action is taken against a provider that requests an integrated organization determination or integrated reconsideration, or supports an enrollee's request for these actions.

(j) *Information to providers and subcontractors.* The applicable integrated plan must provide information about the integrated grievance and integrated appeal system to all providers and subcontractors at the time they enter into a contract including, at minimum, information on integrated grievance, integrated reconsideration, and fair hearing procedures and timeframes as applicable. Such information must include the following:

(1) The right to file an integrated grievance and integrated reconsideration.

(2) The requirements and timeframes for filing an integrated grievance or integrated reconsideration.

(3) The availability of assistance in the filing process.

(k) *Review decision-making requirements*—(1) *General rules.* Individuals making decisions on integrated appeals and grievances must take into account all comments, documents, records, and other information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse integrated organization determination.

(2) *Integrated grievances.* Individuals making decisions on integrated grievances must be individuals who—

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual; and

(ii) If deciding any of the following, have the appropriate clinical expertise in treating the enrollee's condition or disease:

(A) A grievance regarding denial of expedited resolution of an appeal.

(B) A grievance that involves clinical issues.

(3) *Integrated organization determinations.* If the applicable integrated plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the integrated organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare and Medicaid

coverage criteria, before the applicable integrated plan issues the integrated organization determination. Any physician or other health care professional who reviews an integrated organization determination must have a current and unrestricted license to practice within the scope of his or her profession.

(4) *Integrated reconsideration determinations.* Individuals making an integrated reconsideration determination must be individuals who—

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual; and

(ii) If deciding an appeal of a denial that is based on lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), are a physician or other appropriate health care professional who have the appropriate clinical expertise, in treating the enrollee's condition or disease, and knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision.

(l) *Parties.* (1) The following individuals or entities can request an integrated grievance, integrated organization determination, and integrated reconsideration, and are parties to the case:

(i) The enrollee or his or her representative;

(ii) An assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service), or any other provider or entity (other than the applicable integrated plan) who has an appealable interest in the proceeding;

(iii) The legal representative of a deceased enrollee's estate; or

(iv) Subject to paragraph (l)(3) of this section, any provider that furnishes, or intends to furnish, services to the enrollee. If the provider requests that the benefits continue while the appeal is pending, pursuant to § 422.632 and consistent with State law, the provider must obtain the written consent of the enrollee to request the appeal on behalf of the enrollee.

(2) When the term ''enrollee'' is used throughout §§ 422.629 through 422.634, it includes providers that file a request and authorized representatives consistent with this paragraph, unless otherwise specified.

(3) A provider who is providing treatment to the enrollee may, upon providing notice to the enrollee, request a standard or expedited pre-service integrated reconsideration on behalf of an enrollee.

§ 422.630 Integrated grievances.

(a) *General rule.* In lieu of complying with § 422.564, and the grievance requirements of §§ 438.402, 438.406, 438.408, 438.414, and 438.416 of this chapter, each applicable integrated plan must comply with this section. Each applicable integrated plan must provide meaningful procedures for timely hearing and resolving integrated grievances between enrollees and the applicable integrated plan or any other entity or individual through which the applicable integrated plan provides covered items and services.

(b) *Timing.* An enrollee may file an integrated grievance at any time with the applicable integrated plan.

(c) *Filing.* An enrollee may file an integrated grievance orally or in writing with the applicable integrated plan, or with the State for an integrated grievance related to a Medicaid benefit, if the State has a process for accepting Medicaid grievances.

(d) *Expedited grievances.* An applicable integrated plan must respond to an enrollee's grievance within 24 hours if the complaint involves the applicable integrated plan's—

(1) Decision to invoke an extension relating to an integrated organization determination or integrated reconsideration; or

(2) Refusal to grant an enrollee's request for an expedited integrated organization determination under § 422.631 or expedited integrated reconsideration under § 422.633.

(e) *Resolution and notice.* (1) The applicable integrated plan must resolve standard integrated grievances as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 calendar days from the date it receives the integrated grievance.

(i) All integrated grievances submitted in writing must be responded to in writing.

(ii) Integrated grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All integrated grievances related to quality of care, regardless of how the integrated grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO with regard to Medicare covered services. For any complaint submitted to a QIO, the applicable integrated plan must cooperate with the QIO in resolving the complaint.

(2) The timeframe for resolving the integrated grievance may be extended by 14 calendar days if the enrollee requests an extension or if the applicable integrated plan justifies the need for additional information and documents how the delay is in the interest of the enrollee. When the applicable integrated plan extends the timeframe, it must—

(i) Make reasonable efforts to promptly notify the enrollee orally of the reasons for the delay; and

(ii) Send written notice to the enrollee of the reasons for the delay immediately, but no later than within 2 calendar days of making the decision to extend the timeframe to resolve the integrated grievance. This notice must explain the right to file an integrated grievance if the enrollee disagrees with the decision to delay.

§ 422.631 Integrated organization determinations.

(a) *General rule.* An applicable integrated plan must adopt and implement a process for enrollees to request that the plan make an integrated organization determination. The process for requesting that the applicable integrated plan make an integrated organization determination must be the same for all covered benefits.

(b) *Requests.* The enrollee, or a provider on behalf of an enrollee, may request an integrated organization determination orally or in writing, except for requests for payment, which must be in writing (unless the applicable integrated plan or entity responsible for making the determination has implemented a voluntary policy of accepting verbal payment requests).

(c) *Expedited integrated organization determinations.* (1) An enrollee, or a provider on behalf of an enrollee, may request an expedited integrated organization determination.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must complete an expedited integrated organization determination when the applicable integrated plan determines (based on a request from the enrollee or on its own) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(d) *Timeframes and notice*—(1) *Integrated organization determination notice.* (i) The applicable integrated plan must send an enrollee a written

notice of any adverse decision on an integrated organization determination (including a determination to authorize a service or item in an amount, duration, or scope that is less than the amount previously requested or authorized for an ongoing course of treatment) within the timeframes set forth in this section.

(ii) For an integrated organization determination not reached within the timeframes specified in this section (which constitutes a denial and is thus an adverse decision), the applicable integrated plan must send a notice on the date that the timeframes expire. Such notice must describe all applicable Medicare and Medicaid appeal rights.

(iii) Integrated organization determination notices must be written in plain language, be available in a language and format that is accessible to the enrollee, and explain the following:

(A) The applicable integrated plan's determination.

(B) The date the determination was made.

(C) The date the determination will take effect.

(D) The reasons for the determination.

(E) The enrollee's right to file an integrated reconsideration and the ability for someone else to file an appeal on the enrollee's behalf.

(F) Procedures for exercising enrollee's rights to an integrated reconsideration.

(G) Circumstances under which expedited resolution is available and how to request it.

(H) If applicable, the enrollee's rights to have benefits continue pending the resolution of the integrated appeal process.

(2) *Timing of notice*—(i) *Standard integrated organization determinations.* (A) The applicable integrated plan must send a notice of its integrated organization determination at least 10 days before the date of action (that is, before the date on which a termination, suspension, or reduction becomes effective), in cases where a previously approved service is being reduced, suspended, or terminated, except in circumstances where an exception is permitted under §§ 431.213 and 431.214 of this chapter.

(B) For other integrated organization determinations that are not expedited integrated organization determinations, the applicable integrated plan must send a notice of its integrated organization determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from when it receives the request for the integrated organization determination.

(ii) *Extensions.* The applicable integrated plan may extend the timeframe for a standard or expedited integrated organization determination by up to 14 calendar days if—

(A) The enrollee or provider requests the extension; or

(B) The applicable integrated plan can show that—

(*1*) The extension is in the enrollee's interest; and

(*2*) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(iii) *Notices in cases of extension.* (A) When the applicable integrated plan extends the timeframe, it must notify the enrollee in writing of the reasons for the delay as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension, and inform the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision to grant an extension.

(B) If the applicable integrated plan extends the timeframe for making its integrated organization determination, it must send the notice of its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(iv) *Expedited integrated organization determinations.* (A) The applicable integrated plan must provide notice of its expedited integrated organization determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(B) If the applicable integrated plan denies the request for an expedited integrated organization determination, it must:

(*1*) Automatically transfer a request to the standard timeframe and make the determination within the 14-day timeframe established in this paragraph for a standard integrated organization determination. The 14-day period begins with the day the applicable integrated plan receives the request for expedited integrated organization determination.

(*2*) Give the enrollee prompt oral notice of the denial and transfer and subsequently deliver, within 3 calendar days, a written letter that—

(*i*) Explains that the applicable integrated plan will process the request using the 14-day timeframe for standard integrated organization determinations;

(*ii*) Informs the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision not to expedite;

(*iii*) Informs the enrollee of the right to resubmit a request for an expedited integrated organization determination with any physician's support; and

(*iv*) Provides instructions about the integrated grievance process and its timeframes.

(C) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited integrated organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting the timeframe and notice requirements of this section.

§ 422.632 Continuation of benefits while the applicable integrated plan reconsideration is pending.

(a) *Definition.* As used in this section, timely files means files for continuation of benefits on or before the later of the following:

(1) Within 10 calendar days of the applicable integrated plan sending the notice of adverse integrated organization determination.

(2) The intended effective date of the applicable integrated plan's proposed adverse integrated organization determination.

(b) *Continuation of benefits.* The applicable integrated plan must continue the enrollee's benefits under Parts A and B of title XVIII and title XIX if all of the following occur:

(1) The enrollee files the request for an integrated appeal timely in accordance with § 422.633(e);

(2) The integrated appeal involves the termination, suspension, or reduction of previously authorized services;

(3) The services were ordered by an authorized provider;

(4) The period covered by the original authorization has not expired; and

(5) The enrollee timely files for continuation of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the applicable integrated plan continues or reinstates the enrollee's benefits, as described in paragraph (b) of this section, while the integrated reconsideration is pending, the benefits must be continued until—

(1) The enrollee withdraws the request for an integrated reconsideration;

(2) The applicable integrated plan issues an integrated reconsideration that is unfavorable to the enrollee related to the benefit that has been continued;

(3) For an appeal involving Medicaid benefits—

(i) The enrollee fails to file a request for a State fair hearing and continuation of benefits, within 10 calendar days after the applicable integrated plan sends the notice of the integrated reconsideration;

(ii) The enrollee withdraws the appeal or request for a State fair hearing; or

(iii) A State fair hearing office issues a hearing decision adverse to the enrollee.

(d) *Recovery of costs.* In the event the appeal or State fair hearing is adverse to the enrollee—

(1) The applicable integrated plan or State agency may not pursue recovery for costs of services furnished by the applicable integrated plan pending the integrated reconsideration, to the extent that the services were furnished solely under of the requirements of this section.

(2) If, after the integrated reconsideration decision is final, an enrollee requests that Medicaid services continue through a State fair hearing, state rules on recovery of costs, in accordance with the requirements of § 438.420(d) of this chapter, apply for costs incurred for services furnished pending appeal subsequent to the date of the integrated reconsideration decision.

§ 422.633 Integrated reconsideration.

(a) *General rule.* An applicable integrated plan may only have one level of integrated reconsideration for an enrollee.

(b) *External medical reviews.* If a State has established an external medical review process, the requirements of § 438.402(c)(1)(i)(B) of this chapter apply to each applicable integrated plan that is a Medicaid managed care organization, as defined in section 1903 of the Act.

(c) *Case file.* Upon request of the enrollee or his or her representative, the applicable integrated plan must provide the enrollee and his or her representative the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the applicable integrated plan (or at the direction of the applicable integrated plan) in connection with the appeal of the integrated organization determination. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for the integrated reconsideration, or subsequent appeal, as specified in this section.

(d) *Timing.* (1) *Timeframe for filing*—An enrollee has 60 calendar days from the date on the adverse organization determination notice to file a request for an integrated reconsideration with the applicable integrated plan.

(2) *Oral inquires*—Oral inquires seeking to appeal an adverse integrated organization determination must be treated as a request for an integrated reconsideration (to establish the earliest possible filing date for the appeal).

(3) *Extending the time for filing a request*—(i) *General rule.* If a party or physician acting on behalf of an enrollee shows good cause, the applicable integrated plan may extend the timeframe for filing a request for an integrated reconsideration.

(ii) *How to request an extension of timeframe.* If the 60-day period in which to file a request for an integrated reconsideration has expired, a party to the integrated organization determination or a physician acting on behalf of an enrollee may file a request for integrated reconsideration with the applicable integrated plan. The request for integrated reconsideration and to extend the timeframe must—

(A) Be in writing; and

(B) State why the request for integrated reconsideration was not filed on time.

(e) *Expedited integrated reconsiderations.* (1) An enrollee may request, or a provider may request on behalf of an enrollee, an expedited review of the integrated reconsideration.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must grant the request to expedite the integrated reconsideration when it determines (for a request from the enrollee), or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request), that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(4) If an applicable integrated plan denies an enrollee's request for an expedited integrated reconsideration, it must automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in paragraph (f)(1) of this section for a standard integrated reconsideration. The 30-day period begins with the day the applicable integrated plan receives the request for expedited integrated reconsideration. The applicable integrated plan must give the enrollee prompt oral notice of the decision, and give the enrollee written notice within 2 calendar days. The written notice must do all of the following:

(i) Include the reason for the denial.

(ii) Inform the enrollee of the right to file a grievance if the enrollee disagrees with the decision not to expedite, including timeframes and procedures for filing a grievance.

(iii) Inform the enrollee of the right to resubmit a request for an expedited determination with any physician's support.

(5) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited integrated reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting the timeframe and notice requirements of this section.

(f) *Resolution and notification.* The applicable integrated plan must make integrated reconsidered determinations as expeditiously as the enrollee's health condition requires but no later than the timeframes established in this section.

(1) *Standard integrated reconsiderations.* The applicable integrated plan must resolve integrated reconsiderations as expeditiously as the enrollee's health condition requires but no longer than 30 calendar days from the date of receipt of the request for the integrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section.

(2) *Expedited integrated reconsiderations.* The applicable integrated plan must resolve expedited integrated reconsiderations as expeditiously as the enrollee's health condition requires but no later than within 72 hours of receipt for the integrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section. In addition to the written notice required under paragraph (f)(4) of this section, the applicable integrated plan must make reasonable efforts to provide prompt oral notice of the expedited resolution to the enrollee.

(3) *Extensions.* (i) The applicable integrated plan may extend the timeframe for resolving integrated reconsiderations by 14 calendar days if—

(A) The enrollee requests the extension; or

(B) The applicable integrated plan can show that—

(*1*) The extension is in the enrollee's interest; and

(*2*) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(ii) If the applicable integrated plan extends the timeframe for resolving the integrated reconsideration, it must make reasonable efforts to give the enrollee prompt oral notice of the delay, and give the enrollee written notice within 2 calendar days of making the decision to extend the timeframe to resolve the integrated reconsideration. The notice must include the reason for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the decision to grant an extension.

(4) *Notice of resolution.* The applicable integrated plan must send a written notice to enrollees that includes the integrated reconsidered determination, within the resolution timeframes set forth in this section. The notice of determination must be written in plain language and available in a language and format that is accessible to the enrollee and must explain the following:

(i) The resolution of and basis for the integrated reconsideration and the date it was completed.

(ii) For integrated reconsiderations not resolved wholly in favor of the enrollee:

(A) An explanation of the next level of appeal available under the Medicare and Medicaid programs, and what steps the enrollee must take to pursue the next level of appeal under each program, and how the enrollee can obtain assistance in pursuing the next level of appeal under each program; and

(B) The right to request and receive Medicaid-covered benefits while the next level of appeal is pending, if applicable.

§ 422.634 Effect.

(a) *Failure of the applicable integrated plan to send timely notice of a determination.* If the applicable integrated plan fails to adhere to the notice and timing for an integrated organization determination or integrated reconsideration, this failure constitutes an adverse determination for the enrollee.

(1) For an integrated organization determination, this means that the enrollee may request an integrated reconsideration.

(2) For integrated reconsiderations of Medicare benefits, this means the applicable integrated plan must forward the case to the independent review entity, in accordance with the timeframes under paragraph (b) of this section and § 422.592. For integrated reconsiderations of Medicaid benefits, this means that an enrollee or other party may file for a State fair hearing in accordance with § 438.408(f) of this chapter, or if applicable, a State external medical review in accordance with § 438.402(c) of this chapter.

(b) *Adverse integrated reconsiderations.* (1) Subject to paragraph (b)(2) of this section, when the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicare benefit—

(i) The issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS, in accordance with §§ 422.592 and 422.594 through 422.619;

(ii) For standard integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review entity contracted by CMS, as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity; and

(iii) For expedited integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than within 24 hours of its affirmation (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(2) When the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicaid benefit, the enrollee or other party (that is not the applicable integrated plan) may initiate a State fair hearing in the timeframe specified in § 438.408(f)(2) following the integrated plan's notice of resolution. If a provider is filing for a State fair hearing on behalf of the enrollee as permitted by State law, the provider needs the written consent of the enrollee, if he or she has not already obtained such consent.

(c) *Final determination.* The reconsidered determination of the applicable integrated plan is binding on all parties unless it is appealed to the next applicable level. In the event that the enrollee pursues the appeal in multiple forums and receives conflicting decisions, the applicable integrated plan is bound by, and must act in accordance with, decisions favorable to the enrollee.

(d) *Services not furnished while the appeal is pending.* If an applicable integrated plan reverses its decision, or, for a Medicaid benefit, a State fair hearing reverses an applicable plan's integrated reconsideration decision, to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination in lieu of the timeframes described in § 422.618(a). Reversals by the Part C independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council must be effectuated under same timelines applicable to other MA plans as specified in §§ 422.618 and 422.619.

(e) *Services furnished while the appeal is pending.* If the applicable integrated plan or the State fair hearing officer reverses a decision to deny, limit, or delay Medicaid-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the applicable integrated plan or the State must pay for those services, in accordance with State policy and regulations. If the applicable integrated plan reverses a decision to deny, limit, or delay Medicare-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the applicable integrated plan must pay for those services.

■ 25. Effective January 1, 2021, § 422.752 is amended by adding paragraph (d) to read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

* * * * *

(d) *Special rule for non-compliant dual eligible special needs plans.* Notwithstanding any other provision of this section, CMS must impose during plan years 2021 through 2025 intermediate sanctions specified at § 422.750(a) on an MA organization with a contract to operate a dual eligible special needs plan if CMS determines that the dual eligible special needs plan fails to comply with at least one of the criteria for the integration of Medicare and Medicaid benefits provided in the definition of a dual eligible special needs plan at § 422.2. If CMS imposes such an intermediate sanction, the MA organization must submit to CMS a corrective action plan in a form, manner, and timeframe established by CMS. The procedures outlined in § 422.756 apply to the imposition of the intermediate sanction under this provision.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 26. The authority citation for part 423 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh.

■ 27. In 423.100, in the definition of ''Preclusion list'', revise paragraphs (1)(i), (2)(i), (2)(ii)(C) and add paragraph (3) to read as follows:

§ 423.100 Definitions.

* * * * *

Preclusion list * * *

(1) * * *

(i) The prescriber is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.

* * * * *

(2) * * *

(i) The prescriber has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the individual to the extent applicable had he or she been enrolled in Medicare.

(ii) * * *

(C) Any other evidence that CMS deems relevant to its determination; or

(3) The prescriber, regardless of whether he or she is or was enrolled in Medicare, has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph are as follows:

(i) The severity of the offense.

(ii) When the offense occurred.

(iii) Any other information that CMS deems relevant to its determination.

* * * * *

■ 28. Effective June 17, 2019, § 423.120 is amended by revising paragraphs (c)(6)(iv) to read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(c) * * *

(6) * * *

(iv) With respect to Part D prescribers who have been added to an updated preclusion list but are not currently excluded by the OIG, the Part D plan sponsor must do all of the following:

(A) Subject to all other Part D rules and plan coverage requirements, and no later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received a Part D drug prescribed by an individual added to the preclusion list in this update and whom the plan sponsor has identified during the applicable 30-day period.

(B)(*1*) Subject to paragraph (c)(6)(iv)(B)(*2*) of this section, must ensure that reasonable efforts are made to notify the individual described in paragraph (c)(6)(iv) of this section of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(A) of this section.

(*2*) Paragraph (c)(6)(iv)(B)(*1*) of this section applies only upon a prescriber writing a prescription in Medicare Part D when:

(*i*) The plan sponsor has enough information on file to either copy the prescriber on the notification previously sent to the beneficiary or send a new notice informing the prescriber that they may not see plan beneficiaries due to their preclusion status; and

(*ii*) The claim is received after the claim denial or reject date in the preclusion file.

(C) Must not reject a pharmacy claim or deny a beneficiary request for reimbursement for a Part D drug prescribed by the prescriber, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (c)(6)(iv)(A) of this section.

■ 29. Section 423.120 is further amended by—

■ a. Revising paragraphs (c)(6)(v); and

■ b. Adding paragraphs (c)(6)(vii) and (viii).

The revision and additions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(c) * * *

(6) * * *

(v)(A) CMS sends written notice to the prescriber via letter of his or her inclusion on the preclusion list. The notice must contain the reason for the inclusion on the preclusion list and inform the prescriber of his or her appeal rights. A prescriber may appeal his or her inclusion on the preclusion list under this section in accordance with part 498 of this chapter.

(B) If the prescriber's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(*1*) The notice described in paragraph (c)(6)(v)(A) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the prescriber's appeal rights concerning the revocation.

(*2*) The appeals of the prescriber's inclusion on the preclusion list and the prescriber's revocation must be filed jointly by the prescriber and, as applicable, considered jointly under part 498 of this chapter.

(C)(*1*) Except as provided in paragraph (c)(6)(v)(C)(*2*) of this section, a prescriber will only be included on the preclusion list after the expiration of either of the following:

(*i*) If the prescriber does not file a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list upon the expiration of the 60-day period in which the prescriber may request a reconsideration.

(ii) If the prescriber files a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list effective on the date on which CMS, if applicable, denies the prescriber's reconsideration.

(2) An OIG excluded prescriber is added to the preclusion list effective on the date of the exclusion.

* * * * *

(vii)(A) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the prescriber's reenrollment bar.

(B) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the prescriber had the prescriber been enrolled and then revoked.

(C) Except as provided in paragraph (c)(6)(vii)(D) of this section, an

individual, regardless of whether the individual is or was enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are—

(*1*) The severity of the offense;

(*2*) When the offense occurred; and

(*3*) Any other information that CMS deems relevant to its determination.

(D) In cases where an individual is excluded by the OIG, the individual must remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(viii) Payment denials under paragraph (c)(6) of this section that are based upon the prescriber's inclusion on the preclusion list are not appealable by beneficiaries.

* * * * *

■ 30. Section 423.153 is amended by revising the section heading and adding paragraph (g) to read as follows:

§ 423.153 Prescription drug plan sponsors' access to Medicare Parts A and B claims data extracts.

* * * * *

(g) *Parts A and B claims data extracts*—(1) *General rule.* (i) Beginning in plan year 2020, a PDP sponsor may submit a request to CMS for the data described in paragraph (g)(2) of this section about enrollees in its prescription drug plans.

(ii) CMS makes the data requested in paragraph (g)(1)(i) of this section available to eligible PDP sponsors, in accordance with all applicable laws. The data is provided at least quarterly on a specified release date, and in an electronic format to be determined by CMS.

(iii) If CMS determines or has a reasonable belief that the PDP sponsor has violated the requirements of this paragraph (g) or that unauthorized uses, reuses, or disclosures of the Medicare claims data have taken place, at CMS' sole discretion, the PDP sponsor may be denied further access to the data described in paragraph (g)(2) of this section.

(2) *Data described.* The data that may be requested under paragraph (g)(1) of this section are standardized extracts of claims data under Medicare parts A and B for items and services furnished under such parts to beneficiaries who are enrolled in a plan offered by the PDP sponsor at the time of the disclosure.

(3) *Purposes.* A PDP sponsor must comply with all laws that may be applicable to data received under this provision, including State and Federal privacy and security laws, and, furthermore subject to the limitations in paragraph (g)(4) of this section may only use or disclose the data provided by CMS under paragraph (g)(1) of this section for the following purposes:

(i) To optimize therapeutic outcomes through improved medication use, as such phrase is used in paragraph (d)(1)(i) of this section.

(ii) To improve care coordination so as to prevent adverse health outcomes, such as preventable emergency department visits and hospital readmissions.

(iii) For activities falling under paragraph (1) of the definition of ''health care operations'' under 45 CFR 164.501.

(iv) For activities falling under paragraph (2) of the definition of ''health care operations'' under 45 CFR 164.501.

(v) For ''fraud and abuse detection or compliance activities'' under 45 CFR 164.506(c)(4)(ii).

(vi) For disclosures that qualify as ''required by law'' disclosures at 45 CFR 164.103.

(4) *Limitations.* A PDP sponsor must comply with the following requirements regarding the data provided by CMS under this paragraph (g):

(i) The PDP sponsor will not use the data to inform coverage determinations under Part D.

(ii) The PDP sponsor will not use the data to conduct retroactive reviews of medically accepted indications determinations.

(iii) The PDP sponsor will not use the data to facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization.

(iv) The PDP sponsor will not use the data to inform marketing of benefits.

(v) The PDP sponsor will contractually bind its contractors that have access to the Medicare claims data, and require their contractors to contractually bind any other potential downstream data recipients, to the terms and conditions imposed on the PDP sponsor under this paragraph (g).

(5) *Ensuring the privacy and security of data.* As a condition of receiving the requested data, the PDP sponsor must attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data listed in paragraphs (g)(3) and (4) of this section.

■ 31. Section 423.182(a) is amended by adding the definitions ''Absolute percentage cap'', ''Cut point cap'', ''Guardrail'', ''Mean resampling'', ''Restricted range'', and ''Restricted range cap'' in alphabetical order to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

(a) * * *

Absolute percentage cap is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

* * * * *

Cut point cap is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.

* * * * *

Guardrail is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

* * * * *

Mean resampling refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchal clustering algorithm is done 10 times, each time leaving one of the 10 groups out. By leaving out one of the 10 groups for each run, 9 of the 10 groups, which is 90 percent of the applicable measure scores, are used for each run of the clustering algorithm. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

* * * * *

Restricted range is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile −3*Interquartile Range (IQR) and third quartile + 3*IQR).

Restricted range cap is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

* * * * *

■ 32. Section 423.184 is amended by adding paragraphs (f)(1)(iv), (g)(1)(ii)(M), and (h) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(f) * * *

(1) * * *

(iv) CMS excludes any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s).

* * * * *

(g) * * *

(1) * * *

(ii) * * *

(M) CMS reduces the measure rating to 1 star for the applicable appeals measure(s) if a contract fails to submit Timeliness Monitoring Project data for CMS's review to ensure the completeness of the contract's IRE data.

* * * * *

(h) *Review of sponsors' data.* (1) A Part D plan sponsor may request that CMS or the IRE review its' contract's appeals data provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

(2) A Part D plan sponsor may request that CMS review its' contract's Complaints Tracking Module (CTM) data provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

■ 33. Section 423.186 is amended by revising paragraph (a)(2)(i) and adding paragraph (i) to read as follows:

§ 423.186 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data, and a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for three years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

(i) *Extreme and uncontrollable circumstances.* In the event of extreme and uncontrollable circumstances that may negatively impact operational and clinical systems and contracts' abilities to conduct surveys needed for accurate performance measurement, CMS calculates the Star Ratings as specified in paragraphs (i)(2) through (8) of this section for each contract that is an affected contract during the performance period for the applicable measures. We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

(1) *Identification of affected contracts.* A contract that meets all of the following criteria is an affected contract:

(i) The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Act.

(ii) The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).

(iii) As specified in paragraphs (i)(2) through (8) of this section, a certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

(2) *CAHPS adjustments.* (i) A contract, even if an affected contract, must administer the CAHPS survey unless exempt under paragraph (i)(2)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from administering the CAHPS survey if the contract completes both of the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section in the prior calendar year.

(B) Requests and receives a CMS approved exemption.

(iii) An affected contract with an exemption described in paragraph (i)(2)(ii) of this section receives the contract's CAHPS measure stars and corresponding measure scores from the prior year.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure.

(v) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(3) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS holds the affected contract harmless by using the higher of the contract's summary or overall rating or both with and without including all of the applicable new measures.

(4) *Other Star Ratings measure adjustments.* (i) For all other Part D measures except those measures identified in this paragraph (i)(4)(ii) of this section, affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance receive the higher of the previous or current year's measure Star Rating (and corresponding measure score).

(ii) CMS does not adjust the scores of the Star Ratings for the Part D Call Center—Foreign Language Interpreter and TTY Availability measure, unless the exemption listed in paragraph (i)(4)(iii) of this section applies.

(iii) CMS adjusts the measure listed in paragraph (i)(4)(ii) of this section using the adjustments listed in paragraph (i)(4)(i) of this section for contracts affected by extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study.

(iv) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(5) *Exclusion from improvement measures.* Any measure that reverts back to the data underlying the previous year's Star Rating due to the adjustments made in paragraph (i) of this section is excluded from both the count of measures and the applicable improvement measures for the current and next year's Star Ratings for the affected contract. Contracts affected by extreme and uncontrollable circumstances do not have the option of reverting to the prior year's improvement rating.

(6) *Missing data.* For an affected contract that has missing data in the current or previous year, the final measure rating comes from the current year unless an exemption described in paragraph (i)(2)(ii) of this section applies.

(7) *Cut points for non-CAHPS measures.* (i) CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

(ii) The cut points calculated as described in paragraph (i)(7)(i) of this section are used to assess all affected contracts' measure Star Ratings.

(8) *Reward factor.* (i) CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the Reward Factor described in paragraph (f)(1) of this section.

(ii) All affected contracts are eligible for the Reward Factor based on the calculations described in paragraph (i)(8)(i) of this section.

■ 34. Section 423.568 is amended by revising paragraph (b) to read as follows:

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

* * * * *

(b) *Timeframe for requests for drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the end of 14 calendar days from receipt of the exceptions request.

* * * * *

■ 35. Section 423.570 is amended by revising paragraph (d)(1) to read as follows:

§ 423.570 Expediting certain coverage determinations.

* * * * *

(d) * * *

(1) Make the determination within the 72-hour timeframe established in § 423.568(b) for a standard determination. The 72-hour period begins on the day the Part D plan sponsor receives the request for expedited determination. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the end of 14 calendar days from receipt of the exceptions request.

* * * * *

■ 36. Section 423.572 is amended by revising paragraph (a) to read as follows:

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determination and notification.* Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the physician's or other prescriber's supporting statement. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours from the end of 14 calendar days from receipt of the exceptions request.

* * * * *

PART 438—MANAGED CARE

■ 37. The authority for part 438 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 38. Effective January 1, 2021, § 438.210 is amended by—

■ a. Revising paragraph (c);

■ b. Adding paragraph (d)(4); and

■ c. Revising paragraph (f).

The addition and revisions read as follows:

§ 438.210 Coverage and authorization of services.

* * * * *

(c) *Notice of adverse benefit determination.* Each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than

requested. For MCOs, PIHPs, and PAHPs, the enrollee's notice must meet the requirements of § 438.404. For Medicaid contracts with an applicable integrated plan, as defined in § 422.561 of this chapter, in lieu of the provisions in this paragraph governing notices of adverse benefit determinations, the provisions set forth in §§ 422.629 through 422.634 of this chapter apply to determinations affecting dually eligible individuals who are also enrolled in a dual eligible special needs plan with exclusively aligned enrollment, as defined in § 422.2 of this chapter.

(d) * * *

* * * * *

(4) For Medicaid contracts with an applicable integrated plan, as defined in § 422.561 of this chapter, timelines for decisions and notices must be compliant with the provisions set forth in §§ 422.629 through 422.634 of this chapter in lieu of §§ 438.404 through 438.424.

* * * * *

(f) *Applicability date.* (1) Subject to paragraph (f)(2) of this section, this section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, States are required to continue to comply with § 438.210 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

(2) Provisions in this section affecting applicable integrated plans, as defined in § 422.561 of this chapter, are applicable no later than January 1, 2021.

■ 39. Effective January 1, 20121, § 438.400 is amendedby adding paragraph (a)(4) and revising paragraph (c) to read as follows:

§ 438.400 Statutory basis, definitions, and applicability.

(a) * * *

(4) Section 1859(f)(8)(B) of the Act requires that the Secretary, to the extent feasible, establish procedures unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act for items and services provided, by specialized Medicare Advantage plans for special needs individuals described in section 1859(b)(6)(B)(ii), under Titles XVIII and XIX of the Act.

* * * * *

(c) *Applicability.* (1) Subject to paragraph (c)(2) of this section, this subpart applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, States, MCOs, PIHPs, and PAHPs are required to continue to comply with subpart F contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

(2) Provisions in this part affecting applicable integrated plans, as defined in § 422.561 of this chapter, are applicable no later than January 1, 2021.

■ 40. Effective January 1, 2021, § 438.402 is amended by revising paragraph (a) to read as follows:

§ 438.402 General requirements.

(a) *The grievance and appeal system.* Each MCO, PIHP, and PAHP must have a grievance and appeal system in place for enrollees. Non-emergency medical transportation PAHPs, as defined in § 438.9, are not subject to this subpart F. For grievances and appeals at the plan level, an applicable integrated plan as defined in § 422.561 of this chapter is not subject to this subpart F, and is instead subject to the requirements of §§ 422.629 through 422.634 of this chapter. For appeals of integrated reconsiderations, applicable integrated plans are subject to § 438.408(f).

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 41. The authority for part 498 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7j, and 1395hh.

■ 42. Effective June 17, 2019, § 498.5 is amended by revising paragraph (n)(1) to read as follows:

§ 498.5 Appeal rights.

* * * * *

(n) * * *

(1)(i) Any individual or entity that is dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list (as defined in § 422.2 or § 423.100 of this chapter) may request a reconsideration in accordance with § 498.22(a).

(ii)(A) If the individual's or entity's inclusion on the preclusion list is based on a Medicare revocation under § 424.535 of this chapter and the individual or entity receives contemporaneous notice of both actions, the individual or entity may request a joint reconsideration of both the preclusion list inclusion and the revocation in accordance with § 498.22(a).

(B) The individual or entity may not submit separate reconsideration requests under paragraph (n)(1)(ii)(A) of this section for inclusion on the preclusion list or a revocation if the individual or entity received contemporaneous notice of both actions.

* * * * *

Dated: March 27, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: March 28, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–06822 Filed 4–5–19; 4:15 pm]

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Part III

Environmental Protection Agency

40 CFR Part 60
Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Commercial and Industrial Solid Waste Incineration Units; Technical Amendments; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA–HQ–OAR–2003–0119; FRL–9991–32–OAR]

RIN 2060–AT84

Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Commercial and Industrial Solid Waste Incineration Units; Technical Amendments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Following requests for clarification of its June 2016 final action, the Environmental Protection Agency (EPA) published proposed amendments to several provisions of the 2016 New Source Performance Standards (NSPS) and Emission Guidelines (EG) for Commercial and Industrial Solid Waste Incineration (CISWI). This action finalizes the proposed amendments, which provide clarity and address implementation issues in the final CISWI NSPS and EG, as well as correcting inconsistencies and errors in these provisions.

DATES: This final rule is effective on April 16, 2019. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of February 7, 2013.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2003–0119. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed, some information is not publicly available, *e.g.,* confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov*, or in hard copy at the EPA Docket Center, WJC West Building, Room Number 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Dr. Nabanita Modak Fischer, Fuels and Incineration Group, Sector Policies and Programs Division (E143–05), Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5572; fax number: (919) 541–0516; email address: *modak.nabanita@epa.gov*.

SUPPLEMENTARY INFORMATION: *Acronyms and Abbreviations.* A number of acronyms and abbreviations are used in this preamble. While this may not be an exhaustive list, to ease the reading of this preamble and for reference purposes, the following terms and acronyms are defined:

ACI air curtain incinerator
CAA Clean Air Act
CEDRI Compliance and Emissions Data Reporting Interface
CEMS Continuous Emissions Monitoring System
CFR Code of Federal Regulations
CISWI Commercial and Industrial Solid Waste Incineration
CO carbon monoxide
COMS Continuous Opacity Monitoring System
CPMS Continuous Parameter Monitoring System
EG Emission Guidelines
EPA U.S. Environmental Protection Agency
ESP electrostatic precipitator
HCl hydrogen chloride
Hg mercury
mg/dscm milligrams per dry standard cubic meter
NAICS North American Industry Classification System
NESHAP National Emission Standards for Hazardous Air Pollutants
NHSM Non-Hazardous Secondary Material(s)
NSPS New Source Performance Standards
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
PC Portland Cement
ppmv parts per million by volume
ppmvd parts per million by dry volume
RIN Regulatory Information Number
UMRA Unfunded Mandates Reform Act
U.S.C. United States Code

Organization of this Document. The following outline is provided to aid in locating information in this preamble.

I. General Information
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B. Where can I get a copy of this document and other related information?
C. Judicial Review
II. Background
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A. EG 30-Day Rolling Average Provisions
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A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
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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 (NTTAA)
K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
L. Congressional Review Act (CRA)

I. General Information

A. Does this action apply to me?

Categories and entities affected by the final action are those that operate CISWI units. The NSPS and EG, herein after referred to as ''standards,'' for CISWI affect the following categories of sources:

Category	NAICS [1] code	Examples of potentially regulated entities
Any industrial or commercial facility using a solid waste incinerator.	211, 212, 486	Oil and gas exploration operations; Mining, pipeline operators.
	221	Utility providers.

Category	NAICS [1] code	Examples of potentially regulated entities
	321, 322, 337	Manufacturers of wood products; Manufacturers of pulp, paper, and paperboard; Manufacturers of furniture and related products.
	325, 326	Manufacturers of chemicals and allied products; Manufacturers of plastics and rubber products.
	327	Manufacturers of cement; Nonmetallic mineral product manufacturing.
	333, 336	Manufacturers of machinery; Manufacturers of transportation equipment.
	423, 44	Merchant wholesalers, durable goods; Retail trade.

[1] North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by the final action. To determine whether your facility will be affected by this action, you should examine the applicability criteria in 40 Code of Federal Regulations (CFR) 60.2010 of subpart CCCC, 40 CFR 60.2505 of subpart DDDD, and 40 CFR 241. If you have any questions regarding the applicability of the final action to a particular entity, contact the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Where can I get a copy of this document and other related information?

The docket number for this final action regarding the CISWI Technical Amendments is Docket ID No. EPA–HQ–OAR–2003–0119.

In addition to being available in the docket, an electronic copy of this action is available on the internet. Following signature by the Administrator, the EPA will post a copy of this final action at *https://www.epa.gov/stationary-sources-air-pollution/commercial-and-industrial-solid-waste-incineration-units-ciswi-new*. Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at the same website.

C. Judicial Review

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final rule is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) by June 17, 2019. Under CAA section 307(d)(7)(B), only an objection to this final rule that was raised with reasonable specificity during the period for public comment can be raised during judicial review. Any person who believes the final rule contains provisions that were not reasonably forseeable based on the proposed rule should submit a Petition for Reconsideration to the Office of the Administrator, Environmental Protection Agency, Room 3000, EPA WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460. Note, under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce these requirements.

II. Background

A. What is the statutory authority for taking this action?

Section 129 of the CAA requires the EPA to establish NSPS and EG pursuant to sections 111 and 129 of the CAA for new and existing solid waste incineration units located at commercial and industrial facilities. This action amends standards developed under these authorities.

B. Background Information

On March 21, 2011, the EPA promulgated revised NSPS and EG for CISWI units (*i.e.,* solid waste incineration units located at commercial or industrial facilities). Following that action, the Administrator received petitions for reconsideration that identified certain issues that warranted further opportunity for public comment. In response to the petitions, the EPA reconsidered, proposed revisions to, and requested comment on several provisions of the March 2011 final NSPS and EG for CISWI units. These proposed revisions were published on December 23, 2011 (76 FR 80452).

On February 7, 2013, the EPA finalized revisions to the CISWI NSPS and EG (78 FR 9112). In that final action, the EPA made additional revisions in response to comments that had not been proposed in the December 23, 2011, **Federal Register** document. Subsequently, the EPA received petitions for reconsideration of the final 2013 action. These petitions assert that the public did not have sufficient opportunity to comment on some of the provisions contained in that final rule. In response, the EPA proposed to reconsider four provisions of the 2013 final revisions to the NSPS and EG for CISWI units (80 FR 3018, January 21, 2015). The EPA took final action on that proposal on June 23, 2016 (81 FR 40956). We will refer to this final CISWI rule, as revised through June 2016, as the 2016 CISWI rule.

Following promulgation of the 2016 CISWI rule, the EPA received requests from industry stakeholders and implementing agencies to clarify various issues with implementation of the standards. In addition, the EPA identified certain testing and monitoring issues and inconsistencies within the rules that required further clarification or correction. On June 15, 2018, the EPA proposed amendments to several provisions of the 2016 CISWI rule to address these issues (83 FR 28068). In addition, the EPA identified additional regulatory provisions, beyond those raised by the requests from industry stakeholders and implementing agencies, that require clarification and editorial correction to address inconsistencies and errors in the final rules. In this document, the EPA is taking final action on the June 2018 proposal by promulgating clarifying changes and corrections to the 2016 CISWI rule.

For more detailed background and additional information on how this rule is related to other CAA combustion rules issued under CAA section 112 and the Resource Conservation and Recovery Act definition of solid waste, refer to the prior final actions discussed above (76 FR 15704, March 21, 2011; 78 FR 9112, February 7, 2013).

III. Summary of Final Action

In this final rule, we are amending the 2016 CISWI rule to address certain

issues raised by industry stakeholders and implementing agencies, as well as to address other issues identified during implementation of the CISWI rule. Provisions affected by the amendments are: (1) Alternative equivalent emission limit for mercury (Hg) for the waste-burning kiln subcategory; (2) timing of initial test and initial performance evaluation; (3) extension of the date by which electronic data reporting requirements must be met; (4) clarification of non-delegated authorities; (5) demonstration of initial and continuous compliance when using a continuous emissions monitoring system (CEMS); (6) continuous opacity monitoring requirements; (7) other CEMS requirements; (8) clarification of skip testing requirements; (9) deviation reporting requirements for continuous monitoring data; and (10) clarification of air curtain incinerator (ACI) requirements. In addition to these provisions, we are also correcting minor typographical errors identified in the rule as noted in section V.B of this preamble.

This final rule provides meaningful burden reduction by providing regulated facilities additional time to complete initial compliance demonstrations and by allowing facilities to comply with production-based emission limits in lieu of the concentration-based limits in the 2016 CISWI rule. Specifically, cement kilns would be allowed to report mercury emissions on a mass-based production basis (pounds per million (lb/MM) ton of clinker) in lieu of reporting on a concentration based limit (milligrams per dry standard cubic meter (mg/dscm)). This alternative provision may result in lower costs for the cement industry by making the format of the mercury emission limits consistent with the Portland Cement NESHAP (PC NESHAP). Further, the rule adds flexibilities in the compliance demonstration process by extending the timeline for performance evaluation tests from 60 days to 180 days and allows facilities to use CEMS for demonstrating initial compliance. These provisions may lower compliance testing costs as stack testing could be avoided if the facilities use CEMS. Moreover, facilities with CEMS will not be required to retest in the event of original stack testing failure.

The EPA is taking final action on all the amendments discussed in the June 15, 2018 (83 FR 28068), proposed rule and also making two additional changes to clarify provisions of the 2016 CISWI rule. A more detailed discussion of the rationale behind the technical amendments is located in section V.A of this preamble.

A. EG 30-Day Rolling Average Provisions

A commenter noted that the 30-day rolling average language found in 40 CFR 60.2710(c) was inconsistent with how the averaging period is defined elsewhere in the rule because it contained the additional qualifier ''over the previous 30 days of operation.'' The EPA realizes that units may not necessarily operate continuously, and that valid operating data exclude periods when a unit is not operating. The EPA has removed the phrase ''over the previous 30 days of operation'' from 40 CFR 60.2710(c) to be consistent with similar provisions elsewhere in the EG and in the NSPS.

B. Clarification of Operating Parameter Monitoring for a Pollutant's Control When CEMS are Being Used for Continuous Compliance Demonstration for the Pollutant

The EPA is clarifying that continuous operating parameter monitoring is not required when CEMS are used for direct and continuous compliance demonstrations for the pollutant. *See* section V.A.5 of this preamble for further discussion.

IV. Public Comments

Public comments on the proposed rule and the EPA's responses to these comments are addressed in a separate response to comment document, available in the docket for this action at Docket ID No. EPA–HQ–OAR–2003–0119.

V. Rationale for Final Amendments to 2016 CISWI Rule

A. Discussion of Final Technical Amendments

This section of the preamble explains the basis for the changes in this final rule.

1. Alternative Equivalent Emission Limit for Hg for the Waste-Burning Kiln Subcategory

The December 23, 2011, proposed CISWI reconsideration rule preamble discussed and presented equivalent emission limits for waste-burning kilns expressed on a production basis (76 FR 80458). In the February 2013 CISWI final reconsideration rule preamble, the EPA again included these equivalent production-based limits, but at that time the EPA decided not to codify these within the rule text. In the process of approving state plans to implement the CISWI EG, the EPA has recognized that there is a benefit to some affected sources and implementing agencies in codifying the emission limit for Hg for waste-burning kilns expressed as a production-based limit (*i.e.,* lb/MM ton clinker) as an alternative equivalent standard to the existing concentration-based standard (*i.e.,* mg/dscm), because this is the format of the Hg standards found in the PC NESHAP. The EPA strives to make compliance with both CISWI standards and the PC NESHAP as streamlined and consistent as possible to facilitate compliance with both standards because these sources (and energy recovery units) must comply with the CISWI standard when they are combusting solid waste and must comply with the PC NESHAP or Boiler Maximum Achievable Control Technology standards, as applicable, when combusting nonwaste materials. Having an equivalent emission limit in the same units as the PC NESHAP will, thus, aid affected sources in demonstrating compliance with both standards, and will aid implementing agencies in enforcing the standards.

As discussed in 2011 and repeated in 2013 (78 FR 9122–3, February 7, 2013), the Hg emission limit of 58 lb/MM ton clinker and 21 lb/MM ton clinker for existing and new sources, respectively, are equivalent to the concentration-based Hg standards of 0.011 mg/dscm and 0.0037 mg/dscm within the currently published 2016 CISWI rule. To facilitate use of the equivalent production-based emission limits, the EPA is adding these emission limits to the emission limitation tables, and including recordkeeping, calculation, and reporting requirements for clinker production rate as necessary. The regulatory provisions and calculations being made final are consistent with those found in the PC NESHAP, *see* 40 CFR 63, subpart LLL.

2. Timing of Initial Test and Initial Performance Evaluation

The current CISWI NSPS and EG (2016 CISWI Rule) require affected sources to conduct a performance evaluation of each continuous monitoring system within 60 days of installation of the monitoring system (see 40 CFR 60.2135 and 60.2700). The rule also allows up to 180 days from the final compliance date for affected sources to conduct an initial performance test. The EPA received questions from implementing agencies asking whether these requirements can be synchronized to prevent duplicate testing requirements because the continuous monitoring system performance evaluation would require an emissions test being conducted at the same time regardless. We recognize that

the requirement to conduct a performance evaluation within 60 days of installation could present a situation for sources where the deadline for conducting the performance evaluation would precede the deadline for conducting the initial performance test. The EPA did not intend to require sources to conduct duplicative initial performance tests, and we see a benefit to sources and implementing agencies to be able to schedule and conduct both of these demonstrations at the same time. Therefore, the EPA is adjusting the timing of the continuous monitoring system initial performance evaluation to allow 180 days from installation to match the schedule which is allowed for conducting the initial performance test. The EPA has determined that making these timelines consistent (*i.e.,* 180 days from installation) will streamline compliance demonstrations and prevent possible duplicative testing requirements.

3. Extension of Electronic Data Reporting Requirement

In this action, the EPA is extending the electronic reporting requirement dates found in 40 CFR 60.2235(a) and 60.2795(a). The electronic reporting provisions promulgated in CISWI require submittal of initial, annual, and deviation reports electronically through the EPA's Compliance and Emissions Data Reporting Interface (CEDRI), which is accessed through the EPA's Central Data Exchange. The existing rule provides that the requirement for electronic submittal will take effect once the relevant forms have been available in CEDRI for 90 calendar days. As stated in the CISWI reconsideration (81 FR 40956), the EPA intended to make the requirements of the CISWI rule consistent with the *Electronic Reporting and Recordkeeping Requirements for New Source Performance Standards,* which was proposed on March 20, 2015 (80 FR 15100).[1] However, the CISWI reconsideration final rule was published on June 23, 2016 (81 FR 40956), before the *Electronic Reporting and Recordkeeping Requirements for New Source Performance Standards* rule [2] was finalized and did not take into account comments received on that rule.

The extension for CISWI units in this action is consistent with the EPA's approach to electronic reporting outlined in the *Electronic Reporting and Recordkeeping Requirements for New Source Performance Standards* final rule.[3] This approach has also been used in recent EPA rulemakings (*e.g., National Emissions Standards for Hazardous Air Pollutants for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semi Chemical Pulp Mills,* 82 FR 47328 (October 11, 2017); *National Emissions Standards for Hazardous Air Pollutants: Publicly Owned Treatment Works Residual Risk and Technology Review,* 82 FR 49513, October 26, 2017). The extension requires electronic submission of initial, annual, and deviation reports 2 years from publication of the final rule or 1 year after the reporting form becomes available in CEDRI, whichever date is later. This extension is necessary to allow the EPA time to develop and adequately test the new forms and for regulated entities to become familiar with the forms and reprogram systems that collect data for periodic reports once the forms are available. The extension also allows state, local, and tribal agencies more time to implement electronic reporting and to make any needed permit revisions to accommodate electronic reporting and allows for development of third-party software to populate the reporting forms.

4. Clarification of Non-Delegated Authorities

In this action, the EPA is making final corrections to the authorities listed in 40 CFR 60.2030(c). Specifically, the reference to 40 CFR 60.2125(j) is an outdated reference to previously proposed, but never promulgated, performance test waiver provisions. These provisions were included in the June 4, 2010, CISWI proposed rule (*see* 75 FR 31975), but were not made final in the March 21, 2011, final rule (*see* 76 FR 15752–3). This reference was inadvertently not included in the final rule to reflect that the proposed 40 CFR 60.2125(j) was not finalized. Another correction relates to the provisions of 40 CFR 60.2030(c)(10) that require obtaining a determination from the EPA of whether a qualifying small power facility or cogeneration facility is combusting homogeneous waste. We intended to remove these provisions in the 2013 CISWI final rule as part of the removal of the definition of homogeneous waste (*see* 78 FR 9124, February 7, 2013). As discussed in the preamble to the February 7, 2013, final revision action, the EPA determined that the proposed ''definition and provisions could be interpreted in a manner that would be unduly restrictive.'' Therefore, the EPA did not include a definition of ''homogeneous waste'' in the final CISWI rule and the Agency stated it was (without actually amending the CFR text to reflect its intent) ''removing the requirement that qualifying small power producers and qualifying cogeneration facilities that combust solid waste obtain a determination from the EPA that such waste is homogeneous.'' *Id.* Accordingly, the EPA is removing paragraph 40 CFR 60.2030(c)(10). While no other authorities have been added or removed from this list, the EPA is making minor revisions to streamline the section by removing the reserved subparagraphs *(i.e.,* (5) and (10)) and renumbering the subparagraphs sequentially.

In this action, we are also clarifying, with respect to the EG, which authorities will not be delegated. Language in 40 CFR 60.2542 simply contains a reference to the analogous paragraph (40 CFR 60.2030(c)) within the CISWI NSPS. However, since the CISWI NSPS applies to new sources, applicability of these non-delegated authorities to state plans implementing the emission guidelines for existing sources was unclear to implementing agencies. To remove this confusion, we have eliminated the cross reference to 40 CFR 60.2030(c) and have instead provided the specific details on which authorities will not be delegated within the text of 40 CFR 60.2542. The final list of authorities in 40 CFR 60.2542 matches the updated list found in 40 CFR 60.2030(c), with the appropriate adjustments made to subpart section cross references.

5. Demonstrating Initial Compliance When Using CEMS

As the EPA noted at proposal, (*see* 83 FR 28072, June 15, 2018), the provisions regarding CEMS monitoring for demonstrating initial compliance are inconsistent and somewhat unclear. The final CISWI rules require some sources to demonstrate compliance using CEMS, and allow the option for any source to use CEMS to demonstrate compliance ''with any of the emission limits of this subpart'' (*see* 40 CFR 60.2145(u) and 60.2710(u)). However, for most of the

[1] Originally, the *Electronic Reporting and Recordkeeping Requirements for New Source Performance Standards* rule included CISWI as one of the affected subparts. However, because the CISWI reconsideration package was proposed at nearly the same time as that rule, CISWI was removed as an affected subpart, and the language associated with the *Electronic Reporting and Recordkeeping Requirements for New Source Performance Standards* rule was inserted into the CISWI reconsideration proposal.

[2] This final rule was signed on December 21, 2016, but was withdrawn from the Office of the Federal Register prior to publication.

[3] The prepublication version of the final rule is available at *https://www.epa.gov/sites/production/files/2017-04/documents/e-reporting-nsps-final-rule-pre-publication.pdf.* Accessed November 15, 2018.

paragraphs containing the pollutant-specific CEMS requirements, the language was unclear on whether these demonstrations were applicable to demonstrating initial compliance, with the exception of carbon monoxide (CO). The EPA's intent was to allow CEMS for demonstrating initial compliance for any pollutant (*i.e.,* with any of the emission limits of this subpart). To express the EPA's intent of providing this flexibility for compliance demonstration more clearly, we have revised several sections of the rule in this final action. For example, the initial compliance requirements in 40 CFR 60.2135 and 60.2700 have been revised to also reflect use of CEMS data as an initial compliance demonstration alternative to an emissions test, provided that the initial CEMS performance evaluation has been conducted prior to collecting CEMS data used for the initial performance test. Likewise, language surrounding the CEMS requirements found in 40 CFR 60.2145, 60.2165, 60.2710, and 60.2730, and the emission limitation tables, has been revised and streamlined to clarify that CEMS data may be used to demonstrate compliance *(i.e.,* initial and continuing) with the standards.

In addition to clarifying initial compliance demonstrations using CEMS, commenters suggested a similar issue occurs with continuous parametric monitoring requirements for sources that use CEMS to demonstrate compliance for a pollutant. It was not the EPA's intent to require duplicative operating parameter monitoring for pollutants if emissions for the pollutants are directly and continuously monitored using CEMS. Therefore, the EPA has clarified the CEMS requirements in 40 CFR 60.2165 and 40 CFR 60.2730 to indicate that sources using CEMS to monitor for a pollutant are not required to monitor the associated operating parameters unless it is necessary for compliance with the monitoring requirements of another regulated pollutant. This clarification is not removing any monitoring requirements, but only acknowledging that direct pollutant emission measurement with CEMS is a suitable, if not even preferential, alternative to continuous parameter monitoring.

6. Clarification of Continuous Opacity Monitoring System (COMS) Requirements

In addition to the clarifications to CEMS provisions, we are also revising 40 CFR 60.2145(i) and 60.2710(i) to clarify our intent regarding the types of units required to install COMS and to make it consistent with the COMS monitoring requirement language found in 40 CFR 60.2165(m) and 60.2730(m), respectively. We are adding language clarifying that energy recovery units between 10 and 250 million British thermal units/hour design heat input that are equipped with electrostatic precipitators (ESP), particulate matter CEMS, or particulate matter continuous parameter monitoring systems (CPMS) are not required to additionally install and operate COMS because these units have an air pollution control device that has continuous parameter monitoring requirements or are using continuous particulate matter monitoring compliant with provisions within the rule already (*see* 40 CFR 60.2145(q), for example). The rule currently excludes the COMS requirement for energy recovery units using other types of particulate matter control devices or that use particulate matter CEMS for continuous particulate matter monitoring, but inadvertently omitted ESPs and particulate matter CPMS from the list. Therefore, we are adding ''electrostatic precipitator'' and ''particulate matter CPMS'' to the list (that currently includes CO wet scrubbers and fabric filters) found in 40 CFR 60.2165(m) and 60.2730(m) as types of units that do not require COMS. As a further clarification, we are also amending the text to 40 CFR 60.2145(i) and 60.2710(i) to clearly specify that the COMS requirement is applicable to units within the specified size range ''that do not use a wet scrubber, fabric filter with bag leak detection system, an electrostatic precipitator, particulate matter CEMS, or particulate matter CPMS.''

7. Clarification of Other CEMS Requirements

In addition to the CEMS-related requirements discussed above, the EPA is making two other CEMS-related clarifications in this final rule: (1) To not require CO CEMS for new waste-burning kilns; and (2) to remove outdated notification requirements when particulate matter CEMS are being used. For the CO CEMS issue, the rule as finalized in February 7, 2013, erroneously includes a requirement at 40 CFR 60.2145(j) for new waste-burning kilns to demonstrate compliance with CO emission limits using CEMS. This issue was not corrected in the 2016 final rules and is inconsistent with the requirements found in Table 7 to 40 CFR 60, subpart CCCC, and with the EPA's intent to remove CO CEMS requirements for new CISWI sources, as stated in the February 7, 2013, final CISWI rules (*see* 78 FR 9120). Carbon monoxide CEMS are allowed as an alternative compliance demonstration, but sources who adopt this alternative are not required to conduct annual testing using EPA Method 10. To make this clarification, the EPA is revising 40 CFR 60.2145(j) to reflect that CO is one of the pollutants for which an annual test is required and removing CO from the list of pollutants requiring CEMS for demonstrating compliance.

Regarding the removal of outdated notification requirements when particulate matter CEMS are used, the EPA is removing the outdated requirements to notify the Administrator prior to beginning and stopping use of an optional particulate matter CEMS. These provisions are 40 CFR 60.2165(n)(1) and (2), and 40 CFR 60.2730(n)(1) and (2). These provisions are an inadvertent holdover from model provisions from a prior rule. CEMS technology and application has progressed to an extent that these notifications are no longer needed or desired by the EPA. Furthermore, these notifications do not appear in the reporting requirements outlined in the reporting requirement tables (Table 4 to 40 CFR part 60, subpart CCCC and Table 3 to 40 CFR part 60, subpart DDDD), nor the other notification requirements, so they introduced an unintended inconsistency within the rule. To resolve this, we are deleting the current subparagraphs (1) and (2) of these sections and renumbering the remaining subparagraphs sequentially to streamline these requirements.

8. Clarification of Reduced Testing Requirements

It has come to the EPA's attention that there is confusion regarding how reduced testing is applied after a source has demonstrated good performance and has skipped testing for 2 years (*see* 40 CFR 60.2155 and 60.2720). Stakeholders suggest that the current CISWI rule language would have a good-performing source return to an annual testing schedule after being able to skip testing for 2 years, with no opportunity for additional reduced testing. It was not the EPA's intent to only offer this allowance once when developing these provisions. To the contrary, the EPA intended this allowance to be available for as long as good performance could be reaffirmed with testing every 3 years instead of annually (*see* 76 FR 15714, March 21, 2011). The intended sequence of testing consisted of two consecutive annual tests showing 75 percent or less of the applicable standard is achieved; followed by 2 years of testing being skipped; followed by an annual test showing that 75 percent of the standard is achieved; followed by 2 years of

testing being skipped; etc. In other words, starting with the initial compliance test (first year), for the first and second years, a source would perform compliance testing; for the third and fourth years, the source could skip testing (if both the first and second-year results showed that the source achieves 75 percent or less of the applicable standard); for the fifth year a source would perform compliance testing; for the sixth and seventh years, the source could skip testing (if the fifth-year results showed that the source achieves 75 percent or less of the applicable standard); for the eighth year, a source would perform compliance testing, and so on. Since the promulgation of these standards, these skip testing provisions have been refined and promulgated during regulatory development efforts in the CAA section 129 rulemakings for sewage sludge incinerators (40 CFR part 60, subparts LLLL and MMMM). In this action, the EPA is clarifying the ongoing allowance for reduced testing provisions we intended, based largely on language used in the recent sewage sludge incinerator rule (*see* 81 FR 26039, April 29, 2016).

9. Clarification of Deviation Reporting Requirements for Continuous Monitoring Data

The EPA has become aware of some unclear requirements in the deviation reporting requirements of 40 CFR 60.2215(a) and 60.2775(a). In particular, the requirements for continuously measured parameters or emissions using CEMS are not clearly outlined within these sections. While these provisions are clear for 3-hour average parameters and performance testing, the EPA recognizes that 30-day averages allowed for energy recovery units and particulate matter CEMS were inadvertently omitted, as well as requirements for any other 30-day average measured using CEMS that deviated from an emission limit. The EPA is adding language to these paragraphs to clarify that deviations for these other operating parameters or CEMS measurements that deviate from an operating limit or emissions limitation must be included in a deviation report.

10. Clarification of ACI Requirements

Since promulgation of the 2016 CISWI final rule, the EPA has received various questions from implementing agencies regarding the applicability of CISWI to ACI. While the limited requirements of ACIs burning only wood waste, clean lumber, or a mixture of wood waste, clean lumber, and/or yard waste are defined within the rule, ACIs' status as a CISWI-affected source is unclear to some implementing agencies as they work to prepare state plans and negative declarations because of confusing language in the 2016 CISWI Rule. *See* 40 CFR 60.2550. Specifically, the section of the EG addressing the units subject to the final CISWI rule includes a reference to ACI in 40 CFR 60.2550(a)(1), but 40 CFR 60.2550(a)(2) further states that only units that meet the definition of a CISWI unit are subject to the final rule, and ACIs do not meet the regulatory definition of a CISWI unit.[4]

Notwithstanding that provision, the record demonstrates that the EPA considers ACIs located at commercial and industrial facilities and otherwise meeting the definition of an ACI as being CISWI-affected sources. *See* CAA section 129(g)(1)(C) (defining ACIs) and 40 CFR 60.2245–2260 of the NSPS and 60.2810–2870 of the EG (setting forth the CISWI EG requirements applicable to ACI). Facilities can have CISWI-affected ACIs even if they do not have CISWI units located at the facility. If an ACI begins burning solid waste as defined in the *Non Hazardous Secondary Materials* rule (*see* 40 CFR part 241) in addition to, or instead of, wood waste, clean lumber, or a mixture of wood waste, clean lumber, and/or yard waste, it is a solid waste incineration unit that is subject to the applicable numerical emission standards contained in CISWI or another CAA section 129 standard, depending on the type of waste combusted (*e.g.,* such as a unit burning more than 30-percent municipal solid waste would be a municipal solid waste incineration unit instead of a CISWI unit).

The EPA's intent is further demonstrated in a response to comment on title V permitting requirements for ACIs in the preamble to the March 21, 2011, final CISWI rule (76 FR 15741):

Commenters are correct that ACIs are not solid waste incineration units pursuant to CAA section 129(g)(1)(C), but that is only correct if the units ''only burn wood wastes, yard wastes and clean lumber and [they] * * * comply with opacity limitations to be established by the Administrator by rule.'' The EPA has established opacity limitations for ACIs pursuant to CAA sections 111 and 129.

Pursuant to CAA section 502(a), sources subject to standards or regulations under CAA section 111 must obtain a title V permit; therefore, ACIs are required to obtain a title V permit. As commenters note, the EPA may exempt minor and area sources from the requirement to obtain a title V permit, but the EPA must first determine that compliance with title V requirements is ''impracticable, infeasible, or unnecessarily burdensome'' for the sources before exempting them (CAA section 502(a)). The EPA has not made the necessary finding pursuant to CAA section 502(a) for ACIs in any of the CAA section 129 rulemakings, and we believe that ACIs exist at CAA section 129 facilities other than at the commercial and industrial facilities subject to this final rule. Because we think it is important to treat all ACIs in the same manner, we decline to consider a title V exemption for minor and area source ACIs at commercial and industrial facilities.

As the record demonstrates, the EPA determined that ACIs located at commercial and industrial facilities are CISWI-affected sources that must be included in state plans and regulated consistent with the final CISWI standards applicable to such units. To address the uncertainty created by the CISWI rule, the EPA is clarifying the affected source status of ACIs by revising the regulations to make clear that ''air curtain incinerators'' do not need to meet the definition of a ''CISWI unit'' to be subject to the CISWI rule (40 CFR 60.2010 of the NSPS and 40 CFR 60.2500 and 60.2550 of the EG).

B. Typographical Errors and Corrections

In this action, we are also revising the final rule to correct minor typographical errors and clarify provisions that are unclear. The list of these changes is included in the *Typographical Errors and Corrections for Final Technical Amendments* memorandum in Docket ID No. EPA–OAR–HQ–2003–0119.

C. Environmental, Energy, and Economic Impacts

This action makes technical and clarifying corrections to aid in implementation and compliance, but does not make substantive changes to the February 7, 2013, final CISWI rule (78 FR 9112).[5] As such, there are no environmental, energy, or economic impacts associated with this final action. The impacts associated with the CISWI rule were discussed in detail in

[4] The phrasing of the regulations at 40 CFR 60.2010 and 60.2015 of the NSPS similarly confuse the applicability of the final CISWI rule to new ACIs located at commercial and industrial facilities.

[5] The June 23, 2016, final CISWI rule amendments (81 FR 40956) also did not entail any environmental, energy or economic impacts, and therefore the February 7, 2013, final CISWI rule presents the impacts associated with the CISWI rule.

the February 7, 2013, final CISWI rule document.

VI. Statutory and Executive Order Reviews

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

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory action. This final rule provides meaningful burden reduction by providing additional regulatory flexibilities that address several implementation issues raised by the stakeholders.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB Control number 2060–0662 for 40 CFR part 60, subpart CCCC, and OMB Control number 2060–0664 for 40 CFR part 60, subpart DDDD. This action is believed to result in no changes to the information collection requirements of the 2016 CISWI rule, so that the information collection estimate of project cost and hour burden from the 2016 CISWI Rule have not been revised.

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 final rule will not impose any new requirements on any entities because it does not impose any additional regulatory requirements relative to those specified in the 2016 CISWI rule, which also did not impose any additional regulatory requirements beyond those specified in the February 2013 final CISWI rule. The February 2013 final CISWI rule was certified as not having a significant economic impact on a substantial number of small entities. 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. The EPA is not aware of any CISWI in Indian country or owned or operated by Indian tribal governments. The CISWI aspects of this rule may, however, invoke minor indirect tribal implications to the extent that entities generating solid wastes on tribal lands could be affected. 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 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 (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (58 FR 7629, February 16, 1994).

It does not affect the level of protection provided to human health or the environment. The final corrections do not relax the control measures on sources regulated by the 2016 CISWI rule, which also did not relax any control measures on sources regulated by the February 2013 final CISWI rule. Therefore, this final action will not cause emissions increases from these sources. The February 2013 final CISWI rule reduced emissions of all the listed toxics emitted from this source, thereby helping to further ensure against any disproportionately high and adverse human health or environmental effects on minority or low-income populations.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 60

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Incorporation by reference.

Dated: March 18, 2019.

Andrew R. Wheeler,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency is amending title 40, chapter I, of the Code of Federal Regulations as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

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

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

§ 60.17 [Amended]

■ 2. Amend § 60.17 by:

■ a. In paragraph (g)(14), by removing ''60.2710(s), (t), and (w),''and adding, it its place, ''60.2710(s) and (t),''; and
■ b. In paragraph (h)(190), by removing ''tables 1, 5,'' and adding, in its place, ''tables 5,''.

■ 3. Revise subpart CCCC to read as follows:

Sec.

Subpart CCCC—Standards of Performance for Commercial and Industrial Solid Waste Incineration Units

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Subpart CCCC—Standards of Performance for Commercial and Industrial Solid Waste Incineration Units

Introduction

§ 60.2000 What does this subpart do?

This subpart establishes new source performance standards for commercial and industrial solid waste incineration units (CISWIs) and air curtain incinerators (ACIs).

§ 60.2005 When did this subpart become effective?

This subpart became effective on August 7, 2013. Some of the requirements in this subpart apply to planning the CISWI or ACI (*i.e.,* the preconstruction requirements in

§§ 60.2045 and 60.2050). Other requirements such as the emission limitations and operating limits apply after the CISWI or ACI begins operation.

Applicability

§ 60.2010 Does this subpart apply to my incineration unit?

Yes, this subpart applies if your incineration unit meets all the requirements specified in paragraphs (a) through (c) of this section:

(a) Your incineration unit is a new incineration unit as defined in § 60.2015;

(b) Your incineration unit is a CISWI as defined in § 60.2265, or an ACI as defined in § 60.2265; and

(c) Your incineration unit is not exempt under § 60.2020.

§ 60.2015 What is a new incineration unit?

(a) A new incineration unit is an incineration unit that meets any of the criteria specified in paragraphs (a)(1) through (3) of this section:

(1) A CISWI or ACI that commenced construction after June 4, 2010;

(2) A CISWI or ACI that commenced reconstruction or modification after August 7, 2013; and

(3) Incinerators and ACIs, as defined in this subpart, that commenced construction after November 30, 1999, but no later than June 4, 2010, or that commenced reconstruction or modification on or after June 1, 2001, but no later than August 7, 2013, are considered new incineration units and remain subject to the applicable requirements of this subpart until the units become subject to the requirements of an approved state plan or federal plan that implements subpart DDDD of this part (Emission Guidelines and Compliance Times for Commercial and Industrial Solid Waste Incineration Units).

(b) This subpart does not affect your CISWI or ACI if you make physical or operational changes to your incineration unit primarily to comply with subpart DDDD of this part (Emission Guidelines and Compliance Times for Commercial and Industrial Solid Waste Incineration Units). Such changes do not qualify as reconstruction or modification under this subpart.

§ 60.2020 What combustion units are exempt from this subpart?

This subpart exempts the types of units described in paragraphs (a) through (j) of this section, but some units are required to provide notifications.

(a) *Pathological waste incineration units.* Incineration units burning 90 percent or more by weight (on a calendar quarter basis and excluding the weight of auxiliary fuel and combustion air) of pathological waste, low-level radioactive waste, and/or chemotherapeutic waste as defined in § 60.2265 are not subject to this subpart if you meet the two requirements specified in paragraphs (a)(1) and (2) of this section:

(1) Notify the Administrator that the unit meets these criteria; and

(2) Keep records on a calendar quarter basis of the weight of pathological waste, low-level radioactive waste, and/or chemotherapeutic waste burned, and the weight of all other fuels and wastes burned in the unit.

(b) *Municipal waste combustion units.* Incineration units that are subject to subpart Ea of this part (Standards of Performance for Municipal Waste Combustors); subpart Eb of this part (Standards of Performance for Large Municipal Waste Combustors); subpart Cb of this part (Emission Guidelines and Compliance Time for Large Municipal Combustors); subpart AAAA of this part (Standards of Performance for Small Municipal Waste Combustion Units); or subpart BBBB of this part (Emission Guidelines for Small Municipal Waste Combustion Units).

(c) *Medical waste incineration units.* Incineration units regulated under subpart Ec of this part (Standards of Performance for Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996) or subpart Ce of this part (Emission Guidelines and Compliance Times for Hospital/Medical/Infectious Waste Incinerators).

(d) *Small power production facilities.* Units that meet the four requirements specified in paragraphs (d)(1) through (4) of this section:

(1) The unit qualifies as a small power-production facility under section 3(17)(C) of the Federal Power Act (16 U.S.C. 796(17)(C));

(2) The unit burns homogeneous waste (not including refuse-derived fuel) to produce electricity;

(3) You submit documentation to the Administrator notifying the EPA that the qualifying small power production facility is combusting homogenous waste; and

(4) You maintain the records specified in § 60.2175(w).

(e) *Cogeneration facilities.* Units that meet the four requirements specified in paragraphs (e)(1) through (4) of this section:

(1) The unit qualifies as a cogeneration facility under section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B));

(2) The unit burns homogeneous waste (not including refuse-derived fuel) to produce electricity and steam or other forms of energy used for industrial, commercial, heating, or cooling purposes;

(3) You submit documentation to the Administrator notifying the Agency that the qualifying cogeneration facility is combusting homogenous waste; and

(4) You maintain the records specified in § 60.2175(x).

(f) *Hazardous waste combustion units.* Units for which you are required to get a permit under section 3005 of the Solid Waste Disposal Act.

(g) *Materials recovery units.* Units that combust waste for the primary purpose of recovering metals, such as primary and secondary smelters.

(h) *Sewage treatment plants.* Incineration units regulated under subpart O of this part (Standards of Performance for Sewage Treatment Plants).

(i) *Sewage sludge incineration units.* Incineration units combusting sewage sludge for the purpose of reducing the volume of the sewage sludge by removing combustible matter that are subject to subpart LLLL of this part (Standards of Performance for New Sewage Sludge Incineration Units) or subpart MMMM of this part (Emission Guidelines and Compliance Times for Existing Sewage Sludge Incineration Units).

(j) *Other solid waste incineration units.* Incineration units that are subject to subpart EEEE of this part (Standards of Performance for Other Solid Waste Incineration Units for Which Construction is Commenced After December 9, 2004, or for Which Modification or Reconstruction is Commenced on or After June 16, 2006) or subpart FFFF of this part (Emission Guidelines and Compliance Times for Other Solid Waste Incineration Units That Commenced Construction On or Before December 9, 2004).

§ 60.2030 Who implements and enforces this subpart?

(a) This subpart can be implemented and enforced by the U.S. Environmental Protection Agency (EPA), or a delegated authority such as your state, local, or tribal agency. If the EPA Administrator has delegated authority to your state, local, or tribal agency, then that agency (as well as EPA) has the authority to implement and enforce this subpart. You should contact your EPA Regional Office to find out if this subpart is delegated to your state, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to

a state, local, or tribal agency, the authorities contained in paragraph (c) of this section are retained by the EPA Administrator and are not transferred to the state, local, or tribal agency.

(c) The authorities that will not be delegated to state, local, or tribal agencies are specified in paragraphs (c)(1) through (9) of this section:

(1) Approval of alternatives to the emission limitations in tables 1, 5, 6, 7, and 8 of this subpart and operating limits established under § 60.2110;

(2) Approval of major alternatives to test methods;

(3) Approval of major alternatives to monitoring;

(4) Approval of major alternatives to recordkeeping and reporting;

(5) The requirements in § 60.2115;

(6) The requirements in § 60.2100(b)(2);

(7) Approval of alternative opacity emission limits in § 60.2105 under § 60.11(e)(6) through (8);

(8) Performance test and data reduction waivers under § 60.8(b)(4) and (5);

(9) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

§ 60.2035 How are these new source performance standards structured?

These new source performance standards contain the eleven major components listed in paragraphs (a) through (k) of this section:

(a) Preconstruction siting analysis;

(b) Waste management plan;

(c) Operator training and qualification;

(d) Emission limitations and operating limits;

(e) Performance testing;

(f) Initial compliance requirements;

(g) Continuous compliance requirements;

(h) Monitoring;

(i) Recordkeeping and reporting;

(j) Definitions; and

(k) Tables.

§ 60.2040 Do all eleven components of these new source performance standards apply at the same time?

No. You must meet the preconstruction siting analysis and waste management plan requirements before you commence construction of the CISWI. The operator training and qualification, emission limitations, operating limits, performance testing and compliance, monitoring, and most recordkeeping and reporting requirements are met after the CISWI begins operation.

Preconstruction Siting Analysis

§ 60.2045 Who must prepare a siting analysis?

(a) You must prepare a siting analysis if you plan to commence construction of an incinerator after December 1, 2000.

(b) You must prepare a siting analysis for CISWIs that commenced construction after June 4, 2010, or that commenced reconstruction or modification after August 7, 2013.

(c) You must prepare a siting analysis if you are required to submit an initial application for a construction permit under 40 CFR part 51, subpart I, or 40 CFR part 52, as applicable, for the reconstruction or modification of your CISWI.

§ 60.2050 What is a siting analysis?

(a) The siting analysis must consider air pollution control alternatives that minimize, on a site-specific basis, to the maximum extent practicable, potential risks to public health or the environment. In considering such alternatives, the analysis may consider costs, energy impacts, nonair environmental impacts, or any other factors related to the practicability of the alternatives.

(b) Analyses of your CISWI's impacts that are prepared to comply with state, local, or other federal regulatory requirements may be used to satisfy the requirements of this section, provided they include the consideration of air pollution control alternatives specified in paragraph (a) of this section.

(c) You must complete and submit the siting requirements of this section as required under § 60.2190(c) prior to commencing construction.

Waste Management Plan

§ 60.2055 What is a waste management plan?

A waste management plan is a written plan that identifies both the feasibility and the methods used to reduce or separate certain components of solid waste from the waste stream in order to reduce or eliminate toxic emissions from incinerated waste.

§ 60.2060 When must I submit my waste management plan?

(a) You must submit a waste management plan prior to commencing construction.

(b) For CISWIs that commence reconstruction or modification after August 7, 2013, you must submit a waste management plan prior to the commencement of modification or reconstruction.

§ 60.2065 What should I include in my waste management plan?

A waste management plan must include consideration of the reduction or separation of waste-stream elements such as paper, cardboard, plastics, glass, batteries, or metals; or the use of recyclable materials. The plan must identify any additional waste management measures and implement those measures the source considers practical and feasible, considering the effectiveness of waste management measures already in place, the costs of additional measures, the emissions reductions expected to be achieved, and any other environmental or energy impacts they might have.

Operator Training and Qualification

§ 60.2070 What are the operator training and qualification requirements?

(a) No CISWI can be operated unless a fully trained and qualified CISWI operator is accessible, either at the facility or can be at the facility within 1 hour. The trained and qualified CISWI operator may operate the CISWI directly or be the direct supervisor of one or more other plant personnel who operate the unit. If all qualified CISWI operators are temporarily not accessible, you must follow the procedures in § 60.2100.

(b) Operator training and qualification must be obtained through a state-approved program or by completing the requirements included in paragraph (c) of this section.

(c) Training must be obtained by completing an incinerator operator training course that includes, at a minimum, the three elements described in paragraphs (c)(1) through (3) of this section:

(1) Training on the eleven subjects listed in paragraphs (c)(1)(i) through (xi) of this section;

(i) Environmental concerns, including types of emissions;

(ii) Basic combustion principles, including products of combustion;

(iii) Operation of the specific type of incinerator to be used by the operator, including proper startup, waste charging, and shutdown procedures;

(iv) Combustion controls and monitoring;

(v) Operation of air pollution control equipment and factors affecting performance (if applicable);

(vi) Inspection and maintenance of the incinerator and air pollution control devices;

(vii) Actions to prevent and correct malfunctions or to prevent conditions that may lead to malfunctions;

(viii) Bottom and fly ash characteristics and handling procedures;

(ix) Applicable federal, state, and local regulations, including Occupational Safety and Health Administration workplace standards;

(x) Pollution prevention; and

(xi) Waste management practices.

(2) An examination designed and administered by the instructor.

(3) Written material covering the training course topics that may serve as reference material following completion of the course.

§ 60.2075 When must the operator training course be completed?

The operator training course must be completed by the later of the three dates specified in paragraphs (a) through (c) of this section:

(a) Six months after your CISWI startup;

(b) December 3, 2001; and

(c) The date before an employee assumes responsibility for operating the CISWI or assumes responsibility for supervising the operation of the CISWI.

§ 60.2080 How do I obtain my operator qualification?

(a) You must obtain operator qualification by completing a training course that satisfies the criteria under § 60.2070(b).

(b) Qualification is valid from the date on which the training course is completed and the operator successfully passes the examination required under § 60.2070(c)(2).

§ 60.2085 How do I maintain my operator qualification?

To maintain qualification, you must complete an annual review or refresher course covering, at a minimum, the five topics described in paragraphs (a) through (e) of this section:

(a) Update of regulations;

(b) Incinerator operation, including startup and shutdown procedures, waste charging, and ash handling;

(c) Inspection and maintenance;

(d) Prevention and correction of malfunctions or conditions that may lead to malfunction; and

(e) Discussion of operating problems encountered by attendees.

§ 60.2090 How do I renew my lapsed operator qualification?

You must renew a lapsed operator qualification by one of the two methods specified in paragraphs (a) and (b) of this section:

(a) For a lapse of less than 3 years, you must complete a standard annual refresher course described in § 60.2085; and

(b) For a lapse of 3 years or more, you must repeat the initial qualification requirements in § 60.2080(a).

§ 60.2095 What site-specific documentation is required?

(a) Documentation must be available at the facility and readily accessible for all CISWI operators that addresses the ten topics described in paragraphs (a)(1) through (10) of this section. You must maintain this information and the training records required by paragraph (c) of this section in a manner that they can be readily accessed and are suitable for inspection upon request:

(1) Summary of the applicable standards under this subpart;

(2) Procedures for receiving, handling, and charging waste;

(3) Incinerator startup, shutdown, and malfunction procedures;

(4) Procedures for maintaining proper combustion air supply levels;

(5) Procedures for operating the incinerator and associated air pollution control systems within the standards established under this subpart;

(6) Monitoring procedures for demonstrating compliance with the incinerator operating limits;

(7) Reporting and recordkeeping procedures;

(8) The waste management plan required under §§ 60.2055 through 60.2065;

(9) Procedures for handling ash; and

(10) A list of the wastes burned during the performance test.

(b) You must establish a program for reviewing the information listed in paragraph (a) of this section with each incinerator operator:

(1) The initial review of the information listed in paragraph (a) of this section must be conducted within 6 months after the effective date of this subpart or prior to an employee's assumption of responsibilities for operation of the CISWI, whichever date is later; and

(2) Subsequent annual reviews of the information listed in paragraph (a) of this section must be conducted no later than 12 months following the previous review.

(c) You must also maintain the information specified in paragraphs (c)(1) through (3) of this section:

(1) Records showing the names of CISWI operators who have completed review of the information in § 60.2095(a) as required by § 60.2095(b), including the date of the initial review and all subsequent annual reviews;

(2) Records showing the names of the CISWI operators who have completed the operator training requirements under § 60.2070, met the criteria for qualification under § 60.2080, and maintained or renewed their qualification under § 60.2085 or § 60.2090. Records must include documentation of training, the dates of the initial and refresher training, and the dates of their qualification and all subsequent renewals of such qualifications; and

(3) For each qualified operator, the phone and/or pager number at which they can be reached during operating hours.

§ 60.2100 What if all the qualified operators are temporarily not accessible?

If all qualified operators are temporarily not accessible (*i.e.,* not at the facility and not able to be at the facility within 1 hour), you must meet one of the two criteria specified in paragraphs (a) and (b) of this section, depending on the length of time that a qualified operator is not accessible:

(a) When all qualified operators are not accessible for more than 8 hours, but less than 2 weeks, the CISWI may be operated by other plant personnel familiar with the operation of the CISWI who have completed a review of the information specified in § 60.2095(a) within the past 12 months. However, you must record the period when all qualified operators were not accessible and include this deviation in the annual report as specified under § 60.2210; and

(b) When all qualified operators are not accessible for 2 weeks or more, you must take the two actions that are described in paragraphs (b)(1) and (2) of this section:

(1) Notify the Administrator of this deviation in writing within 10 days. In the notice, state what caused this deviation, what you are doing to ensure that a qualified operator is accessible, and when you anticipate that a qualified operator will be accessible; and

(2) Submit a status report to the Administrator every 4 weeks outlining what you are doing to ensure that a qualified operator is accessible, stating when you anticipate that a qualified operator will be accessible and requesting approval from the Administrator to continue operation of the CISWI. You must submit the first status report 4 weeks after you notify the Administrator of the deviation under paragraph (b)(1) of this section. If the Administrator notifies you that your request to continue operation of the CISWI is disapproved, the CISWI may continue operation for 90 days, then must cease operation. Operation of the unit may resume if you meet the two requirements in paragraphs (b)(2)(i) and (ii) of this section:

(i) A qualified operator is accessible as required under § 60.2070(a); and

(ii) You notify the Administrator that a qualified operator is accessible and that you are resuming operation.

Emission Limitations and Operating Limits

§ 60.2105 What emission limitations must I meet and by when?

(a) You must meet the emission limitations for each CISWI, including bypass stack or vent, specified in table 1 of this subpart or tables 5 through 8 of this subpart by the applicable date in § 60.2140. You must be in compliance with the emission limitations of this subpart that apply to you at all times.

(b) A CISWI or ACI that commenced construction after November 30, 1999, but no later than June 4, 2010, or that commenced reconstruction or modification on or after June 1, 2001 but no later than August 7, 2013, must continue to meet the emission limits in table 1 of this subpart for units in the incinerator subcategory and § 60.2250 for ACIs until the units become subject to the requirements of an approved state plan or federal plan that implements subpart DDDD of this part (Emission Guidelines and Compliance Times for Commercial and Industrial Solid Waste Incineration Units).

§ 60.2110 What operating limits must I meet and by when?

(a) If you use a wet scrubber(s) to comply with the emission limitations, you must establish operating limits for up to four operating parameters (as specified in table 2 of this subpart) as described in paragraphs (a)(1) through (4) of this section during the initial performance test:

(1) Maximum charge rate, calculated using one of the two different procedures in paragraph (a)(1)(i) or (ii) of this section, as appropriate:

(i) For continuous and intermittent units, maximum charge rate is 110 percent of the average charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limitations; and

(ii) For batch units, maximum charge rate is 110 percent of the daily charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limitations.

(2) Minimum pressure drop across the wet particulate matter scrubber, which is calculated as the lowest 1-hour average pressure drop across the wet scrubber measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations; or minimum amperage to the wet scrubber, which is calculated as the lowest 1-hour average amperage to the wet scrubber measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations;

(3) Minimum scrubber liquid flow rate, which is calculated as the lowest 1-hour average liquid flow rate at the inlet to the wet acid gas or particulate matter scrubber measured during the most recent performance test demonstrating compliance with all applicable emission limitations; and

(4) Minimum scrubber liquor pH, which is calculated as the lowest 1-hour average liquor pH at the inlet to the wet acid gas scrubber measured during the most recent performance test demonstrating compliance with the hydrogen chloride (HCl) emission limitation.

(b) You must meet the operating limits established during the initial performance test 60 days after your CISWI reaches the charge rate at which it will operate, but no later than 180 days after its initial startup.

(c) If you use a fabric filter to comply with the emission limitations and you do not use a particulate matter (PM) continuous parameter monitoring system (CPMS) for monitoring PM compliance, you must operate each fabric filter system such that the bag leak detection system alarm does not sound more than 5 percent of the operating time during a 6-month period. In calculating this operating time percentage, if inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted. If corrective action is required, each alarm shall be counted as a minimum of 1 hour. If you take longer than 1 hour to initiate corrective action, the alarm time shall be counted as the actual amount of time taken by you to initiate corrective action.

(d) If you use an electrostatic precipitator to comply with the emission limitations and you do not use a PM CPMS for monitoring PM compliance, you must measure the (secondary) voltage and amperage of the electrostatic precipitator collection plates during the particulate matter performance test. Calculate the average electric power value (secondary voltage × secondary current = secondary electric power) for each test run. The operating limit for the electrostatic precipitator is calculated as the lowest 1-hour average secondary electric power measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations.

(e) If you use activated carbon sorbent injection to comply with the emission limitations, you must measure the sorbent flow rate during the performance testing. The operating limit for the carbon sorbent injection is calculated as the lowest 1-hour average sorbent flow rate measured during the most recent performance test demonstrating compliance with the mercury emission limitations. For energy recovery units, when your unit operates at lower loads, multiply your sorbent injection rate by the load fraction, as defined in this subpart, to determine the required injection rate (*e.g.,* for 50 percent load, multiply the injection rate operating limit by 0.5).

(f) If you use selective noncatalytic reduction to comply with the emission limitations, you must measure the charge rate, the secondary chamber temperature (if applicable to your CISWI), and the reagent flow rate during the nitrogen oxides performance testing. The operating limits for the selective noncatalytic reduction are calculated as the highest 1-hour average charge rate, lower secondary chamber temperature, and lowest reagent flow rate measured during the most recent performance test demonstrating compliance with the nitrogen oxides emission limitations.

(g) If you use a dry scrubber to comply with the emission limitations, you must measure the injection rate of each sorbent during the performance testing. The operating limit for the injection rate of each sorbent is calculated as the lowest 1-hour average injection rate for each sorbent measured during the most recent performance test demonstrating compliance with the hydrogen chloride emission limitations. For energy recovery units, when your unit operates at lower loads, multiply your sorbent injection rate by the load fraction, as defined in this subpart, to determine the required injection rate (*e.g.,* for 50 percent load, multiply the injection rate operating limit by 0.5).

(h) If you do not use a wet scrubber, electrostatic precipitator, or fabric filter to comply with the emission limitations, and if you do not determine compliance with your particulate matter emission limitation with either a particulate matter CEMS or a particulate matter CPMS, you must maintain opacity to less than or equal to 10 percent opacity (1-hour block average).

(i) If you use a PM CPMS to demonstrate compliance, you must establish your PM CPMS operating limit and determine compliance with it according to paragraphs (i)(1) through (5) of this section:

(1) Determine your operating limit as the average PM CPMS output value recorded during the performance test or at a PM CPMS output value corresponding to 75 percent of the emission limit if your PM performance test demonstrates compliance below 75 percent of the emission limit. You must

verify an existing or establish a new operating limit after each repeated performance test. You must repeat the performance test annually and reassess and adjust the site-specific operating limit in accordance with the results of the performance test:

(i) Your PM CPMS must provide a 4–20 milliamp output, or digital equivalent, and the establishment of its relationship to manual reference method measurements must be determined in units of milliamps;

(ii) Your PM CPMS operating range must be capable of reading PM concentrations from zero to a level equivalent to at least two times your allowable emission limit. If your PM CPMS is an auto-ranging instrument capable of multiple scales, the primary range of the instrument must be capable of reading PM concentration from zero to a level equivalent to two times your allowable emission limit; and

(iii) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, record and average all milliamp output values, or their digital equivalent, from the PM CPMS for the periods corresponding to the compliance test runs (*e.g.,* average all your PM CPMS output values for three corresponding 2-hour Method 5I test runs).

(2) If the average of your three PM performance test runs are below 75 percent of your PM emission limit, you must calculate an operating limit by establishing a relationship of PM CPMS signal to PM concentration using the PM CPMS instrument zero, the average PM CPMS output values corresponding to the three compliance test runs, and the average PM concentration from the Method 5 or performance test with the procedures in (i)(1) through (5) of this section:

(i) Determine your instrument zero output with one of the following procedures:

(A) Zero point data for *in-situ* instruments should be obtained by removing the instrument from the stack and monitoring ambient air on a test bench;

(B) Zero point data for extractive instruments should be obtained by removing the extractive probe from the stack and drawing in clean ambient air;

(C) The zero point can also can be established obtained by performing manual reference method measurements when the flue gas is free of PM emissions or contains very low PM concentrations (*e.g.,* when your process is not operating, but the fans are operating or your source is combusting only natural gas) and plotting these with the compliance data to find the zero intercept; and

(D) If none of the steps in paragraphs (i)(2)(i)(A) through (C) of this section are possible, you must use a zero output value provided by the manufacturer.

(ii) Determine your PM CPMS instrument average in milliamps, or the digital equivalent, and the average of your corresponding three PM compliance test runs, using equation 1:

$$\overline{x} = \frac{1}{n}\sum_{i=1}^{n} X_1, \overline{y} = \frac{1}{n}\sum_{i=1}^{n} Y_1 \qquad \text{(Eq. 1)}$$

Where:

X_1 = the PM CPMS output data points for the three runs constituting the performance test,

Y_1 = the PM concentration value for the three runs constituting the performance test, and

n = the number of data points.

(iii) With your instrument zero expressed in milliamps, or the digital equivalent, your three run average PM CPMS milliamp value, or its digital equivalent, and your three run average PM concentration from your three compliance tests, determine a relationship of mg/dscm per milliamp or digital signal equivalent with equation 2:

$$R = \left(\frac{Y_1}{X_{1-z}}\right) \qquad \text{(Eq. 2)}$$

Where:

R = the relative mg/dscm per milliamp or digital equivalent for your PM CPMS,

Y_1 = the three run average mg/dscm PM concentration,

X_1 = the three run average milliamp or digital signal output from you PM CPMS, and

z = the milliamp or digital signal equivalent of your instrument zero determined from paragraph (2)(i) of this section.

(iv) Determine your source specific 30-day rolling average operating limit using the mg/dscm per milliamp or digital value from equation 2 in equation 3, below. This sets your operating limit at the PM CPMS output value corresponding to 75 percent of your emission limit:

$$O_l = z + \frac{0.75(L)}{R} \qquad \text{(Eq. 3)}$$

Where:

O_l = the operating limit for your PM CPMS on a 30-day rolling average, in milliamps or their digital signal equivalent,

L = your source emission limit expressed in mg/dscm,

z = your instrument zero in milliamps or the digital equivalent, determined from paragraph (2)(i) of this secction, and

R = the relative mg/dscm per milliamp or digital signal output equivalent for your PM CPMS, from equation 2.

(3) If the average of your three PM compliance test runs is at or above 75 percent of your PM emission limit you must determine your operating limit by averaging the PM CPMS milliamp or digital signal output corresponding to your three PM performance test runs that demonstrate compliance with the emission limit using equation 4 and you must submit all compliance test and PM CPMS data according to the reporting requirements in paragraph (i)(5) of this section:

$$O_n = \frac{1}{n}\sum_{i=1}^{n} X_1 \qquad \text{(Eq. 4)}$$

Where:

X_1 = the PM CPMS data points for all runs i,

n = the number of data points, and

O_h = your site specific operating limit, in milliamps or digital signal equivalent.

(4) To determine continuous compliance, you must record the PM CPMS output data for all periods when the process is operating and the PM CPMS is not out-of-control. You must demonstrate continuous compliance by using all quality-assured hourly average data collected by the PM CPMS for all operating hours to calculate the arithmetic average operating parameter in units of the operating limit (*e.g.,* milliamps or digital signal bits, PM concentration, raw data signal) on a 30-day rolling average basis.

(5) For PM performance test reports used to set a PM CPMS operating limit, the electronic submission of the test report must also include the make and model of the PM CPMS instrument, serial number of the instrument, analytical principle of the instrument (*e.g.,* beta attenuation), span of the instruments primary analytical range, milliamp or digital signal value equivalent to the instrument zero output, technique by which this zero value was determined, and the average milliamp or digital signals corresponding to each PM compliance test run.

§ 60.2115 What if I do not use a wet scrubber, fabric filter, activated carbon injection, selective noncatalytic reduction, an electrostatic precipitator, or a dry scrubber to comply with the emission limitations?

If you use an air pollution control device other than a wet scrubber, activated carbon injection, selective noncatalytic reduction, fabric filter, an electrostatic precipitator, or a dry scrubber or limit emissions in some other manner, including material balances, to comply with the emission limitations under § 60.2105, you must petition the EPA Administrator for specific operating limits to be established during the initial performance test and continuously monitored thereafter. You must submit the petition at least sixty days before the performance test is scheduled to begin. Your petition must include the five items listed in paragraphs (a) through (e) of this section:

(a) Identification of the specific parameters you propose to use as additional operating limits;

(b) A discussion of the relationship between these parameters and emissions of regulated pollutants, identifying how emissions of regulated pollutants change with changes in these parameters and how limits on these parameters will serve to limit emissions of regulated pollutants;

(c) A discussion of how you will establish the upper and/or lower values for these parameters which will establish the operating limits on these parameters;

(d) A discussion identifying the methods you will use to measure and the instruments you will use to monitor these parameters, as well as the relative accuracy and precision of these methods and instruments; and

(e) A discussion identifying the frequency and methods for recalibrating the instruments you will use for monitoring these parameters.

Performance Testing

§ 60.2125 How do I conduct the initial and annual performance test?

(a) All performance tests must consist of a minimum of three test runs conducted under conditions representative of normal operations.

(b) You must document that the waste burned during the performance test is representative of the waste burned under normal operating conditions by maintaining a log of the quantity of waste burned (as required in § 60.2175(b)(1)) and the types of waste burned during the performance test.

(c) All performance tests must be conducted using the minimum run duration specified in table 1 of this subpart or tables 5 through 8 of this subpart.

(d) Method 1 of appendix A of this part must be used to select the sampling location and number of traverse points.

(e) Method 3A or 3B of appendix A of this part must be used for gas composition analysis, including measurement of oxygen concentration. Method 3A or 3B of appendix A of this part must be used simultaneously with each method (except when using Method 9 and Method 22).

(f) All pollutant concentrations, except for opacity, must be adjusted to 7 percent oxygen using equation 5 of this section:

$$C_{adj} = C_{meas}\,(20.9\text{-}7)/(20.9\text{-}\%O_2) \qquad \text{(Eq. 5)}$$

Where:

C_{adj} = pollutant concentration adjusted to 7 percent oxygen;

C_{meas} = pollutant concentration measured on a dry basis;

(20.9–7) = 20.9 percent oxygen − 7 percent oxygen (defined oxygen correction basis);

20.9 = oxygen concentration in air, percent; and

$\%O_2$ = oxygen concentration measured on a dry basis, percent.

(g) You must determine dioxins/furans toxic equivalency by following the procedures in paragraphs (g)(1) through (4) of this section:

(1) Measure the concentration of each dioxin/furan tetra-through octa-chlorinated isomer emitted using EPA Method 23 at 40 CFR part 60, appendix A–7;

(2) Quantify isomers meeting identification criteria 2, 3, 4, and 5 in Section 5.3.2.5 of Method 23, regardless of whether the isomers meet identification criteria 1 and 7. You must quantify the isomers per Section 9.0 of Method 23. (Note: You may reanalyze the sample aliquot or split to reduce the number of isomers not meeting identification criteria 1 or 7 of Section 5.3.2.5.);

(3) For each dioxin/furan (tetra-through octa-chlorinated) isomer measured in accordance with paragraphs (g)(1) and (2) of this section, multiply the isomer concentration by its corresponding toxic equivalency factor specified in table 3 of this subpart; and

(4) Sum the products calculated in accordance with paragraph (g)(3) of this section to obtain the total concentration of dioxins/furans emitted in terms of toxic equivalency.

(h) Method 22 at 40 CFR part 60, appendix A–7 of this part must be used to determine compliance with the fugitive ash emission limit in table 1 of this subpart or tables 5 through 8 of this subpart.

(i) If you have an applicable opacity operating limit, you must determine compliance with the opacity limit using Method 9 at 40 CFR part 60, appendix A–4, based on three 1-hour blocks consisting of ten 6-minute average opacity values, unless you are required to install a continuous opacity monitoring system, consistent with §§ 60.2145 and 60.2165.

(j) You must determine dioxins/furans total mass basis by following the procedures in paragraphs (j)(1) through (3) of this section:

(1) Measure the concentration of each dioxin/furan tetra-through octa-chlorinated isomer emitted using EPA Method 23 at 40 CFR part 60, appendix A–7;

(2) Quantify isomers meeting identification criteria 2, 3, 4, and 5 in Section 5.3.2.5 of Method 23, regardless of whether the isomers meet identification criteria 1 and 7. You must quantify the isomers per Section 9.0 of Method 23. (Note: You may reanalyze the sample aliquot or split to reduce the number of isomers not meeting identification criteria 1 or 7 of Section 5.3.2.5.); and

(3) Sum the quantities measured in accordance with paragraphs (j)(1) and (2) of this section to obtain the total concentration of dioxins/furans emitted in terms of total mass basis.

§ 60.2130 How are the performance test data used?

You use results of performance tests to demonstrate compliance with the emission limitations in table 1 of this subpart or tables 5 through 8 of this subpart.

Initial Compliance Requirements

§ 60.2135 How do I demonstrate initial compliance with the emission limitations and establish the operating limits?

(a) You must conduct a performance test, as required under §§ 60.2125 and 60.2105to determine compliance with the emission limitations in table 1 of this subpart or tables 5 through 8 of this subpart, to establish compliance with any opacity operating limit in § 60.2110, to establish the kiln-specific emission limit in § 60.2145(y), as applicable, and to establish operating limits using the procedures in § 60.2110 or § 60.2115. The performance test must be conducted using the test methods listed in table 1 of this subpart or tables 5 through 8 of this subpart and the procedures in § 60.2125. The use of the bypass stack during a performance test shall invalidate the performance test.

(b) As an alternative to conducting a performance test, as required under §§ 60.2125 and 60.2105, you may use a 30-day rolling average of the 1-hour arithmetic average CEMS data, including CEMS data during startup and shutdown as defined in this subpart, to determine compliance with the emission limitations in Table 1 of this subpart or tables 5 through 8 of this subpart. You must conduct a performance evaluation of each continuous monitoring system within 180 days of installation of the monitoring system. The initial performance evaluation must be conducted prior to collecting CEMS data that will be used for the initial compliance demonstration.

§ 60.2140 By what date must I conduct the initial performance test?

(a) The initial performance test must be conducted within 60 days after your CISWI reaches the charge rate at which it will operate, but no later than 180 days after its initial startup.

(b) If you commence or recommence combusting a solid waste at an existing combustion unit at any commercial or industrial facility, and you conducted a test consistent with the provisions of this subpart while combusting the solid waste within the 6 months preceding the reintroduction of that solid waste in the combustion chamber, you do not need to retest until 6 months from the date you reintroduce that solid waste.

(c) If you commence or recommence combusting a solid waste at an existing combustion unit at any commercial or industrial facility and you have not conducted a performance test consistent with the provisions of this subpart while combusting the solid waste within the 6 months preceding the reintroduction of that solid waste in the combustion chamber, you must conduct a performance test within 60 days from the date you reintroduce that solid waste.

§ 60.2141 By what date must I conduct the initial air pollution control device inspection?

(a) The initial air pollution control device inspection must be conducted within 60 days after installation of the control device and the associated CISWI reaches the charge rate at which it will operate, but no later than 180 days after the device's initial startup.

(b) Within 10 operating days following an air pollution control device inspection, all necessary repairs must be completed unless the owner or operator obtains written approval from the state agency establishing a date whereby all necessary repairs of the designated facility must be completed.

Continuous Compliance Requirements

§ 60.2145 How do I demonstrate continuous compliance with the emission limitations and the operating limits?

(a) General compliance with standards, considering some units may be able to switch between solid waste and non-waste fuel combustion, is specified in paragraph (a)(1) through (6) of this section.

(1) The emission standards and operating requirements set forth in this subpart apply at all times;

(2) If you cease combusting solid waste, you may opt to remain subject to the provisions of this subpart. Consistent with the definition of CISWI, you are subject to the requirements of this subpart at least 6 months following the last date of solid waste combustion. Solid waste combustion is ceased when solid waste is not in the combustion chamber (*i.e.,* the solid waste feed to the combustor has been cut off for a period of time not less than the solid waste residence time);

(3) If you cease combusting solid waste, you must be in compliance with

any newly applicable standards on the effective date of the waste-to-fuel switch. The effective date of the waste-to-fuel switch is a date selected by you, that must be at least 6 months from the date that you ceased combusting solid waste, consistent with § 60.2145(a)(2). Your source must remain in compliance with this subpart until the effective date of the waste-to-fuel switch;

(4) If you own or operate an existing commercial or industrial combustion unit that combusted a fuel or non-waste material, and you commence or recommence combustion of solid waste, you are subject to the provisions of this subpart as of the first day you introduce or reintroduce solid waste to the combustion chamber, and this date constitutes the effective date of the fuel-to-waste switch. You must complete all initial compliance demonstrations for any section 112 standards that are applicable to your facility before you commence or recommence combustion of solid waste. You must provide 30 days prior notice of the effective date of the waste-to-fuel switch. The notification must identify:

(i) The name of the owner or operator of the CISWI, the location of the source, the emissions unit(s) that will cease burning solid waste, and the date of the notice;

(ii) The currently applicable subcategory under this subpart, and any 40 CFR part 63 subpart and subcategory that will be applicable after you cease combusting solid waste;

(iii) The fuel(s), non-waste material(s) and solid waste(s) the CISWI is currently combusting and has combusted over the past 6 months, and the fuel(s) or non-waste materials the unit will commence combusting;

(iv) The date on which you became subject to the currently applicable emission limits; and

(v) The date upon which you will cease combusting solid waste, and the date (if different) that you intend for any new requirements to become applicable (*i.e.,* the effective date of the waste-to-fuel switch), consistent with paragraphs (a)(2) and (3) of this section.

(5) All air pollution control equipment necessary for compliance with any newly applicable emissions limits which apply as a result of the cessation or commencement or recommencement of combusting solid waste must be installed and operational as of the effective date of the waste-to-fuel, or fuel-to-waste switch.

(6) All monitoring systems necessary for compliance with any newly applicable monitoring requirements which apply as a result of the cessation or commencement or recommencement of combusting solid waste must be installed and operational as of the effective date of the waste-to-fuel, or fuel-to-waste switch. All calibration and drift checks must be performed as of the effective date of the waste-to-fuel, or fuel-to-waste switch. Relative accuracy tests must be performed as of the performance test deadline for PM CEMS (if PM CEMS are elected to demonstrate continuous compliance with the particulate matter emission limits). Relative accuracy testing for other CEMS need not be repeated if that testing was previously performed consistent with Clean Air Act section 112 monitoring requirements or monitoring requirements under this subpart.

(b) You must conduct an annual performance test for the pollutants listed in table 1 of this subpart or tables 5 through 8 of this subpart and opacity for each CISWI as required under § 60.2125. The annual performance test must be conducted using the test methods listed in table 1 of this subpart or tables 5 through 8 of this subpart and the procedures in § 60.2125. Annual performance tests are not required if you use CEMS or continuous opacity monitoring systems to determine compliance.

(c) You must continuously monitor the operating parameters specified in § 60.2110 or established under § 60.2115 and as specified in § 60.2170. Use 3-hour block average values to determine compliance (except for baghouse leak detection system alarms) unless a different averaging period is established under § 60.2115 or, for energy recovery units, where the averaging time for each operating parameter is a 30-day rolling, calculated each hour as the average of the previous 720 operating hours. Operation above the established maximum, below the established minimum, or outside the allowable range of operating limits specified in paragraph (a) of this section constitutes a deviation from your operating limits established under this subpart, except during performance tests conducted to determine compliance with the emission and operating limits or to establish new operating limits. Operating limits are confirmed or reestablished during performance tests.

(d) You must burn only the same types of waste and fuels used to establish subcategory applicability (for energy recovery units) and operating limits during the performance test.

(e) For energy recovery units, incinerators, and small remote units, you must perform an annual visual emissions test for ash handling.

(f) For energy recovery units, you must conduct an annual performance test for opacity (except where particulate matter CEMS or continuous opacity monitoring systems are used are used) and the pollutants listed in table 6 of this subpart.

(g) You may elect to demonstrate initial and continuous compliance with the carbon monoxide emission limit using a carbon monoxide CEMS, as described in § 60.2165(o).

(h) Coal and liquid/gas energy recovery units with average annual heat input rates greater than or equal to 250 million British thermal units/hour (MMBtu/hr) may elect to demonstrate initial and continuous compliance with the particulate matter emissions limit using a particulate matter CEMS according to the procedures in § 60.2165(n) instead of the PM CPMS specified in § 60.2145. Coal and liquid/gas energy recovery units with annual average heat input rates less than 250 MMBtu/hr, incinerators, and small remote incinerators may also elect to demonstrate initial and continuous compliance using a particulate matter CEMS according to the procedures in § 60.2165(n) instead of particulate matter testing with EPA Method 5 at 40 CFR part 60, appendix A–3 and, if applicable, the continuous opacity monitoring requirements in paragraph (i) of this section.

(i) For energy recovery units with annual average heat input rates greater than or equal to 10 MMBtu/hr and less than 250 MMBtu/hr that do not use a wet scrubber, fabric filter with bag leak detection system, an electrostatic precipitator, particulate matter CEMS, or particulate matter CPMS, you must install, operate, certify and maintain a continuous opacity monitoring system (COMS) according to the procedures in § 60.2165(m).

(j) For waste-burning kilns, you must conduct an annual performance test for cadmium, lead, carbon monoxide, dioxins/furans and hydrogen chloride as listed in Table 7 of this subpart, unless you choose to demonstrate initial and continuous compliance using CEMS, as allowed in paragraph (u) of this section. If you do not use an acid gas wet scrubber or dry scrubber, you must determine compliance with the hydrogen chloride emissions limit using a HCl CEMS according to the requirements in paragraph (j)(1) of this section. You must determine compliance with the mercury emissions limit using a mercury CEMS or an integrated sorbent trap monitoring system according to paragraph (j)(2) of this section. You must determine compliance with nitrogen oxides and

sulfur dioxide using CEMS. You must determine compliance with particulate matter using CPMS.

(1) If you monitor compliance with the HCl emissions limit by operating an HCl CEMS, you must do so in accordance with Performance Specification 15 (PS 15) of appendix B to 40 CFR part 60 or PS 18 of appendix B to 40 CFR part 60. You must operate, maintain, and quality assure a HCl CEMS installed and certified under PS 15 according to the quality assurance requirements in Procedure 1 of appendix F to 40 CFR part 60 except that the Relative Accuracy Test Audit requirements of Procedure 1 must be replaced with the validation requirements and criteria of sections 11.1.1 and 12.0 of PS 15. You must operate, maintain and quality assure a HCl CEMS installed and certified under PS 18 according to the quality assurance requirements in Procedure 6 of appendix F to 40 CFR part 60. For any performance specification that you use, you must use Method 321 of appendix A to 40 CFR part 63 as the reference test method for conducting relative accuracy testing. The span value and calibration requirements in paragraphs (j)(1)(i) and (ii) of this section apply to all HCl CEMS used under this subpart:

(i) You must use a measurement span value for any HCl CEMS of 0–10 ppmvw unless the monitor is installed on a kiln without an inline raw mill. Kilns without an inline raw mill may use a higher span value sufficient to quantify all expected emissions concentrations. The HCl CEMS data recorder output range must include the full range of expected HCl concentration values which would include those expected during ''mill off'' conditions. The corresponding data recorder range shall be documented in the site-specific monitoring plan and associated records;

(ii) In order to quality assure data measured above the span value, you must use one of the three options in paragraphs (j)(1)(ii)(A) through (C) of this section:

(A) Include a second span that encompasses the HCl emission concentrations expected to be encountered during ''mill off'' conditions. This second span may be rounded to a multiple of 5 ppm of total HCl. The requirements of the appropriate HCl monitor performance specification shall be followed for this second span with the exception that a RATA with the mill off is not required;

(B) Quality assure any data above the span value by proving instrument linearity beyond the span value established in paragraph (j)(1)(i) of this section using the following procedure. Conduct a weekly ''above span linearity'' calibration challenge of the monitoring system using a reference gas with a certified value greater than your highest expected hourly concentration or greater than 75% of the highest measured hourly concentration. The ''above span'' reference gas must meet the requirements of the applicable performance specification and must be introduced to the measurement system at the probe. Record and report the results of this procedure as you would for a daily calibration. The ''above span linearity'' challenge is successful if the value measured by the HCl CEMS falls within 10 percent of the certified value of the reference gas. If the value measured by the HCl CEMS during the above span linearity challenge exceeds 10 percent of the certified value of the reference gas, the monitoring system must be evaluated and repaired and a new ''above span linearity'' challenge met before returning the HCl CEMS to service, or data above span from the HCl CEMS must be subject to the quality assurance procedures established in (j)(1)(ii)(D) of this section. In this manner values measured by the HCl CEMS during the above span linearity challenge exceeding +/− 20 percent of the certified value of the reference gas must be normalized using equation 6;

(C) Quality assure any data above the span value established in paragraph (j)(1)(i) of this section using the following procedure. Any time two consecutive one-hour average measured concentration of HCl exceeds the span value you must, within 24 hours before or after, introduce a higher, ''above span'' HCl reference gas standard to the HCl CEMS. The ''above span'' reference gas must meet the requirements of the applicable performance specification and target a concentration level between 50 and 150 percent of the highest expected hourly concentration measured during the period of measurements above span, and must be introduced at the probe. While this target represents a desired concentration range that is not always achievable in practice, it is expected that the intent to meet this range is demonstrated by the value of the reference gas. Expected values may include above span calibrations done before or after the above-span measurement period. Record and report the results of this procedure as you would for a daily calibration. The ''above span'' calibration is successful if the value measured by the HCl CEMS is within 20 percent of the certified value of the reference gas. If the value measured by the HCl CEMS is not within 20 percent of the certified value of the reference gas, then you must normalize the stack gas values measured above span as described in paragraph (j)(1)(ii)(D) of this section. If the ''above span'' calibration is conducted during the period when measured emissions are above span and there is a failure to collect the one data point in an hour due to the calibration duration, then you must determine the emissions average for that missed hour as the average of hourly averages for the hour preceding the missed hour and the hour following the missed hour. In an hour where an ''above span'' calibration is being conducted and one or more data points are collected, the emissions average is represented by the average of all valid data points collected in that hour;

(D) In the event that the ''above span'' calibration is not successful (*i.e.,* the HCl CEMS measured value is not within 20 percent of the certified value of the reference gas), then you must normalize the one-hour average stack gas values measured above the span during the 24-hour period preceding or following the ''above span'' calibration for reporting based on the HCl CEMS response to the reference gas as shown in equation 6:

$$\frac{Certified\ reference\ gas\ value}{Measured\ value\ of\ reference\ gas}\ x\ Measured\ stack\ gas\ result = Normalized\ stack\ gas\ result \qquad \text{(Eq. 6)}$$

Only one ''above span'' calibration is needed per 24-hour period.

(2) Compliance with the mercury emissions limit must be determined using a mercury CEMS or integrated sorbent trap monitoring system according to the following requirements:

(i) You must operate a mercury CEMS system in accordance with performance specification 12A of 40 CFR part 60, appendix B or an integrated sorbent trap monitoring system in accordance with performance specification 12B of 40 CFR part 60, appendix B; these monitoring systems must be quality assured according to procedure 5 of 40

CFR 60, appendix F. For the purposes of emissions calculations when using an integrated sorbent trap monitoring system, the mercury concentration determined for each sampling period must be assigned to each hour during the sampling period. If you choose to comply with the production-rate based mercury limit for your waste-burning kiln, you must also monitor hourly clinker production and determine the hourly mercury emissions rate in pounds per million ton of clinker produced. You must demonstrate compliance with the mercury emissions limit using a 30-day rolling average of these 1-hour mercury concentrations or mass emissions rates, including CEMS and integrated sorbent trap monitoring system data during startup and shutdown as defined in this subpart, calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7 of this part. Integrated sorbent trap monitoring system and CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content;

(ii) Owners or operators using a mercury CEMS or integrated sorbent trap monitoring system to determine mass emission rate must install, operate, calibrate, and maintain an instrument for continuously measuring and recording the mercury mass emissions rate to the atmosphere according to the requirements of performance specification 6 of 40 CFR part 60, appendix B, and conducting an annual relative accuracy test of the continuous emission rate monitoring system according to section 8.2 of performance specification 6; and

(iii) The owner or operator of a waste-burning kiln must demonstrate initial compliance by operating a mercury CEMS or integrated sorbent trap monitoring system while the raw mill of the in-line kiln/raw mill is operating under normal conditions and including at least one period when the raw mill is off.

(k) If you use an air pollution control device to meet the emission limitations in this subpart, you must conduct an initial and annual inspection of the air pollution control device. The inspection must include, at a minimum, the following:

(1) Inspect air pollution control device(s) for proper operation; and

(2) Develop a site-specific monitoring plan according to the requirements in paragraph (l) of this section. This requirement also applies to you if you petition the EPA Administrator for alternative monitoring parameters under § 60.13(i).

(l) For each continuous monitoring system required in this section, you must develop and submit to the EPA Administrator for approval a site-specific monitoring plan according to the requirements of this paragraph (l) that addresses paragraphs (l)(1)(i) through (vi) of this section:

(1) You must submit this site-specific monitoring plan at least 60 days before your initial performance evaluation of your continuous monitoring system:

(i) Installation of the continuous monitoring system sampling probe or other interface at a measurement location relative to each affected process unit such that the measurement is representative of control of the exhaust emissions (*e.g.,* on or downstream of the last control device);

(ii) Performance and equipment specifications for the sample interface, the pollutant concentration or parametric signal analyzer and the data collection and reduction systems.

(iii) Performance evaluation procedures and acceptance criteria (*e.g.,* calibrations);

(iv) Ongoing operation and maintenance procedures in accordance with the general requirements of § 60.11(d);

(v) Ongoing data quality assurance procedures in accordance with the general requirements of § 60.13; and

(vi) Ongoing recordkeeping and reporting procedures in accordance with the general requirements of § 60.7(b), (c) introductory text, (c)(1) and (4), and (d) through (g).

(2) You must conduct a performance evaluation of each continuous monitoring system in accordance with your site-specific monitoring plan.

(3) You must operate and maintain the continuous monitoring system in continuous operation according to the site-specific monitoring plan.

(m) If you have an operating limit that requires the use of a flow monitoring system, you must meet the requirements in paragraphs (l) and (m)(1) through (4) of this section:

(1) Install the flow sensor and other necessary equipment in a position that provides a representative flow;

(2) Use a flow sensor with a measurement sensitivity at full scale of no greater than 2 percent;

(3) Minimize the effects of swirling flow or abnormal velocity distributions due to upstream and downstream disturbances; and

(4) Conduct a flow monitoring system performance evaluation in accordance with your monitoring plan at the time of each performance test but no less frequently than annually.

(n) If you have an operating limit that requires the use of a pressure monitoring system, you must meet the requirements in paragraphs (l) and (n)(1) through (6) of this section:

(1) Install the pressure sensor(s) in a position that provides a representative measurement of the pressure (*e.g.,* PM scrubber pressure drop);

(2) Minimize or eliminate pulsating pressure, vibration, and internal and external corrosion;

(3) Use a pressure sensor with a minimum tolerance of 1.27 centimeters of water or a minimum tolerance of 1 percent of the pressure monitoring system operating range, whichever is less;

(4) Perform checks at the frequency outlined in your site-specific monitoring plan to ensure pressure measurements are not obstructed (*e.g.,* check for pressure tap plugging daily);

(5) Conduct a performance evaluation of the pressure monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than annually; and

(6) If at any time the measured pressure exceeds the manufacturer's specified maximum operating pressure range, conduct a performance evaluation of the pressure monitoring system in accordance with your monitoring plan and confirm that the pressure monitoring system continues to meet the performance requirements in your monitoring plan. Alternatively, install and verify the operation of a new pressure sensor.

(o) If you have an operating limit that requires a pH monitoring system, you must meet the requirements in paragraphs (l) and (o)(1) through (4) of this section:

(1) Install the pH sensor in a position that provides a representative measurement of scrubber effluent pH;

(2) Ensure the sample is properly mixed and representative of the fluid to be measured;

(3) Conduct a performance evaluation of the pH monitoring system in accordance with your monitoring plan at least once each process operating day; and

(4) Conduct a performance evaluation (including a two-point calibration with one of the two buffer solutions having a pH within 1 of the pH of the operating limit) of the pH monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than quarterly.

(p) If you have an operating limit that requires a secondary electric power monitoring system for an electrostatic

precipitator, you must meet the requirements in paragraphs (l) and (p)(1) and (2) of this section:

(1) Install sensors to measure (secondary) voltage and current to the precipitator collection plates; and

(2) Conduct a performance evaluation of the electric power monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than annually.

(q) If you have an operating limit that requires the use of a monitoring system to measure sorbent injection rate (*e.g.,* weigh belt, weigh hopper, or hopper flow measurement device), you must meet the requirements in paragraphs (l) and (q)(1) and (2) of this section:

(1) Install the system in a position(s) that provides a representative measurement of the total sorbent injection rate; and

(2) Conduct a performance evaluation of the sorbent injection rate monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than annually.

(r) If you elect to use a fabric filter bag leak detection system to comply with the requirements of this subpart, you must install, calibrate, maintain, and continuously operate a bag leak detection system as specified in paragraphs (l) and (r)(1) through (5) of this section:

(1) Install a bag leak detection sensor(s) in a position(s) that will be representative of the relative or absolute particulate matter loadings for each exhaust stack, roof vent, or compartment (*e.g.,* for a positive pressure fabric filter) of the fabric filter;

(2) Use a bag leak detection system certified by the manufacturer to be capable of detecting particulate matter emissions at concentrations of 10 milligrams per actual cubic meter or less;

(3) Conduct a performance evaluation of the bag leak detection system in accordance with your monitoring plan and consistent with the guidance provided in EPA–454/R–98–015 (incorporated by reference, *see* § 60.17);

(4) Use a bag leak detection system equipped with a device to continuously record the output signal from the sensor; and

(5) Use a bag leak detection system equipped with a system that will sound an alarm when an increase in relative particulate matter emissions over a preset level is detected. The alarm must be located where it is observed readily by plant operating personnel.

(s) For facilities using a CEMS to demonstrate initial and continuous compliance with the sulfur dioxide emission limit, compliance with the sulfur dioxide emission limit may be demonstrated by using the CEMS specified in § 60.2165(l) to measure sulfur dioxide. The sulfur dioxide CEMS must follow the procedures and methods specified in paragraph (s) of this section. For sources that have actual inlet emissions less than 100 parts per million dry volume, the relative accuracy criterion for inlet sulfur dioxide CEMS should be no greater than 20 percent of the mean value of the reference method test data in terms of the units of the emission standard, or 5 parts per million dry volume absolute value of the mean difference between the reference method and the CEMS, whichever is greater:

(1) During each relative accuracy test run of the CEMS required by performance specification 2 in appendix B of this part, collect sulfur dioxide and oxygen (or carbon dioxide) data concurrently (or within a 30- to 60-minute period) with both the CEMS and the test methods specified in paragraphs (s)(1)(i) and (ii) of this section:

(i) For sulfur dioxide, EPA Reference Method 6 or 6C, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, *see* § 60.17) must be used; and

(ii) For oxygen (or carbon dioxide), EPA Reference Method 3A or 3B, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, *see* § 60.17), must be used.

(2) The span value of the CEMS at the inlet to the sulfur dioxide control device must be 125 percent of the maximum estimated hourly potential sulfur dioxide emissions of the unit subject to this subpart. The span value of the CEMS at the outlet of the sulfur dioxide control device must be 50 percent of the maximum estimated hourly potential sulfur dioxide emissions of the unit subject to this subpart.

(3) Conduct accuracy determinations quarterly and calibration drift tests daily in accordance with procedure 1 in appendix F of this part.

(t) For facilities using a CEMS to demonstrate initial and continuous compliance with the nitrogen oxides emission limit, compliance with the nitrogen oxides emission limit may be demonstrated by using the CEMS specified in § 60.2165 to measure nitrogen oxides. The nitrogen oxides CEMS must follow the procedures and methods specified in paragraphs (t)(1) through (4) of this section:

(1) During each relative accuracy test run of the CEMS required by performance specification 2 of appendix B of this part, collect nitrogen oxides and oxygen (or carbon dioxide) data concurrently (or within a 30- to 60-minute period) with both the CEMS and the test methods specified in paragraphs (t)(1)(i) and (ii) of this section:

(i) For nitrogen oxides, EPA Reference Method 7 or 7E at 40 CFR part 60, appendix A–4 must be used; and

(ii) For oxygen (or carbon dioxide), EPA Reference Method 3A or 3B at 40 CFR part 60, appendix A–3, or as an alternative ANSI/ASME PTC 19–10.1981 (incorporated by reference, *see* § 60.17), as applicable, must be used.

(2) The span value of the continuous emission monitoring system must be 125 percent of the maximum estimated hourly potential nitrogen oxide emissions of the unit.

(3) Conduct accuracy determinations quarterly and calibration drift tests daily in accordance with procedure 1 in appendix F of this part.

(4) The owner or operator of an affected facility may request that compliance with the nitrogen oxides emission limit be determined using carbon dioxide measurements corrected to an equivalent of 7 percent oxygen. If carbon dioxide is selected for use in diluent corrections, the relationship between oxygen and carbon dioxide levels must be established during the initial performance test according to the procedures and methods specified in paragraphs (t)(4)(i) through (iv) of this section. This relationship may be re-established during performance compliance tests:

(i) The fuel factor equation in Method 3B must be used to determine the relationship between oxygen and carbon dioxide at a sampling location. Method 3A or 3B, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, *see* § 60.17), as applicable, must be used to determine the oxygen concentration at the same location as the carbon dioxide monitor;

(ii) Samples must be taken for at least 30 minutes in each hour;

(iii) Each sample must represent a 1-hour average; and

(iv) A minimum of three runs must be performed.

(u) For facilities using a CEMS or an integrated sorbent trap monitoring system for mercury to demonstrate initial and continuouscompliance with any of the emission limits of this subpart, you must complete the following:

(1) Demonstrate compliance with the appropriate emission limit(s) using a 30-day rolling average of 1-hour arithmetic average emission concentrations, including CEMS or integrated sorbent trap monitoring systems data during startup and shutdown as defined in this

subpart, calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at appendix A–7 of this part. The 1-hour arithmetic averages for CEMS must be calculated using the data points required under § 60.13(e)(2). Except for CEMS or integrated sorbent trap monitoring systems data during startup and shutdown, the 1-hour arithmetic averages used to calculate the 30-day rolling average emission concentrations must be corrected to 7 percent oxygen (dry basis). Integrated sorbent trap monitoring systems or CEMS data during startup and shutdown, as defined in the subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content; and

(2) Operate all CEMS and integrated sorbent trap monitoring systems in accordance with the applicable procedures under appendices B and F of this part.

(v) Use of the bypass stack at any time is an emissions standards deviation for PM, HCl, lead, cadmium, mercury, nitrogen oxides, sulfur dioxide, and dioxin/furans.

(w) For energy recovery units with a design heat input capacity of 100 MMBtu/hr or greater that do not use a carbon monoxide CEMS, you must install, operate, and maintain a oxygen analyzer system as defined in § 60.2265 according to the procedures in paragraphs (w)(1) through (4) of this section:

(1) The oxygen analyzer system must be installed by the initial performance test date specified in § 60.2140;

(2) You must operate the oxygen trim system within compliance with paragraph (w)(3) of this section at all times;

(3) You must maintain the oxygen level such that the 30-day rolling average that is established as the operating limit for oxygen is not below the lowest hourly average oxygen concentration measured during the most recent CO performance test; and

(4) You must calculate and record a 30-day rolling average oxygen concentration using equation 19–19 in section 12.4.1 of EPA Reference Method 19 of Appendix A–7 of this part.

(x) For energy recovery units with annual average heat input rates greater than or equal to 250 MMBtu/hr and waste-burning kilns, you must install, calibrate, maintain, and operate a PM CPMS and record the output of the system as specified in paragraphs (x)(1) through (8) of this section. For other energy recovery units, you may elect to use PM CPMS operated in accordance with this section. PM CPMS are suitable in lieu of using other CMS for monitoring PM compliance (*e.g.,* bag leak detectors, ESP secondary power, PM scrubber pressure):

(1) Install, calibrate, operate, and maintain your PM CPMS according to the procedures in your approved site-specific monitoring plan developed in accordance with paragraphs (l) and (x)(1)(i) through (iii) of this section:

(i) The operating principle of the PM CPMS must be based on in-stack or extractive light scatter, light scintillation, beta attenuation, or mass accumulation detection of the exhaust gas or representative sample. The reportable measurement output from the PM CPMS must be expressed as milliamps or the digital signal equivalent;

(ii) The PM CPMS must have a cycle time (*i.e.,* period required to complete sampling, measurement, and reporting for each measurement) no longer than 60 minutes; and

(iii) The PM CPMS must be capable of detecting and responding to particulate matter concentrations increments no greater than 0.5 mg/actual cubic meter.

(2) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, you must adjust the site-specific operating limit in accordance with the results of the performance test according to the procedures specified in § 60.2110.

(3) Collect PM CPMS hourly average output data for all energy recovery unit or waste-burning kiln operating hours. Express the PM CPMS output as milliamps.

(4) Calculate the arithmetic 30-day rolling average of all of the hourly average PM CPMS output collected during all energy recovery unit or waste-burning kiln operating hours data (milliamps or their digital equivalent).

(5) You must collect data using the PM CPMS at all times the energy recovery unit or waste-burning kiln is operating and at the intervals specified in paragraph (x)(1)(ii) of this section, except for periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments), and any scheduled maintenance as defined in your site-specific monitoring plan.

(6) You must use all the data collected during all energy recovery unit or waste-burning kiln operating hours in assessing the compliance with your operating limit except:

(i) Any data collected during monitoring system malfunctions, repairs associated with monitoring system malfunctions, or required monitoring system quality assurance or quality control activities conducted during monitoring system malfunctions are not used in calculations (report any such periods in your annual deviation report);

(ii) Any data collected during periods when the monitoring system is out of control as specified in your site-specific monitoring plan, repairs associated with periods when the monitoring system is out of control, or required monitoring system quality assurance or quality control activities conducted during out-of-control periods are not used in calculations (report emissions or operating levels and report any such periods in your annual deviation report);

(iii) Any PM CPMS data recorded during periods of CEMS data during startup and shutdown, as defined in this subpart.

(7) You must record and make available upon request results of PM CPMS system performance audits, as well as the dates and duration of periods from when the PM CPMS is out of control until completion of the corrective actions necessary to return the PM CPMS to operation consistent with your site-specific monitoring plan.

(8) For any deviation of the 30-day rolling average PM CPMS average value from the established operating parameter limit, you must:

(i) Within 48 hours of the deviation, visually inspect the air pollution control device;

(ii) If inspection of the air pollution control device identifies the cause of the deviation, take corrective action as soon as possible and return the PM CPMS measurement to within the established value;

(iii) Within 30 days of the deviation or at the time of the annual compliance test, whichever comes first, conduct a PM emissions compliance test to determine compliance with the PM emissions limit. Within 45 days of the deviation, you must re-establish the CPMS operating limit. You are not required to conduct additional testing for any deviations that occur between the time of the original deviation and the PM emissions compliance test required under paragraph (x) of this section; and

(iv) PM CPMS deviations leading to more than four required performance tests in a 12-month process operating period (rolling monthly) constitute a violation of this subpart.

(y) When there is an alkali bypass and/or an in-line coal mill that exhaust emissions through a separate stack(s),

the combined emissions are subject to the emission limits applicable to waste-burning kilns. To determine the kiln-specific emission limit for demonstrating compliance, you must:

(1) Calculate a kiln-specific emission limit using equation 7:

$$C_{ks} = ((\text{Emission limit} \times (Q_{ab}+Q_{cm}+Q_{ks})) - (Q_{ab} \times C_{ab}) - (Q_{cm} \times C_{cm}))/Q_{ks} \quad \text{(Eq. 7)}$$

Where:

C_{ks} = Kiln stack concentration (ppmvd, mg/dscm, ng/dscm, depending on pollutant. Each corrected to 7% O_2.)
Q_{ab} = Alkali bypass flow rate (volume/hr)
C_{ab} = Alkali bypass concentration (ppmvd, mg/dscm, ng/dscm, depending on pollutant. Each corrected to 7% O_2.)
Q_{cm} = In-line coal mill flow rate (volume/hr)
C_{cm} = In-line coal mill concentration (ppmvd, mg/dscm, ng/dscm, depending on pollutant. Each corrected to 7% O_2.)
Q_{ks} = Kiln stack flow rate (volume/hr)

(2) Particulate matter concentration must be measured downstream of the in-line coal mill. All other pollutant concentrations must be measured either upstream or downstream of the in-line coal mill; and

(3) For purposes of determining the combined emissions from kilns equipped with an alkali bypass or that exhaust kiln gases to a coal mill that exhausts through a separate stack, instead of installing a CEMS or PM CPMS on the alkali bypass stack or in-line coal mill stack, the results of the initial and subsequent performance test can be used to demonstrate compliance with the relevant emissions limit. A performance test must be conducted on an annual basis (between 11 and 13 calendar months following the previous performance test).

§ 60.2150 By what date must I conduct the annual performance test?

You must conduct annual performance tests between 11 and 13 months of the previous performance test.

§ 60.2151 By what date must I conduct the annual air pollution control device inspection?

On an annual basis (no more than 12 months following the previous annual air pollution control device inspection), you must complete the air pollution control device inspection as described in § 60.2141.

§ 60.2155 May I conduct performance testing less often?

(a) You must conduct annual performance tests according to the schedule specified in § 60.2150, with the following exceptions:

(1) You may conduct a repeat performance test at any time to establish new values for the operating limits, as specified in § 60.2160. New operating limits become effective on the date that the performance test report is submitted to the EPA's Central Data Exchange or postmarked, per the requirements of § 60.2235(b). The Administrator may request a repeat performance test at any time;

(2) You must repeat the performance test within 60 days of a process change, as defined in § 60.2265;

(3) You can conduct performance tests less often if you meet the following conditions: your performance tests for the pollutant for at least 2 consecutive performance tests demonstrates that the emission level for the pollutant is no greater than the emission level specified in paragraph (a)(3)(i) or (ii) of this section, as applicable; there are no changes in the operation of the affected source or air pollution control equipment that could increase emissions; and you are not required to conduct a performance test for the pollutant in response to a request by the Administrator in paragraph (a)(1) of this section or a process change in paragraph (a)(2) of this section. In this case, you do not have to conduct a performance test for that pollutant for the next 2 years. You must conduct a performance test for the pollutant no more than 37 months following the previous performance test for the pollutant. If the emission level for your CISWI continues to meet the emission level specified in paragraph (a)(3)(i) or (ii) of this section, as applicable, you may choose to conduct performance tests for the pollutant every third year, as long as there are no changes in the operation of the affected source or air pollution control equipment that could increase emissions. Each such performance test must be conducted no more than 37 months after the previous performance test.

(i) For particulate matter, hydrogen chloride, mercury, nitrogen oxides, sulfur dioxide, cadmium, lead and dioxins/furans, the emission level equal to 75 percent of the applicable emission limit in table 1 or tables 5 through 8 of this subpart, as applicable; and

(ii) For fugitive emissions, visible emissions (of combustion ash from the ash conveying system) for 2 percent of the time during each of the three 1-hour observations periods.

(4) If you are conducting less frequent testing for a pollutant as provided in paragraph (a)(3) of this section and a subsequent performance test for the pollutant indicates that your CISWI does not meet the emission level specified in paragraph (a)(3)(i) or (ii) of this section, as applicable, you must conduct annual performance tests for the pollutant according to the schedule specified in paragraph (a) of this section until you qualify for less frequent testing for the pollutant as specified in paragraph (a)(3) of this section.

(b) [Reserved]

§ 60.2160 May I conduct a repeat performance test to establish new operating limits?

(a) Yes. You may conduct a repeat performance test at any time to establish new values for the operating limits. The Administrator may request a repeat performance test at any time.

(b) You must repeat the performance test if your feed stream is different than the feed streams used during any performance test used to demonstrate compliance.

Monitoring

§ 60.2165 What monitoring equipment must I install and what parameters must I monitor?

(a) If you are using a wet scrubber to comply with the emission limitation under § 60.2105, you must install, calibrate (to manufacturers' specifications), maintain, and operate devices (or establish methods) for monitoring the value of the operating parameters used to determine compliance with the operating limits listed in table 2 of this subpart. These devices (or methods) must measure and record the values for these operating parameters at the frequencies indicated in table 2 of this subpart at all times except as specified in § 60.2170(a).

(b) If you use a fabric filter to comply with the requirements of this subpart and you do not use a PM CPMS or PM CEMS for monitoring PM compliance, you must install, calibrate, maintain, and continuously operate a bag leak detection system as specified in paragraphs (b)(1) through (8) of this section:

(1) You must install and operate a bag leak detection system for each exhaust stack of the fabric filter;

(2) Each bag leak detection system must be installed, operated, calibrated, and maintained in a manner consistent with the manufacturer's written specifications and recommendations;

(3) The bag leak detection system must be certified by the manufacturer to be capable of detecting particulate matter emissions at concentrations of 10 milligrams per actual cubic meter or less;

(4) The bag leak detection system sensor must provide output of relative or absolute particulate matter loadings;

(5) The bag leak detection system must be equipped with a device to continuously record the output signal from the sensor;

(6) The bag leak detection system must be equipped with an alarm system that will alert automatically an operator when an increase in relative particulate matter emissions over a preset level is detected. The alarm must be located where it is observed easily by plant operating personnel;

(7) For positive pressure fabric filter systems, a bag leak detection system must be installed in each baghouse compartment or cell. For negative pressure or induced air fabric filters, the bag leak detector must be installed downstream of the fabric filter; and

(8) Where multiple detectors are required, the system's instrumentation and alarm may be shared among detectors.

(c) If you are using something other than a wet scrubber, activated carbon, selective non-catalytic reduction, an electrostatic precipitator, or a dry scrubber to comply with the emission limitations under § 60.2105, you must install, calibrate (to the manufacturers' specifications), maintain, and operate the equipment necessary to monitor compliance with the site-specific operating limits established using the procedures in § 60.2115.

(d) If you use activated carbon injection to comply with the emission limitations in this subpart, you must measure the minimum mercury sorbent flow rate once per hour.

(e) If you use selective noncatalytic reduction to comply with the emission limitations, you must complete the following:

(1) Following the date on which the initial performance test is completed or is required to be completed under § 60.2125, whichever date comes first, ensure that the affected facility does not operate above the maximum charge rate, or below the minimum secondary chamber temperature (if applicable to your CISWI) or the minimum reagent flow rate measured as 3-hour block averages at all times; and

(2) Operation of the affected facility above the maximum charge rate, below the minimum secondary chamber temperature and below the minimum reagent flow rate simultaneously constitute a violation of the nitrogen oxides emissions limit.

(f) If you use an electrostatic precipitator to comply with the emission limits of this subpart and you do not use a PM CPMS for monitoring PM compliance, you must monitor the secondary power to the electrostatic precipitator collection plates and maintain the 3-hour block averages at or above the operating limits established during the mercury or particulate matter performance test.

(g) For waste-burning kilns not equipped with a wet scrubber or dry scrubber, you must install, calibrate, maintain, and operate a CEMS for monitoring hydrogen chloride emissions discharged to the atmosphere, as specified in § 60.2145(j), and record the output of the system. You may substitute use of a HCl CEMS for conducting the HCl initial and annual testing with EPA Method 321 at 40 CFR part 63, appendix A. For units other than waste-burning kilns not equipped with a wet scrubber or dry scrubber, a facility may substitute use of a hydrogen chloride CEMS for conducting the hydrogen chloride initial and annual performance test. For units equipped with a hydrogen chloride CEMS, you are not required to monitor the minimum hydrogen chloride sorbent flow rate, the minimum scrubber liquor pH, or the monitoring minimum injection rate.

(h) To demonstrate compliance with the particulate matter emissions limit, a facility may substitute use of a particulate matter CEMS for conducting the PM initial and annual performance test. For units equipped with a particulate matter CEMS, you are not required to use other CMS for monitoring PM compliance (*e.g.,* bag leak detectors, ESP secondary power, PM scrubber pressure).

(i) To demonstrate initial and continuous compliance with the dioxin/furan emissions limit, a facility may substitute use of a continuous automated sampling system for the dioxin/furan initial and annual performance tests. You must record the output of the system and analyze the sample according to EPA Method 23 at 40 CFR part 60, Appendix A–7 of this part. This option to use a continuous automated sampling system takes effect on the date a final performance specification applicable to dioxin/furan from continuous monitors is published in the **Federal Register**. The owner or operator who elects to continuously sample dioxin/furan emissions instead of sampling and testing using EPA Method 23 at 40 CFR part 60, appendix A–7 must install, calibrate, maintain, and operate a continuous automated sampling system and must comply with the requirements specified in § 60.58b(p) and (q). A facility may substitute continuous dioxin/furan monitoring for the minimum sorbent flow rate, if activated carbon sorbent injection is used solely for compliance with the dioxin/furan emission limit.

(j) To demonstrate initial and continuous compliance with the mercury emissions limit, a facility may substitute use of a mercury CEMS or an integrated sorbent trap monitoring system for the mercury initial and annual performance test. The owner or operator who elects to continuously measure mercury emissions instead of sampling and testing using EPA Reference Method 29 or 30B at 40 CFR part 60, appendix A–8, ASTM D6784–02 (Reapproved 2008) (incorporated by reference, see § 60.17), or an approved alternative method for measuring mercury emissions, must install, calibrate, maintain, and operate the mercury CEMS or integrated sorbent trap monitoring system and must comply with performance specification 12A or performance specification 12B, respectively, and quality assurance procedure 5. For the purposes of emissions calculations when using an integrated sorbent trap monitoring system, the mercury concentration determined for each sampling period must be assigned to each hour during the sampling period. Waste-burning kilns must install, calibrate, maintain, and operate a mercury CEMS or an integrated sorbent trap monitoring system as specified in § 60.2145(j). For units equipped with a mercury CEMS or an integrated sorbent trap monitoring system, you are not required to monitor the minimum sorbent flow rate, if activated carbon sorbent injection is used solely for compliance with the mercury emission limit.

(k) To demonstrate initial and continuous compliance with the nitrogen oxides emissions limit, a facility may substitute use of a CEMS for the nitrogen oxides initial and annual performance test to demonstrate compliance with the nitrogen oxides emissions limits. For units equipped with a nitrogen oxides CEMS, you are not required to monitor the charge rate, secondary chamber temperature, and reagent flow for selective noncatalytic reduction, if applicable:

(1) Install, calibrate, maintain, and operate a CEMS for measuring nitrogen oxides emissions discharged to the atmosphere and record the output of the system. The requirements under performance specification 2 of appendix B of this part, the quality assurance procedure 1 of appendix F of this part and the procedures under § 60.13 must be followed for installation, evaluation, and operation of the CEMS; and

(2) Compliance with the emission limit for nitrogen oxides must be determined based on the 30-day rolling average of the hourly emission concentrations using CEMS outlet data, as outlined in § 60.2145(u).

(l) To demonstrate initial and continuous compliance with the sulfur dioxide emissions limit, a facility may substitute use of a CEMS for the sulfur dioxide initial and annual performance test to demonstrate compliance with the sulfur dioxide emissions limits:

(1) Install, calibrate, maintain, and operate a CEMS for measuring sulfur dioxide emissions discharged to the atmosphere and record the output of the system. The requirements under performance specification 2 of appendix B of this part, the quality assurance requirements of procedure one of appendix F of this part and procedures under § 60.13 must be followed for installation, evaluation, and operation of the CEMS; and

(2) Compliance with the sulfur dioxide emission limit shall be determined based on the 30-day rolling average of the hourly arithmetic average emission concentrations using CEMS outlet data, as outlined in § 60.2145(u).

(m) For energy recovery units over 10 MMBtu/hr but less than 250 MMBtu/hr annual average heat input rates that do not use a wet scrubber, fabric filter with bag leak detection system, an electrostatic precipitator, particulate matter CEMS, or particulate matter CPMS you must install, operate, certify, and maintain a continuous opacity monitoring system according to the procedures in paragraphs (m)(1) through (5) of this section by the compliance date specified in § 60.2105. Energy recovery units that use a CEMS to demonstrate initial and continuing compliance according to the procedures in § 60.2165(n) are not required to install a continuous opacity monitoring system and must perform the annual performance tests for the opacity consistent with § 60.2145(f):

(1) Install, operate, and maintain each continuous opacity monitoring system according to performance specification 1 of 40 CFR part 60, appendix B;

(2) Conduct a performance evaluation of each continuous opacity monitoring system according to the requirements in § 60.13 and according to PS–1 of 40 CFR part 60, appendix B;

(3) As specified in § 60.13(e)(1), each continuous opacity monitoring system must complete a minimum of one cycle of sampling and analyzing for each successive 10-second period and one cycle of data recording for each successive 6-minute period;

(4) Reduce the continuous opacity monitoring system data as specified in § 60.13(h)(1); and

(5) Determine and record all the 6-minute averages (and 1-hour block averages as applicable) collected.

(n) For coal and liquid/gas energy recovery units, incinerators, and small remote incinerators, an owner or operator may elect to install, calibrate, maintain, and operate a CEMS for monitoring particulate matter emissions discharged to the atmosphere and record the output of the system. The owner or operator of an affected facility who continuously monitors particulate matter emissions instead of conducting performance testing using EPA Method 5 at 40 CFR part 60, appendix A–3 or monitoring with a particulate matter CPMS according to paragraph (r) of this section, must install, calibrate, maintain, and operate a PM CEMS and must comply with the requirements specified in paragraphs (n)(1) through (10) of this section:

(1) The PM CEMS must be installed, evaluated, and operated in accordance with the requirements of performance specification 11 of appendix B of this part and quality assurance requirements of procedure 2 of appendix F of this part and § 60.13. Use Method 5 or Method 5I of appendix A of this part for the PM CEMS correlation testing;

(2) The initial performance evaluation must be completed no later than 180 days after the date of initial startup of the affected facility, as specified under § 60.2125 or within 180 days of notification to the Administrator of use of the continuous monitoring system if the owner or operator was previously determining compliance by Method 5 performance tests, whichever is later;

(3) The owner or operator of an affected facility may request that compliance with the particulate matter emission limit be determined using carbon dioxide measurements corrected to an equivalent of 7 percent oxygen. The relationship between oxygen and carbon dioxide levels for the affected facility must be established according to the procedures and methods specified in § 60.2145(t)(4)(i) through (iv);

(4) The owner or operator of an affected facility must conduct an initial performance test for particulate matter emissions. If PM CEMS are elected for demonstrating compliance, and the initial performance test has not yet been conducted, then initial compliance must be determined by using the CEMS specified in paragraph (n) of this section to measure particulate matter. You must calculate a 30-day rolling average of 1-hour arithmetic average emission concentrations, including CEMS data during startup and shutdown, as defined in this subpart, using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7;

(5) Continuous compliance with the particulate matter emission limit must be determined based on the 30-day rolling average calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7 from the 1-hour arithmetic average CEMS outlet data;

(6) At a minimum, valid continuous monitoring system hourly averages must be obtained as specified in § 60.2170(e);

(7) The 1-hour arithmetic averages required under paragraph (n)(5) of this section must be expressed in milligrams per dry standard cubic meter corrected to 7 percent oxygen (dry basis) and must be used to calculate the 30-day rolling average emission concentrations. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. The 1-hour arithmetic averages must be calculated using the data points required under § 60.13(e)(2);

(8) All valid CEMS data must be used in calculating average emission concentrations even if the minimum CEMS data requirements of paragraph (n)(6) of this section are not met.

(9) The CEMS must be operated according to performance specification 11 in appendix B of this part; and,

(10) Quarterly and yearly accuracy audits and daily drift, system optics, and sample volume checks must be performed in accordance with procedure 2 in appendix F of this part.

(o) To demonstrate initial and continuous compliance with the carbon monoxide emissions limit, you may substitute use of a CEMS for the carbon monoxide initial and annual performance test:

(1) Install, calibrate, maintain, and operate a CEMS for measuring carbon monoxide emissions discharged to the atmosphere and record the output of the system. The requirements under performance specification 4A or 4B of appendix B of this part, the quality assurance procedure 1 of appendix F of this part and the procedures under § 60.13 must be followed for

installation, evaluation, and operation of the CEMS; and

(2) Compliance with the carbon monoxide emission limit shall be determined based on the 30-day rolling average of the hourly arithmetic average emission concentrations, including CEMS data during startup and shutdown as defined in this subpart, using CEMS outlet data, as outlined in § 60.2145(u).

(p) The owner/operator of an affected source with a bypass stack shall install, calibrate (to manufacturers' specifications), maintain, and operate a device or method for measuring the use of the bypass stack including date, time and duration.

(q) For energy recovery units with a design heat input capacity of 100 MMBtu/hr or greater that do not use a carbon monoxide CEMS, you must install, operate, and maintain a oxygen analyzer system as defined in § 60.2265 according to the procedures in paragraphs (q)(1) through (4) of this section:

(1) The oxygen analyzer system must be installed by the initial performance test date specified in § 60.2140;

(2) You must operate the oxygen trim system within compliance with paragraph (q)(3) of this section at all times;

(3) You must maintain the oxygen level such that the 30-day rolling average that is established as the operating limit for oxygen according to paragraph (q)(4) of this section is not below the lowest hourly average oxygen concentration measured during the most recent CO performance test; and

(4) You must calculate and record a 30-day rolling average oxygen concentration using equation 19–19 in section 12.4.1 of EPA Reference Method 19 of Appendix A–7 of this part.

(r) For energy recovery units with annual average heat input rates greater than or equal to 250 MMBtu/hr and waste-burning kilns, you must install, calibrate, maintain, and operate a PM CPMS and record the output of the system as specified in paragraphs (r)(1) through (8) of this section. If you elect to use a particulate matter CEMS as specified in paragraph (n) of this section, you are not required to use a PM CPMS to monitor particulate matter emissions. For other energy recovery units, you may elect to use PM CPMS operated in accordance with this section. PM CPMS are suitable in lieu of using other CMS for monitoring PM compliance (*e.g.,* bag leak detectors, ESP secondary power, PM scrubber pressure):

(1) Install, calibrate, operate, and maintain your PM CPMS according to the procedures in your approved site-specific monitoring plan developed in accordance with § 60.2145(l) and paragraphs (r)(1)(i) through (iii) of this section:

(i) The operating principle of the PM CPMS must be based on in-stack or extractive light scatter, light scintillation, beta attenuation, or mass accumulation detection of PM in the exhaust gas or representative sample. The reportable measurement output from the PM CPMS must be expressed as milliamps or a digital signal equivalent;

(ii) The PM CPMS must have a cycle time (*i.e.,* period required to complete sampling, measurement, and reporting for each measurement) no longer than 60 minutes; and

(iii) The PM CPMS must be capable of detecting and responding to particulate matter concentration increments no greater than 0.5 mg/actual cubic meter.

(2) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, you must adjust the site-specific operating limit in accordance with the results of the performance test according to the procedures specified in § 60.2110.

(3) Collect PM CPMS hourly average output data for all energy recovery unit or waste-burning kiln operating hours. Express the PM CPMS output as milliamps or the digital signal equivalent.

(4) Calculate the arithmetic 30-day rolling average of all of the hourly average PM CPMS output collected during all energy recovery unit or waste-burning kiln operating hours data (milliamps or digital bits).

(5) You must collect data using the PM CPMS at all times the energy recovery unit or waste-burning kiln is operating and at the intervals specified in paragraph (r)(1)(ii) of this section, except for periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments), and any scheduled maintenance as defined in your site-specific monitoring plan.

(6) You must use all the data collected during all energy recovery unit or waste-burning kiln operating hours in assessing the compliance with your operating limit except:

(i) Any data collected during monitoring system malfunctions, repairs associated with monitoring system malfunctions, or required monitoring system quality assurance or quality control activities conducted during monitoring system malfunctions are not used in calculations (report any such periods in your annual deviation report);

(ii) Any data collected during periods when the monitoring system is out of control as specified in your site-specific monitoring plan, repairs associated with periods when the monitoring system is out of control, or required monitoring system quality assurance or quality control activities conducted during out-of-control periods are not used in calculations (report emissions or operating levels and report any such periods in your annual deviation report); and

(iii) Any PM CPMS data recorded during periods of CEMS data during startup and shutdown, as defined in this subpart.

(7) You must record and make available upon request results of PM CPMS system performance audits, as well as the dates and duration of periods from when the PM CPMS is out of control until completion of the corrective actions necessary to return the PM CPMS to operation consistent with your site-specific monitoring plan.

(8) For any deviation of the 30-day rolling average PM CPMS average value from the established operating parameter limit, you must:

(i) Within 48 hours of the deviation, visually inspect the air pollution control device;

(ii) If inspection of the air pollution control device identifies the cause of the deviation, take corrective action as soon as possible and return the PM CPMS measurement to within the established value;

(iii) Within 30 days of the deviation or at the time of the annual compliance test, whichever comes first, conduct a PM emissions compliance test to determine compliance with the PM emissions limit and to verify the operation of the emissions control device(s). Within 45 days of the deviation, you must re-establish the CPMS operating limit. You are not required to conduct additional testing for any deviations that occur between the time of the original deviation and the PM emissions compliance test required under this paragraph; and

(iv) PM CPMS deviations leading to more than four required performance tests in a 12-month process operating period (rolling monthly) constitute a violation of this subpart.

(s) If you use a dry scrubber to comply with the emission limits of this subpart, you must monitor the injection rate of each sorbent and maintain the 3-hour block averages at or above the operating

limits established during the hydrogen chloride performance test.

(t) If you are required to monitor clinker production because you comply with the production-rate based mercury limit for your waste-burning kiln, you must:

(1) Determine hourly clinker production by one of two methods:

(i) Install, calibrate, maintain, and operate a permanent weigh scale system to measure and record weight rates in tons-mass per hour of the amount of clinker produced. The system of measuring hourly clinker production must be maintained within ±5 percent accuracy, or

(ii) Install, calibrate, maintain, and operate a permanent weigh scale system to measure and record weight rates in tons-mass per hour of the amount of feed to the kiln. The system of measuring feed must be maintained within ±5 percent accuracy. Calculate your hourly clinker production rate using a kiln-specific feed to clinker ratio based on reconciled clinker production determined for accounting purposes and recorded feed rates. Update this ratio monthly. Note that if this ratio changes at clinker reconciliation, you must use the new ratio going forward, but you do not have to retroactively change clinker production rates previously estimated.

(2) Determine the accuracy of the system of measuring hourly clinker production (or feed mass flow if applicable) before the effective date and during each quarter of source operation.

(3) Conduct accuracy checks in accordance with the procedures outlined in your site-specific monitoring plan under § 60.2145(l).

§ 60.2170 Is there a minimum amount of monitoring data I must obtain?

For each continuous monitoring system required or optionally allowed under § 60.2165, you must collect data according to this section:

(a) You must operate the monitoring system and collect data at all required intervals at all times compliance is required except for periods of monitoring system malfunctions or out-of-control periods, repairs associated with monitoring system malfunctions or out-of-control periods (as specified in 60.2210(o)), and required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments). A monitoring system malfunction is any sudden, infrequent, not reasonably preventable failure of the monitoring system to provide valid data. Monitoring system failures that are caused in part by poor maintenance or careless operation are not malfunctions. You are required to effect monitoring system repairs in response to monitoring system malfunctions or out-of-control periods and to return the monitoring system to operation as expeditiously as practicable;

(b) You may not use data recorded during monitoring system malfunctions or out-of-control periods, repairs associated with monitoring system malfunctions or out-of-control periods, or required monitoring system quality assurance or control activities in calculations used to report emissions or operating levels. You must use all the data collected during all other periods, including data normalized for above scale readings, in assessing the operation of the control device and associated control system; and

(c) Except for periods of monitoring system malfunctions or out-of-control periods, repairs associated with monitoring system malfunctions or out-of-control periods, and required monitoring system quality assurance or quality control activities including, as applicable, calibration checks and required zero and span adjustments, failure to collect required data is a deviation of the monitoring requirements.

Recordkeeping and Reporting

§ 60.2175 What records must I keep?

You must maintain the items (as applicable) as specified in paragraphs (a), (b), and (e) through (x) of this section for a period of at least 5 years:

(a) Calendar date of each record; and

(b) Records of the data described in paragraphs (b)(1) through (7) of this section:

(1) The CISWI charge dates, times, weights, and hourly charge rates;

(2) Liquor flow rate to the wet scrubber inlet every 15 minutes of operation, as applicable;

(3) Pressure drop across the wet scrubber system every 15 minutes of operation or amperage to the wet scrubber every 15 minutes of operation, as applicable;

(4) Liquor pH as introduced to the wet scrubber every 15 minutes of operation, as applicable;

(5) For affected CISWIs that establish operating limits for controls other than wet scrubbers under § 60.2110(d) through (g) or § 60.2115, you must maintain data collected for all operating parameters used to determine compliance with the operating limits. For energy recovery units using activated carbon injection or a dry scrubber, you must also maintain records of the load fraction and corresponding sorbent injection rate records;

(6) If a fabric filter is used to comply with the emission limitations, you must record the date, time, and duration of each alarm and the time corrective action was initiated and completed, and a brief description of the cause of the alarm and the corrective action taken. You must also record the percent of operating time during each 6-month period that the alarm sounds, calculated as specified in § 60.2110(c);

(7) If you monitor clinker production in accordance with § 60.2165(t):

(i) Hourly clinker rate produced if clinker production is measured directly;

(ii) Hourly measured kiln feed rates and calculated clinker production rates if clinker production is not measured directly;

(iii) 30-day rolling averages for mercury in pounds per million tons of clinker produced;

(iv) The initial and quarterly accuracy of the system of measruing hourly clinker production (or feed mass flow).

(c)–(d) [Reserved]

(e) Identification of calendar dates and times for which data show a deviation from the operating limits in table 2 of this subpart or a deviation from other operating limits established under § 60.2110(d) through (g) or § 60.2115 with a description of the deviations, reasons for such deviations, and a description of corrective actions taken;

(f) The results of the initial, annual, and any subsequent performance tests conducted to determine compliance with the emission limits and/or to establish operating limits, as applicable. Retain a copy of the complete test report including calculations;

(g) All documentation produced as a result of the siting requirements of §§ 60.2045 and 60.2050;

(h) Records showing the names of CISWI operators who have completed review of the information in § 60.2095(a) as required by § 60.2095(b), including the date of the initial review and all subsequent annual reviews;

(i) Records showing the names of the CISWI operators who have completed the operator training requirements under § 60.2070, met the criteria for qualification under § 60.2080, and maintained or renewed their qualification under § 60.2085 or § 60.2090. Records must include documentation of training, the dates of the initial and refresher training, and the dates of their qualification and all subsequent renewals of such qualifications;

(j) For each qualified operator, the phone and/or pager number at which

they can be reached during operating hours;

(k) Records of calibration of any monitoring devices as required under § 60.2165;

(l) Equipment vendor specifications and related operation and maintenance requirements for the incinerator, emission controls, and monitoring equipment;

(m) The information listed in § 60.2095(a);

(n) On a daily basis, keep a log of the quantity of waste burned and the types of waste burned (always required);

(o) Maintain records of the annual air pollution control device inspections that are required for each CISWI subject to the emissions limits in table 1 of this subpart or tables 5 through 8 of this subpart, any required maintenance, and any repairs not completed within 10 days of an inspection or the timeframe established by the state regulatory agency;

(p) For continuously monitored pollutants or parameters, you must document and keep a record of the following parameters measured using continuous monitoring systems. If you monitor emissions with a CEMS, you must indicate which data are CEMS data during startup and shutdown:

(1) All 6-minute average levels of opacity;

(2) All 1-hour average concentrations of sulfur dioxide emissions;

(3) All 1-hour average concentrations of nitrogen oxides emissions;

(4) All 1-hour average concentrations of carbon monoxide emissions;

(5) All 1-hour average concentrations of particulate matter emissions;

(6) All 1-hour average concentrations of mercury emissions;

(7) All 1-hour average concentrations of HCl CEMS outputs;

(8) All 1-hour average percent oxygen concentrations; and

(9) All 1-hour average PM CPMS readings or particulate matter CEMS outputs;

(q) Records indicating use of the bypass stack, including dates, times, and durations.

(r) If you choose to stack test less frequently than annually, consistent with § 60.2155(a) through (c), you must keep annual records that document that your emissions in the previous stack test(s) were less than 75 percent of the applicable emission limit and document that there was no change in source operations including fuel composition and operation of air pollution control equipment that would cause emissions of the relevant pollutant to increase within the past year.

(s) Records of the occurrence and duration of each malfunction of operation (*i.e.,* process equipment) or the air pollution control and monitoring equipment.

(t) Records of all required maintenance performed on the air pollution control and monitoring equipment.

(u) Records of actions taken during periods of malfunction to minimize emissions in accordance with § 60.11(d), including corrective actions to restore malfunctioning process and air pollution control and monitoring equipment to its normal or usual manner of operation.

(v) For operating units that combust non-hazardous secondary materials that have been determined not to be solid waste pursuant to § 241.3(b)(1) of this chapter, you must keep a record which documents how the secondary material meets each of the legitimacy criteria under § 241.3(d)(1). If you combust a fuel that has been processed from a discarded non-hazardous secondary material pursuant to § 241.3(b)(4) of this chapter, you must keep records as to how the operations that produced the fuel satisfies the definition of processing in § 241.2 and each of the legitimacy criteria of § 241.3(d)(1) of this chapter. If the fuel received a non-waste determination pursuant to the petition process submitted under § 241.3(c) of this chapter, you must keep a record that documents how the fuel satisfies the requirements of the petition process. For operating units that combust non-hazardous secondary materials as fuel per § 241.4, you must keep records documenting that the material is a listed non-waste under § 241.4(a).

(w) Records of the criteria used to establish that the unit qualifies as a small power production facility under section 3(17)(C) of the Federal Power Act (16 U.S.C. 796(17)(C)) and that the waste material the unit is proposed to burn is homogeneous.

(x) Records of the criteria used to establish that the unit qualifies as a cogeneration facility under section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B)) and that the waste material the unit is proposed to burn is homogeneous.

§ 60.2180 Where and in what format must I keep my records?

All records must be available onsite in either paper copy or computer-readable format that can be printed upon request, unless an alternative format is approved by the Administrator.

§ 60.2185 What reports must I submit?

See table 4 of this subpart for a summary of the reporting requirements.

§ 60.2190 What must I submit prior to commencing construction?

You must submit a notification prior to commencing construction that includes the five items listed in paragraphs (a) through (e) of this section:

(a) A statement of intent to construct;

(b) The anticipated date of commencement of construction;

(c) All documentation produced as a result of the siting requirements of § 60.2050;

(d) The waste management plan as specified in §§ 60.2055 through 60.2065; and

(e) Anticipated date of initial startup.

§ 60.2195 What information must I submit prior to initial startup?

You must submit the information specified in paragraphs (a) through (e) of this section prior to initial startup:

(a) The type(s) of waste to be burned;

(b) The maximum design waste burning capacity;

(c) The anticipated maximum charge rate;

(d) If applicable, the petition for site-specific operating limits under § 60.2115; and

(e) The anticipated date of initial startup.

§ 60.2200 What information must I submit following my initial performance test?

You must submit the information specified in paragraphs (a) through (c) of this section no later than 60 days following the initial performance test. All reports must be signed by the facilities manager:

(a) The complete test report for the initial performance test results obtained under § 60.2135, as applicable;

(b) The values for the site-specific operating limits established in § 60.2110 or § 60.2115; and

(c) If you are using a fabric filter to comply with the emission limitations, documentation that a bag leak detection system has been installed and is being operated, calibrated, and maintained as required by § 60.2165(b).

§ 60.2205 When must I submit my annual report?

You must submit an annual report no later than 12 months following the submission of the information in § 60.2200. You must submit subsequent reports no more than 12 months following the previous report. (If the unit is subject to permitting requirements under title V of the Clean Air Act, you may be required by the permit to submit these reports more frequently.)

§ 60.2210 What information must I include in my annual report?

The annual report required under § 60.2205 must include the items listed in paragraphs (a) through (o) of this section. If you have a deviation from the operating limits or the emission limitations, you must also submit deviation reports as specified in §§ 60.2215, 60.2220, and 60.2225:

(a) Company name and address;

(b) Statement by a responsible official, with that official's name, title, and signature, certifying the accuracy of the content of the report;

(c) Date of report and beginning and ending dates of the reporting period;

(d) The values for the operating limits established pursuant to § 60.2110 or § 60.2115;

(e) If no deviation from any emission limitation or operating limit that applies to you has been reported, a statement that there was no deviation from the emission limitations or operating limits during the reporting period;

(f) The highest recorded 3-hour average and the lowest recorded 3-hour average (30-day average for energy recovery units), as applicable, for each operating parameter recorded for the calendar year being reported;

(g) Information recorded under § 60.2175(b)(6) and (c) through (e) for the calendar year being reported;

(h) For each performance test conducted during the reporting period, if any performance test is conducted, the process unit(s) tested, the pollutant(s) tested and the date that such performance test was conducted. Submit, following the procedure specified in § 60.2235(b)(1), the performance test report no later than the date that you submit the annual report;

(i) If you met the requirements of § 60.2155(a) or (b), and did not conduct a performance test during the reporting period, you must state that you met the requirements of § 60.2155(a) or (b), and, therefore, you were not required to conduct a performance test during the reporting period;

(j) Documentation of periods when all qualified CISWI operators were unavailable for more than 8 hours, but less than 2 weeks;

(k) If you had a malfunction during the reporting period, the compliance report must include the number, duration, and a brief description for each type of malfunction that occurred during the reporting period and that caused or may have caused any applicable emission limitation to be exceeded. The report must also include a description of actions taken by an owner or operator during a malfunction of an affected source to minimize emissions in accordance with § 60.11(d), including actions taken to correct a malfunction;

(l) For each deviation from an emission or operating limitation that occurs for a CISWI for which you are not using a continuous monitoring system to comply with the emission or operating limitations in this subpart, the annual report must contain the following information:

(1) The total operating time of the CISWI at which the deviation occurred during the reporting period; and

(2) Information on the number, duration, and cause of deviations (including unknown cause, if applicable), as applicable, and the corrective action taken.

(m) If there were periods during which the continuous monitoring system, including the CEMS, was out of control as specified in paragraph (o) of this section, the annual report must contain the following information for each deviation from an emission or operating limitation occurring for a CISWI for which you are using a continuous monitoring system to comply with the emission and operating limitations in this subpart:

(1) The date and time that each malfunction started and stopped;

(2) The date, time, and duration that each CMS was inoperative, except for zero (low-level) and high-level checks;

(3) The date, time, and duration that each continuous monitoring system was out-of-control, including start and end dates and hours and descriptions of corrective actions taken;

(4) The date and time that each deviation started and stopped, and whether each deviation occurred during a period of malfunction or during another period;

(5) A summary of the total duration of the deviation during the reporting period, and the total duration as a percent of the total source operating time during that reporting period;

(6) A breakdown of the total duration of the deviations during the reporting period into those that are due to control equipment problems, process problems, other known causes, and other unknown causes;

(7) A summary of the total duration of continuous monitoring system downtime during the reporting period, and the total duration of continuous monitoring system downtime as a percent of the total operating time of the CISWI at which the continuous monitoring system downtime occurred during that reporting period;

(8) An identification of each parameter and pollutant that was monitored at the CISWI;

(9) A brief description of the CISWI;

(10) A brief description of the continuous monitoring system;

(11) The date of the latest continuous monitoring system certification or audit; and

(12) A description of any changes in continuous monitoring system, processes, or controls since the last reporting period.

(n) If there were periods during which the continuous monitoring system, including the CEMS, was not out of control as specified in paragraph (o) of this section, a statement that there were not periods during which the continuous monitoring system was out of control during the reporting period.

(o) A continuous monitoring system is out of control in accordance with the procedure in 40 CFR part 60, appendix F of this part, as if any of the following occur:

(1) The zero (low-level), mid-level (if applicable), or high-level calibration drift exceeds two times the applicable calibration drift specification in the applicable performance specification or in the relevant standard;

(2) The continuous monitoring system fails a performance test audit (*e.g.,* cylinder gas audit), relative accuracy audit, relative accuracy test audit, or linearity test audit; and

(3) The continuous opacity monitoring system calibration drift exceeds two times the limit in the applicable performance specification in the relevant standard.

§ 60.2215 What else must I report if I have a deviation from the operating limits or the emission limitations?

(a) You must submit a deviation report if any recorded 3-hour average (30-day average for energy recovery units or for PM CPMS) parameter level is above the maximum operating limit or below the minimum operating limit established under this subpart, if the bag leak detection system alarm sounds for more than 5 percent of the operating time for the 6-month reporting period, if a performance test was conducted that deviated from any emission limitation, if a 30-day average measured using CEMS deviated from any emission limitation.

(b) The deviation report must be submitted by August 1 of that year for data collected during the first half of the calendar year (January 1 to June 30), and by February 1 of the following year for data you collected during the second half of the calendar year (July 1 to December 31).

§ 60.2220 What must I include in the deviation report?

In each report required under § 60.2215, for any pollutant or parameter that deviated from the emission limitations or operating limits specified in this subpart, include the six items described in paragraphs (a) through (d) of this section:

(a) The calendar dates and times your unit deviated from the emission limitations or operating limit requirements;

(b) The averaged and recorded data for those dates;

(c) Durations and causes of the following:

(1) Each deviation from emission limitations or operating limits and your corrective actions;

(2) Bypass events and your corrective actions; and

(d) A copy of the operating limit monitoring data during each deviation and for any test report that documents the emission levels the process unit(s) tested, the pollutant(s) tested and the date that the performance test was conducted. Submit, following the procedure specified in § 60.2235(b)(1), the performance test report no later than the date that you submit the deviation report.

§ 60.2225 What else must I report if I have a deviation from the requirement to have a qualified operator accessible?

(a) If all qualified operators are not accessible for 2 weeks or more, you must take the two actions in paragraphs (a)(1) and (2) of this section:

(1) Submit a notification of the deviation within 10 days that includes the three items in paragraphs (a)(1)(i) through (iii) of this section:

(i) A statement of what caused the deviation;

(ii) A description of what you are doing to ensure that a qualified operator is accessible; and

(iii) The date when you anticipate that a qualified operator will be available.

(2) Submit a status report to the Administrator every 4 weeks that includes the three items in paragraphs (a)(2)(i) through (iii) of this section:

(i) A description of what you are doing to ensure that a qualified operator is accessible;

(ii) The date when you anticipate that a qualified operator will be accessible; and

(iii) Request approval from the Administrator to continue operation of the CISWI.

(b) If your unit was shut down by the Administrator, under the provisions of § 60.2100(b)(2), due to a failure to provide an accessible qualified operator, you must notify the Administrator that you are resuming operation once a qualified operator is accessible.

§ 60.2230 Are there any other notifications or reports that I must submit?

(a) Yes. You must submit notifications as provided by § 60.7.

(b) If you cease combusting solid waste but continue to operate, you must provide 30 days prior notice of the effective date of the waste-to-fuel switch, consistent with 60.2145(a). The notification must identify:

(1) The name of the owner or operator of the CISWI, the location of the source, the emissions unit(s) that will cease burning solid waste, and the date of the notice;

(2) The currently applicable subcategory under this subpart, and any 40 CFR part 63 subpart and subcategory that will be applicable after you cease combusting solid waste;

(3) The fuel(s), non-waste material(s) and solid waste(s) the CISWI is currently combusting and has combusted over the past 6 months, and the fuel(s) or non-waste materials the unit will commence combusting;

(4) The date on which you became subject to the currently applicable emission limits; and

(5) The date upon which you will cease combusting solid waste, and the date (if different) that you intend for any new requirements to become applicable (*i.e.,* the effective date of the waste-to-fuel switch), consistent with paragraphs (b)(2) and (3) of this section.

§ 60.2235 In what form can I submit my reports?

(a) Submit initial, annual and deviation reports electronically or in paper format, postmarked on or before the submittal due dates. Beginning on April 16, 2021 or once the reporting form has been available in CEDRI for 1 year, whichever is later, you must submit subsequent reports on or before the submittal dates to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI),which can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*). Use the appropriate electronic report in CEDRI for this subpart or an alternate electronic file format consistent with the extensible markup language (XML) schema listed on the CEDRI website (*https://www3.epa.gov/ttn/chief/cedri/index.html*). The date forms become available in CEDRI will be listed on the CEDRI website. The reports must be submitted by the deadlines specified in this subpart, regardless of the method in which the report is submitted.

(b) Submit results of each performance test and CEMS performance evaluation required by this subpart as follows:

(1) Within 60 days after the date of completing each performance test (*see* § 60.8) required by this subpart, you must submit the results of the performance test following the procedure specified in either paragraph (b)(1)(i) or (b)(1)(ii) of this section:

(i) For data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (*https://www3.epa.gov/ttn/chief/ert/ert_info.html*) at the time of the test, you must submit the results of the performance test to the EPA via the CEDRI. (CEDRI can be accessed through the EPA's CDX (*https://cdx.epa.gov/*).) Performance test data must be submitted in a file format generated through the use of the EPA's ERT or an alternate electronic file format consistent with the XML schema listed on the EPA's ERT website. If you claim that some of the performance test information being submitted is confidential business information (CBI), you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage media to the EPA. The electronic media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph; and

(ii) For data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test, you must submit the results of the performance test to the Administrator at the appropriate address listed in § 60.4.

(2) Within 60 days after the date of completing each continuous emissions monitoring system performance evaluation you must submit the results of the performance evaluation following the procedure specified in either paragraph (b)(2)(i) or (b)(2)(ii) of this section:

(i) For performance evaluations of continuous monitoring systems measuring relative accuracy test audit (RATA) pollutants that are supported by the EPA's ERT as listed on the EPA's ERT website at the time of the

evaluation, you must submit the results of the performance evaluation to the EPA via the CEDRI. (CEDRI can be accessed through the EPA's CDX.) Performance evaluation data must be submitted in a file format generated through the use of the EPA's ERT or an alternate file format consistent with the XML schema listed on the EPA's ERT website. If you claim that some of the performance evaluation information being submitted is CBI, you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage media to the EPA. The electronic storage media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph; and

(ii) For any performance evaluations of continuous monitoring systems measuring RATA pollutants that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation, you must submit the results of the performance evaluation to the Administrator at the appropriate address listed in § 60.4.

(c) If you are required to electronically submit a report through the Compliance and Emissions Data Reporting Interface (CEDRI) in the EPA's Central Data Exchange (CDX), and due to a planned or actual outage of either the EPA's CEDRI or CDX systems within the period of time beginning 5 business days prior to the date that the submission is due, you will be or are precluded from accessing CEDRI or CDX and submitting a required report within the time prescribed, you may assert a claim of EPA system outage for failure to timely comply with the reporting requirement. You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or caused a delay in reporting. You must provide to the Administrator a written description identifying the date, time and length of the outage; a rationale for attributing the delay in reporting beyond the regulatory deadline to the EPA system outage; describe the measures taken or to be taken to minimize the delay in reporting; and identify a date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported. In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved. The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(d) If you are required to electronically submit a report through CEDRI in the EPA's CDX and a force majeure event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning 5 business days prior to the date the submission is due, the owner or operator may assert a claim of force majeure for failure to timely comply with the reporting requirement. For the purposes of this section, a force majeure event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (*e.g.,* hurricanes, earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (*e.g.,* large scale power outage). If you intend to assert a claim of force majeure, you must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or caused a delay in reporting. You must provide to the Administrator a written description of the force majeure event and a rationale for attributing the delay in reporting beyond the regulatory deadline to the force majeure event; describe the measures taken or to be taken to minimize the delay in reporting; and identify a date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported. In any circumstance, the reporting must occur as soon as possible after the force majeure event occurs. The decision to accept the claim of force majeure and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

§ 60.2240 Can reporting dates be changed?

If the Administrator agrees, you may change the semiannual or annual reporting dates. See § 60.19(c) for procedures to seek approval to change your reporting date.

Title V Operating Permits

§ 60.2242 Am I required to apply for and obtain a Title V operating permit for my unit?

Yes. Each CISWI and ACI subject to standards under this subpart must operate pursuant to a permit issued under Section 129(e) and Title V of the Clean Air Act.

Air Curtain Incinerators (ACIs)

§ 60.2245 What is an air curtain incinerator?

(a) An ACI operates by forcefully projecting a curtain of air across an open chamber or open pit in which combustion occurs. Incinerators of this type can be constructed above or below ground and with or without refractory walls and floor. Air curtain incinerators are not to be confused with conventional combustion devices with enclosed fireboxes and controlled air technology such as mass burn, modular, and fluidized bed combustors.

(b) Air curtain incinerators that burn only the materials listed in paragraphs (b)(1) through (3) of this section are only required to meet the requirements under § 60.2242 and under ''Air Curtain Incinerators'' (§§ 60.2245 through 60.2260):

(1) 100 percent wood waste;

(2) 100 percent clean lumber; and

(3) 100 percent mixture of only wood waste, clean lumber, and/or yard waste.

§ 60.2250 What are the emission limitations for air curtain incinerators?

Within 60 days after your ACI reaches the charge rate at which it will operate, but no later than 180 days after its initial startup, you must meet the two limitations specified in paragraphs (a) and (b) of this section:

(a) Maintain opacity to less than or equal to 10 percent opacity (as determined by the average of three 1-hour blocks consisting of ten 6-minute average opacity values), except as described in paragraph (b) of this section; and

(b) Maintain opacity to less than or equal to 35 percent opacity (as determined by the average of three 1-hour blocks consisting of ten 6-minute average opacity values) during the startup period that is within the first 30 minutes of operation.

§ 60.2255 How must I monitor opacity for air curtain incinerators?

(a) Use Method 9 of appendix A of this part to determine compliance with the opacity limitation.

(b) Conduct an initial test for opacity as specified in § 60.8.

(c) After the initial test for opacity, conduct annual tests no more than 12 calendar months following the date of your previous test.

§ 60.2260 What are the recordkeeping and reporting requirements for air curtain incinerators?

(a) Prior to commencing construction on your ACI, submit the three items described in paragraphs (a)(1) through (3) of this section:

(1) Notification of your intent to construct the ACI;

(2) Your planned initial startup date; and

(3) Types of materials you plan to burn in your ACI.

(b) Keep records of results of all initial and annual opacity tests onsite in either paper copy or electronic format, unless the Administrator approves another format, for at least 5 years.

(c) Make all records available for submittal to the Administrator or for an inspector's onsite review.

(d) You must submit the results (as determined by the average of three 1-hour blocks consisting of ten 6-minute average opacity values) of the initial opacity tests no later than 60 days following the initial test. Submit annual opacity test results within 12 months following the previous report.

(e) Submit initial and annual opacity test reports as electronic or paper copy on or before the applicable submittal date.

(f) Keep a copy of the initial and annual reports onsite for a period of 5 years.

Definitions

§ 60.2265 What definitions must I know?

Terms used but not defined in this subpart are defined in the Clean Air Act and subpart A (General Provisions) of this part.

30-day rolling average means the arithmetic mean of the previous 720 hours of valid operating data. Valid data excludes periods when this unit is not operating. The 720 hours should be consecutive, but not necessarily continuous if operations are intermittent.

Administrator means the Administrator of the U.S. Environmental Protection Agency or his/her authorized representative or Administrator of a State Air Pollution Control Agency.

Air curtain incinerator (ACI) means an incinerator that operates by forcefully projecting a curtain of air across an open chamber or pit in which combustion occurs. Incinerators of this type can be constructed above or below ground and with or without refractory walls and floor. Air curtain incinerators are not to be confused with conventional combustion devices with enclosed fireboxes and controlled air technology such as mass burn, modular, and fluidized bed combustors.

Annual heat input means the heat input for the 12 months preceding the compliance demonstration.

Auxiliary fuel means natural gas, liquified petroleum gas, fuel oil, or diesel fuel.

Average annual heat input rate means annual heat input divided by the hours of operation for the 12 months preceding the compliance demonstration.

Bag leak detection system means an instrument that is capable of monitoring particulate matter loadings in the exhaust of a fabric filter (*i.e.,* baghouse) in order to detect bag failures. A bag leak detection system includes, but is not limited to, an instrument that operates on triboelectric, light scattering, light transmittance, or other principle to monitor relative particulate matter loadings.

Burn-off oven means any rack reclamation unit, part reclamation unit, or drum reclamation unit. A burn-off oven is not an incinerator, waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Bypass stack means a device used for discharging combustion gases to avoid severe damage to the air pollution control device or other equipment.

Calendar quarter means three consecutive months (nonoverlapping) beginning on: January 1, April 1, July 1, or October 1.

Calendar year means 365 consecutive days starting on January 1 and ending on December 31.

CEMS data during startup and shutdown means the following:

(1) For incinerators and small remote incinerators: CEMS data collected during the first hours of a CISWI startup from a cold start until waste is fed to the unit and the hours of operation following the cessation of waste material being fed to the CISWI during a unit shutdown. For each startup event, the length of time that CEMS data may be claimed as being CEMS data during startup must be 48 operating hours or less. For each shutdown event, the length of time that CEMS data may be claimed as being CEMS data during shutdown must be 24 operating hours or less;

(2) For energy recovery units: CEMS data collected during the startup or shutdown periods of operation. Startup begins with either the first-ever firing of fuel in a boiler or process heater for the purpose of supplying useful thermal energy (such as steam or heat) for heating, cooling or process purposes, or producing electricity, or the firing of fuel in a boiler or process heater for any purpose after a shutdown event. Startup ends four hours after when the boiler or process heater makes useful thermal energy (such as heat or steam) for heating, cooling, or process purposes, or generates electricity, whichever is earlier. Shutdown begins when the boiler or process heater no longer makes useful thermal energy (such as heat or steam) for heating, cooling, or process purposes and/or generates electricity or when no fuel is being fed to the boiler or process heater, whichever is earlier. Shutdown ends when the boiler or process heater no longer makes useful thermal energy (such as steam or heat) for heating, cooling, or process purposes and/or generates electricity, and no fuel is being combusted in the boiler or process heater; and

(3) For waste-burning kilns: CEMS data collected during the periods of kiln operation that do not include normal operations. Startup means the time from when a shutdown kiln first begins firing fuel until it begins producing clinker. Startup begins when a shutdown kiln turns on the induced draft fan and begins firing fuel in the main burner. Startup ends when feed is being continuously introduced into the kiln for at least 120 minutes or when the feed rate exceeds 60 percent of the kiln design limitation rate, whichever occurs first. Shutdown means the cessation of kiln operation. Shutdown begins when feed to the kiln is halted and ends when continuous kiln rotation ceases.

Chemical recovery unit means combustion units burning materials to recover chemical constituents or to produce chemical compounds where there is an existing commercial market for such recovered chemical constituents or compounds. A chemical recovery unit is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart. The following seven types of units are considered chemical recovery units:

(1) Units burning only pulping liquors (*i.e.,* black liquor) that are reclaimed in a pulping liquor recovery process and reused in the pulping process;

(2) Units burning only spent sulfuric acid used to produce virgin sulfuric acid;

(3) Units burning only wood or coal feedstock for the production of charcoal;

(4) Units burning only manufacturing byproduct streams/residue containing

catalyst metals that are reclaimed and reused as catalysts or used to produce commercial grade catalysts;

(5) Units burning only coke to produce purified carbon monoxide that is used as an intermediate in the production of other chemical compounds;

(6) Units burning only hydrocarbon liquids or solids to produce hydrogen, carbon monoxide, synthesis gas, or other gases for use in other manufacturing processes; and

(7) Units burning only photographic film to recover silver.

Chemotherapeutic waste means waste material resulting from the production or use of antineoplastic agents used for the purpose of stopping or reversing the growth of malignant cells.

Clean lumber means wood or wood products that have been cut or shaped and include wet, air-dried, and kiln-dried wood products. Clean lumber does not include wood products that have been painted, pigment-stained, or pressure-treated by compounds such as chromate copper arsenate, pentachlorophenol, and creosote.

Commercial and industrial solid waste incineration unit (CISWI) means any distinct operating unit of any commercial or industrial facility that combusts, or has combusted in the preceding 6 months, any solid waste as that term is defined in 40 CFR part 241. If the operating unit burns materials other than traditional fuels as defined in § 241.2 that have been discarded, and you do not keep and produce records as required by § 60.2175(v), the operating unit is a CISWI. While not all CISWIs will include all of the following components, a CISWI includes, but is not limited to, the solid waste feed system, grate system, flue gas system, waste heat recovery equipment, if any, and bottom ash system. The CISWI does not include air pollution control equipment or the stack. The CISWI boundary starts at the solid waste hopper (if applicable) and extends through two areas: The combustion unit flue gas system, which ends immediately after the last combustion chamber or after the waste heat recovery equipment, if any; and the combustion unit bottom ash system, which ends at the truck loading station or similar equipment that transfers the ash to final disposal. The CISWI includes all ash handling systems connected to the bottom ash handling system.

Contained gaseous material means gases that are in a container when that container is combusted.

Continuous emission monitoring system (CEMS) means the total equipment that may be required to meet the data acquisition and availability requirements of this subpart, used to sample, condition (if applicable), analyze, and provide a record of emissions.

Continuous monitoring system (CMS) means the total equipment, required under the emission monitoring sections in applicable subparts, used to sample and condition (if applicable), to analyze, and to provide a permanent record of emissions or process parameters. A particulate matter continuous parameter monitoring system (PM CPMS) is a type of CMS.

Cyclonic burn barrel means a combustion device for waste materials that is attached to a 55 gallon, open-head drum. The device consists of a lid, which fits onto and encloses the drum, and a blower that forces combustion air into the drum in a cyclonic manner to enhance the mixing of waste material and air. A cyclonic burn barrel is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Deviation means any instance in which an affected source subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart, including but not limited to any emission limitation, operating limit, or operator qualification and accessibility requirements; and

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit.

Dioxins/furans means tetra- through octa-chlorinated dibenzo-p-dioxins and dibenzofurans.

Discard means, for purposes of this subpart and 40 CFR part 60, subpart DDDD, only, burned in an incineration unit without energy recovery.

Drum reclamation unit means a unit that burns residues out of drums (*e.g.,* 55 gallon drums) so that the drums can be reused.

Dry scrubber means an add-on air pollution control system that injects dry alkaline sorbent (dry injection) or sprays an alkaline sorbent (spray dryer) to react with and neutralize acid gas in the exhaust stream forming a dry powder material. Sorbent injection systems in fluidized bed boilers and process heaters are included in this definition. A dry scrubber is a dry control system.

Energy recovery means the process of recovering thermal energy from combustion for useful purposes such as steam generation or process heating.

Energy recovery unit means a combustion unit combusting solid waste (as that term is defined by the Administrator in 40 CFR part 241) for energy recovery. Energy recovery units include units that would be considered boilers and process heaters if they did not combust solid waste.

Energy recovery unit designed to burn biomass (Biomass) means an energy recovery unit that burns solid waste, biomass, and non-coal solid materials but less than 10 percent coal, on a heat input basis on an annual average, either alone or in combination with liquid waste, liquid fuel or gaseous fuels.

Energy recovery unit designed to burn coal (Coal) means an energy recovery unit that burns solid waste and at least 10 percent coal on a heat input basis on an annual average, either alone or in combination with liquid waste, liquid fuel or gaseous fuels.

Energy recovery unit designed to burn liquid waste materials and gas (Liquid/gas) means an energy recovery unit that burns a liquid waste with liquid or gaseous fuels not combined with any solid fuel or waste materials.

Energy recovery unit designed to burn solid materials (Solids) includes energy recovery units designed to burn coal and energy recovery units designed to burn biomass.

Fabric filter means an add-on air pollution control device used to capture particulate matter by filtering gas streams through filter media, also known as a baghouse.

Foundry sand thermal reclamation unit means a type of part reclamation unit that removes coatings that are on foundry sand. A foundry sand thermal reclamation unit is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Incinerator means any furnace used in the process of combusting solid waste (as that term is defined by the Administrator in 40 CFR part 241) for the purpose of reducing the volume of the waste by removing combustible matter. Incinerator designs include single chamber and two-chamber.

In-line coal mill means those coal mills using kiln exhaust gases in their process. Coal mills with a heat source other than the kiln or coal mills using exhaust gases from the clinker cooler alone are not an in-line coal mill.

In-line kiln/raw mill means a system in a Portland Cement production process where a dry kiln system is integrated with the raw mill so that all or a portion of the kiln exhaust gases are used to perform the drying operation of the raw mill, with no auxiliary heat source used. In this system the kiln is

capable of operating without the raw mill operating, but the raw mill cannot operate without the kiln gases, and consequently, the raw mill does not generate a separate exhaust gas stream.

Kiln means an oven or furnace, including any associated preheater or precalciner devices, in-line raw mills, in-line coal mills or alkali bypasses used for processing a substance by burning, firing or drying. Kilns include cement kilns that produce clinker by heating limestone and other materials for subsequent production of Portland Cement. Because the alkali bypass, in-line raw mill and in-line coal mill are considered an integral part of the kiln, the kiln emissions limits also apply to the exhaust of the alkali bypass, in-line raw mill and in-line coal mill.

Laboratory analysis unit means units that burn samples of materials for the purpose of chemical or physical analysis. A laboratory analysis unit is not an incinerator, waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Load fraction means the actual heat input of an energy recovery unit divided by heat input during the performance test that established the minimum sorbent injection rate or minimum activated carbon injection rate, expressed as a fraction (*e.g.,* for 50 percent load the load fraction is 0.5).

Low-level radioactive waste means waste material which contains radioactive nuclides emitting primarily beta or gamma radiation, or both, in concentrations or quantities that exceed applicable federal or state standards for unrestricted release. Low-level radioactive waste is not high-level radioactive waste, spent nuclear fuel, or byproduct material as defined by the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)(2)).

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, process equipment, or a process to operate in a normal or usual manner. Failures that are caused, in part, by poor maintenance or careless operation are not malfunctions.

Minimum voltage or amperage means 90 percent of the lowest test-run average voltage or amperage to the electrostatic precipitator measured during the most recent particulate matter or mercury performance test demonstrating compliance with the applicable emission limits.

Modification or *modified CISWI* means a CISWI that has been changed later than August 7, 2013 and that meets one of two criteria:

(1) The cumulative cost of the changes over the life of the unit exceeds 50 percent of the original cost of building and installing the CISWI (not including the cost of land) updated to current costs (current dollars). To determine what systems are within the boundary of the CISWI used to calculate these costs, see the definition of CISWI; and

(2) Any physical change in the CISWI or change in the method of operating it that increases the amount of any air pollutant emitted for which section 129 or section 111 of the Clean Air Act has established standards.

Municipal solid waste or municipal-type solid waste means household, commercial/retail, or institutional waste. Household waste includes material discarded by residential dwellings, hotels, motels, and other similar permanent or temporary housing. Commercial/retail waste includes material discarded by stores, offices, restaurants, warehouses, nonmanufacturing activities at industrial facilities, and other similar establishments or facilities. Institutional waste includes materials discarded by schools, by hospitals (nonmedical), by nonmanufacturing activities at prisons and government facilities, and other similar establishments or facilities. Household, commercial/retail, and institutional waste does include yard waste and refuse-derived fuel. Household, commercial/retail, and institutional waste does not include used oil; sewage sludge; wood pallets; construction, renovation, and demolition wastes (which include railroad ties and telephone poles); clean wood; industrial process or manufacturing wastes; medical waste; or motor vehicles (including motor vehicle parts or vehicle fluff).

Opacity means the degree to which emissions reduce the transmission of light and obscure the view of an object in the background.

Operating day means a 24-hour period between 12 midnight and the following midnight during which any amount of solid waste is combusted at any time in the CISWI.

Oxygen analyzer system means all equipment required to determine the oxygen content of a gas stream and used to monitor oxygen in the boiler or process heater flue gas, boiler or process heater, firebox, or other appropriate location. This definition includes oxygen trim systems and certified oxygen CEMS. The source owner or operator is responsible to install, calibrate, maintain, and operate the oxygen analyzer system in accordance with the manufacturer's recommendations.

Oxygen trim system means a system of monitors that is used to maintain excess air at the desired level in a combustion device over its operating range. A typical system consists of a flue gas oxygen and/or carbon monoxide monitor that automatically provides a feedback signal to the combustion air controller or draft controller.

Part reclamation unit means a unit that burns coatings off parts (*e.g.,* tools, equipment) so that the parts can be reconditioned and reused.

Particulate matter means total particulate matter emitted from CISWIs as measured by Method 5 or Method 29 of appendix A of this part.

Pathological waste means waste material consisting of only human or animal remains, anatomical parts, and/or tissue, the bags/containers used to collect and transport the waste material, and animal bedding (if applicable).

Performance evaluation means the conduct of relative accuracy testing, calibration error testing, and other measurements used in validating the continuous monitoring system data.

Performance test means the collection of data resulting from the execution of a test method (usually three emission test runs) used to demonstrate compliance with a relevant emission standard as specified in the performance test section of the relevant standard.

Process change means any of the following physical or operational changes:

(1) A physical change (maintenance activities excluded) to the CISWI which may increase the emission rate of any air pollutant to which a standard applies;

(2) An operational change to the CISWI where a new type of non-hazardous secondary material is being combusted;

(3) A physical change (maintenance activities excluded) to the air pollution control devices used to comply with the emission limits for the CISWI (*e.g.,* replacing an electrostatic precipitator with a fabric filter); and

(4) An operational change to the air pollution control devices used to comply with the emission limits for the affected CISWI (*e.g.,* change in the sorbent injection rate used for activated carbon injection).

Rack reclamation unit means a unit that burns the coatings off racks used to hold small items for application of a coating. The unit burns the coating overspray off the rack so the rack can be reused.

Raw mill means a ball or tube mill, vertical roller mill or other size reduction equipment, that is not part of an in-line kiln/raw mill, used to grind feed to the appropriate size. Moisture may be added or removed from the feed

during the grinding operation. If the raw mill is used to remove moisture from feed materials, it is also, by definition, a raw material dryer. The raw mill also includes the air separator associated with the raw mill.

Reconstruction means rebuilding a CISWI and meeting two criteria:

(1) The reconstruction begins on or after August 7, 2013; and

(2) The cumulative cost of the construction over the life of the incineration unit exceeds 50 percent of the original cost of building and installing the CISWI (not including land) updated to current costs (current dollars). To determine what systems are within the boundary of the CISWI used to calculate these costs, see the definition of CISWI.

Refuse-derived fuel means a type of municipal solid waste produced by processing municipal solid waste through shredding and size classification. This includes all classes of refuse-derived fuel including two fuels:

(1) Low-density fluff refuse-derived fuel through densified refuse-derived fuel; and

(2) Pelletized refuse-derived fuel.

Responsible official means one of the following:

(1) For a corporation: A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:

(i) The facilities employ more than 250 persons or have gross annual sales or expenditures exceeding $25 million (in second quarter 1980 dollars); or

(ii) The delegation of authority to such representatives is approved in advance by the permitting authority;

(2) For a partnership or sole proprietorship: A general partner or the proprietor, respectively;

(3) For a municipality, state, federal, or other public agency: Either a principal executive officer or ranking elected official. For the purposes of this part, a principal executive officer of a federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (*e.g.,* a Regional Administrator of EPA); or

(4) For affected facilities:

(i) The designated representative in so far as actions, standards, requirements, or prohibitions under Title IV of the Clean Air Act or the regulations promulgated thereunder are concerned; or

(ii) The designated representative for any other purposes under part 60.

Shutdown means, for incinerators and small, remote incinerators, the period of time after all waste has been combusted in the primary chamber.

Small, remote incinerator means an incinerator that combusts solid waste (as that term is defined by the Administrator in 40 CFR part 241) and combusts 3 tons per day or less solid waste and is more than 25 miles driving distance to the nearest municipal solid waste landfill.

Soil treatment unit means a unit that thermally treats petroleum-contaminated soils for the sole purpose of site remediation. A soil treatment unit may be direct-fired or indirect fired. A soil treatment unit is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Solid waste means the term solid waste as defined in 40 CFR 241.2.

Solid waste incineration unit means a distinct operating unit of any facility which combusts any solid waste (as that term is defined by the Administrator in 40 CFR part 241) material from commercial or industrial establishments or the general public (including single and multiple residences, hotels and motels). Such term does not include incinerators or other units required to have a permit under section 3005 of the Solid Waste Disposal Act. The term ''solid waste incineration unit'' does not include:

(1) Materials recovery facilities (including primary or secondary smelters) which combust waste for the primary purpose of recovering metals;

(2) Qualifying small power production facilities, as defined in section 3(17)(C) of the Federal Power Act (16 U.S.C. 769(17)(C)), or qualifying cogeneration facilities, as defined in section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B)), which burn homogeneous waste (such as units which burn tires or used oil, but not including refuse-derived fuel) for the production of electric energy or in the case of qualifying cogeneration facilities which burn homogeneous waste for the production of electric energy and steam or forms of useful energy (such as heat) which are used for industrial, commercial, heating or cooling purposes; or

(3) Air curtain incineratorsprovided that such incinerators only burn wood wastes, yard wastes, and clean lumber and that such ACIs comply with opacity limitations to be established by the Administrator by rule.

Space heater means a unit that meets the requirements of 40 CFR 279.23. A space heater is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Standard conditions, when referring to units of measure, means a temperature of 68 °F (20 °C) and a pressure of 1 atmosphere (101.3 kilopascals).

Startup period means, for incinerators and small, remote incinerators, the period of time between the activation of the system and the first charge to the unit.

Useful thermal energy means energy (*i.e.,* steam, hot water, or process heat) that meets the minimum operating temperature and/or pressure required by any energy use system that uses energy provided by the affected energy recovery unit.

Waste-burning kiln means a kiln that is heated, in whole or in part, by combusting solid waste (as that term is defined by the Administrator in 40 CFR part 241). Secondary materials used in Portland cement kilns shall not be deemed to be combusted unless they are introduced into the flame zone in the hot end of the kiln or mixed with the precalciner fuel.

Wet scrubber means an add-on air pollution control device that uses an aqueous or alkaline scrubbing liquor to collect particulate matter (including nonvaporous metals and condensed organics) and/or to absorb and neutralize acid gases.

Wood waste means untreated wood and untreated wood products, including tree stumps (whole or chipped), trees, tree limbs (whole or chipped), bark, sawdust, chips, scraps, slabs, millings, and shavings. Wood waste does not include:

(1) Grass, grass clippings, bushes, shrubs, and clippings from bushes and shrubs from residential, commercial/retail, institutional, or industrial sources as part of maintaining yards or other private or public lands;

(2) Construction, renovation, or demolition wastes; and

(3) Clean lumber.

TABLE 1 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR INCINERATORS FOR WHICH CONSTRUCTION IS COMMENCED AFTER NOVEMBER 30, 1999, BUT NO LATER THAN JUNE 4, 2010, OR FOR WHICH MODIFICATION OR RECONSTRUCTION IS COMMENCED ON OR AFTER JUNE 1, 2001, BUT NO LATER THAN AUGUST 7, 2013

For the air pollutant	You must meet this emission limitation [1]	Using this averaging time [2]	And determining compliance using this method [2]
Cadmium	0.004 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run)	Performance test (Method 29 of appendix A of this part).
Carbon monoxide	157 parts per million by dry volume.	3-run average (1 hour minimum sample time per run)	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxin/Furan (toxic equivalency basis).	0.41 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 23 of appendix A–7 of this part).
Hydrogen chloride	62 parts per million by dry volume.	3-run average (For Method 26, collect a minimum volume of 120 liters per run. For Method 26A, collect a minimum volume of 1 dry standard cubic meter per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	0.04 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run)	Performance test (Method 29 of appendix A of this part).
Mercury	0.47 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run)	Performance test (Method 29 of appendix A of this part).
Nitrogen oxides	388 parts per million by dry volume.	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Opacity	10 percent	6-minute averages	Performance test (Method 9 of appendix A of this part).
Particulate matter	70 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run)	Performance test (Method 5 or 29 of appendix A of this part).
Sulfur dioxide	20 parts per million by dry volume.	3-run average (For Method 6, collect a minimum volume of 20 liters per run. For Method 6C, collect sample for a minimum duration of 1 hour per run).	Performance test (Method 6 or 6C at 40 CFR part 60, appendix A–4).

[1] All emission limitations (except for opacity) are measured at 7 percent oxygen, dry basis at standard conditions.

[2] In lieu of performance testing, you may use a CEMS or, for mercury, an integrated sorbent trap monitoring system, to demonstrate initial and continuing compliance with an emissions limit, as long as you comply with the CEMS or integrated sorbent trap monitoring system requirements applicable to the specific pollutant in §§ 60.2145 and 60.2165. As prescribed in § 60.2145(u), if you use a CEMS or an integrated sorbent trap monitoring system to demonstrate compliance with an emissions limit, your averaging time is a 30-day rolling average of 1-hour arithmetic average emission concentrations.

TABLE 2 TO SUBPART CCCC OF PART 60—OPERATING LIMITS FOR WET SCRUBBERS

For these operating parameters	You must establish these operating limits	And monitoring using these minimum frequencies		
		Data measurement	Data recording	Averaging time
Charge rate	Maximum charge rate	Continuous	Every hour	Daily (batch units) 3-hour rolling (continuous and intermittent units).[1]
Pressure drop across the wet scrubber or amperage to wet scrubber.	Minimum pressure drop or amperage.	Continuous	Every 15 minutes	3-hour rolling.[1]
Scrubber liquor flow rate	Minimum flow rate	Continuous	Every 15 minutes	3-hour rolling.[1]
Scrubber liquor pH	Minimum pH	Continuous	Every 15 minutes	3-hour rolling.[1]

[1] Calculated each hour as the average of the previous 3 operating hours.

TABLE 3 TO SUBPART CCCC OF PART 60—TOXIC EQUIVALENCY FACTORS

Dioxin/furan congener	Toxic equivalency factor
2,3,7,8-tetrachlorinated dibenzo-p-dioxin	1
1,2,3,7,8-pentachlorinated dibenzo-p-dioxin	0.5
1,2,3,4,7,8-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,7,8,9-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,6,7,8-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,4,6,7,8-heptachlorinated dibenzo-p-dioxin	0.01
octachlorinated dibenzo-p-dioxin	0.001
2,3,7,8-tetrachlorinated dibenzofuran	0.1
2,3,4,7,8-pentachlorinated dibenzofuran	0.5
1,2,3,7,8-pentachlorinated dibenzofuran	0.05
1,2,3,4,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,6,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,7,8,9-hexachlorinated dibenzofuran	0.1
2,3,4,6,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,4,6,7,8-heptachlorinated dibenzofuran	0.01
1,2,3,4,7,8,9-heptachlorinated dibenzofuran	0.01
octachlorinated dibenzofuran	0.001

TABLE 4 TO SUBPART CCCC OF PART 60—SUMMARY OF REPORTING REQUIREMENTS [1]

Report	Due date	Contents	Reference
Preconstruction report	Prior to commencing construction	• Statement of intent to construct • Anticipated date of commencement of construction. • Documentation for siting requirements • Waste management plan • Anticipated date of initial startup.	§ 60.2190.
Startup notification	Prior to initial startup	• Type of waste to be burned • Maximum design waste burning capacity. • Anticipated maximum charge rate • If applicable, the petition for site-specific operating limits.	§ 60.2195.
Initial test report	No later than 60 days following the initial performance test.	• Complete test report for the initial performance test. • The values for the site-specific operating limits. • Installation of bag leak detection system for fabric filter.	§ 60.2200.
Annual report	No later than 12 months following the submission of the initial test report. Subsequent reports are to be submitted no more than 12 months following the previous report.	• Name and address • Statement and signature by responsible official. • Date of report • Values for the operating limits • Highest recorded 3-hour average and the lowest 3-hour average, as applicable, (or 30-day average, if applicable) for each operating parameter recorded for the calendar year being reported. • For each performance test conducted during the reporting period, if any performance test is conducted, the process unit(s) tested, the pollutant(s) tested, and the date that such performance test was conducted. • If a performance test was not conducted during the reporting period, a statement that the requirements of § 60.2155(a) were met. • Documentation of periods when all qualified CISWI operators were unavailable for more than 8 hours but less than 2 weeks. • If you are conducting performance tests once every 3 years consistent with § 60.2155(a), the date of the last 2 performance tests, a comparison of the emission level you achieved in the last 2 performance tests to the 75 percent emission limit threshold required in § 60.2155(a) and a statement as to whether there have been any operational changes since the last performance test that could increase emissions. • Any malfunction, deviation, or continuous monitoring system out of control periods information as specified in § 60.2210(k) through (o).	§§ 60.2205 and 60.2210.
Emission limitation or operating limit deviation report.	By August 1 of that year for data collected during the first half of the calendar year. By February 1 of the following year for data collected during the second half of the calendar year.	• Dates and times of deviation • Averaged and recorded data for those dates. • Duration and causes of each deviation and the corrective actions taken. • Copy of operating limit monitoring data and, if any performance test was conducted that documents emission levels, the process unit(s) tested, the pollutant(s) tested, and the date that such performance test was conducted. • Dates, times and causes for monitor downtime incidents.	§ 60.2215 and 60.2220.

TABLE 4 TO SUBPART CCCC OF PART 60—SUMMARY OF REPORTING REQUIREMENTS [1]—Continued

Report	Due date	Contents	Reference
Qualified operator deviation notification.	Within 10 days of deviation	• Statement of cause of deviation • Description of efforts to have an accessible qualified operator. • The date a qualified operator will be accessible.	§ 60.2225(a)(1).
Qualified operator deviation status report.	Every 4 weeks following deviation	• Description of efforts to have an accessible qualified operator. • The date a qualified operator will be accessible. • Request for approval to continue operation.	§ 60.2225(a)(2).
Qualified operator deviation notification of resumed operation.	Prior to resuming operation	• Notification that you are resuming operation.	§ 60.2225(b).

[1] This table is only a summary, see the referenced sections of the rule for the complete requirements.

TABLE 5 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR INCINERATORS THAT COMMENCED CONSTRUCTION AFTER JUNE 4, 2010, OR THAT COMMENCED RECONSTRUCTION OR MODIFICATION AFTER AUGUST 7, 2013

For the air pollutant	You must meet this emission limitation [1]	Using this averaging time [2]	And determining compliance using this method [2]
Cadmium	0.0023 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meter per run).	Performance test (Method 29 at 40 CFR part 60, appendix A–8 of this part). Use ICPMS for the analytical finish.
Carbon monoxide	17 parts per million by dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxin/furan (Total Mass Basis).	0.58 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxin/furan (toxic equivalency basis).	0.13 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meter per run).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Fugitive ash	Visible emissions for no more than 5 percent of the hourly observation period.	Three 1-hour observation periods	Visible emission test (Method 22 at 40 CFR part 60, appendix A–7).
Hydrogen chloride	0.091 parts per million by dry volume.	3-run average (For Method 26, collect a minimum volume of 360 liters per run. For Method 26A, collect a minimum volume of 3 dry standard cubic meters per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	0.015 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 29 of appendix A–8 at 40 CFR part 60). Use ICPMS for the analytical finish.
Mercury	0.00084 milligrams per dry standard cubic meter.	3-run average (collect enough volume to meet a detection limit data quality objective of 0.03 ug/dry standard cubic meter).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008).[3]
Nitrogen oxides	23 parts per million dry volume.	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter (filterable).	18 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters per run).	Performance test (Method 5 or 29 at 40 CFR part 60, appendix A–3 or appendix A–8 at 40 CFR part 60).
Sulfur dioxide	11 parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 6 or 6C at 40 CFR part 60, appendix A–4).

[1] All emission limitations are measured at 7 percent oxygen, dry basis at standard conditions. For dioxins/furans, you must meet either the Total Mass Limit or the toxic equivalency basis limit.

[2] In lieu of performance testing, you may use a CEMS or, for mercury, an integrated sorbent trap monitoring system to demonstrate initial and continuing compliance with an emissions limit, as long as you comply with the CEMS or integrated sorbent trap monitoring system requirements applicable to the specific pollutant in §§ 60.2145 and 60.2165. As prescribed in § 60.2145(u), if you use a CEMS or an integrated sorbent trap monitoring system to demonstrate compliance with an emissions limit, your averaging time is a 30-day rolling average of 1-hour arithmetic average emission concentrations.

[3] Incorporated by reference, *see* § 60.17.

TABLE 6 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR ENERGY RECOVERY UNITS THAT COMMENCED CONSTRUCTION AFTER JUNE 4, 2010, OR THAT COMMENCED RECONSTRUCTION OR MODIFICATION AFTER AUGUST 7, 2013

For the air pollutant	You must meet this emission limitation [1]		Using this averaging time [2]	And determining compliance using this method [2]
	Liquid/gas	Solids		
Cadmium	0.023 milligrams per dry standard cubic meter.	Biomass-0.0014 milligrams per dry standard cubic meter. Coal-0.0017 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Carbon monoxide	35 parts per million dry volume	Biomass-240 parts per million dry volume. Coal-95 parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxin/furans (Total Mass Basis).	No Total Mass Basis limit, must meet the toxic equivalency basis limit below.	Biomass-0.52 nanograms per dry standard cubic meter. Coal-5.1 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	0.093 nanograms per dry standard cubic meter.	Biomass-0.076 nanograms per dry standard cubic meter [3]. Coal-0.075 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 23 of appendix A–7 of this part).
Fugitive ash	Visible emissions for no more than 5 percent of the hourly observation period.	Three 1-hour observation periods.	Visible emission test (Method 22 at 40 CFR part 60, appendix A–7).	Fugitive ash.
Hydrogen chloride	14 parts per million dry volume	Biomass-0.20 parts per million dry volume. Coal-58 parts per million dry volume.	3-run average (For Method 26, collect a minimum volume of 360 liters per run. For Method 26A, collect a minimum volume of 3 dry standard cubic meters per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	0.096 milligrams per dry standard cubic meter.	Biomass-0.014 milligrams per dry standard cubic meter. Coal-0.057 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Mercury	0.00056 milligrams per dry standard cubic meter.	Biomass-0.0022 milligrams per dry standard cubic meter. Coal-0.013 milligrams per dry standard cubic meter.	3-run average (collect enough volume to meet an in-stack detection limit data quality objective of 0.03 ug/dscm).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008).[3]
Nitrogen oxides	76 parts per million dry volume	Biomass-290 parts per million dry volume. Coal-460 parts per million dry volume.	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter (filterable).	110 milligrams per dry standard cubic meter.	Biomass-5.1 milligrams per dry standard cubic meter. Coal-130 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meter per run).	Performance test (Method 5 or 29 at 40 CFR part 60, appendix A–3 or appendix A–8) if the unit has an annual average heat input rate less than 250 MMBtu/hr; or PM CPMS (as specified in §60.2145(x)) if the unit has an annual average heat input rate equal to or greater than 250 MMBtu/hr.
Sulfur dioxide	720 parts per million dry volume.	Biomass-7.3 parts per million dry volume. Coal-850 parts per million dry volume.	3-run average (for Method 6, collect a minimum of 60 liters, for Method 6C,1 hour minimum sample time per run).	Performance test (Method 6 or 6C at 40 CFR part 60, appendix A–4).

[1] All emission limitations are measured at 7 percent oxygen, dry basis at standard conditions. For dioxins/furans, you must meet either the Total Mass Basis limit or the toxic equivalency basis limit.

[2] In lieu of performance testing, you may use a CEMS or, for mercury, an integrated sorbent trap monitoring system to demonstrate initial and continuing compliance with an emissions limit, as long as you comply with the CEMS or integrated sorbent trap monitoring system requirements applicable to the specific pollutant in §§60.2145 and 60.2165. As prescribed in §60.2145(u), if you use a CEMS or an integrated sorbent trap monitoring system to demonstrate compliance with an emissions limit, your averaging time is a 30-day rolling average of 1-hour arithmetic average emission concentrations.

[3] Incorporated by reference, *see* §60.17.

TABLE 7 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR WASTE-BURNING KILNS THAT COMMENCED CONSTRUCTION AFTER JUNE 4, 2010, OR RECONSTRUCTION OR MODIFICATION AFTER AUGUST 7, 2013

For the air pollutant	You must meet this emission limitation [1]	Using this averaging time [2]	And determining compliance using this method [2 3]
Cadmium	0.0014 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Carbon monoxide	90 (long kilns)/190 (preheater/precalciner) parts per million dry volume.	3-run average (1 hour minimum sample time per run)	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxins/furans (total mass basis).	0.51 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters per run).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	0.075 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).

TABLE 7 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR WASTE-BURNING KILNS THAT COMMENCED CONSTRUCTION AFTER JUNE 4, 2010, OR RECONSTRUCTION OR MODIFICATION AFTER AUGUST 7, 2013—Continued

For the air pollutant	You must meet this emission limitation [1]	Using this averaging time [2]	And determining compliance using this method [2 3]
Hydrogen chloride	3.0 parts per million dry volume.	3-run average (1 hour minimum sample time per run) or 30-day rolling average if HCl CEMS is being used.	If a wet scrubber or dry scrubber is used, performance test (Method 321 at 40 CFR part 63, appendix A). If a wet scrubber or dry scrubber is not used, HCl CEMS as specified in § 60.2145(j).
Lead	0.014 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Mercury	0.0037 milligrams per dry standard cubic meter. Or 21 pounds/million tons of clinker [3].	30-day rolling average	Mercury CEMS or integrated sorbent trap monitoring system (performance specification 12A or 12B, respectively, of appendix B and procedure 5 of appendix F of this part), as specified in § 60.2145(j).
Nitrogen oxides	200 parts per million dry volume.	30-day rolling average	Nitrogen oxides CEMS (performance specification 2 of appendix B and procedure 1 of appendix F of this part).
Particulate matter (filterable)	4.9 milligrams per dry standard cubic meter.	30-day rolling average	PM CPMS (as specified in § 60.2145(x)).
Sulfur dioxide	28 parts per million dry volume.	30-day rolling average	Sulfur dioxide CEMS (performance specification 2 of appendix B and procedure 1 of appendix F of this part).

[1] All emission limitations are measured at 7 percent oxygen (except for CEMS and integrated sorbent trap monitoring system data during startup and shutdown), dry basis at standard conditions. For dioxins/furans, you must meet either the Total Mass Basis limit or the toxic equivalency basis limit.

[2] In lieu of performance testing, you may use a CEMS or, for mercury, an integrated sorbent trap monitoring system, to demonstrate initial and continuing compliance with an emissions limit, as long as you comply with the CEMS or integrated sorbent trap monitoring system requirements applicable to the specific pollutant in §§ 60.2145 and 60.2165. As prescribed in § 60.2145(u), if you use a CEMS or integrated sorbent trap monitoring system to demonstrate compliance with an emissions limit, your averaging time is a 30-day rolling average of 1-hour arithmetic average emission concentrations.

[3] Alkali bypass and in-line coal mill stacks are subject to performance testing only, as specified in § 60.2145(y)(3). They are not subject to the CEMS, integrated sorbent trap monitoring system, or CPMS requirements that otherwise may apply to the main kiln exhaust.

TABLE 8 TO SUBPART CCCC OF PART 60—EMISSION LIMITATIONS FOR SMALL, REMOTE INCINERATORS THAT COMMENCED CONSTRUCTION AFTER JUNE 4, 2010, OR THAT COMMENCED RECONSTRUCTION OR MODIFICATION AFTER AUGUST 7, 2013

For the air pollutant	You must meet this emission limitation [1]	Using this averaging time [2]	And determining compliance using this method [2]
Cadmium	0.67 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters per run).	Performance test (Method 29 at 40 CFR part 60, appendix A–8).
Carbon monoxide	13 parts per million dry volume.	3-run average (1 hour minimum sample time per run)	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxins/furans (total mass basis).	1,800 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters per run).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	31 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Fugitive ash	Visible emissions for no more than 5 percent of the hourly observation period.	Three 1-hour observation periods	Visible emissions test (Method 22 at 40 CFR part 60, appendix A–7).
Hydrogen chloride	200 parts per million by dry volume.	3-run average (For Method 26, collect a minimum volume of 60 liters per run. For Method 26A, collect a minimum volume of 1 dry standard cubic meter per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	2.0 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Mercury	0.0035 milligrams per dry standard cubic meter.	3-run average (For Method 29 and ASTM D6784–02 (Reapproved 2008) [2], collect a minimum volume of 2 dry standard cubic meters per run. For Method 30B, collect a minimum volume as specified in Method 30B at 40 CFR part 60, appendix A).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008).[3]
Nitrogen oxides	170 parts per million dry volume.	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter (filterable)	270 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters).	Performance test (Method 5 or 29 at 40 CFR part 60, appendix A–3 or appendix A–8).
Sulfur dioxide	1.2 parts per million dry volume.	3-run average (1 hour minimum sample time per run)	Performance test (Method 6 or 6c at 40 CFR part 60, appendix A–4).

[1] All emission limitations are measured at 7 percent oxygen, dry basis at standard conditions. For dioxins/furans, you must meet either the Total Mass Basis limit or the toxic equivalency basis limit.

[2] In lieu of performance testing, you may use a CEMS or, for mercury, an integrated sorbent trap monitoring system to demonstrate initial and continuing compliance with an emissions limit, as long as you comply with the CEMS or integrated sorbent trap monitoring system requirements applicable to the specific pollutant in §§ 60.2145 and 60.2165. As prescribed in § 60.2145(u), if you use a CEMS or an integrated sorbent trap monitoring system to demonstrate compliance with an emissions limit, your averaging time is a 30-day rolling average of 1-hour arithmetic average emission concentrations.

[3] Incorporated by reference, *see* § 60.17.

■ 3. Revise subpart DDDD to read as follows:

Sec.

Subpart DDDD—Emissions Guidelines and Compliance Times for Commercial and Industrial Solid Waste Incineration Units

Introduction

60.2500 What is the purpose of this subpart?
60.2505 Am I affected by this subpart?
60.2510 Is a state plan required for all states?
60.2515 What must I include in my state plan?
60.2520 Is there an approval process for my state plan?
60.2525 What if my state plan is not approvable?
60.2530 Is there an approval process for a negative declaration letter?
60.2535 What compliance schedule must I include in my state plan?
60.2540 Are there any state plan requirements for this subpart that apply instead of the requirements specified in subpart B?
60.2541 In lieu of a state plan submittal, are there other acceptable option(s) for a state to meet its Clean Air Act section 111(d)/129(b)(2) obligations?
60.2542 What authorities will not be delegated to state, local, or tribal agencies?
60.2545 Does this subpart directly affect CISWI owners and operators in my state?

Applicability of State Plans

60.2550 What CISWIs must I address in my state plan?
60.2555 What combustion units are exempt from my state plan?

Use of Model Rule

60.2560 What is the ''model rule'' in this subpart?
60.2565 How does the model rule relate to the required elements of my state plan?
60.2570 What are the principal components of the model rule?

Model Rule—Increments of Progress

60.2575 What are my requirements for meeting increments of progress and achieving final compliance?
60.2580 When must I complete each increment of progress?
60.2585 What must I include in the notifications of achievement of increments of progress?
60.2590 When must I submit the notifications of achievement of increments of progress?
60.2595 What if I do not meet an increment of progress?
60.2600 How do I comply with the increment of progress for submittal of a control plan?
60.2605 How do I comply with the increment of progress for achieving final compliance?
60.2610 What must I do if I close my CISWI and then restart it?
60.2615 What must I do if I plan to permanently close my CISWI and not restart it?

Model Rule—Waste Management Plan

60.2620 What is a waste management plan?
60.2625 When must I submit my waste management plan?
60.2630 What should I include in my waste management plan?

Model Rule—Operator Training and Qualification

60.2635 What are the operator training and qualification requirements?
60.2640 When must the operator training course be completed?
60.2645 How do I obtain my operator qualification?
60.2650 How do I maintain my operator qualification?
60.2655 How do I renew my lapsed operator qualification?
60.2660 What site-specific documentation is required?
60.2665 What if all the qualified operators are temporarily not accessible?

Model Rule—Emission Limitations and Operating Limits

60.2670 What emission limitations must I meet and by when?
60.2675 What operating limits must I meet and by when?
60.2680 What if I do not use a wet scrubber, fabric filter, activated carbon injection, selective noncatalytic reduction, an electrostatic precipitator, or a dry scrubber to comply with the emission limitations?

Model Rule—Performance Testing

60.2690 How do I conduct the initial and annual performance test?
60.2695 How are the performance test data used?

Model Rule—Initial Compliance Requirements

60.2700 How do I demonstrate initial compliance with the amended emission limitations and establish the operating limits?
60.2705 By what date must I conduct the initial performance test?
60.2706 By what date must I conduct the initial air pollution control device inspection?

Model Rule—Continuous Compliance Requirements

60.2710 How do I demonstrate continuous compliance with the amended emission limitations and the operating limits?
60.2715 By what date must I conduct the annual performance test?
60.2716 By what date must I conduct the annual air pollution control device inspection?
60.2720 May I conduct performance testing less often?
60.2725 May I conduct a repeat performance test to establish new operating limits?

Model Rule—Monitoring

60.2730 What monitoring equipment must I install and what parameters must I monitor?
60.2735 Is there a minimum amount of monitoring data I must obtain?

Model Rule—Recordkeeping and Reporting

60.2740 What records must I keep?
60.2745 Where and in what format must I keep my records?
60.2750 What reports must I submit?
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Subpart DDDD—Emissions Guidelines and Compliance Times for Commercial and Industrial Solid Waste Incineration Units

Introduction

§ 60.2500 What is the purpose of this subpart?

This subpart establishes emission guidelines and compliance schedules for the control of emissions from commercial and industrial solid waste incineration units (CISWIs) and air curtain incinerators (ACIs). The pollutants addressed by these emission guidelines are listed in table 2 of this subpart and tables 6 through 9 of this subpart. These emission guidelines are developed in accordance with sections 111(d) and 129 of the Clean Air Act and subpart B of this part.

§ 60.2505 Am I affected by this subpart?

(a) If you are the Administrator of an air quality program in a state or United States protectorate with one or more existing CISWIs that meet the criteria in paragraphs (b) through (d) of this section, you must submit a state plan to U.S. Environmental Protection Agency (EPA) that implements the emission guidelines contained in this subpart.

(b) You must submit a state plan to EPA by December 3, 2001 for incinerator units that commenced construction on or before November 30, 1999 and that were not modified or reconstructed after June 1, 2001.

(c) You must submit a state plan that meets the requirements of this subpart and contains the more stringent emission limit for the respective pollutant in table 6 of this subpart or table 1 of subpart CCCC of this part to EPA by February 7, 2014 for incinerators that commenced construction after November 30, 1999, but no later than June 4, 2010, or commenced modification or reconstruction after June 1, 2001 but no later than August 7, 2013.

(d) You must submit a state plan to EPA that meets the requirements of this subpart and contains the emission limits in tables 7 through 9 of this subpart by February 7, 2014, for CISWIs other than incinerator units that commenced construction on or before June 4, 2010, or commenced modification or reconstruction after June 4, 2010 but no later than August 7, 2013.

§ 60.2510 Is a state plan required for all states?

No. You are not required to submit a state plan if there are no existing CISWIs in your state, and you submit a negative declaration letter in place of the state plan.

§ 60.2515 What must I include in my state plan?

(a) You must include the nine items described in paragraphs (a)(1) through (9) of this section in your state plan:

(1) Inventory of affected CISWIs, including those that have ceased operation but have not been dismantled;

(2) Inventory of emissions from affected CISWIs in your state;

(3) Compliance schedules for each affected CISWI;

(4) Emission limitations, operator training and qualification requirements, a waste management plan, and operating limits for affected CISWIs that are at least as protective as the emission guidelines contained in this subpart;

(5) Performance testing, recordkeeping, and reporting requirements;

(6) Certification that the hearing on the state plan was held, a list of witnesses and their organizational affiliations, if any, appearing at the hearing, and a brief written summary of each presentation or written submission;

(7) Provision for state progress reports to EPA;

(8) Identification of enforceable state mechanisms that you selected for implementing the emission guidelines of this subpart; and

(9) Demonstration of your state's legal authority to carry out the sections 111(d) and 129 state plan.

(b) Your state plan may deviate from the format and content of the emission guidelines contained in this subpart. However, if your state plan does deviate in content, you must demonstrate that your state plan is at least as protective as the emission guidelines contained in this subpart. Your state plan must address regulatory applicability, increments of progress for retrofit, operator training and qualification, a waste management plan, emission limitations, performance testing, operating limits, monitoring, recordkeeping and reporting, and ACI requirements.

(c) You must follow the requirements of subpart B of this part (Adoption and Submittal of State Plans for Designated Facilities) in your state plan.

§ 60.2520 Is there an approval process for my state plan?

Yes. The EPA will review your state plan according to § 60.27.

§ 60.2525 What if my state plan is not approvable?

(a) If you do not submit an approvable state plan (or a negative declaration letter) by December 2, 2002, EPA will develop a federal plan according to § 60.27 to implement the emission guidelines contained in this subpart. Owners and operators of CISWIs not covered by an approved state plan must comply with the federal plan. The federal plan is an interim action and will be automatically withdrawn when your state plan is approved.

(b) If you do not submit an approvable state plan (or a negative declaration letter) to EPA that meets the requirements of this subpart and contains the emission limits in tables 6 through 9 of this subpart for CISWIs that commenced construction on or before June 4, 2010 and incinerator or ACIs that commenced reconstruction or modification on or after June 1, 2001 but no later than August 7, 2013, then EPA will develop a federal plan according to § 60.27 to implement the emission guidelines contained in this subpart. Owners and operators of CISWIs not covered by an approved state plan must comply with the federal plan. The federal plan is an interim action and will be automatically withdrawn when your state plan is approved.

§ 60.2530 Is there an approval process for a negative declaration letter?

No. The EPA has no formal review process for negative declaration letters. Once your negative declaration letter has been received, EPA will place a copy in the public docket and publish a document in the **Federal Register**. If, at a later date, an existing CISWI is found in your state, the federal plan implementing the emission guidelines contained in this subpart would automatically apply to that CISWI until your state plan is approved.

§ 60.2535 What compliance schedule must I include in my state plan?

(a) For CISWIs in the incinerator subcategory and ACIs that commenced construction on or before November 30, 1999, your state plan must include compliance schedules that require CISWIs in the incinerator subcategory and ACIs to achieve final compliance as expeditiously as practicable after approval of the state plan but not later than the earlier of the two dates specified in paragraphs (a)(1) and (2) of this section:

(1) December 1, 2005; and

(2) Three years after the effective date of state plan approval.

(b) For CISWIs in the incinerator subcategory and ACIs that commenced construction after November 30, 1999, but on or before June 4, 2010 or that commenced reconstruction or modification on or after June 1, 2001 but no later than August 7, 2013, and for CISWIs in the small remote incinerator, energy recovery unit, and waste-burning kiln subcategories that commenced construction before June 4, 2010, your state plan must include compliance schedules that require CISWIs to achieve final compliance as expeditiously as practicable after approval of the state plan but not later than the earlier of the two dates specified in paragraphs (b)(1) and (2) of this section:

(1) February 7, 2018; and

(2) Three years after the effective date of State plan approval.

(c) For compliance schedules more than 1 year following the effective date of State plan approval, State plans must include dates for enforceable increments of progress as specified in § 60.2580.

§ 60.2540 Are there any state plan requirements for this subpart that apply instead of the requirements specified in subpart B?

Yes. Subpart B establishes general requirements for developing and processing section 111(d) plans. This subpart applies instead of the requirements in subpart B of this part for paragraphs (a) and (b) of this section:

(a) State plans developed to implement this subpart must be as protective as the emission guidelines contained in this subpart. State plans must require all CISWIs to comply by the dates specified in § 60.2535. This applies instead of the option for case-by-case less stringent emission standards and longer compliance schedules in § 60.24(f); and

(b) State plans developed to implement this subpart are required to include two increments of progress for the affected CISWIs. These two minimum increments are the final control plan submittal date and final compliance date in § 60.21(h)(1) and (5). This applies instead of the requirement of § 60.24(e)(1) that would require a state plan to include all five increments of progress for all CISWIs.

§ 60.2541 In lieu of a state plan submittal, are there other acceptable option(s) for a state to meet its Clean Air Act section 111(d)/129(b)(2) obligations?

Yes, a state may meet its Clean Air Act section 111(d)/129 obligations by submitting an acceptable written request for delegation of the federal plan that meets the requirements of this section. This is the only other option for a state to meet its Clean Air Act section 111(d)/129 obligations.

(a) An acceptable federal plan delegation request must include the following:

(1) A demonstration of adequate resources and legal authority to administer and enforce the federal plan;

(2) The items under § 60.2515(a)(1), (2) and (7);

(3) Certification that the hearing on the state delegation request, similar to the hearing for a state plan submittal, was held, a list of witnesses and their organizational affiliations, if any, appearing at the hearing, and a brief written summary of each presentation or written submission; and

(4) A commitment to enter into a Memorandum of Agreement with the Regional Administrator who sets forth the terms, conditions, and effective date of the delegation and that serves as the mechanism for the transfer of authority. Additional guidance and information is given in EPA's Delegation Manual, Item 7–139, Implementation and Enforcement of 111(d)(2) and 111(d)/(2)/129(b)(3) federal plans.

(b) A state with an already approved CISWI Clean Air Act section 111(d)/129 state plan is not precluded from receiving EPA approval of a delegation request for the revised federal plan, providing the requirements of paragraph (a) of this section are met, and at the time of the delegation request, the state also requests withdrawal of EPA's previous state plan approval.

(c) A state's Clean Air Act section 111(d)/129 obligations are separate from its obligations under Title V of the Clean Air Act.

§ 60.2542 What authorities will not be delegated to state, local, or tribal agencies?

The authorities that will not be delegated to state, local, or tribal agencies are specified in paragraphs (a) through (i) of this section:

(a) Approval of alternatives to the emission limitations in tables 2, 6, 7, 8, and 9 of this subpart and operating limits established under § 60.2675;

(b) Approval of major alternatives to test methods;

(c) Approval of major alternatives to monitoring;

(d) Approval of major alternatives to recordkeeping and reporting;

(e) The requirements in § 60.2680;

(f) The requirements in § 60.2665(b)(2);

(g) Approval of alternative opacity emission limits in § 60.2670 under § 60.11(e)(6) through (8);

(h) Performance test and data reduction waivers under § 60.8(b)(4) and (5); and

(i) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

§ 60.2545 Does this subpart directly affect CISWI owners and operators in my state?

(a) No. This subpart does not directly affect CISWI owners and operators in your state. However, CISWI owners and operators must comply with the state plan you develop to implement the emission guidelines contained in this subpart. States may choose to incorporate the model rule text directly in their state plan.

(b) If you do not submit an approvable plan to implement and enforce the guidelines contained in this subpart for CISWIs that commenced construction before November 30, 1999 by December 2, 2002, EPA will implement and enforce a federal plan, as provided in § 60.2525, to ensure that each unit within your state reaches compliance with all the provisions of this subpart by December 1, 2005.

(c) If you do not submit an approvable plan to implement and enforce the guidelines contained in this subpart by February 7, 2014, for CISWIs that commenced construction on or before June 4, 2010, EPA will implement and enforce a federal plan, as provided in § 60.2525, to ensure that each unit within your state that commenced construction on or before June 4, 2010, reaches compliance with all the provisions of this subpart by February 7, 2018.

Applicability of State Plans

§ 60.2550 What CISWIs must I address in my state plan?

(a) Your state plan must address incineration units that meet all three criteria described in paragraphs (a)(1) through (3) of this section:

(1) Commercial and industrial solid waste incineration units and ACIs in your state that commenced construction on or before June 4, 2010, or commenced modification or

reconstruction after June 4, 2010 but no later than August 7, 2013;

(2) Incineration units that meet the definition of a CISWI as defined in § 60.2875 or an ACI as defined in § 60.2875; and

(3) Incineration units not exempt under § 60.2555.

(b) If the owner or operator of a CISWI or ACI makes changes that meet the definition of modification or reconstruction after August 7, 2013, the CISWI or ACI becomes subject to subpart CCCC of this part and the state plan no longer applies to that unit.

(c) If the owner or operator of a CISWI or ACI makes physical or operational changes to an existing CISWI or ACI primarily to comply with your state plan, subpart CCCC of this part does not apply to that unit. Such changes do not qualify as modifications or reconstructions under subpart CCCC of this part.

§ 60.2555 What combustion units are exempt from my state plan?

This subpart exempts the types of units described in paragraphs (a) through (j) of this section, but some units are required to provide notifications.

(a) *Pathological waste incineration units.* Incineration units burning 90 percent or more by weight (on a calendar quarter basis and excluding the weight of auxiliary fuel and combustion air) of pathological waste, low-level radioactive waste, and/or chemotherapeutic waste as defined in § 60.2875 are not subject to this subpart if you meet the two requirements specified in paragraphs (a)(1) and (2) of this section:

(1) Notify the Administrator that the unit meets these criteria; and

(2) Keep records on a calendar quarter basis of the weight of pathological waste, low-level radioactive waste, and/or chemotherapeutic waste burned, and the weight of all other fuels and wastes burned in the unit.

(b) *Municipal waste combustion units.* Incineration units that are subject to subpart Ea of this part (Standards of Performance for Municipal Waste Combustors); subpart Eb of this part (Standards of Performance for Large Municipal Waste Combustors); subpart Cb of this part (Emission Guidelines and Compliance Time for Large Municipal Combustors); AAAA of this part (Standards of Performance for Small Municipal Waste Combustion Units); or subpart BBBB of this part (Emission Guidelines for Small Municipal Waste Combustion Units).

(c) *Medical waste incineration units.* Incineration units regulated under subpart Ec of this part (Standards of Performance for Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996) or subpart Ca of this part (Emission Guidelines and Compliance Times for Hospital/Medical/Infectious Waste Incinerators).

(d) *Small power production facilities.* Units that meet the four requirements specified in paragraphs (d)(1) through (4) of this section:

(1) The unit qualifies as a small power-production facility under section 3(17)(C) of the Federal Power Act (16 U.S.C. 796(17)(C));

(2) The unit burns homogeneous waste (not including refuse-derived fuel) to produce electricity;

(3) You submit documentation to the Administrator notifying the Agency that the qualifying small power production facility is combusting homogenous waste; and

(4) You maintain the records specified in § 60.2740(v).

(e) *Cogeneration facilities.* Units that meet the four requirements specified in paragraphs (e)(1) through (4) of this section:

(1) The unit qualifies as a cogeneration facility under section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B));

(2) The unit burns homogeneous waste (not including refuse-derived fuel) to produce electricity and steam or other forms of energy used for industrial, commercial, heating, or cooling purposes;

(3) You submit documentation to the Administrator notifying the Agency that the qualifying cogeneration facility is combusting homogenous waste; and

(4) You maintain the records specified in § 60.2740(w).

(f) *Hazardous waste combustion units.* Units for which you are required to get a permit under section 3005 of the Solid Waste Disposal Act.

(g) *Materials recovery units.* Units that combust waste for the primary purpose of recovering metals, such as primary and secondary smelters.

(h) *Sewage treatment plants.* Incineration units regulated under subpart O of this part (Standards of Performance for Sewage Treatment Plants).

(i) *Sewage sludge incineration units.* Incineration units combusting sewage sludge for the purpose of reducing the volume of the sewage sludge by removing combustible matter that are subject to subpart LLLL of this part (Standards of Performance for New Sewage Sludge Incineration Units) or subpart MMMM of this part (Emission Guidelines and Compliance Times for Existing Sewage Sludge Incineration Units).

(j) *Other solid waste incineration units.* Incineration units that are subject to subpart EEEE of this part (Standards of Performance for Other Solid Waste Incineration Units for Which Construction is Commenced After December 9, 2004, or for Which Modification or Reconstruction is Commenced on or After June 16, 2006) or subpart FFFF of this part (Emission Guidelines and Compliance Times for Other Solid Waste Incineration Units That Commenced Construction On or Before December 9, 2004).

Use of Model Rule

§ 60.2560 What is the ''model rule'' in this subpart?

(a) The model rule is the portion of these emission guidelines (§§ 60.2575 through 60.2875 of this part) that addresses the regulatory requirements applicable to CISWIs. The model rule provides these requirements in regulation format. You must develop a state plan that is at least as protective as the model rule. You may use the model rule language as part of your state plan. Alternative language may be used in your state plan if you demonstrate that the alternative language is at least as protective as the model rule contained in this subpart.

(b) In the model rule of §§ 60.2575 to 60.2875, ''you'' means the owner or operator of a CISWI.

§ 60.2565 How does the model rule relate to the required elements of my state plan?

Use the model rule to satisfy the state plan requirements specified in § 60.2515(a)(4) and (5) of this part.

§ 60.2570 What are the principal components of the model rule?

The model rule contains the eleven major components listed in paragraphs (a) through (k) of this section:

(a) Increments of progress toward compliance;

(b) Waste management plan;

(c) Operator training and qualification;

(d) Emission limitations and operating limits;

(e) Performance testing;

(f) Initial compliance requirements;

(g) Continuous compliance requirements;

(h) Monitoring;

(i) Recordkeeping and reporting;

(j) Definitions; and

(k) Tables.

Model Rule—Increments of Progress

§ 60.2575 What are my requirements for meeting increments of progress and achieving final compliance?

If you plan to achieve compliance more than 1 year following the effective date of state plan approval, you must meet the two increments of progress specified in paragraphs (a) and (b) of this section:

(a) Submit a final control plan; and

(b) Achieve final compliance.

§ 60.2580 When must I complete each increment of progress?

Table 1 of this subpart specifies compliance dates for each of the increments of progress.

§ 60.2585 What must I include in the notifications of achievement of increments of progress?

Your notification of achievement of increments of progress must include the three items specified in paragraphs (a) through (c) of this section:

(a) Notification that the increment of progress has been achieved;

(b) Any items required to be submitted with each increment of progress; and

(c) Signature of the owner or operator of the CISWI.

§ 60.2590 When must I submit the notifications of achievement of increments of progress?

Notifications for achieving increments of progress must be postmarked no later than 10 business days after the compliance date for the increment.

§ 60.2595 What if I do not meet an increment of progress?

If you fail to meet an increment of progress, you must submit a notification to the Administrator postmarked within 10 business days after the date for that increment of progress in table 1 of this subpart. You must inform the Administrator that you did not meet the increment, and you must continue to submit reports each subsequent calendar month until the increment of progress is met.

§ 60.2600 How do I comply with the increment of progress for submittal of a control plan?

For your control plan increment of progress, you must satisfy the two requirements specified in paragraphs (a) and (b) of this section:

(a) Submit the final control plan that includes the five items described in paragraphs (a)(1) through (5) of this section:

(1) A description of the devices for air pollution control and process changes that you will use to comply with the emission limitations and other requirements of this subpart;

(2) The type(s) of waste to be burned;

(3) The maximum design waste burning capacity;

(4) The anticipated maximum charge rate; and

(5) If applicable, the petition for site-specific operating limits under § 60.2680.

(b) Maintain an onsite copy of the final control plan.

§ 60.2605 How do I comply with the increment of progress for achieving final compliance?

For the final compliance increment of progress, you must complete all process changes and retrofit construction of control devices, as specified in the final control plan, so that, if the affected CISWI is brought online, all necessary process changes and air pollution control devices would operate as designed.

§ 60.2610 What must I do if I close my CISWI and then restart it?

(a) If you close your CISWI but will restart it prior to the final compliance date in your state plan, you must meet the increments of progress specified in § 60.2575.

(b) If you close your CISWI but will restart it after your final compliance date, you must complete emission control retrofits and meet the emission limitations and operating limits on the date your unit restarts operation.

§ 60.2615 What must I do if I plan to permanently close my CISWI and not restart it?

If you plan to close your CISWI rather than comply with the state plan, submit a closure notification, including the date of closure, to the Administrator by the date your final control plan is due.

Model Rule—Waste Management Plan

§ 60.2620 What is a waste management plan?

A waste management plan is a written plan that identifies both the feasibility and the methods used to reduce or separate certain components of solid waste from the waste stream in order to reduce or eliminate toxic emissions from incinerated waste.

§ 60.2625 When must I submit my waste management plan?

You must submit a waste management plan no later than the date specified in table 1 of this subpart for submittal of the final control plan.

§ 60.2630 What should I include in my waste management plan?

A waste management plan must include consideration of the reduction or separation of waste-stream elements such as paper, cardboard, plastics, glass, batteries, or metals; or the use of recyclable materials. The plan must identify any additional waste management measures, and the source must implement those measures considered practical and feasible, based on the effectiveness of waste management measures already in place, the costs of additional measures, the emissions reductions expected to be achieved, and any other environmental or energy impacts they might have.

Model Rule—Operator Training and Qualification

§ 60.2635 What are the operator training and qualification requirements?

(a) No CISWI can be operated unless a fully trained and qualified CISWI operator is accessible, either at the facility or can be at the facility within 1 hour. The trained and qualified CISWI operator may operate the CISWI directly or be the direct supervisor of one or more other plant personnel who operate the unit. If all qualified CISWI operators are temporarily not accessible, you must follow the procedures in § 60.2665.

(b) Operator training and qualification must be obtained through a state-approved program or by completing the requirements included in paragraph (c) of this section.

(c) Training must be obtained by completing an incinerator operator training course that includes, at a minimum, the three elements described in paragraphs (c)(1) through (3) of this section:

(1) Training on the eleven subjects listed in paragraphs (c)(1)(i) through (xi) of this section:

(i) Environmental concerns, including types of emissions;

(ii) Basic combustion principles, including products of combustion;

(iii) Operation of the specific type of incinerator to be used by the operator, including proper startup, waste charging, and shutdown procedures;

(iv) Combustion controls and monitoring;

(v) Operation of air pollution control equipment and factors affecting performance (if applicable);

(vi) Inspection and maintenance of the incinerator and air pollution control devices;

(vii) Actions to prevent and correct malfunctions or to prevent conditions that may lead to malfunctions;

(viii) Bottom and fly ash characteristics and handling procedures;

(ix) Applicable federal, state, and local regulations, including Occupational Safety and Health Administration workplace standards;

(x) Pollution prevention; and

(xi) Waste management practices.

(2) An examination designed and administered by the instructor.

(3) Written material covering the training course topics that can serve as reference material following completion of the course.

§ 60.2640 When must the operator training course be completed?

The operator training course must be completed by the later of the three dates specified in paragraphs (a) through (c) of this section:

(a) The final compliance date (Increment 2);

(b) Six months after CISWI startup; and

(c) Six months after an employee assumes responsibility for operating the CISWI or assumes responsibility for supervising the operation of the CISWI.

§ 60.2645 How do I obtain my operator qualification?

(a) You must obtain operator qualification by completing a training course that satisfies the criteria under § 60.2635(b).

(b) Qualification is valid from the date on which the training course is completed and the operator successfully passes the examination required under § 60.2635(c)(2).

§ 60.2650 How do I maintain my operator qualification?

To maintain qualification, you must complete an annual review or refresher course covering, at a minimum, the five topics described in paragraphs (a) through (e) of this section:

(a) Update of regulations;

(b) Incinerator operation, including startup and shutdown procedures, waste charging, and ash handling;

(c) Inspection and maintenance;

(d) Prevention and correction of malfunctions or conditions that may lead to malfunction; and

(e) Discussion of operating problems encountered by attendees.

§ 60.2655 How do I renew my lapsed operator qualification?

You must renew a lapsed operator qualification by one of the two methods specified in paragraphs (a) and (b) of this section:

(a) For a lapse of less than 3 years, you must complete a standard annual refresher course described in § 60.2650; and

(b) For a lapse of 3 years or more, you must repeat the initial qualification requirements in § 60.2645(a).

§ 60.2660 What site-specific documentation is required?

(a) Documentation must be available at the facility and readily accessible for all CISWI operators that addresses the ten topics described in paragraphs (a)(1) through (10) of this section. You must maintain this information and the training records required by paragraph (c) of this section in a manner that they can be readily accessed and are suitable for inspection upon request:

(1) Summary of the applicable standards under this subpart;

(2) Procedures for receiving, handling, and charging waste;

(3) Incinerator startup, shutdown, and malfunction procedures;

(4) Procedures for maintaining proper combustion air supply levels;

(5) Procedures for operating the incinerator and associated air pollution control systems within the standards established under this subpart;

(6) Monitoring procedures for demonstrating compliance with the incinerator operating limits;

(7) Reporting and recordkeeping procedures;

(8) The waste management plan required under §§ 60.2620 through 60.2630;

(9) Procedures for handling ash; and

(10) A list of the wastes burned during the performance test.

(b) You must establish a program for reviewing the information listed in paragraph (a) of this section with each incinerator operator:

(1) The initial review of the information listed in paragraph (a) of this section must be conducted by the later of the three dates specified in paragraphs (b)(1)(i) through (iii) of this section:

(i) The final compliance date (Increment 2);

(ii) Six months after CISWI startup; and

(iii) Six months after being assigned to operate the CISWI.

(2) Subsequent annual reviews of the information listed in paragraph (a) of this section must be conducted no later than 12 months following the previous review.

(c) You must also maintain the information specified in paragraphs (c)(1) through (3) of this section:

(1) Records showing the names of CISWI operators who have completed review of the information in § 60.2660(a) as required by § 60.2660(b), including the date of the initial review and all subsequent annual reviews;

(2) Records showing the names of the CISWI operators who have completed the operator training requirements under § 60.2635, met the criteria for qualification under § 60.2645, and maintained or renewed their qualification under § 60.2650 or § 60.2655. Records must include documentation of training, the dates of the initial refresher training, and the dates of their qualification and all subsequent renewals of such qualifications; and

(3) For each qualified operator, the phone and/or pager number at which they can be reached during operating hours.

§ 60.2665 What if all the qualified operators are temporarily not accessible?

If all qualified operators are temporarily not accessible (*i.e.,* not at the facility and not able to be at the facility within 1 hour), you must meet one of the two criteria specified in paragraphs (a) and (b) of this section, depending on the length of time that a qualified operator is not accessible:

(a) When all qualified operators are not accessible for more than 8 hours, but less than 2 weeks, the CISWI may be operated by other plant personnel familiar with the operation of the CISWI who have completed a review of the information specified in § 60.2660(a) within the past 12 months. However, you must record the period when all qualified operators were not accessible and include this deviation in the annual report as specified under § 60.2770;

(b) When all qualified operators are not accessible for 2 weeks or more, you must take the two actions that are described in paragraphs (b)(1) and (2) of this section:

(1) Notify the Administrator of this deviation in writing within 10 days. In the notice, state what caused this deviation, what you are doing to ensure that a qualified operator is accessible, and when you anticipate that a qualified operator will be accessible; and

(2) Submit a status report to the Administrator every 4 weeks outlining what you are doing to ensure that a qualified operator is accessible, stating when you anticipate that a qualified operator will be accessible and requesting approval from the Administrator to continue operation of the CISWI. You must submit the first status report 4 weeks after you notify the Administrator of the deviation under paragraph (b)(1) of this section. If the Administrator notifies you that your request to continue operation of the CISWI is disapproved, the CISWI may continue operation for 90 days, then must cease operation. Operation of the unit may resume if you meet the two requirements in paragraphs (b)(2)(i) and (ii) of this section:

(i) A qualified operator is accessible as required under § 60.2635(a); and

(ii) You notify the Administrator that a qualified operator is accessible and that you are resuming operation.

Model Rule—Emission Limitations and Operating Limits

§ 60.2670 What emission limitations must I meet and by when?

(a) You must meet the emission limitations for each CISWI, including bypass stack or vent, specified in table 2 of this subpart or tables 6 through 9 of this subpart by the final compliance date under the approved state plan, federal plan, or delegation, as applicable. The emission limitations apply at all times the unit is operating including and not limited to startup, shutdown, or malfunction.

(b) Units that do not use wet scrubbers must maintain opacity to less than or equal to the percent opacity (three 1-hour blocks consisting of ten 6-minute average opacity values) specified in table 2 of this subpart, as applicable.

§ 60.2675 What operating limits must I meet and by when?

(a) If you use a wet scrubber(s) to comply with the emission limitations, you must establish operating limits for up to four operating parameters (as specified in table 3 of this subpart) as described in paragraphs (a)(1) through (4) of this section during the initial performance test:

(1) Maximum charge rate, calculated using one of the two different procedures in paragraph (a)(1)(i) or (ii) of this section, as appropriate:

(i) For continuous and intermittent units, maximum charge rate is 110 percent of the average charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limitations; and

(ii) For batch units, maximum charge rate is 110 percent of the daily charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limitations.

(2) Minimum pressure drop across the wet particulate matter scrubber, which is calculated as the lowest 1-hour average pressure drop across the wet scrubber measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations; or minimum amperage to the wet scrubber, which is calculated as the lowest 1-hour average amperage to the wet scrubber measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations.

(3) Minimum scrubber liquid flow rate, which is calculated as the lowest 1-hour average liquid flow rate at the inlet to the wet acid gas or particulate matter scrubber measured during the most recent performance test demonstrating compliance with all applicable emission limitations.

(4) Minimum scrubber liquor pH, which is calculated as the lowest 1-hour average liquor pH at the inlet to the wet acid gas scrubber measured during the most recent performance test demonstrating compliance with the hydrogen chloride (HCl) emission limitation.

(b) You must meet the operating limits established on the date that the performance test report is submitted to the EPA's Central Data Exchange or postmarked, per the requirements of § 60.2795(b).

(c) If you use a fabric filter to comply with the emission limitations and you do not use a particulate matter (PM) continuous parameter monitoring system (CPMS) for monitoring PM compliance, you must operate each fabric filter system such that the bag leak detection system alarm does not sound more than 5 percent of the operating time during a 6-month period. In calculating this operating time percentage, if inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted. If corrective action is required, each alarm shall be counted as a minimum of 1 hour. If you take longer than 1 hour to initiate corrective action, the alarm time shall be counted as the actual amount of time taken by you to initiate corrective action.

(d) If you use an electrostatic precipitator to comply with the emission limitations and you do not use a PM CPMS for monitoring PM compliance, you must measure the (secondary) voltage and amperage of the electrostatic precipitator collection plates during the particulate matter performance test. Calculate the average electric power value (secondary voltage × secondary current = secondary electric power) for each test run. The operating limit for the electrostatic precipitator is calculated as the lowest 1-hour average secondary electric power measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations.

(e) If you use activated carbon sorbent injection to comply with the emission limitations, you must measure the sorbent flow rate during the performance testing. The operating limit for the carbon sorbent injection is calculated as the lowest 1-hour average sorbent flow rate measured during the most recent performance test demonstrating compliance with the mercury emission limitations. For energy recovery units, when your unit operates at lower loads, multiply your sorbent injection rate by the load fraction, as defined in this subpart, to determine the required injection rate (*e.g.,* for 50 percent load, multiply the injection rate operating limit by 0.5).

(f) If you use selective noncatalytic reduction to comply with the emission limitations, you must measure the charge rate, the secondary chamber temperature (if applicable to your CISWI), and the reagent flow rate during the nitrogen oxides performance testing. The operating limits for the selective noncatalytic reduction are calculated as the highest 1-hour average charge rate, lowest secondary chamber temperature, and lowest reagent flow rate measured during the most recent performance test demonstrating compliance with the nitrogen oxides emission limitations.

(g) If you use a dry scrubber to comply with the emission limitations, you must measure the injection rate of each sorbent during the performance testing. The operating limit for the injection rate of each sorbent is calculated as the lowest 1-hour average injection rate of each sorbent measured during the most recent performance test demonstrating compliance with the hydrogen chloride emission limitations. For energy recovery units, when your unit operates at lower loads, multiply your sorbent injection rate by the load fraction, as defined in this subpart, to determine the required injection rate (*e.g.,* for 50 percent load, multiply the injection rate operating limit by 0.5).

(h) If you do not use a wet scrubber, electrostatic precipitator, or fabric filter to comply with the emission limitations, and if you do not determine compliance with your particulate matter emission limitation with either a particulate matter CEMS or a particulate matter CPMS, you must maintain opacity to less than or equal to ten percent opacity (1-hour block average).

(i) If you use a PM CPMS to demonstrate compliance, you must establish your PM CPMS operating limit and determine compliance with it according to paragraphs (i)(1) through (5) of this section:

(1) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, record all hourly average output values (milliamps, or the digital signal equivalent) from the PM CPMS for the periods corresponding to the test runs (*e.g.,* three 1-hour average PM CPMS output values for three 1-hour test runs):

(i) Your PM CPMS must provide a 4–20 milliamp output, or the digital signal equivalent, and the establishment of its relationship to manual reference method measurements must be determined in units of milliamps or digital bits;

(ii) Your PM CPMS operating range must be capable of reading PM concentrations from zero to a level equivalent to at least two times your allowable emission limit. If your PM CPMS is an auto-ranging instrument capable of multiple scales, the primary range of the instrument must be capable of reading PM concentration from zero to a level equivalent to two times your allowable emission limit; and

(iii) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, record and average all milliamp output values, or their digital equivalent, from the PM CPMS for the periods corresponding to the compliance test runs (*e.g.,* average all your PM CPMS output values for three corresponding 2-hour Method 5I test runs).

(2) If the average of your three PM performance test runs are below 75 percent of your PM emission limit, you must calculate an operating limit by establishing a relationship of PM CPMS signal to PM concentration using the PM CPMS instrument zero, the average PM CPMS output values corresponding to the three compliance test runs, and the average PM concentration from the Method 5 or performance test with the procedures in (i)(1)through (5) of this section:

(i) Determine your instrument zero output with one of the following procedures:

(A) Zero point data for *in-situ* instruments should be obtained by removing the instrument from the stack and monitoring ambient air on a test bench;

(B) Zero point data for extractive instruments should be obtained by removing the extractive probe from the stack and drawing in clean ambient air;

(C) The zero point can also can be established obtained by performing manual reference method measurements when the flue gas is free of PM emissions or contains very low PM concentrations (*e.g.,* when your process is not operating, but the fans are operating or your source is combusting only natural gas) and plotting these with the compliance data to find the zero intercept; and

(D) If none of the steps in paragraphs (i)(2)(i)(A) through (C) of this section are possible, you must use a zero output value provided by the manufacturer.

(ii) Determine your PM CPMS instrument average in milliamps, or the digital equivalent, and the average of your corresponding three PM compliance test runs, using equation 1:

$$\overline{x} = \frac{1}{n}\sum_{i=1}^{n} X_1, \overline{y} = \frac{1}{n}\sum_{i=1}^{n} Y_1 \quad \text{(Eq. 1)}$$

Where:

X_1 = the PM CPMS output data points for the three runs constituting the performance test,

Y_1 = the PM concentration value for the three runs constituting the performance test, and

n = the number of data points.

(iii) With your instrument zero expressed in milliamps, or the digital equivalent, your three run average PM CPMS milliamp value, or its digital equivalent, and your three run average PM concentration from your three compliance tests, determine a relationship of mg/dscm per milliamp or digital signal equivalent, with equation 2:

$$R = \left(\frac{Y_1}{X_{1-z}}\right) \quad \text{(Eq. 2)}$$

Where:

R = the relative mg/dscm per milliamp, or the digital equivalent, for your PM CPMS,

Y_1 = the three run average mg/dscm PM concentration,

X_1 = the three run average milliamp output, or the digital equivalent, from you PM CPMS, and

z = the milliamp or digital signal equivalent of your instrument zero determined from paragraph (i)(2)(i) of this section.

(iv) Determine your source specific 30-day rolling average operating limit using the mg/dscm per milliamp value, or per digital signal equivalent, from equation 2 in equation 3, below. This sets your operating limit at the PM CPMS output value corresponding to 75 percent of your emission limit:

$$O_l = z + \frac{0.75(L)}{R} \quad \text{(Eq. 3)}$$

Where:

O_l = the operating limit for your PM CPMS on a 30-day rolling average, in milliamps or their digital signal equivalent,

L = your source emission limit expressed in mg/dscm,

z = your instrument zero in milliamps or digital equivalent, determined from paragraph (i)(2)(i) of this section, and
R = the relative mg/dscm per milliamp, or per digital signal output equivalent, for your PM CPMS, from equation 2.

(3) If the average of your three PM compliance test runs is at or above 75 percent of your PM emission limit you must determine your operating limit by averaging the PM CPMS milliamp or digital signal output corresponding to your three PM performance test runs that demonstrate compliance with the emission limit using equation 4 and you must submit all compliance test and PM CPMS data according to the reporting requirements in paragraph (i)(5) of this section:

$$O_n = \frac{1}{n}\sum_{i=1}^{n} X_1 \qquad \text{(Eq. 4)}$$

Where:
X_1 = the PM CPMS data points for all runs i,
n = the number of data points, and
O_h = your site specific operating limit, in milliamps or digital signal equivalent.

(4) To determine continuous compliance, you must record the PM CPMS output data for all periods when the process is operating and the PM CPMS is not out-of-control. You must demonstrate continuous compliance by using all quality-assured hourly average data collected by the PM CPMS for all operating hours to calculate the arithmetic average operating parameter in units of the operating limit (*e.g.,* milliamps or digital signal bits, PM concentration, raw data signal) on a 30-day rolling average basis.

(5) For PM performance test reports used to set a PM CPMS operating limit, the electronic submission of the test report must also include the make and model of the PM CPMS instrument, serial number of the instrument, analytical principle of the instrument (*e.g.,* beta attenuation), span of the instruments primary analytical range, milliamp or digital signal value equivalent to the instrument zero output, technique by which this zero value was determined, and the average milliamp or digital signals corresponding to each PM compliance test run.

§ 60.2680 What if I do not use a wet scrubber, fabric filter, activated carbon injection, selective noncatalytic reduction, an electrostatic precipitator, or a dry scrubber to comply with the emission limitations?

(a) If you use an air pollution control device other than a wet scrubber, activated carbon injection, selective noncatalytic reduction, fabric filter, an electrostatic precipitator, or a dry scrubber or limit emissions in some other manner, including mass balances, to comply with the emission limitations under § 60.2670, you must petition the EPA Administrator for specific operating limits to be established during the initial performance test and continuously monitored thereafter. You must submit the petition at least sixty days before the performance test is scheduled to begin. Your petition must include the five items listed in paragraphs (a)(1) through (5) of this section:

(1) Identification of the specific parameters you propose to use as additional operating limits;

(2) A discussion of the relationship between these parameters and emissions of regulated pollutants, identifying how emissions of regulated pollutants change with changes in these parameters and how limits on these parameters will serve to limit emissions of regulated pollutants;

(3) A discussion of how you will establish the upper and/or lower values for these parameters which will establish the operating limits on these parameters;

(4) A discussion identifying the methods you will use to measure and the instruments you will use to monitor these parameters, as well as the relative accuracy and precision of these methods and instruments; and

(5) A discussion identifying the frequency and methods for recalibrating the instruments you will use for monitoring these parameters.

(b) [Reserved]

Model Rule—Performance Testing

§ 60.2690 How do I conduct the initial and annual performance test?

(a) All performance tests must consist of a minimum of three test runs conducted under conditions representative of normal operations.

(b) You must document that the waste burned during the performance test is representative of the waste burned under normal operating conditions by maintaining a log of the quantity of waste burned (as required in § 60.2740(b)(1)) and the types of waste burned during the performance test.

(c) All performance tests must be conducted using the minimum run duration specified in tables 2 and 6 through 9 of this subpart.

(d) Method 1 of appendix A of this part must be used to select the sampling location and number of traverse points.

(e) Method 3A or 3B of appendix A of this part must be used for gas composition analysis, including measurement of oxygen concentration. Method 3A or 3B of appendix A of this part must be used simultaneously with each method (except when using Method 9 and Method 22).

(f) All pollutant concentrations, except for opacity, must be adjusted to 7 percent oxygen using equation 5 of this section:

$$C_{adj} = C_{meas}\,(20.9-7)/(20.9-\%O_2) \qquad \text{(Eq. 5)}$$

Where:
C_{adj} = pollutant concentration adjusted to 7 percent oxygen;
C_{meas} = pollutant concentration measured on a dry basis;
(20.9 − 7) = 20.9 percent oxygen − 7 percent oxygen (defined oxygen correction basis);

20.9 = oxygen concentration in air, percent; and

$\%O_2$ = oxygen concentration measured on a dry basis, percent.

(g) You must determine dioxins/furans toxic equivalency by following the procedures in paragraphs (g)(1) through (4) of this section:

(1) Measure the concentration of each dioxin/furan tetra- through octa-isomer emitted using EPA Method 23 at 40 CFR part 60, appendix A;

(2) Quantify isomers meeting identification criteria 2, 3, 4, and 5 in Section 5.3.2.5 of Method 23, regardless of whether the isomers meet identification criteria 1 and 7. You must quantify the isomers per Section 9.0 of Method 23. [Note: You may reanalyze the sample aliquot or split to reduce the number of isomers not meeting identification criteria 1 or 7 of Section 5.3.2.5.];

(3) For each dioxin/furan (tetra- through octa-chlorinated) isomer measured in accordance with paragraph (g)(1) and (2) of this section, multiply the isomer concentration by its corresponding toxic equivalency factor specified in table 4 of this subpart; and

(4) Sum the products calculated in accordance with paragraph (g)(3) of this section to obtain the total concentration of dioxins/furans emitted in terms of toxic equivalency.

(h) Method 22 at 40 CFR part 60, appendix A–7 must be used to determine compliance with the fugitive ash emission limit in table 2 of this subpart or tables 6 through 9 of this subpart.

(i) If you have an applicable opacity operating limit, you must determine compliance with the opacity limit using Method 9 at 40 CFR part 60, appendix A–4, based on three 1-hour blocks consisting of ten 6-minute average opacity values, unless you are required to install a continuous opacity monitoring system, consistent with § 60.2710 and § 60.2730.

(j) You must determine dioxins/furans total mass basis by following the procedures in paragraphs (j)(1) through (3) of this section:

(1) Measure the concentration of each dioxin/furan tetra- through octa-chlorinated isomer emitted using EPA Method 23 at 40 CFR part 60, appendix A–7;

(2) Quantify isomers meeting identification criteria 2, 3, 4, and 5 in Section 5.3.2.5 of Method 23, regardless of whether the isomers meet identification criteria 1 and 7. You must quantify the isomers per Section 9.0 of Method 23. (Note: You may reanalyze the sample aliquot or split to reduce the number of isomers not meeting identification criteria 1 or 7 of Section 5.3.2.5.); and

(3) Sum the quantities measured in accordance with paragraphs (j)(1) and (2) of this section to obtain the total concentration of dioxins/furans emitted in terms of total mass basis.

§ 60.2695 How are the performance test data used?

You use results of performance tests to demonstrate compliance with the emission limitations in table 2 of this subpart or tables 6 through 9 of this subpart.

Model Rule—Initial Compliance Requirements

§ 60.2700 How do I demonstrate initial compliance with the amended emission limitations and establish the operating limits?

(a) You must conduct a performance test, as required under §§ 60.2670 and 60.2690, to determine compliance with the emission limitations in table 2 of this subpart and tables 6 through 9 of this subpart, to establish compliance with any opacity operating limits in § 60.2675, to establish the kiln-specific emission limit in § 60.2710(y), as applicable, and to establish operating limits using the procedures in § 60.2675 or § 60.2680. The performance test must be conducted using the test methods listed in table 2 of this subpart and tables 6 through 9 of this subpart and the procedures in § 60.2690. The use of the bypass stack during a performance test shall invalidate the performance test.

(b) As an alternative to conducting a performance test, as required under §§ 60.2690 and 60.2670, you may use a 30-day rolling average of the 1-hour arithmetic average CEMS data, including CEMS data during startup and shutdown as defined in this subpart, to determine compliance with the emission limitations in Table 1 of this subpart or Tables 5 through 8 of this subpart. You must conduct a performance evaluation of each continuous monitoring system within 180 days of installation of the monitoring system. The initial performance evaluation must be conducted prior to collecting CEMS data that will be used for the initial compliance demonstration.

§ 60.2705 By what date must I conduct the initial performance test?

(a) The initial performance test must be conducted no later than 180 days after your final compliance date. Your final compliance date is specified in table 1 of this subpart.

(b) If you commence or recommence combusting a solid waste at an existing combustion unit at any commercial or industrial facility and you conducted a test consistent with the provisions of this subpart while combusting the given solid waste within the 6 months preceding the reintroduction of that solid waste in the combustion chamber, you do not need to retest until 6 months from the date you reintroduce that solid waste.

(c) If you commence or recommence combusting a solid waste at an existing combustion unit at any commercial or industrial facility and you have not conducted a performance test consistent with the provisions of this subpart while combusting the given solid waste within the 6 months preceding the reintroduction of that solid waste in the combustion chamber, you must conduct a performance test within 60 days from the date you reintroduce solid waste.

§ 60.2706 By what date must I conduct the initial air pollution control device inspection?

(a) The initial air pollution control device inspection must be conducted within 60 days after installation of the control device and the associated CISWI reaches the charge rate at which it will operate, but no later than 180 days after the final compliance date for meeting the amended emission limitations.

(b) Within 10 operating days following an air pollution control device inspection, all necessary repairs must be completed unless the owner or operator obtains written approval from the state agency establishing a date whereby all necessary repairs of the designated facility must be completed.

Model Rule—Continuous Compliance Requirements

§ 60.2710 How do I demonstrate continuous compliance with the amended emission limitations and the operating limits?

(a) General compliance with standards, considering some units may be able to switch between solid waste and non-waste fuel combustion, is specified in paragraph (a)(1) through (6) of this section.

(1) The emission standards and operating requirements set forth in this subpart apply at all times.

(2) If you cease combusting solid waste you may opt to remain subject to the provisions of this subpart. Consistent with the definition of CISWI, you are subject to the requirements of this subpart at least 6 months following the last date of solid waste combustion. Solid waste combustion is ceased when solid waste is not in the combustion

chamber (*i.e.,* the solid waste feed to the combustor has been cut off for a period of time not less than the solid waste residence time).

(3) If you cease combusting solid waste you must be in compliance with any newly applicable standards on the effective date of the waste-to-fuel switch. The effective date of the waste-to-fuel switch is a date selected by you, that must be at least 6 months from the date that you ceased combusting solid waste, consistent with § 60.2710(a)(2). Your source must remain in compliance with this subpart until the effective date of the waste-to-fuel switch.

(4) If you own or operate an existing commercial or industrial combustion unit that combusted a fuel or non-waste material, and you commence or recommence combustion of solid waste, you are subject to the provisions of this subpart as of the first day you introduce or reintroduce solid waste to the combustion chamber, and this date constitutes the effective date of the fuel-to-waste switch. You must complete all initial compliance demonstrations for any Section 112 standards that are applicable to your facility before you commence or recommence combustion of solid waste. You must provide 30 days prior notice of the effective date of the waste-to-fuel switch. The notification must identify:

(i) The name of the owner or operator of the CISWI, the location of the source, the emissions unit(s) that will cease burning solid waste, and the date of the notice;

(ii) The currently applicable subcategory under this subpart, and any 40 CFR part 63 subpart and subcategory that will be applicable after you cease combusting solid waste;

(iii) The fuel(s), non-waste material(s) and solid waste(s) the CISWI is currently combusting and has combusted over the past 6 months, and the fuel(s) or non-waste materials the unit will commence combusting;

(iv) The date on which you became subject to the currently applicable emission limits;

(v) The date upon which you will cease combusting solid waste, and the date (if different) that you intend for any new requirements to become applicable (*i.e.,* the effective date of the waste-to-fuel switch), consistent with paragraphs (a)(2) and (3) of this section.

(5) All air pollution control equipment necessary for compliance with any newly applicable emissions limits which apply as a result of the cessation or commencement or recommencement of combusting solid waste must be installed and operational as of the effective date of the waste-to-fuel, or fuel-to-waste switch.

(6) All monitoring systems necessary for compliance with any newly applicable monitoring requirements which apply as a result of the cessation or commencement or recommencement of combusting solid waste must be installed and operational as of the effective date of the waste-to-fuel, or fuel-to-waste switch. All calibration and drift checks must be performed as of the effective date of the waste-to-fuel, or fuel-to-waste switch. Relative accuracy tests must be performed as of the performance test deadline for PM CEMS (if PM CEMS are elected to demonstrate continuous compliance with the particulate matter emission limits). Relative accuracy testing for other CEMS need not be repeated if that testing was previously performed consistent with section 112 monitoring requirements or monitoring requirements under this subpart.

(b) You must conduct an annual performance test for the pollutants listed in table 2 of this subpart or tables 6 through 9 of this subpart and opacity for each CISWI as required under § 60.2690. The annual performance test must be conducted using the test methods listed in table 2 of this subpart or tables 6 through 9 of this subpart and the procedures in § 60.2690. Opacity must be measured using EPA Reference Method 9 at 40 CFR part 60. Annual performance tests are not required if you use CEMS or continuous opacity monitoring systems to determine compliance.

(c) You must continuously monitor the operating parameters specified in § 60.2675 or established under § 60.2680 and as specified in § 60.2735. Operation above the established maximum or below the established minimum operating limits constitutes a deviation from the established operating limits. Three-hour block average values are used to determine compliance (except for baghouse leak detection system alarms) unless a different averaging period is established under § 60.2680 or, for energy recovery units, where the averaging time for each operating parameter is a 30-day rolling, calculated each hour as the average of the previous 720 operating hours. Operation above the established maximum, below the established minimum, or outside the allowable range of the operating limits specified in paragraph (a) of this section constitutes a deviation from your operating limits established under this subpart, except during performance tests conducted to determine compliance with the emission and operating limits or to establish new operating limits. Operating limits are confirmed or reestablished during performance tests.

(d) You must burn only the same types of waste and fuels used to establish subcategory applicability (for ERUs) and operating limits during the performance test.

(e) For energy recovery units, incinerators, and small remote units, you must perform annual visual emissions test for ash handling.

(f) For energy recovery units, you must conduct an annual performance test for opacity using EPA Reference Method 9 at 40 CFR part 60 (except where particulate matter continuous monitoring system or CPMS are used) and the pollutants listed in table 7 of this subpart.

(g) For facilities using a CEMS to demonstrate compliance with the carbon monoxide emission limit, compliance with the carbon monoxide emission limit may be demonstrated by using the CEMS, as described in § 60.2730(o).

(h) Coal and liquid/gas energy recovery units with annual average heat input rates greater than 250 MMBtu/hr may elect to demonstrate continuous compliance with the particulate matter emissions limit using a particulate matter CEMS according to the procedures in § 60.2730(n) instead of the CPMS specified in § 60.2710(i). Coal and liquid/gas energy recovery units with annual average heat input rates less than 250 MMBtu/hr, incinerators, and small remote incinerators may also elect to demonstrate compliance using a particulate matter CEMS according to the procedures in § 60.2730(n) instead of particulate matter testing with EPA Method 5 at 40 CFR part 60, appendix A–3 and, if applicable, the continuous opacity monitoring requirements in paragraph (i) of this section.

(i) For energy recovery units with annual average heat input rates greater than or equal to 10 MMBtu/hr but less than 250 MMBtu/hr that do not use a wet scrubber, fabric filter with bag leak detection system, an electrostatic precipitator, particulate matter CEMS, or particulate matter CPMS, you must install, operate, certify and maintain a continuous opacity monitoring system (COMS) according to the procedures in § 60.2730(m).

(j) For waste-burning kilns, you must conduct an annual performance test for the pollutants (except mercury and particulate matter, and hydrogen chloride if no acid gas wet scrubber or dry scrubber is used) listed in table 8 of this subpart, unless you choose to demonstrate initial and continuous compliance using CEMS, as allowed in

paragraph (u) of this section. If you do not use an acid gas wet scrubber or dry scrubber, you must determine compliance with the hydrogen chloride emissions limit using a HCl CEMS according to the requirements in paragraph (j)(1) of this section. You must determine compliance with the mercury emissions limit using a mercury CEMS or an integrated sorbent trap monitoring system according to paragraph (j)(2) of this section. You must determine compliance with particulate matter using CPMS.

(1) If you monitor compliance with the HCl emissions limit by operating an HCl CEMS, you must do so in accordance with Performance Specification 15 (PS 15) of appendix B to 40 CFR part 60, or, PS 18 of appendix B to 40 CFR part 60. You must operate, maintain, and quality assure a HCl CEMS installed and certified under PS 15 according to the quality assurance requirements in Procedure 1 of appendix F to 40 CFR part 60 except that the Relative Accuracy Test Audit requirements of Procedure 1 must be replaced with the validation requirements and criteria of sections 11.1.1 and 12.0 of PS 15. You must operate, maintain and quality assure a HCl CEMS installed and certified under PS 18 according to the quality assurance requirements in Procedure 6 of appendix F to 40 CFR part 60. For any performance specification that you use, you must use Method 321 of appendix A to 40 CFR part 63 as the reference test method for conducting relative accuracy testing. The span value and calibration requirements in paragraphs (j)(1)(i) and (ii) of this section apply to all HCl CEMS used under this subpart:

(i) You must use a measurement span value for any HCl CEMS of 0–10 ppmvw unless the monitor is installed on a kiln without an inline raw mill. Kilns without an inline raw mill may use a higher span value sufficient to quantify all expected emissions concentrations. The HCl CEMS data recorder output range must include the full range of expected HCl concentration values which would include those expected during ''mill off'' conditions. The corresponding data recorder range shall be documented in the site-specific monitoring plan and associated records; and

(ii) In order to quality assure data measured above the span value, you must use one of the three options in paragraphs (j)(1)(ii)(A) through (C) of this section:

(A) Include a second span that encompasses the HCl emission concentrations expected to be encountered during ''mill off'' conditions. This second span may be rounded to a multiple of 5 ppm of total HCl. The requirements of the appropriate HCl monitor performance specification shall be followed for this second span with the exception that a RATA with the mill off is not required;

(B) Quality assure any data above the span value by proving instrument linearity beyond the span value established in paragraph (j)(1)(i) of this section using the following procedure. Conduct a weekly ''above span linearity'' calibration challenge of the monitoring system using a reference gas with a certified value greater than your highest expected hourly concentration or greater than 75% of the highest measured hourly concentration. The ''above span'' reference gas must meet the requirements of the applicable performance specification and must be introduced to the measurement system at the probe. Record and report the results of this procedure as you would for a daily calibration. The ''above span linearity'' challenge is successful if the value measured by the HCl CEMS falls within 10 percent of the certified value of the reference gas. If the value measured by the HCl CEMS during the above span linearity challenge exceeds 10 percent of the certified value of the reference gas, the monitoring system must be evaluated and repaired and a new ''above span linearity'' challenge met before returning the HCl CEMS to service, or data above span from the HCl CEMS must be subject to the quality assurance procedures established in (j)(1)(ii)(D) of this section. In this manner values measured by the HCl CEMS during the above span linearity challenge exceeding +/-20 percent of the certified value of the reference gas must be normalized using equation 6;

(C) Quality assure any data above the span value established in paragraph (j)(1)(i) of this section using the following procedure. Any time two consecutive one-hour average measured concentration of HCl exceeds the span value you must, within 24 hours before or after, introduce a higher, ''above span'' HCl reference gas standard to the HCl CEMS. The ''above span'' reference gas must meet the requirements of the applicable performance specification and target a concentration level between 50 and 150 percent of the highest expected hourly concentration measured during the period of measurements above span, and must be introduced at the probe. While this target represents a desired concentration range that is not always achievable in practice, it is expected that the intent to meet this range is demonstrated by the value of the reference gas. Expected values may include above span calibrations done before or after the above-span measurement period. Record and report the results of this procedure as you would for a daily calibration. The ''above span'' calibration is successful if the value measured by the HCl CEMS is within 20 percent of the certified value of the reference gas. If the value measured by the HCl CEMS is not within 20 percent of the certified value of the reference gas, then you must normalize the stack gas values measured above span as described in paragraph (j)(1)(ii)(D) of this section. If the ''above span'' calibration is conducted during the period when measured emissions are above span and there is a failure to collect the one data point in an hour due to the calibration duration, then you must determine the emissions average for that missed hour as the average of hourly averages for the hour preceding the missed hour and the hour following the missed hour. In an hour where an ''above span'' calibration is being conducted and one or more data points are collected, the emissions average is represented by the average of all valid data points collected in that hour; and

(D) In the event that the ''above span'' calibration is not successful (*i.e.,* the HCl CEMS measured value is not within 20 percent of the certified value of the reference gas), then you must normalize the one-hour average stack gas values measured above the span during the 24-hour period preceding or following the ''above span'' calibration for reporting based on the HCl CEMS response to the reference gas as shown in equation 6:

$$\frac{\text{Certified reference gas value}}{\text{Measured value of reference gas}} = \text{Measured stack gas} = \text{Normalized stack gas result} \quad \text{(Eq. 6)}$$

Only one ''above span'' calibration is needed per 24-hour period.

(2) Compliance with the mercury emissions limit must be determined using a mercury CEMS or integrated sorbent trap monitoring system according to the following requirements:

(i) You must operate a mercury CEMS in accordance with performance specification 12A at 40 CFR part 60, appendix B or an integrated sorbent trap monitoring system in accordance with performance specification 12B at 40 CFR part 60, appendix B; these monitoring systems must be quality assured according to procedure 5 of 40 CFR 60, appendix F. For the purposes of emissions calculations when using an integrated sorbent trap monitoring system, the mercury concentration determined for each sampling period must be assigned to each hour during the sampling period. If you choose to comply with the production-rate based mercury limit for your waste-burning kiln, you must also monitor hourly clinker production and determine the hourly mercury emissions rate in pounds per million ton of clinker produced. You must demonstrate compliance with the mercury emissions limit using a 30-day rolling average of these 1-hour mercury concentrations or mass emissions rates, including CEMS data during startup and shutdown as defined in this subpart, calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7 of this part. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content;

(ii) Owners or operators using a mercury CEMS or integrated sorbent trap monitoring system to determine mass emission rate must install, operate, calibrate and maintain an instrument for continuously measuring and recording the mercury mass emissions rate to the atmosphere according to the requirements of performance specification 6 at 40 CFR part 60, appendix B and conducting an annual relative accuracy test of the continuous emission rate monitoring system according to section 8.2 of performance specification 6; and

(iii) The owner or operator of a waste-burning kiln must demonstrate initial compliance by operating a mercury CEMS or integrated sorbent trap monitoring system while the raw mill of the in-line kiln/raw mill is operating under normal conditions and including at least one period when the raw mill is off.

(k) If you use an air pollution control device to meet the emission limitations in this subpart, you must conduct an initial and annual inspection of the air pollution control device. The inspection must include, at a minimum, the following:

(1) Inspect air pollution control device(s) for proper operation; and

(2) Develop a site-specific monitoring plan according to the requirements in paragraph (l) of this section. This requirement also applies to you if you petition the EPA Administrator for alternative monitoring parameters under § 60.13(i).

(l) For each CMS required in this section, you must develop and submit to the EPA Administrator for approval a site-specific monitoring plan according to the requirements of this paragraph (l) that addresses paragraphs (l)(1)(i) through (vi) of this section:

(1) You must submit this site-specific monitoring plan at least 60 days before your initial performance evaluation of your continuous monitoring system:

(i) Installation of the continuous monitoring system sampling probe or other interface at a measurement location relative to each affected process unit such that the measurement is representative of control of the exhaust emissions (*e.g.,* on or downstream of the last control device);

(ii) Performance and equipment specifications for the sample interface, the pollutant concentration or parametric signal analyzer and the data collection and reduction systems;

(iii) Performance evaluation procedures and acceptance criteria (*e.g.,* calibrations);

(iv) Ongoing operation and maintenance procedures in accordance with the general requirements of § 60.11(d);

(v) Ongoing data quality assurance procedures in accordance with the general requirements of § 60.13; and

(vi) Ongoing recordkeeping and reporting procedures in accordance with the general requirements of § 60.7(b), (c) introductory text, (c)(1) and (4), and (d) through (g).

(2) You must conduct a performance evaluation of each continuous monitoring system in accordance with your site-specific monitoring plan.

(3) You must operate and maintain the continuous monitoring system in continuous operation according to the site-specific monitoring plan.

(m) If you have an operating limit that requires the use of a flow monitoring system, you must meet the requirements in paragraphs (l) and (m)(1) through (4) of this section:

(1) Install the flow sensor and other necessary equipment in a position that provides a representative flow;

(2) Use a flow sensor with a measurement sensitivity at full scale of no greater than 2 percent;

(3) Minimize the effects of swirling flow or abnormal velocity distributions due to upstream and downstream disturbances; and

(4) Conduct a flow monitoring system performance evaluation in accordance with your monitoring plan at the time of each performance test but no less frequently than annually.

(n) If you have an operating limit that requires the use of a pressure monitoring system, you must meet the requirements in paragraphs (l) and (n)(1) through (6) of this section:

(1) Install the pressure sensor(s) in a position that provides a representative measurement of the pressure (*e.g.,* PM scrubber pressure drop);

(2) Minimize or eliminate pulsating pressure, vibration, and internal and external corrosion;

(3) Use a pressure sensor with a minimum tolerance of 1.27 centimeters of water or a minimum tolerance of 1 percent of the pressure monitoring system operating range, whichever is less;

(4) Perform checks at the frequency outlined in your site-specific monitoring plan to ensure pressure measurements are not obstructed (*e.g.,* check for pressure tap plugging daily);

(5) Conduct a performance evaluation of the pressure monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than annually; and

(6) If at any time the measured pressure exceeds the manufacturer's specified maximum operating pressure range, conduct a performance evaluation of the pressure monitoring system in accordance with your monitoring plan and confirm that the pressure monitoring system continues to meet the performance requirements in your monitoring plan. Alternatively, install and verify the operation of a new pressure sensor.

(o) If you have an operating limit that requires a pH monitoring system, you must meet the requirements in paragraphs (l) and (o)(1) through (4) of this section:

(1) Install the pH sensor in a position that provides a representative measurement of scrubber effluent pH;

(2) Ensure the sample is properly mixed and representative of the fluid to be measured;

(3) Conduct a performance evaluation of the pH monitoring system in accordance with your monitoring plan at least once each process operating day; and

(4) Conduct a performance evaluation (including a two-point calibration with one of the two buffer solutions having a pH within 1 of the pH of the operating limit) of the pH monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than quarterly.

(p) If you have an operating limit that requires a secondary electric power monitoring system for an electrostatic precipitator, you must meet the requirements in paragraphs (l) and (p)(1) and (2) of this section:

(1) Install sensors to measure (secondary) voltage and current to the precipitator collection plates; and

(2) Conduct a performance evaluation of the electric power monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than annually.

(q) If you have an operating limit that requires the use of a monitoring system to measure sorbent injection rate (*e.g.,* weigh belt, weigh hopper, or hopper flow measurement device), you must meet the requirements in paragraphs (l) and (q)(1) and (2) of this section:

(1) Install the system in a position(s) that provides a representative measurement of the total sorbent injection rate; and

(2) Conduct a performance evaluation of the sorbent injection rate monitoring system in accordance with your monitoring plan at the time of each performance test but no less frequently than annually.

(r) If you elect to use a fabric filter bag leak detection system to comply with the requirements of this subpart, you must install, calibrate, maintain, and continuously operate a bag leak detection system as specified in paragraphs (l) and (r)(1) through (5) of this section:

(1) Install a bag leak detection sensor(s) in a position(s) that will be representative of the relative or absolute particulate matter loadings for each exhaust stack, roof vent, or compartment (*e.g.,* for a positive pressure fabric filter) of the fabric filter;

(2) Use a bag leak detection system certified by the manufacturer to be capable of detecting particulate matter emissions at concentrations of 10 milligrams per actual cubic meter or less;

(3) Conduct a performance evaluation of the bag leak detection system in accordance with your monitoring plan and consistent with the guidance provided in EPA–454/R–98–015 (incorporated by reference, *see* § 60.17);

(4) Use a bag leak detection system equipped with a device to continuously record the output signal from the sensor; and

(5) Use a bag leak detection system equipped with a system that will sound an alarm when an increase in relative particulate matter emissions over a preset level is detected. The alarm must be located where it is observed readily by plant operating personnel.

(s) For facilities using a CEMS to demonstrate initial and continuous compliance with the sulfur dioxide emission limit, compliance with the sulfur dioxide emission limit may be demonstrated by using the CEMS specified in § 60.2730(l) to measure sulfur dioxide. The sulfur dioxide CEMS must follow the procedures and methods specified in paragraph (s) of this section. For sources that have actual inlet emissions less than 100 parts per million dry volume, the relative accuracy criterion for inlet sulfur dioxide CEMS should be no greater than 20 percent of the mean value of the reference method test data in terms of the units of the emission standard, or 5 parts per million dry volume absolute value of the mean difference between the reference method and the CEMS, whichever is greater:

(1) During each relative accuracy test run of the CEMS required by performance specification 2 in appendix B of this part, collect sulfur dioxide and oxygen (or carbon dioxide) data concurrently (or within a 30- to 60-minute period) with both the CEMS and the test methods specified in paragraphs (s)(1)(i) and (ii) of this section:

(i) For sulfur dioxide, EPA Reference Method 6 or 6C, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, see § 60.17) must be used; and

(ii) For oxygen (or carbon dioxide), EPA Reference Method 3A or 3B, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, see § 60.17), as applicable, must be used.

(2) The span value of the CEMS at the inlet to the sulfur dioxide control device must be 125 percent of the maximum estimated hourly potential sulfur dioxide emissions of the unit subject to this subpart. The span value of the CEMS at the outlet of the sulfur dioxide control device must be 50 percent of the maximum estimated hourly potential sulfur dioxide emissions of the unit subject to this subpart.

(3) Conduct accuracy determinations quarterly and calibration drift tests daily in accordance with procedure 1 in appendix F of this part.

(t) For facilities using a CEMS to demonstrate initial and continuous compliance with the nitrogen oxides emission limit, compliance with the nitrogen oxides emission limit may be demonstrated by using the CEMS specified in § 60.2730 to measure nitrogen oxides. The nitrogen oxides CEMS must follow the procedures and methods specified in paragraphs (t)(1) through (4) of this section:

(1) During each relative accuracy test run of the CEMS required by performance specification 2 of appendix B of this part, collect nitrogen oxides and oxygen (or carbon dioxide) data concurrently (or within a 30- to 60-minute period) with both the CEMS and the test methods specified in paragraphs (t)(1)(i) and (ii) of this section:

(i) For nitrogen oxides, EPA Reference Method 7 or 7E at 40 CFR part 60, appendix A–4 must be used; and

(ii) For oxygen (or carbon dioxide), EPA Reference Method 3A or 3B, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, see § 60.17), as applicable, must be used.

(2) The span value of the CEMS must be 125 percent of the maximum estimated hourly potential nitrogen oxide emissions of unit.

(3) Conduct accuracy determinations quarterly and calibration drift tests daily in accordance with procedure 1 in appendix F of this part.

(4) The owner or operator of an affected facility may request that compliance with the nitrogen oxides emission limit be determined using carbon dioxide measurements corrected to an equivalent of 7 percent oxygen. If carbon dioxide is selected for use in diluent corrections, the relationship between oxygen and carbon dioxide levels must be established during the initial performance test according to the procedures and methods specified in paragraphs (t)(4)(i) through (iv) of this section. This relationship may be reestablished during performance compliance tests:

(i) The fuel factor equation in Method 3B must be used to determine the relationship between oxygen and carbon dioxide at a sampling location. Method 3A, 3B, or as an alternative ANSI/ASME PTC 19.10–1981 (incorporated by reference, see § 60.17), as applicable, must be used to determine the oxygen concentration at the same location as the carbon dioxide monitor;

(ii) Samples must be taken for at least 30 minutes in each hour;

(iii) Each sample must represent a 1-hour average; and

(iv) A minimum of 3 runs must be performed.

(u) For facilities using a CEMS or an integrated sorbent trap monitoring system for mercury to demonstrate initial and continuous compliance with any of the emission limits of this subpart, you must complete the following:

(1) Demonstrate compliance with the appropriate emission limit(s) using a 30-day rolling average of 1-hour arithmetic average emission concentrations, including CEMS or an integrated

sorbent trap monitoring system data during startup and shutdown, as defined in this subpart, calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at appendix A–7 of this part. The 1-hour arithmetic averages for CEMS must be calculated using the data points required under § 60.13(e)(2). Except for CEMS or an integrated sorbent trap monitoring system data during startup and shutdown, the 1-hour arithmetic averages used to calculate the 30-day rolling average emission concentrations must be corrected to 7 percent oxygen (dry basis). Integrated sorbent trap monitoring system or CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content; and

(2) Operate all CEMS and integrated sorbent trap monitoring systems in accordance with the applicable procedures under appendices B and F of this part.

(v) Use of the bypass stack at any time is an emissions standards deviation for PM, HCl, lead, cadmium, mercury, nitrogen oxides, sulfur dioxide, and dioxin/furans.

(w) For energy recovery units with a design heat input capacity of 100 MMBtu/hr or greater that do not use a carbon monoxide CEMS, you must install, operate, and maintain an oxygen analyzer system as defined in § 60.2875 according to the procedures in paragraphs (w)(1) through (4) of this section:

(1) The oxygen analyzer system must be installed by the initial performance test date specified in § 60.2675;

(2) You must operate the oxygen trim system within compliance with paragraph (w)(3) of this section at all times;

(3) You must maintain the oxygen level such that the 30-day rolling average that is established as the operating limit for oxygen is not below the lowest hourly average oxygen concentration measured during the most recent CO performance test; and

(4) You must calculate and record a 30-day rolling average oxygen concentration using equation 19–19 in section 12.4.1 of EPA Reference Method 19 of Appendix A–7 of this part.

(x) For energy recovery units with annual average heat input rates greater than or equal to 250 MMBtu/hr and waste-burning kilns, you must install, calibrate, maintain, and operate a PM CPMS and record the output of the system as specified in paragraphs (x)(1) through (8) of this section. For other energy recovery units, you may elect to use PM CPMS operated in accordance with this section. PM CPMS are suitable in lieu of using other CMS for monitoring PM compliance (*e.g.,* bag leak detectors, ESP secondary power, PM scrubber pressure):

(1) Install, calibrate, operate, and maintain your PM CPMS according to the procedures in your approved site-specific monitoring plan developed in accordance with paragraphs (l) and (x)(1)(i) through (iii) of this section:

(i) The operating principle of the PM CPMS must be based on in-stack or extractive light scatter, light scintillation, beta attenuation, or mass accumulation of the exhaust gas or representative sample. The reportable measurement output from the PM CPMS must be expressed as milliamps or the digital signal equivalent;

(ii) The PM CPMS must have a cycle time (*i.e.,* period required to complete sampling, measurement, and reporting for each measurement) no longer than 60 minutes; and

(iii) The PM CPMS must be capable of detecting and responding to particulate matter concentrations increments no greater than 0.5 mg/actual cubic meter.

(2) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, you must adjust the site-specific operating limit in accordance with the results of the performance test according to the procedures specified in § 60.2675.

(3) Collect PM CPMS hourly average output data for all energy recovery unit or waste-burning kiln operating hours. Express the PM CPMS output as milliamps or the digital signal equivalent.

(4) Calculate the arithmetic 30-day rolling average of all of the hourly average PM CPMS output collected during all energy recovery unit or waste-burning kiln operating hours data (milliamps or their digital equivalent).

(5) You must collect data using the PM CPMS at all times the energy recovery unit or waste-burning kiln is operating and at the intervals specified in paragraph (x)(1)(ii) of this section, except for periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments), and any scheduled maintenance as defined in your site-specific monitoring plan.

(6) You must use all the data collected during all energy recovery unit or waste-burning kiln operating hours in assessing the compliance with your operating limit except:

(i) Any data collected during monitoring system malfunctions, repairs associated with monitoring system malfunctions, or required monitoring system quality assurance or quality control activities conducted during monitoring system malfunctions are not used in calculations (report any such periods in your annual deviation report);

(ii) Any data collected during periods when the monitoring system is out of control as specified in your site-specific monitoring plan, repairs associated with periods when the monitoring system is out of control, or required monitoring system quality assurance or quality control activities conducted during out-of-control periods are not used in calculations (report emissions or operating levels and report any such periods in your annual deviation report);

(iii) Any PM CPMS data recorded during periods of CEMS data during startup and shutdown, as defined in this subpart.

(7) You must record and make available upon request results of PM CPMS system performance audits, as well as the dates and duration of periods from when the PM CPMS is out of control until completion of the corrective actions necessary to return the PM CPMS to operation consistent with your site-specific monitoring plan.

(8) For any deviation of the 30-day rolling average PM CPMS average value from the established operating parameter limit, you must:

(i) Within 48 hours of the deviation, visually inspect the air pollution control device;

(ii) If inspection of the air pollution control device identifies the cause of the deviation, take corrective action as soon as possible and return the PM CPMS measurement to within the established value;

(iii) Within 30 days of the deviation or at the time of the annual compliance test, whichever comes first, conduct a PM emissions compliance test to determine compliance with the PM emissions limit. Within 45 days of the deviation, you must re-establish the CPMS operating limit. You are not required to conduct additional testing for any deviations that occur between the time of the original deviation and the PM emissions compliance test required under paragraph (x) of this section; and

(iv) PM CPMS deviations leading to more than four required performance tests in a 12-month process operating period (rolling monthly) constitute a violation of this subpart.

(y) When there is an alkali bypass and/or an in-line coal mill that exhaust emissions through a separate stack(s), the combined emissions are subject to the emission limits applicable to waste-burning kilns. To determine the kiln-specific emission limit for demonstrating compliance, you must:

(1) Calculate a kiln-specific emission limit using equation 7:

$$C_{ks} = ((\text{Emission limit} \times (Q_{ab}+Q_{cm}+Q_{ks})) - (Q_{ab} \times C_{ab}) - (Q_{cm} \times C_{cm}))/Q_{ks} \quad \text{(Eq. 7)}$$

Where:

C_{ks} = Kiln stack concentration (ppmvd, mg/dscm, ng/dscm, depending on pollutant. Each corrected to 7% O_2.)
Q_{ab} = Alkali bypass flow rate (volume/hr)
C_{ab} = Alkali bypass concentration (ppmvd, mg/dscm, ng/dscm, depending on pollutant. Each corrected to 7% O_2.)
Q_{cm} = In-line coal mill flow rate (volume/hr)
C_{cm} = In-line coal mill concentration (ppmvd, mg/dscm, ng/dscm, depending on pollutant. Each corrected to 7% O_2.)
Q_{ks} = Kiln stack flow rate (volume/hr)

(2) Particulate matter concentration must be measured downstream of the in-line coal mill. All other pollutant concentrations must be measured either upstream or downstream of the in-line coal mill.

(3) For purposes of determining the combined emissions from kilns equipped with an alkali bypass or that exhaust kiln gases to a coal mill that exhausts through a separate stack, instead of installing a CEMS or PM CPMS on the alkali bypass stack or in-line coal mill stack, the results of the initial and subsequent performance test can be used to demonstrate compliance with the relevant emissions limit. A performance test must be conducted on an annual basis (between 11 and 13 calendar months following the previous performance test).

§ 60.2715 By what date must I conduct the annual performance test?

You must conduct annual performance tests between 11 and 13 calendar months of the previous performance test.

§ 60.2716 By what date must I conduct the annual air pollution control device inspection?

On an annual basis (no more than 12 months following the previous annual air pollution control device inspection), you must complete the air pollution control device inspection as described in § 60.2706.

§ 60.2720 May I conduct performance testing less often?

(a) You must conduct annual performance tests according to the schedule specified in § 60.2715, with the following exceptions:

(1) You may conduct a repeat performance test at any time to establish new values for the operating limits, as specified in § 60.2725. New operating limits become effective on the date that the performance test report is submitted to the EPA's Central Data Exchange or postmarked, per the requirements of § 60.2795(b). The Administrator may request a repeat performance test at any time;

(2) You must repeat the performance test within 60 days of a process change, as defined in § 60.2875; and

(3) You can conduct performance tests less often if you meet the following conditions: Your performance tests for the pollutant for at least 2 consecutive performance tests demonstrates that the emission level for the pollutant is no greater than the emission level specified in paragraph (a)(3)(i) or (ii) of this section, as applicable; there are no changes in the operation of the affected source or air pollution control equipment that could increase emissions; and you are not required to conduct a performance test for the pollutant in response to a request by the Administrator in paragraph (a)(1) of this section or a process change in paragraph (a)(2) of this section. In this case, you do not have to conduct a performance test for that pollutant for the next 2 years. You must conduct a performance test for the pollutant no more than 37 months following the previous performance test for the pollutant. If the emission level for your CISWI continues to meet the emission level specified in paragraph (a)(3)(i) or (ii) of this section, as applicable, you may choose to conduct performance tests for the pollutant every third year, as long as there are no changes in the operation of the affected source or air pollution control equipment that could increase emissions. Each such performance test must be conducted no more than 37 months after the previous performance test.

(i) For particulate matter, hydrogen chloride, mercury, carbon monoxide, nitrogen oxides, sulfur dioxide, cadmium, lead, and dioxins/furans, the emission level equal to 75 percent of the applicable emission limit in table 2 or tables 6 through 9 of this subpart, as applicable; and

(ii) For fugitive emissions, visible emissions (of combustion ash from the ash conveying system) for 2 percent of the time during each of the three 1-hour observation periods.

(4) If you are conducting less frequent testing for a pollutant as provided in paragraph (a)(3) of this section and a subsequent performance test for the pollutant indicates that your CISWI does not meet the emission level specified in paragraph (a)(3)(i) or (a)(3)(ii) of this section, as applicable, you must conduct annual performance tests for the pollutant according to the schedule specified in paragraph (a) of this section until you qualify for less frequent testing for the pollutant as specified in paragraph (a)(3) of this section.

(b) [Reserved]

§ 60.2725 May I conduct a repeat performance test to establish new operating limits?

(a) Yes. You may conduct a repeat performance test at any time to establish new values for the operating limits. The Administrator may request a repeat performance test at any time.

(b) You must repeat the performance test if your feed stream is different than the feed streams used during any performance test used to demonstrate compliance.

Model Rule—Monitoring

§ 60.2730 What monitoring equipment must I install and what parameters must I monitor?

(a) If you are using a wet scrubber to comply with the emission limitation under § 60.2670, you must install, calibrate (to manufacturers' specifications), maintain, and operate devices (or establish methods) for monitoring the value of the operating parameters used to determine compliance with the operating limits listed in table 3 of this subpart. These devices (or methods) must measure and record the values for these operating parameters at the frequencies indicated in table 3 of this subpart at all times except as specified in § 60.2735(a).

(b) If you use a fabric filter to comply with the requirements of this subpart and you do not use a PM CPMS or PM CEMS for monitoring PM compliance,

you must install, calibrate, maintain, and continuously operate a bag leak detection system as specified in paragraphs (b)(1) through (8) of this section:

(1) You must install and operate a bag leak detection system for each exhaust stack of the fabric filter;

(2) Each bag leak detection system must be installed, operated, calibrated, and maintained in a manner consistent with the manufacturer's written specifications and recommendations;

(3) The bag leak detection system must be certified by the manufacturer to be capable of detecting particulate matter emissions at concentrations of 10 milligrams per actual cubic meter or less;

(4) The bag leak detection system sensor must provide output of relative or absolute particulate matter loadings;

(5) The bag leak detection system must be equipped with a device to continuously record the output signal from the sensor;

(6) The bag leak detection system must be equipped with an alarm system that will alert automatically an operator when an increase in relative particulate matter emission over a preset level is detected. The alarm must be located where it is observed easily by plant operating personnel;

(7) For positive pressure fabric filter systems, a bag leak detection system must be installed in each baghouse compartment or cell. For negative pressure or induced air fabric filters, the bag leak detector must be installed downstream of the fabric filter; and

(8) Where multiple detectors are required, the system's instrumentation and alarm may be shared among detectors.

(c) If you are using something other than a wet scrubber, activated carbon, selective non-catalytic reduction, an electrostatic precipitator, or a dry scrubber to comply with the emission limitations under § 60.2670, you must install, calibrate (to the manufacturers' specifications), maintain, and operate the equipment necessary to monitor compliance with the site-specific operating limits established using the procedures in § 60.2680.

(d) If you use activated carbon injection to comply with the emission limitations in this subpart, you must measure the minimum sorbent flow rate once per hour.

(e) If you use selective noncatalytic reduction to comply with the emission limitations, you must complete the following:

(1) Following the date on which the initial performance test is completed or is required to be completed under § 60.2690, whichever date comes first, ensure that the affected facility does not operate above the maximum charge rate, or below the minimum secondary chamber temperature (if applicable to your CISWI) or the minimum reagent flow rate measured as 3-hour block averages at all times; and

(2) Operation of the affected facility above the maximum charge rate, below the minimum secondary chamber temperature and below the minimum reagent flow rate simultaneously constitute a violation of the nitrogen oxides emissions limit.

(f) If you use an electrostatic precipitator to comply with the emission limits of this subpart and you do not use a PM CPMS for monitoring PM compliance, you must monitor the secondary power to the electrostatic precipitator collection plates and maintain the 3-hour block averages at or above the operating limits established during the mercury or particulate matter performance test.

(g) For waste-burning kilns not equipped with a wet scrubber or dry scrubber, you must install, calibrate, maintain, and operate a CEMS for monitoring hydrogen chloride emissions discharged to the atmosphere, as specified in § 60.2710(j), and record the output of the system. You may substitute use of a HCl CEMS for conducting the HCl initial and annual testing with EPA Method 321 at 40 CFR part 63, appendix A. For units other than waste-burning kilns not equipped with a wet scrubber or dry scrubber, a facility may substitute use of a hydrogen chloride CEMS for conducting the hydrogen chloride initial and annual performance test. For units equipped with a hydrogen chloride CEMS, you are not required to monitor the minimum hydrogen chloride sorbent flow rate, monitoring the minimum scrubber liquor pH, and monitoring minimum injection rate.

(h) To demonstrate continuous compliance with the particulate matter emissions limit, a facility may substitute use of either a particulate matter CEMS or a particulate matter CPMS for conducting the particulate matter annual performance test. For units equipped with a particulate matter CEMS, you are not required to use other CMS monitoring for PM compliance (*e.g.,* bag leak detectors, ESP secondary power, PM scrubber pressure). A facility may also substitute use of a particulate matter CEMS for conducting the PM initial performance test.

(i) To demonstrate initial and continuous compliance with the dioxin/furan emissions limit, a facility may substitute use of a continuous automated sampling system for the dioxin/furan initial and annual performance test. You must record the output of the system and analyze the sample according to EPA Method 23 at 40 CFR part 60, appendix A–7. This option to use a continuous automated sampling system takes effect on the date a final performance specification applicable to dioxin/furan from continuous monitors is published in the **Federal Register**. The owner or operator who elects to continuously sample dioxin/furan emissions instead of sampling and testing using EPA Method 23 at 40 CFR part 60, appendix A–7 must install, calibrate, maintain and operate a continuous automated sampling system and must comply with the requirements specified in § 60.58b(p) and (q). A facility may substitute continuous dioxin/furan monitoring for the minimum sorbent flow rate, if activated carbon sorbent injection is used solely for compliance with the dioxin/furan emission limit.

(j) To demonstrate initial and continuous compliance with the mercury emissions limit, a facility may substitute use of a mercury CEMS or and integrated sorbent trap monitoring system for the mercury initial and annual performance test. The owner or operator who elects to continuously measure mercury emissions instead of sampling and testing using EPA Method 29 or 30B at 40 CFR part 60, appendix A–8, ASTM D6784–02 (Reapproved 2008) (incorporated by reference, see § 60.17), or an approved alternative method for measuring mercury emissions, must install, calibrate, maintain and operate the mercury CEMS or integrated sorbent trap monitoringsystem and must comply with performance specification 12A or performance specification 12B, respectively, and quality assurance procedure 5. For the purposes of emissions calculations when using an integrated sorbent trap monitoring system, the mercury concentration determined for each sampling period must be assigned to each hour during the sampling period. For units equipped with a mercury CEMS or an integrated sorbent trap monitoring system, you are not required to monitor the minimum sorbent flow rate, if activated carbon sorbent injection is used solely for compliance with the mercury emission limit. Waste-burning kilns must install, calibrate, maintain, and operate a mercury CEMS or an integrated sorbent trap monitoring system as specified in § 60.2710(j).

(k) To demonstrate initial and continuous compliance with the nitrogen oxides emissions limit, a

facility may substitute use of a CEMS for the nitrogen oxides initial and annual performance test to demonstrate compliance with the nitrogen oxides emissions limits. For units equipped with a nitrogen xides CEMS, you are not required to monitor the charge rate, secondary chamber temperature and reagent flow for selective noncatalytic reduction, if applicable:

(1) Install, calibrate, maintain and operate a CEMS for measuring nitrogen oxides emissions discharged to the atmosphere and record the output of the system. The requirements under performance specification 2 of appendix B of this part, the quality assurance procedure 1 of appendix F of this part and the procedures under § 60.13 must be followed for installation, evaluation and operation of the CEMS; and

(2) Compliance with the emission limit for nitrogen oxides must be determined based on the 30-day rolling average of the hourly emission concentrations using CEMS outlet data, as outlined in § 60.2710(u).

(l) To demonstrate initial and continuous compliance with the sulfur dioxide emissions limit, a facility may substitute use of a CEMS for the sulfur dioxide initial and annual performance test to demonstrate compliance with the sulfur dioxide emissions limits:

(1) Install, calibrate, maintain and operate a CEMS for measuring sulfur dioxide emissions discharged to the atmosphere and record the output of the system. The requirements under performance specification 2 of appendix B of this part, the quality assurance requirements of procedure 1 of appendix F of this part and the procedures under § 60.13 must be followed for installation, evaluation and operation of the CEMS; and

(2) Compliance with the sulfur dioxide emission limit shall be determined based on the 30-day rolling average of the hourly arithmetic average emission concentrations using CEMS outlet data, as outlined in § 60.2710(u).

(m) For energy recovery units over 10 MMBtu/hr but less than 250 MMBtu/hr annual average heat input rates that do not use a wet scrubber, fabric filter with bag leak detection system, an electrostatic precipitator, particulate matter CEMS, or particulate matter CPMS, you must install, operate, certify and maintain a continuous opacity monitoring system according to the procedures in paragraphs (m)(1) through (5) of this section by the compliance date specified in § 60.2670. Energy recovery units that use a particulate matter CEMS to demonstrate initial and continuing compliance according to the procedures in § 60.2730(n) are not required to install a continuous opacity monitoring system and must perform the annual performance tests for opacity consistent with § 60.2710(f):

(1) Install, operate and maintain each continuous opacity monitoring system according to performance specification 1 at 40 CFR part 60, appendix B;

(2) Conduct a performance evaluation of each continuous opacity monitoring system according to the requirements in § 60.13 and according to performance specification 1 at 40 CFR part 60, appendix B;

(3) As specified in § 60.13(e)(1), each continuous opacity monitoring system must complete a minimum of one cycle of sampling and analyzing for each successive 10-second period and one cycle of data recording for each successive 6-minute period;

(4) Reduce the continuous opacity monitoring system data as specified in § 60.13(h)(1); and

(5) Determine and record all the 6-minute averages (and 1-hour block averages as applicable) collected.

(n) For coal and liquid/gas energy recovery units, incinerators, and small remote incinerators, an owner or operator may elect to install, calibrate, maintain and operate a CEMS for monitoring particulate matter emissions discharged to the atmosphere and record the output of the system. The owner or operator of an affected facility who continuously monitors particulate matter emissions instead of conducting performance testing using EPA Method 5 at 40 CFR part 60, appendix A–3 or monitoring with a particulate matter CPMS according to paragraph (r) of this section, must install, calibrate, maintain and operate a PM CEMS and must comply with the requirements specified in paragraphs (n)(1) through (10) of this section:

(1) The PM CEMS must be installed, evaluated and operated in accordance with the requirements of performance specification 11 of appendix B of this part and quality assurance requirements of procedure 2 of appendix F of this part and § 60.13;

(2) The initial performance evaluation must be completed no later than 180 days after the final compliance date for meeting the amended emission limitations, as specified under § 60.2690 or within 180 days of notification to the Administrator of use of the continuous monitoring system if the owner or operator was previously determining compliance by Method 5 at 40 CFR part 60, appendix A–3 performance tests, whichever is later;

(3) The owner or operator of an affected facility may request that compliance with the particulate matter emission limit be determined using carbon dioxide measurements corrected to an equivalent of 7 percent oxygen. The relationship between oxygen and carbon dioxide levels for the affected facility must be established according to the procedures and methods specified in § 60.2710(t)(4)(i) through (iv);

(4) The owner or operator of an affected facility must conduct an initial performance test for particulate matter emissions. If PM CEMS are elected for demonstrating compliance, and the initial performance test has not yet been conducted, then initial compliance must be determined by using the CEMS specified in paragraph (n) of this section to measure particulate matter. You must calculate a 30-day rolling average of 1-hour arithmetic average emission concentrations, including CEMS data during startup and shutdown, as defined in this subpart, using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, appendix A–7 of this part;

(5) Continuous compliance with the particulate matter emission limit must be determined based on the 30-day rolling average calculated using equation 19–19 in section 12.4.1 of EPA Reference Method 19 at 40 CFR part 60, Appendix A–7 of the part from the 1-hour arithmetic average of the CEMS outlet data.

(6) At a minimum, valid continuous monitoring system hourly averages must be obtained as specified § 60.2735;

(7) The 1-hour arithmetic averages required under paragraph (n)(5) of this section must be expressed in milligrams per dry standard cubic meter corrected to 7 percent oxygen (or carbon dioxide)(dry basis) and must be used to calculate the 30-day rolling average emission concentrations. CEMS data during startup and shutdown, as defined in this subpart, are not corrected to 7 percent oxygen, and are measured at stack oxygen content. The 1-hour arithmetic averages must be calculated using the data points required under § 60.13(e)(2);

(8) All valid CEMS data must be used in calculating average emission concentrations even if the minimum CEMS data requirements of paragraph (n)(6) of this section are not met;

(9) The CEMS must be operated according to performance specification 11 in appendix B of this part; and,

(10) Quarterly and yearly accuracy audits and daily drift, system optics, and sample volume checks must be performed in accordance with procedure 2 in appendix F of this part.

(o) To demonstrate initial and continuous compliance with the carbon monoxide emissions limit, a facility

may substitute use of a CEMS for the carbon monoxide initial and annual performance test to demonstrate compliance with the carbon monoxide emissions limits:

(1) Install, calibrate, maintain, and operate a CEMS for measuring carbon monoxide emissions discharged to the atmosphere and record the output of the system. The requirements under performance specification 4A or 4B of appendix B of this part, the quality assurance procedure 1 of appendix F of this part and the procedures under § 60.13 must be followed for installation, evaluation, and operation of the CEMS; and

(2) Compliance with the carbon monoxide emission limit shall be determined based on the 30-day rolling average of the hourly arithmetic average emission concentrations, including CEMS data during startup and shutdown as defined in this subpart, using CEMS outlet data, as outlined in § 60.2710(u).

(p) The owner/operator of an affected source with a bypass stack shall install, calibrate (to manufacturers' specifications), maintain and operate a device or method for measuring the use of the bypass stack including date, time and duration.

(q) For energy recovery units with a heat input capacity of 100 MMBtu/hr or greater that do not use a carbon monoxide CEMS, you must install, operate and maintain the continuous oxygen monitoring system as defined in § 60.2875 according to the procedures in paragraphs (q)(1) through (4) of this section:

(1) The oxygen analyzer system must be installed by the initial performance test date specified in § 60.2675;

(2) You must operate the oxygen trim system within compliance with paragraph (q)(3) of this section at all times;

(3) You must maintain the oxygen level such that the 30-day rolling average that is established as the operating limit for oxygen according to paragraph (q)(4) of this section is not below the lowest hourly average oxygen concentration measured during the most recent CO performance test; and

(4) You must calculate and record a 30-day rolling average oxygen concentration using equation 19–19 in section 12.4.1 of EPA Reference Method 19 of Appendix A–7 of this part.

(r) For energy recovery units with annual average heat input rates greater than or equal to 250 MMBtu/hr and waste-burning kilns, you must install, calibrate, maintain, and operate a PM CPMS and record the output of the system as specified in paragraphs (r)(1) through (8) of this section. For other energy recovery units, you may elect to use PM CPMS operated in accordance with this section. PM CPMS are suitable in lieu of using other CMS for monitoring PM compliance (*e.g.,* bag leak detectors, ESP secondary power, PM scrubber pressure):

(1) Install, calibrate, operate, and maintain your PM CPMS according to the procedures in your approved site-specific monitoring plan developed in accordance with § 60.2710(l) and (r)(1)(i) through (iii) of this section:

(i) The operating principle of the PM CPMS must be based on in-stack or extractive light scatter, light scintillation, beta attenuation, or mass accumulation of the exhaust gas or representative sample. The reportable measurement output from the PM CPMS must be expressed as milliamps or the digital signal equivalent;

(ii) The PM CPMS must have a cycle time (*i.e.,* period required to complete sampling, measurement, and reporting for each measurement) no longer than 60 minutes; and

(iii) The PM CPMS must be capable of detecting and responding to particulate matter concentrations increments no greater than 0.5 mg/actual cubic meter.

(2) During the initial performance test or any such subsequent performance test that demonstrates compliance with the PM limit, you must adjust the site-specific operating limit in accordance with the results of the performance test according to the procedures specified in § 60.2675.

(3) Collect PM CPMS hourly average output data for all energy recovery unit or waste-burning kiln operating hours. Express the PM CPMS output as milliamps or the digital signal equivalent.

(4) Calculate the arithmetic 30-day rolling average of all of the hourly average PM CPMS output collected during all energy recovery unit or waste-burning kiln operating hours data (milliamps or digital bits).

(5) You must collect data using the PM CPMS at all times the energy recovery unit or waste-burning kiln is operating and at the intervals specified in paragraph (r)(1)(ii) of this section, except for periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments), and any scheduled maintenance as defined in your site-specific monitoring plan.

(6) You must use all the data collected during all energy recovery unit or waste-burning kiln operating hours in assessing the compliance with your operating limit except:

(i) Any data collected during monitoring system malfunctions, repairs associated with monitoring system malfunctions, or required monitoring system quality assurance or quality control activities conducted during monitoring system malfunctions are not used in calculations (report any such periods in your annual deviation report);

(ii) Any data collected during periods when the monitoring system is out of control as specified in your site-specific monitoring plan, repairs associated with periods when the monitoring system is out of control, or required monitoring system quality assurance or quality control activities conducted during out-of-control periods are not used in calculations (report emissions or operating levels and report any such periods in your annual deviation report); and

(iii) Any PM CPMS data recorded during periods of CEMS data during startup and shutdown, as defined in this subpart.

(7) You must record and make available upon request results of PM CPMS system performance audits, as well as the dates and duration of periods from when the PM CPMS is out of control until completion of the corrective actions necessary to return the PM CPMS to operation consistent with your site-specific monitoring plan.

(8) For any deviation of the 30-day rolling average PM CPMS average value from the established operating parameter limit, you must:

(i) Within 48 hours of the deviation, visually inspect the air pollution control device;

(ii) If inspection of the air pollution control device identifies the cause of the deviation, take corrective action as soon as possible and return the PM CPMS measurement to within the established value;

(iii) Within 30 days of the deviation or at the time of the annual compliance test, whichever comes first, conduct a PM emissions compliance test to determine compliance with the PM emissions limit and to verify the operation of the emissions control device(s). Within 45 days of the deviation, you must re-establish the CPMS operating limit. You are not required to conduct additional testing for any deviations that occur between the time of the original deviation and the PM emissions compliance test required under this paragraph; and

(iv) PM CPMS deviations leading to more than four required performance

tests in a 12-month process operating period (rolling monthly) constitute a violation of this subpart.

(s) If you use a dry scrubber to comply with the emission limits of this subpart, you must monitor the injection rate of each sorbent and maintain the 3-hour block averages at or above the operating limits established during the hydrogen chloride performance test.

(t) If you are required to monitor clinker production because you comply with the production-rate based mercury limit for your waste-burning kiln, you must:

(1) Determine hourly clinker production by one of two methods:

(i) Install, calibrate, maintain, and operate a permanent weigh scale system to measure and record weight rates in tons-mass per hour of the amount of clinker produced. The system of measuring hourly clinker production must be maintained within ±5 percent accuracy, or

(ii) Install, calibrate, maintain, and operate a permanent weigh scale system to measure and record weight rates in tons-mass per hour of the amount of feed to the kiln. The system of measuring feed must be maintained within ±5 percent accuracy. Calculate your hourly clinker production rate using a kiln-specific feed to clinker ratio based on reconciled clinker production determined for accounting purposes and recorded feed rates. Update this ratio monthly. Note that if this ratio changes at clinker reconciliation, you must use the new ratio going forward, but you do not have to retroactively change clinker production rates previously estimated.

(2) Determine the accuracy of the system of measuring hourly clinker production (or feed mass flow if applicable) before the final compliance date of this rule and during each quarter of source operation.

(3) Conduct accuracy checks in accordance with the procedures outlined in your site-specific monitoring plan under § 60.2710(l).

§ 60.2735 Is there a minimum amount of monitoring data I must obtain?

For each continuous monitoring system required or optionally allowed under § 60.2730, you must monitor and collect data according to this section:

(a) You must operate the monitoring system and collect data at all required intervals at all times compliance is required except for periods of monitoring system malfunctions or out-of-control periods, repairs associated with monitoring system malfunctions or out-of-control periods (as specified in § 60.2770(o)), and required monitoring system quality assurance or quality control activities including, as applicable, calibration checks and required zero and span adjustments. A monitoring system malfunction is any sudden, infrequent, not reasonably preventable failure of the monitoring system to provide valid data. Monitoring system failures that are caused in part by poor maintenance or careless operation are not malfunctions. You are required to effect monitoring system repairs in response to monitoring system malfunctions or out-of-control periods and to return the monitoring system to operation as expeditiously as practicable.

(b) You may not use data recorded during the monitoring system malfunctions, repairs associated with monitoring system malfunctions or out-of control periods, or required monitoring system quality assurance or control activities in calculations used to report emissions or operating levels. You must use all the data collected during all other periods, including data normalized for above scale readings, in assessing the operation of the control device and associated control system.

(c) Except for periods of monitoring system malfunctions or out-of-control periods, repairs associated with monitoring system malfunctions or out-of-control periods, and required monitoring system quality assurance or quality control activities including, as applicable, calibration checks and required zero and span adjustments, failure to collect required data is a deviation of the monitoring requirements.

Model Rule—Recordkeeping and Reporting

§ 60.2740 What records must I keep?

You must maintain the items (as applicable) as specified in paragraphs (a), (b), and (e) through (w) of this section for a period of at least 5 years:

(a) Calendar date of each record;

(b) Records of the data described in paragraphs (b)(1) through (7) of this section:

(1) The CISWI charge dates, times, weights, and hourly charge rates;

(2) Liquor flow rate to the wet scrubber inlet every 15 minutes of operation, as applicable;

(3) Pressure drop across the wet scrubber system every 15 minutes of operation or amperage to the wet scrubber every 15 minutes of operation, as applicable;

(4) Liquor pH as introduced to the wet scrubber every 15 minutes of operation, as applicable;

(5) For affected CISWIs that establish operating limits for controls other than wet scrubbers under § 60.2675(d) through (g) or § 60.2680, you must maintain data collected for all operating parameters used to determine compliance with the operating limits. For energy recovery units using activated carbon injection or a dry scrubber, you must also maintain records of the load fraction and corresponding sorbent injection rate records; and

(6) If a fabric filter is used to comply with the emission limitations, you must record the date, time, and duration of each alarm and the time corrective action was initiated and completed, and a brief description of the cause of the alarm and the corrective action taken. You must also record the percent of operating time during each 6-month period that the alarm sounds, calculated as specified in § 60.2675(c).

(7) If you monitor clinker production in accordance with § 60.2730(t):

(i) Hourly clinker rate produced if clinker production is measured directly;

(ii) Hourly measured kiln feed rates and calculated clinker production rates if clinker production is not measured directly;

(iii) 30-day rolling averages for mercury in pounds per million tons of clinker produced;

(iv) The initial and quarterly accuracy of the system of measruing hourly clinker production (or feed mass flow).

(c)–(d) [Reserved]

(e) Identification of calendar dates and times for which data show a deviation from the operating limits in table 3 of this subpart or a deviation from other operating limits established under § 60.2675(d) through (g) or § 60.2680 with a description of the deviations, reasons for such deviations, and a description of corrective actions taken.

(f) The results of the initial, annual, and any subsequent performance tests conducted to determine compliance with the emission limits and/or to establish operating limits, as applicable. Retain a copy of the complete test report including calculations.

(g) Records showing the names of CISWI operators who have completed review of the information in § 60.2660(a) as required by § 60.2660(b), including the date of the initial review and all subsequent annual reviews.

(h) Records showing the names of the CISWI operators who have completed the operator training requirements under § 60.2635, met the criteria for qualification under § 60.2645, and maintained or renewed their qualification under § 60.2650 or § 60.2655. Records must include documentation of training, the dates of

the initial and refresher training, and the dates of their qualification and all subsequent renewals of such qualifications.

(i) For each qualified operator, the phone and/or pager number at which they can be reached during operating hours.

(j) Records of calibration of any monitoring devices as required under § 60.2730.

(k) Equipment vendor specifications and related operation and maintenance requirements for the incinerator, emission controls, and monitoring equipment.

(l) The information listed in § 60.2660(a).

(m) On a daily basis, keep a log of the quantity of waste burned and the types of waste burned (always required).

(n) Maintain records of the annual air pollution control device inspections that are required for each CISWI subject to the emissions limits in table 2 of this subpart or tables 6 through 9 of this subpart, any required maintenance and any repairs not completed within 10 days of an inspection or the timeframe established by the state regulatory agency.

(o) For continuously monitored pollutants or parameters, you must document and keep a record of the following parameters measured using continuous monitoring systems. If you monitor emissions with a CEMS, you must indicate which data are CEMS data during startup and shutdown:

(1) All 6-minute average levels of opacity;

(2) All 1-hour average concentrations of sulfur dioxide emissions;

(3) All 1-hour average concentrations of nitrogen oxides emissions;

(4) All 1-hour average concentrations of carbon monoxide emissions;

(5) All 1-hour average concentrations of particulate matter emissions;

(6) All 1-hour average concentrations of mercury emissions;

(7) All 1-hour average concentrations of HCl CEMS outputs;

(8) All 1-hour average percent oxygen concentrations; and

(9) All 1-hour average PM CPMS readings or particulate matter CEMS outputs.

(p) Records indicating use of the bypass stack, including dates, times and durations.

(q) If you choose to stack test less frequently than annually, consistent with § 60.2720(a) through (c), you must keep annual records that document that your emissions in the previous stack test(s) were less than 75 percent of the applicable emission limit and document that there was no change in source operations including fuel composition and operation of air pollution control equipment that would cause emissions of the relevant pollutant to increase within the past year.

(r) Records of the occurrence and duration of each malfunction of operation (*i.e.,* process equipment) or the air pollution control and monitoring equipment.

(s) Records of all required maintenance performed on the air pollution control and monitoring equipment.

(t) Records of actions taken during periods of malfunction to minimize emissions in accordance with § 60.11(d), including corrective actions to restore malfunctioning process and air pollution control and monitoring equipment to its normal or usual manner of operation.

(u) For operating units that combust non-hazardous secondary materials that have been determined not to be solid waste pursuant to § 241.3(b)(1) of this chapter, you must keep a record which documents how the secondary material meets each of the legitimacy criteria under § 241.3(d)(1). If you combust a fuel that has been processed from a discarded non-hazardous secondary material pursuant to § 241.3(b)(4), you must keep records as to how the operations that produced the fuel satisfies the definition of processing in § 241.2 and each of the legitimacy criteria in § 241.3(d)(1) of this chapter. If the fuel received a non-waste determination pursuant to the petition process submitted under § 241.3(c), you must keep a record that documents how the fuel satisfies the requirements of the petition process. For operating units that combust non-hazardous secondary materials as fuel per § 241.4, you must keep records documenting that the material is a listed non-waste under § 241.4(a).

(v) Records of the criteria used to establish that the unit qualifies as a small power production facility under section 3(17)(C) of the Federal Power Act (16 U.S.C. 796(17)(C)) and that the waste material the unit is proposed to burn is homogeneous.

(w) Records of the criteria used to establish that the unit qualifies as a cogeneration facility under section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B)) and that the waste material the unit is proposed to burn is homogeneous.

§ 60.2745 Where and in what format must I keep my records?

All records must be available onsite in either paper copy or computer-readable format that can be printed upon request, unless an alternative format is approved by the Administrator.

§ 60.2750 What reports must I submit?

See table 5 of this subpart for a summary of the reporting requirements.

§ 60.2755 When must I submit my waste management plan?

You must submit the waste management plan no later than the date specified in table 1 of this subpart for submittal of the final control plan.

§ 60.2760 What information must I submit following my initial performance test?

You must submit the information specified in paragraphs (a) through (c) of this section no later than 60 days following the initial performance test. All reports must be signed by the facilities manager:

(a) The complete test report for the initial performance test results obtained under § 60.2700, as applicable;

(b) The values for the site-specific operating limits established in § 60.2675 or § 60.2680; and

(c) If you are using a fabric filter to comply with the emission limitations, documentation that a bag leak detection system has been installed and is being operated, calibrated, and maintained as required by § 60.2730(b).

§ 60.2765 When must I submit my annual report?

You must submit an annual report no later than 12 months following the submission of the information in § 60.2760. You must submit subsequent reports no more than 12 months following the previous report. (If the unit is subject to permitting requirements under title V of the Clean Air Act, you may be required by the permit to submit these reports more frequently.)

§ 60.2770 What information must I include in my annual report?

The annual report required under § 60.2765 must include the items listed in paragraphs (a) through (p) of this section. If you have a deviation from the operating limits or the emission limitations, you must also submit deviation reports as specified in §§ 60.2775, 60.2780, and 60.2785:

(a) Company name and address;

(b) Statement by a responsible official, with that official's name, title, and signature, certifying the accuracy of the content of the report;

(c) Date of report and beginning and ending dates of the reporting period;

(d) The values for the operating limits established pursuant to § 60.2675 or § 60.2680;

(e) If no deviation from any emission limitation or operating limit that applies

to you has been reported, a statement that there was no deviation from the emission limitations or operating limits during the reporting period;

(f) The highest recorded 3-hour average and the lowest recorded 3-hour average (30-day average for energy recovery units), as applicable, for each operating parameter recorded for the calendar year being reported;

(g) Information recorded under § 60.2740(b)(6) and (c) through (e) for the calendar year being reported;

(h) For each performance test conducted during the reporting period, if any performance test is conducted, the process unit(s) tested, the pollutant(s) tested and the date that such performance test was conducted. Submit, following the procedure specified in § 60.2795(b)(1), the performance test report no later than the date that you submit the annual report;

(i) If you met the requirements of § 60.2720(a) or (b), and did not conduct a performance test during the reporting period, you must state that you met the requirements of § 60.2720(a) or (b), and, therefore, you were not required to conduct a performance test during the reporting period;

(j) Documentation of periods when all qualified CISWI operators were unavailable for more than 8 hours, but less than 2 weeks;

(k) If you had a malfunction during the reporting period, the compliance report must include the number, duration, and a brief description for each type of malfunction that occurred during the reporting period and that caused or may have caused any applicable emission limitation to be exceeded. The report must also include a description of actions taken by an owner or operator during a malfunction of an affected source to minimize emissions in accordance with § 60.11(d), including actions taken to correct a malfunction;

(l) For each deviation from an emission or operating limitation that occurs for a CISWI for which you are not using a CMS to comply with the emission or operating limitations in this subpart, the annual report must contain the following information:

(1) The total operating time of the CISWI at which the deviation occurred during the reporting period; and

(2) Information on the number, duration, and cause of deviations (including unknown cause, if applicable), as applicable, and the corrective action taken.

(m) If there were periods during which the continuous monitoring system, including the CEMS, was out of control as specified in paragraph (o) of this section, the annual report must contain the following information for each deviation from an emission or operating limitation occurring for a CISWI for which you are using a continuous monitoring system to comply with the emission and operating limitations in this subpart:

(1) The date and time that each malfunction started and stopped;

(2) The date, time, and duration that each CMS was inoperative, except for zero (low-level) and high-level checks;

(3) The date, time, and duration that each continuous monitoring system was out-of-control, including start and end dates and hours and descriptions of corrective actions taken;

(4) The date and time that each deviation started and stopped, and whether each deviation occurred during a period of malfunction or during another period;

(5) A summary of the total duration of the deviation during the reporting period, and the total duration as a percent of the total source operating time during that reporting period;

(6) A breakdown of the total duration of the deviations during the reporting period into those that are due to control equipment problems, process problems, other known causes, and other unknown causes;

(7) A summary of the total duration of continuous monitoring system downtime during the reporting period, and the total duration of continuous monitoring system downtime as a percent of the total operating time of the CISWI at which the continuous monitoring system downtime occurred during that reporting period;

(8) An identification of each parameter and pollutant that was monitored at the CISWI;

(9) A brief description of the CISWI;

(10) A brief description of the continuous monitoring system;

(11) The date of the latest continuous monitoring system certification or audit; and

(12) A description of any changes in continuous monitoring system, processes, or controls since the last reporting period.

(n) If there were periods during which the continuous monitoring system, including the CEMS, was not out of control as specified in paragraph (o) of this section, a statement that there were not periods during which the continuous monitoring system was out of control during the reporting period.

(o) A continuous monitoring system is out of control if any of the following occur:

(1) The zero (low-level), mid-level (if applicable), or high-level calibration drift exceeds two times the applicable calibration drift specification in the applicable performance specification or in the relevant standard;

(2) The continuous monitoring system fails a performance test audit (*e.g.,* cylinder gas audit), relative accuracy audit, relative accuracy test audit, or linearity test audit; and

(3) The continuous opacity monitoring system calibration drift exceeds two times the limit in the applicable performance specification in the relevant standard.

(p) For energy recovery units, include the annual heat input and average annual heat input rate of all fuels being burned in the unit to verify which subcategory of energy recovery unit applies.

§ 60.2775 What else must I report if I have a deviation from the operating limits or the emission limitations?

(a) You must submit a deviation report if any recorded 3-hour average (30-day average for energy recovery units or for PM CPMS) parameter level is above the maximum operating limit or below the minimum operating limit established under this subpart, if the bag leak detection system alarm sounds for more than 5 percent of the operating time for the 6-month reporting period, if a performance test was conducted that deviated from any emission limitation, if a 30-day average measured using a CEMS deviated from any emission limitation.

(b) The deviation report must be submitted by August 1 of that year for data collected during the first half of the calendar year (January 1 to June 30), and by February 1 of the following year for data you collected during the second half of the calendar year (July 1 to December 31).

§ 60.2780 What must I include in the deviation report?

In each report required under § 60.2775, for any pollutant or parameter that deviated from the emission limitations or operating limits specified in this subpart, include the four items described in paragraphs (a) through (d) of this section:

(a) The calendar dates and times your unit deviated from the emission limitations or operating limit requirements;

(b) The averaged and recorded data for those dates;

(c) Durations and causes of the following:

(1) Each deviation from emission limitations or operating limits and your corrective actions; and

(2) Bypass events and your corrective actions.

(d) A copy of the operating limit monitoring data during each deviation and for any test report that documents the emission levels the process unit(s) tested, the pollutant(s) tested and the date that the performance test was conducted. Submit, following the procedure specified in § 60.2795(b)(1), the performance test report no later than the date that you submit the deviation report.

§ 60.2785 What else must I report if I have a deviation from the requirement to have a qualified operator accessible?

(a) If all qualified operators are not accessible for 2 weeks or more, you must take the two actions in paragraphs (a)(1) and (2) of this section:

(1) Submit a notification of the deviation within 10 days that includes the three items in paragraphs (a)(1)(i) through (iii) of this section:

(i) A statement of what caused the deviation;

(ii) A description of what you are doing to ensure that a qualified operator is accessible; and

(iii) The date when you anticipate that a qualified operator will be available.

(2) Submit a status report to the Administrator every 4 weeks that includes the three items in paragraphs (a)(2)(i) through (iii) of this section:

(i) A description of what you are doing to ensure that a qualified operator is accessible;

(ii) The date when you anticipate that a qualified operator will be accessible; and

(iii) Request approval from the Administrator to continue operation of the CISWI.

(b) If your unit was shut down by the Administrator, under the provisions of § 60.2665(b)(2), due to a failure to provide an accessible qualified operator, you must notify the Administrator that you are resuming operation once a qualified operator is accessible.

§ 60.2790 Are there any other notifications or reports that I must submit?

(a) Yes. You must submit notifications as provided by § 60.7.

(b) If you cease combusting solid waste but continue to operate, you must provide 30 days prior notice of the effective date of the waste-to-fuel switch, consistent with § 60.2710(a). The notification must identify:

(1) The name of the owner or operator of the CISWI, the location of the source, the emissions unit(s) that will cease burning solid waste, and the date of the notice;

(2) The currently applicable subcategory under this subpart, and any 40 CFR part 63 subpart and subcategory that will be applicable after you cease combusting solid waste;

(3) The fuel(s), non-waste material(s) and solid waste(s) the CISWI is currently combusting and has combusted over the past 6 months, and the fuel(s) or non-waste materials the unit will commence combusting;

(4) The date on which you became subject to the currently applicable emission limits; and

(5) The date upon which you will cease combusting solid waste, and the date (if different) that you intend for any new requirements to become applicable (*i.e.,* the effective date of the waste-to-fuel switch), consistent with paragraphs (b)(2) and (3) of this section.

§ 60.2795 In what form can I submit my reports?

(a) Submit initial, annual and deviation reports electronically or in paper format, postmarked on or before the submittal due dates. Beginning on April 16, 2021 or once the reporting form has been available in CEDRI for 1 year, whichever is later, you must submit subsequent reports on or before the submittal dates to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI), which CEDRI can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*). Use the appropriate electronic report in CEDRI for this subpart or an alternate electronic file format consistent with the extensible markup language (XML) schema listed on the CEDRI website (*https://www3.epa.gov/ttn/chief/cedri/index.html*). When the date forms become available in CEDRI will be listed on the CEDRI website. The reports must be submitted by the deadlines specified in this subpart, regardless of the method in which the report is submitted.

(b) Submit results of each performance test and CEMS performance evaluation required by this subpart as follows:

(1) Within 60 days after the date of completing each performance test (*see* § 60.8) required by this subpart, you must submit the results of the performance test following the procedure specified in either paragraph (b)(1)(i) or (b)(1)(ii) of this section:

(i) For data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (*https://www3.epa.gov/ttn/chief/ert/ert_info.html*) at the time of the test, you must submit the results of the performance test to the EPA via the CEDRI. (CEDRI can be accessed through the EPA's CDX (*https://cdx.epa.gov/*).) Performance test data must be submitted in a file format generated through the use of the EPA's ERT or an alternate electronic file format consistent with the XML schema listed on the EPA's ERT website. If you claim that some of the performance test information being submitted is confidential business information (CBI), you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage media to the EPA. The electronic media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph; and

(ii) For data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test, you must submit the results of the performance test to the Administrator at the appropriate address listed in § 60.4.

(2) Within 60 days after the date of completing each continuous emissions monitoring system performance evaluation you must submit the results of the performance evaluation following the procedure specified in either paragraph (b)(1) or (2) of this section:

(i) For performance evaluations of continuous monitoring systems measuring relative accuracy test audit (RATA) pollutants that are supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation, you must submit the results of the performance evaluation to the EPA via the CEDRI. CEDRI can be accessed through the EPA's CDX. Performance evaluation data must be submitted in a file format generated through the use of the EPA's ERT or an alternate file format consistent with the XML schema listed on the EPA's ERT website. If you claim that some of the performance evaluation information being submitted is CBI, you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage media to the EPA. The electronic storage media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention:

Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph; and

(ii) For any performance evaluations of continuous monitoring systems measuring RATA pollutants that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation, you must submit the results of the performance evaluation to the Administrator at the appropriate address listed in § 60.4.

(c) If you are required to electronically submit a report through the Compliance and Emissions Data Reporting Interface (CEDRI) in the EPA's Central Data Exchange (CDX), and due to a planned or actual outage of either the EPA's CEDRI or CDX systems within the period of time beginning 5 business days prior to the date that the submission is due, you will be or are precluded from accessing CEDRI or CDX and submitting a required report within the time prescribed, you may assert a claim of EPA system outage for failure to timely comply with the reporting requirement. You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or caused a delay in reporting. You must provide to the Administrator a written description identifying the date, time and length of the outage; a rationale for attributing the delay in reporting beyond the regulatory deadline to the EPA system outage; describe the measures taken or to be taken to minimize the delay in reporting; and identify a date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported. In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved. The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(d) If you are required to electronically submit a report through CEDRI in the EPA's CDX and a force majeure event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning 5 business days prior to the date the submission is due, the owner or operator may assert a claim of force majeure for failure to timely comply with the reporting requirement. For the purposes of this section, a force majeure event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (*e.g.,* hurricanes, earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (*e.g.,* large scale power outage). If you intend to assert a claim of force majeure, you must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or caused a delay in reporting. You must provide to the Administrator a written description of the force majeure event and a rationale for attributing the delay in reporting beyond the regulatory deadline to the force majeure event; describe the measures taken or to be taken to minimize the delay in reporting; and identify a date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported. In any circumstance, the reporting must occur as soon as possible after the force majeure event occurs. The decision to accept the claim of force majeure and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

§ 60.2800 Can reporting dates be changed?

If the Administrator agrees, you may change the semiannual or annual reporting dates. See § 60.19(c) for procedures to seek approval to change your reporting date.

Model Rule—Title V Operating Permits

§ 60.2805 Am I required to apply for and obtain a Title V operating permit for my unit?

Yes. Each CISWI and ACI subject to standards under this subpart must operate pursuant to a permit issued under Clean Air Act sections 129(e) and Title V.

Model Rule—Air Curtain Incinerators (ACIs)

§ 60.2810 What is an air curtain incinerator?

(a) An ACI operates by forcefully projecting a curtain of air across an open chamber or open pit in which combustion occurs. Incinerators of this type can be constructed above or below ground and with or without refractory walls and floor. Air curtain incinerators are not to be confused with conventional combustion devices with enclosed fireboxes and controlled air technology such as mass burn, modular, and fluidized bed combustors.

(b) Air curtain incinerators that burn only the materials listed in paragraphs (b)(1) through (3) of this section are only required to meet the requirements under § 60.2805 and under ''Air Curtain Incinerators'' (§§ 60.2810 through 60.2870):

(1) 100 percent wood waste;

(2) 100 percent clean lumber; and

(3) 100 percent mixture of only wood waste, clean lumber, and/or yard waste.

§ 60.2815 What are my requirements for meeting increments of progress and achieving final compliance?

If you plan to achieve compliance more than 1 year following the effective date of state plan approval, you must meet the two increments of progress specified in paragraphs (a) and (b) of this section:

(a) Submit a final control plan; and

(b) Achieve final compliance.

§ 60.2820 When must I complete each increment of progress?

Table 1 of this subpart specifies compliance dates for each of the increments of progress.

§ 60.2825 What must I include in the notifications of achievement of increments of progress?

Your notification of achievement of increments of progress must include the three items described in paragraphs (a) through (c) of this section:

(a) Notification that the increment of progress has been achieved;

(b) Any items required to be submitted with each increment of progress (see § 60.2840); and

(c) Signature of the owner or operator of the incinerator.

§ 60.2830 When must I submit the notifications of achievement of increments of progress?

Notifications for achieving increments of progress must be postmarked no later than 10 business days after the compliance date for the increment.

§ 60.2835 What if I do not meet an increment of progress?

If you fail to meet an increment of progress, you must submit a notification to the Administrator postmarked within 10 business days after the date for that increment of progress in table 1 of this subpart. You must inform the Administrator that you did not meet the increment, and you must continue to submit reports each subsequent

calendar month until the increment of progress is met.

§ 60.2840 How do I comply with the increment of progress for submittal of a control plan?

For your control plan increment of progress, you must satisfy the two requirements specified in paragraphs (a) and (b) of this section:

(a) Submit the final control plan, including a description of any devices for air pollution control and any process changes that you will use to comply with the emission limitations and other requirements of this subpart; and

(b) Maintain an onsite copy of the final control plan.

§ 60.2845 How do I comply with the increment of progress for achieving final compliance?

For the final compliance increment of progress, you must complete all process changes and retrofit construction of control devices, as specified in the final control plan, so that, if the affected incinerator is brought online, all necessary process changes and air pollution control devices would operate as designed.

§ 60.2850 What must I do if I close my air curtain incinerator and then restart it?

(a) If you close your incinerator but will reopen it prior to the final compliance date in your state plan, you must meet the increments of progress specified in § 60.2815.

(b) If you close your incinerator but will restart it after your final compliance date, you must complete emission control retrofits and meet the emission limitations on the date your incinerator restarts operation.

§ 60.2855 What must I do if I plan to permanently close my air curtain incinerator and not restart it?

If you plan to close your incinerator rather than comply with the state plan, submit a closure notification, including the date of closure, to the Administrator by the date your final control plan is due.

§ 60.2860 What are the emission limitations for air curtain incinerators?

After the date the initial stack test is required or completed (whichever is earlier), you must meet the limitations in paragraphs (a) and (b) of this section:

(a) Maintain opacity to less than or equal to 10 percent opacity (as determined by the average of three 1-hour blocks consisting of ten 6-minute average opacity values), except as described in paragraph (b) of this section; and

(b) Maintain opacity to less than or equal to 35 percent opacity (as determined by the average of three 1-hour blocks consisting of ten 6-minute average opacity values) during the startup period that is within the first 30 minutes of operation.

§ 60.2865 How must I monitor opacity for air curtain incinerators?

(a) Use Method 9 of appendix A of this part to determine compliance with the opacity limitation.

(b) Conduct an initial test for opacity as specified in § 60.8 no later than 180 days after your final compliance date.

(c) After the initial test for opacity, conduct annual tests no more than 12 calendar months following the date of your previous test.

§ 60.2870 What are the recordkeeping and reporting requirements for air curtain incinerators?

(a) Keep records of results of all initial and annual opacity tests onsite in either paper copy or electronic format, unless the Administrator approves another format, for at least 5 years.

(b) Make all records available for submittal to the Administrator or for an inspector's onsite review.

(c) Submit an initial report no later than 60 days following the initial opacity test that includes the information specified in paragraphs (c)(1) and (2) of this section:

(1) The types of materials you plan to combust in your ACI; and

(2) The results (as determined by the average of three 1-hour blocks consisting of ten 6-minute average opacity values) of the initial opacity tests.

(d) Submit annual opacity test results within 12 months following the previous report.

(e) Submit initial and annual opacity test reports as electronic or paper copy on or before the applicable submittal date and keep a copy onsite for a period of 5 years.

Model Rule—Definitions

§ 60.2875 What definitions must I know?

Terms used but not defined in this subpart are defined in the Clean Air Act and subparts A and B of this part.

30-day rolling average means the arithmetic mean of the previous 720 hours of valid operating data. Valid data excludes periods when this unit is not operating. The 720 hours should be consecutive, but not necessarily continuous if operations are intermittent.

Administrator means the Administrator of the U.S. Environmental Protection Agency or his/her authorized representative or Administrator of a State Air Pollution Control Agency.

Agricultural waste means vegetative agricultural materials such as nut and grain hulls and chaff (*e.g.,* almond, walnut, peanut, rice, and wheat), bagasse, orchard prunings, corn stalks, coffee bean hulls and grounds, and other vegetative waste materials generated as a result of agricultural operations.

Air curtain incinerator (ACI) means an incinerator that operates by forcefully projecting a curtain of air across an open chamber or pit in which combustion occurs. Incinerators of this type can be constructed above or below ground and with or without refractory walls and floor. Air curtain incinerators are not to be confused with conventional combustion devices with enclosed fireboxes and controlled air technology such as mass burn, modular, and fluidized bed combustors.

Annual heat input means the heat input for the 12 months preceding the compliance demonstration.

Auxiliary fuel means natural gas, liquified petroleum gas, fuel oil, or diesel fuel.

Average annual heat input rate means annual heat input divided by the hours of operation for the 12 months preceding the compliance demonstration.

Bag leak detection system means an instrument that is capable of monitoring particulate matter loadings in the exhaust of a fabric filter (*i.e.,* baghouse) in order to detect bag failures. A bag leak detection system includes, but is not limited to, an instrument that operates on triboelectric, light scattering, light transmittance, or other principle to monitor relative particulate matter loadings.

Burn-off oven means any rack reclamation unit, part reclamation unit, or drum reclamation unit. A burn-off oven is not an incinerator, waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Bypass stack means a device used for discharging combustion gases to avoid severe damage to the air pollution control device or other equipment.

Calendar quarter means three consecutive months (nonoverlapping) beginning on: January 1, April 1, July 1, or October 1.

Calendar year means 365 consecutive days starting on January 1 and ending on December 31.

CEMS data during startup and shutdown means the following:

(1) For incinerators and small remote incinerators: CEMS data collected during the first hours of operation of a CISWI startup from a cold start until waste is fed into the unit and the hours

of operation following the cessation of waste material being fed to the CISWI during a unit shutdown. For each startup event, the length of time that CEMS data may be claimed as being CEMS data during startup must be 48 operating hours or less. For each shutdown event, the length of time that CEMS data may be claimed as being CEMS data during shutdown must be 24 operating hours or less;

(2) For energy recovery units: CEMS data collected during the startup or shutdown periods of operation. Startup begins with either the first-ever firing of fuel in a boiler or process heater for the purpose of supplying useful thermal energy (such as steam or heat) for heating, cooling or process purposes, or producing electricity, or the firing of fuel in a boiler or process heater for any purpose after a shutdown event. Startup ends four hours after when the boiler or process heater makes useful thermal energy (such as heat or steam) for heating, cooling, or process purposes, or generates electricity, whichever is earlier. Shutdown begins when the boiler or process heater no longer makes useful thermal energy (such as heat or steam) for heating, cooling, or process purposes and/or generates electricity or when no fuel is being fed to the boiler or process heater, whichever is earlier. Shutdown ends when the boiler or process heater no longer makes useful thermal energy (such as steam or heat) for heating, cooling, or process purposes and/or generates electricity, and no fuel is being combusted in the boiler or process heater; and

(3) For waste-burning kilns: CEMS data collected during the periods of kiln operation that do not include normal operations. Startup means the time from when a shutdown kiln first begins firing fuel until it begins producing clinker. Startup begins when a shutdown kiln turns on the induced draft fan and begins firing fuel in the main burner. Startup ends when feed is being continuously introduced into the kiln for at least 120 minutes or when the feed rate exceeds 60 percent of the kiln design limitation rate, whichever occurs first. Shutdown means the cessation of kiln operation. Shutdown begins when feed to the kiln is halted and ends when continuous kiln rotation ceases.

Chemical recovery unit means combustion units burning materials to recover chemical constituents or to produce chemical compounds where there is an existing commercial market for such recovered chemical constituents or compounds. A chemical recovery unit is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart. The following seven types of units are considered chemical recovery units:

(1) Units burning only pulping liquors (*i.e.,* black liquor) that are reclaimed in a pulping liquor recovery process and reused in the pulping process;

(2) Units burning only spent sulfuric acid used to produce virgin sulfuric acid;

(3) Units burning only wood or coal feedstock for the production of charcoal;

(4) Units burning only manufacturing byproduct streams/residue containing catalyst metals that are reclaimed and reused as catalysts or used to produce commercial grade catalysts;

(5) Units burning only coke to produce purified carbon monoxide that is used as an intermediate in the production of other chemical compounds;

(6) Units burning only hydrocarbon liquids or solids to produce hydrogen, carbon monoxide, synthesis gas, or other gases for use in other manufacturing processes; and

(7) Units burning only photographic film to recover silver.

Chemotherapeutic waste means waste material resulting from the production or use of antineoplastic agents used for the purpose of stopping or reversing the growth of malignant cells.

Clean lumber means wood or wood products that have been cut or shaped and include wet, air-dried, and kiln-dried wood products. Clean lumber does not include wood products that have been painted, pigment-stained, or pressure-treated by compounds such as chromate copper arsenate, pentachlorophenol, and creosote.

Commercial and industrial solid waste incineration unit (CISWI) means any distinct operating unit of any commercial or industrial facility that combusts, or has combusted in the preceding 6 months, any solid waste as that term is defined in 40 CFR part 241. If the operating unit burns materials other than traditional fuels as defined in § 241.2 that have been discarded, and you do not keep and produce records as required by § 60.2740(u), the operating unit is a CISWI. While not all CISWIs will include all of the following components, a CISWI includes, but is not limited to, the solid waste feed system, grate system, flue gas system, waste heat recovery equipment, if any, and bottom ash system. The CISWI does not include air pollution control equipment or the stack. The CISWI boundary starts at the solid waste hopper (if applicable) and extends through two areas: The combustion unit flue gas system, which ends immediately after the last combustion chamber or after the waste heat recovery equipment, if any; and the combustion unit bottom ash system, which ends at the truck loading station or similar equipment that transfers the ash to final disposal. The CISWI includes all ash handling systems connected to the bottom ash handling system.

Contained gaseous material means gases that are in a container when that container is combusted.

Continuous emission monitoring system (CEMS) means the total equipment that may be required to meet the data acquisition and availability requirements of this subpart, used to sample, condition (if applicable), analyze, and provide a record of emissions.

Continuous monitoring system (CMS) means the total equipment, required under the emission monitoring sections in applicable subparts, used to sample and condition (if applicable), to analyze, and to provide a permanent record of emissions or process parameters. A particulate matter continuous parameter monitoring system (PM CPMS) is a type of CMS.

Cyclonic burn barrel means a combustion device for waste materials that is attached to a 55 gallon, open-head drum. The device consists of a lid, which fits onto and encloses the drum, and a blower that forces combustion air into the drum in a cyclonic manner to enhance the mixing of waste material and air. A cyclonic burn barrel is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Deviation means any instance in which an affected source subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart, including but not limited to any emission limitation, operating limit, or operator qualification and accessibility requirements; and

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit.

Dioxins/furans means tetra-through octachlorinated dibenzo-p-dioxins and dibenzofurans.

Discard means, for purposes of this subpart and 40 CFR part 60, subpart DDDD, only, burned in an incineration unit without energy recovery.

Drum reclamation unit means a unit that burns residues out of drums (*e.g.,* 55 gallon drums) so that the drums can be reused.

Dry scrubber means an add-on air pollution control system that injects dry alkaline sorbent (dry injection) or sprays an alkaline sorbent (spray dryer) to react with and neutralize acid gas in the exhaust stream forming a dry powder material. Sorbent injection systems in fluidized bed boilers and process heaters are included in this definition. A dry scrubber is a dry control system.

Energy recovery means the process of recovering thermal energy from combustion for useful purposes such as steam generation or process heating.

Energy recovery unit means a combustion unit combusting solid waste (as that term is defined by the Administrator in 40 CFR part 241) for energy recovery. Energy recovery units include units that would be considered boilers and process heaters if they did not combust solid waste.

Energy recovery unit designed to burn biomass (Biomass) means an energy recovery unit that burns solid waste, biomass, and non-coal solid materials but less than 10 percent coal, on a heat input basis on an annual average, either alone or in combination with liquid waste, liquid fuel or gaseous fuels.

Energy recovery unit designed to burn coal (Coal) means an energy recovery unit that burns solid waste and at least 10 percent coal on a heat input basis on an annual average, either alone or in combination with liquid waste, liquid fuel or gaseous fuels.

Energy recovery unit designed to burn liquid waste materials and gas (Liquid/gas) means an energy recovery unit that burns a liquid waste with liquid or gaseous fuels not combined with any solid fuel or waste materials.

Energy recovery unit designed to burn solid materials (Solids) includes energy recovery units designed to burn coal and energy recovery units designed to burn biomass.

Fabric filter means an add-on air pollution control device used to capture particulate matter by filtering gas streams through filter media, also known as a baghouse.

Foundry sand thermal reclamation unit means a type of part reclamation unit that removes coatings that are on foundry sand. A foundry sand thermal reclamation unit is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Incinerator means any furnace used in the process of combusting solid waste (as that term is defined by the Administrator in 40 CFR part 241) for the purpose of reducing the volume of the waste by removing combustible matter. Incinerator designs include single chamber and two-chamber.

In-line coal mill means those coal mills using kiln exhaust gases in their process. Coal mills with a heat source other than the kiln or coal mills using exhaust gases from the clinker cooler alone are not an in-line coal mill.

In-line kiln/raw mill means a system in a Portland Cement production process where a dry kiln system is integrated with the raw mill so that all or a portion of the kiln exhaust gases are used to perform the drying operation of the raw mill, with no auxiliary heat source used. In this system the kiln is capable of operating without the raw mill operating, but the raw mill cannot operate without the kiln gases, and consequently, the raw mill does not generate a separate exhaust gas stream.

Kiln means an oven or furnace, including any associated preheater or precalciner devices, in-line raw mills, in-line coal mills or alkali bypasses used for processing a substance by burning, firing or drying. Kilns include cement kilns that produce clinker by heating limestone and other materials for subsequent production of Portland Cement. Because the alkali bypass, in-line raw mill and in-line coal mill are considered an integral part of the kiln, the kiln emissions limits also apply to the exhaust of the alkali bypass, in-line raw mill and in-line coal mill.

Laboratory analysis unit means units that burn samples of materials for the purpose of chemical or physical analysis. A laboratory analysis unit is not an incinerator, waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Load fraction means the actual heat input of an energy recovery unit divided by heat input during the performance test that established the minimum sorbent injection rate or minimum activated carbon injection rate, expressed as a fraction (*e.g.,* for 50 percent load the load fraction is 0.5).

Low-level radioactive waste means waste material which contains radioactive nuclides emitting primarily beta or gamma radiation, or both, in concentrations or quantities that exceed applicable federal or state standards for unrestricted release. Low-level radioactive waste is not high-level radioactive waste, spent nuclear fuel, or by-product material as defined by the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)(2)).

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, process equipment, or a process to operate in a normal or usual manner. Failures that are caused, in part, by poor maintenance or careless operation are not malfunctions.

Minimum voltage or amperage means 90 percent of the lowest test-run average voltage or amperage to the electrostatic precipitator measured during the most recent particulate matter or mercury performance test demonstrating compliance with the applicable emission limits.

Modification or *modified CISWI* means a CISWI that has been changed later than August 7, 2013, and that meets one of two criteria:

(1) The cumulative cost of the changes over the life of the unit exceeds 50 percent of the original cost of building and installing the CISWI (not including the cost of land) updated to current costs (current dollars). To determine what systems are within the boundary of the CISWI used to calculate these costs, see the definition of CISWI; and

(2) Any physical change in the CISWI or change in the method of operating it that increases the amount of any air pollutant emitted for which section 129 or section 111 of the Clean Air Act has established standards.

Municipal solid waste or municipal-type solid waste means household, commercial/retail, or institutional waste. Household waste includes material discarded by residential dwellings, hotels, motels, and other similar permanent or temporary housing. Commercial/retail waste includes material discarded by stores, offices, restaurants, warehouses, nonmanufacturing activities at industrial facilities, and other similar establishments or facilities. Institutional waste includes materials discarded by schools, by hospitals (nonmedical), by nonmanufacturing activities at prisons and government facilities, and other similar establishments or facilities. Household, commercial/retail, and institutional waste does include yard waste and refuse-derived fuel. Household, commercial/retail, and institutional waste does not include used oil; sewage sludge; wood pallets; construction, renovation, and demolition wastes (which include railroad ties and telephone poles); clean wood; industrial process or manufacturing wastes; medical waste; or motor vehicles (including motor vehicle parts or vehicle fluff).

Opacity means the degree to which emissions reduce the transmission of light and obscure the view of an object in the background.

Operating day means a 24-hour period between 12:00 midnight and the following midnight during which any amount of solid waste is combusted at any time in the CISWI.

Oxygen analyzer system means all equipment required to determine the

oxygen content of a gas stream and used to monitor oxygen in the boiler or process heater flue gas, boiler/process heater, firebox, or other appropriate location. This definition includes oxygen trim systems and certified oxygen CEMS. The source owner or operator is responsible to install, calibrate, maintain, and operate the oxygen analyzer system in accordance with the manufacturer's recommendations.

Oxygen trim system means a system of monitors that is used to maintain excess air at the desired level in a combustion device over its operating range. A typical system consists of a flue gas oxygen and/or carbon monoxide monitor that automatically provides a feedback signal to the combustion air controller or draft controller.

Part reclamation unit means a unit that burns coatings off parts (*e.g.,* tools, equipment) so that the parts can be reconditioned and reused.

Particulate matter means total particulate matter emitted from CISWIs as measured by Method 5 or Method 29 of appendix A of this part.

Pathological waste means waste material consisting of only human or animal remains, anatomical parts, and/or tissue, the bags/containers used to collect and transport the waste material, and animal bedding (if applicable).

Performance evaluation means the conduct of relative accuracy testing, calibration error testing, and other measurements used in validating the continuous monitoring system data.

Performance test means the collection of data resulting from the execution of a test method (usually three emission test runs) used to demonstrate compliance with a relevant emission standard as specified in the performance test section of the relevant standard.

Process change means any of the following physical or operational changes:

(1) A physical change (maintenance activities excluded) to the CISWI which may increase the emission rate of any air pollutant to which a standard applies;

(2) An operational change to the CISWI where a new type of non-hazardous secondary material is being combusted;

(3) A physical change (maintenance activities excluded) to the air pollution control devices used to comply with the emission limits for the CISWI (*e.g.,* replacing an electrostatic precipitator with a fabric filter); and

(4) An operational change to the air pollution control devices used to comply with the emission limits for the affected CISWI (*e.g.,* change in the sorbent injection rate used for activated carbon injection).

Rack reclamation unit means a unit that burns the coatings off racks used to hold small items for application of a coating. The unit burns the coating overspray off the rack so the rack can be reused.

Raw mill means a ball or tube mill, vertical roller mill or other size reduction equipment, that is not part of an in-line kiln/raw mill, used to grind feed to the appropriate size. Moisture may be added or removed from the feed during the grinding operation. If the raw mill is used to remove moisture from feed materials, it is also, by definition, a raw material dryer. The raw mill also includes the air separator associated with the raw mill.

Reconstruction means rebuilding a CISWI and meeting two criteria:

(1) The reconstruction begins on or after August 7, 2013; and

(2) The cumulative cost of the construction over the life of the incineration unit exceeds 50 percent of the original cost of building and installing the CISWI (not including land) updated to current costs (current dollars). To determine what systems are within the boundary of the CISWI used to calculate these costs, see the definition of CISWI.

Refuse-derived fuel means a type of municipal solid waste produced by processing municipal solid waste through shredding and size classification. This includes all classes of refuse-derived fuel including two fuels:

(1) Low-density fluff refuse-derived fuel through densified refuse-derived fuel; and

(2) Pelletized refuse-derived fuel.

Responsible official means one of the following:

(1) For a corporation: A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:

(i) The facilities employ more than 250 persons or have gross annual sales or expenditures exceeding $25 million (in second quarter 1980 dollars); or

(ii) The delegation of authority to such representatives is approved in advance by the permitting authority;

(2) For a partnership or sole proprietorship: a general partner or the proprietor, respectively;

(3) For a municipality, state, federal, or other public agency: Either a principal executive officer or ranking elected official. For the purposes of this part, a principal executive officer of a Federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (*e.g.,* a Regional Administrator of EPA); or

(4) For affected facilities:

(i) The designated representative in so far as actions, standards, requirements, or prohibitions under Title IV of the Clean Air Act or the regulations promulgated thereunder are concerned; or

(ii) The designated representative for any other purposes under part 60.

Shutdown means, for incinerators and small, remote incinerators, the period of time after all waste has been combusted in the primary chamber.

Small, remote incinerator means an incinerator that combusts solid waste (as that term is defined by the Administrator in 40 CFR part 241) and combusts 3 tons per day or less solid waste and is more than 25 miles driving distance to the nearest municipal solid waste landfill.

Soil treatment unit means a unit that thermally treats petroleum-contaminated soils for the sole purpose of site remediation. A soil treatment unit may be direct-fired or indirect fired. A soil treatment unit is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Solid waste means the term solid waste as defined in 40 CFR 241.2.

Solid waste incineration unit means a distinct operating unit of any facility which combusts any solid waste (as that term is defined by the Administrator in 40 CFR part 241) material from commercial or industrial establishments or the general public (including single and multiple residences, hotels and motels). Such term does not include incinerators or other units required to have a permit under section 3005 of the Solid Waste Disposal Act. The term ''solid waste incineration unit'' does not include:

(1) Materials recovery facilities (including primary or secondary smelters) which combust waste for the primary purpose of recovering metals;

(2) Qualifying small power production facilities, as defined in section 3(17)(C) of the Federal Power Act (16 U.S.C. 769(17)(C)), or qualifying cogeneration facilities, as defined in section 3(18)(B) of the Federal Power

Act (16 U.S.C. 796(18)(B)), which burn homogeneous waste (such as units which burn tires or used oil, but not including refuse-derived fuel) for the production of electric energy or in the case of qualifying cogeneration facilities which burn homogeneous waste for the production of electric energy and steam or forms of useful energy (such as heat) which are used for industrial, commercial, heating or cooling purposes; or

(3) Air curtain incinerators provided that such incinerators only burn wood wastes, yard wastes and clean lumber and that such air curtain incinerators comply with opacity limitations to be established by the Administrator by rule.

Space heater means a unit that meets the requirements of 40 CFR 279.23. A space heater is not an incinerator, a waste-burning kiln, an energy recovery unit or a small, remote incinerator under this subpart.

Standard conditions, when referring to units of measure, means a temperature of 68 °F (20 °C) and a pressure of 1 atmosphere (101.3 kilopascals).

Startup period means, for incinerators and small, remote incinerators, the period of time between the activation of the system and the first charge to the unit.

Useful thermal energy means energy (*i.e.,* steam, hot water, or process heat) that meets the minimum operating temperature and/or pressure required by any energy use system that uses energy provided by the affected energy recovery unit.

Waste-burning kiln means a kiln that is heated, in whole or in part, by combusting solid waste (as the term is defined by the Administrator in 40 CFR part 241). Secondary materials used in Portland cement kilns shall not be deemed to be combusted unless they are introduced into the flame zone in the hot end of the kiln or mixed with the precalciner fuel.

Wet scrubber means an add-on air pollution control device that uses an aqueous or alkaline scrubbing liquor to collect particulate matter (including nonvaporous metals and condensed organics) and/or to absorb and neutralize acid gases.

Wood waste means untreated wood and untreated wood products, including tree stumps (whole or chipped), trees, tree limbs (whole or chipped), bark, sawdust, chips, scraps, slabs, millings, and shavings. Wood waste does not include:

(1) Grass, grass clippings, bushes, shrubs, and clippings from bushes and shrubs from residential, commercial/retail, institutional, or industrial sources as part of maintaining yards or other private or public lands;

(2) Construction, renovation, or demolition wastes; or

(3) Clean lumber.

TABLE 1 TO SUBPART DDDD OF PART 60—MODEL RULE—INCREMENTS OF PROGRESS AND COMPLIANCE SCHEDULES

Comply with these increments of progress	By these dates [1]
Increment 1-Submit final control plan	(Dates to be specified in state plan).
Increment 2-Final compliance	(Dates to be specified in state plan).[2]

[1] Site-specific schedules can be used at the discretion of the state.

[2] The date can be no later than 3 years after the effective date of state plan approval or December 1, 2005 for CISWIs that commenced construction on or before November 30, 1999. The date can be no later than 3 years after the effective date of approval of a revised state plan or February 7, 2018, for CISWIs that commenced construction on or before June 4, 2010.

TABLE 2 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO INCINERATORS BEFORE [DATE TO BE SPECIFIED IN STATE PLAN] [1]

For the air pollutant	You must meet this emission limitation [2]	Using this averaging time [3]	And determining compliance using this method [3]
Cadmium	0.004 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 29 of appendix A of this part).
Carbon monoxide	157 parts per million by dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 10, 10A, or 10B, of appendix A of this part).
Dioxins/furans (toxic equivalency basis).	0.41 nanograms per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 23 of appendix A of this part).
Hydrogen chloride	62 parts per million by dry volume	3-run average (For Method 26, collect a minimum volume of 120 liters per run. For Method 26A, collect a minimum volume of 1 dry standard cubic meter per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	0.04 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 29 of appendix A of this part).
Mercury	0.47 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008).[4]
Opacity	10 percent	Three 1-hour blocks consisting of ten 6-minute average opacity values.	Performance test (Method 9 at 40 CFR part 60, appendix A–4).
Nitrogen oxides	388 parts per million by dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Methods 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter	70 milligrams per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Performance test (Method 5 or 29 of appendix A of this part).

TABLE 2 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO INCINERATORS BEFORE [DATE TO BE SPECIFIED IN STATE PLAN] [1]—Continued

For the air pollutant	You must meet this emission limitation [2]	Using this averaging time [3]	And determining compliance using this method [3]
Sulfur dioxide	20 parts per million by dry volume	3-run average (1 hour minimum sample time per run).	Performance test (Method 6 or 6c of appendix A of this part).

[1] Applies only to incinerators subject to the CISWI standards through a state plan or the Federal plan prior to June 4, 2010. The date specified in the state plan can be no later than 3 years after the effective date of approval of a revised state plan or February 7, 2018.

[2] All emission limitations (except for opacity) are measured at 7 percent oxygen, dry basis at standard conditions.

[3] In lieu of performance testing, you may use a CEMS or, for mercury, an integrated sorbent trap monitoring system, to demonstrate initial and continuing compliance with an emissions limit, as long as you comply with the CEMS or integrated sorbent trap monitoring system requirements applicable to the specific pollutant in §§ 60.2710 and 60.2730. As prescribed in § 60.2710(u), if you use a CEMS or integrated sorbent trap monitoring system to demonstrate compliance with an emissions limit, your averaging time is a 30-day rolling average of 1-hour arithmetic average emission concentrations.

[4] Incorporated by reference, *see* § 60.17.

TABLE 3 TO SUBPART DDDD OF PART 60—MODEL RULE—OPERATING LIMITS FOR WET SCRUBBERS

For these operating parameters	You must establish these operating limits	And monitor using these minimum frequencies		
		Data measurement	Data recording	Averaging time
Charge rate	Maximum charge rate	Continuous	Every hour	Daily (batch units). 3-hour rolling (continuous and intermittent units).[1]
Pressure drop across the wet scrubber or amperage to wet scrubber.	Minimum pressure drop or amperage.	Continuous	Every 15 minutes	3-hour rolling.[1]
Scrubber liquor flow rate	Minimum flow rate	Continuous	Every 15 minutes	3-hour rolling.[1]
Scrubber liquor pH	Minimum pH	Continuous	Every 15 minutes	3-hour rolling.[1]

[1] Calculated each hour as the average of the previous 3 operating hours.

TABLE 4 TO SUBPART DDDD OF PART 60—MODEL RULE—TOXIC EQUIVALENCY FACTORS

Dioxin/furan isomer	Toxic equivalency factor
2,3,7,8-tetrachlorinated dibenzo-p-dioxin	1
1,2,3,7,8-pentachlorinated dibenzo-p-dioxin	0.5
1,2,3,4,7,8-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,7,8,9-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,6,7,8-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,4,6,7,8-heptachlorinated dibenzo-p-dioxin	0.01
octachlorinated dibenzo-p-dioxin	0.001
2,3,7,8-tetrachlorinated dibenzofuran	0.1
2,3,4,7,8-pentachlorinated dibenzofuran	0.5
1,2,3,7,8-pentachlorinated dibenzofuran	0.05
1,2,3,4,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,6,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,7,8,9-hexachlorinated dibenzofuran	0.1
2,3,4,6,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,4,6,7,8-heptachlorinated dibenzofuran	0.01
1,2,3,4,7,8,9-heptachlorinated dibenzofuran	0.01
octachlorinated dibenzofuran	0.001

TABLE 5 TO SUBPART DDDD OF PART 60—MODEL RULE—SUMMARY OF REPORTING REQUIREMENTS [1]

Report	Due date	Contents	Reference
Waste Management Plan	No later than the date specified in table 1 for submittal of the final control plan.	• Waste management plan	§ 60.2755.
Initial Test Report	No later than 60 days following the initial performance test.	• Complete test report for the initial performance test • The values for the site-specific operating limits • Installation of bag leak detection systems for fabric filters.	§ 60.2760.

TABLE 5 TO SUBPART DDDD OF PART 60—MODEL RULE—SUMMARY OF REPORTING REQUIREMENTS [1]—Continued

Report	Due date	Contents	Reference
Annual report	No later than 12 months following the submission of the initial test report. Subsequent reports are to be submitted no more than 12 months following the previous report.	• Name and address • Statement and signature by responsible official • Date of report • Values for the operating limits • Highest recorded 3-hour average and the lowest 3-hour average, as applicable, (or 30-day average, if applicable) for each operating parameter recorded for the calendar year being reported. • If a performance test was conducted during the reporting period, the results of the test. • If a performance test was not conducted during the reporting period, a statement that the requirements of § 60.2720(a) were met. • Documentation of periods when all qualified CISWI operators were unavailable for more than 8 hours but less than 2 weeks. • If you are conducting performance tests once every 3 years consistent with § 60.2720(a), the date of the last 2 performance tests, a comparison of the emission level you achieved in the last 2 performance tests to the 75 percent emission limit threshold required in § 60.2720(a) and a statement as to whether there have been any operational changes since the last performance test that could increase emissions. • Any malfunction, deviation, or continuous monitoring system out of control periods information as specified in § 60.2770(k) through (o). • Fuel input information for energy recovery unit subcategory verification as specified in § 60.2770(p).	§§ 60.2765 and 60.2770.
Emission limitation or operating limit deviation report.	By August 1 of that year for data collected during the first half of the calendar year. By February 1 of the following year for data collected during the second half of the calendar year.	• Dates and times of deviation • Averaged and recorded data for those dates • Duration and causes of each deviation and the corrective actions taken. • Copy of operating limit monitoring data and any test reports. • Dates, times and causes for monitor downtime incidents.	§ 60.2775 and 60.2780.
Qualified Operator Deviation Notification.	Within 10 days of deviation	• Statement of cause of deviation • Description of efforts to have an accessible qualified operator. • The date a qualified operator will be accessible	§ 60.2785(a)(1).
Qualified Operator Deviation Status Report.	Every 4 weeks following deviation.	• Description of efforts to have an accessible qualified operator. • The date a qualified operator will be accessible • Request for approval to continue operation	§ 60.2785(a)(2).
Qualified Operator Deviation Notification of Resumed Operation.	Prior to resuming operation	• Notification that you are resuming operation	§ 60.2785(b).

[1] This table is only a summary, see the referenced sections of the rule for the complete requirements.

TABLE 6 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO INCINERATORS ON AND AFTER [DATE TO BE SPECIFIED IN STATE PLAN] [1]

For the air pollutant	You must meet this emission limitation [2]	Using this averaging time [3]	And determining compliance using this method [3]
Cadmium	0.0026 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Carbon monoxide	17 parts per million dry volume	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxins/furans (total mass basis)	4.6 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	0.13 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).

TABLE 6 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO INCINERATORS ON AND AFTER [DATE TO BE SPECIFIED IN STATE PLAN] [1]—Continued

For the air pollutant	You must meet this emission limitation [2]	Using this averaging time [3]	And determining compliance using this method [3]
Hydrogen chloride	29 parts per million dry volume	3-run average (For Method 26, collect a minimum volume of 60 liters per run. For Method 26A, collect a minimum volume of 1 dry standard cubic meter per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	0.015 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Mercury	0.0048 milligrams per dry standard cubic meter.	3-run average (For Method 29 an ASTM D6784–02 (Reapproved 2008),[4] collect a minimum volume of 2 dry standard cubic meters per run. For Method 30B, collect a minimum sample as specified in Method 30B at 40 CFR part 60, appendix A).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008).[4]
Nitrogen oxides	53 parts per million dry volume	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter filterable	34 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meter).	Performance test (Method 5 or 29 at 40 CFR part 60, appendix A–3 or appendix A–8).
Sulfur dioxide	11 parts per million dry volume	3-run average (1 hour minimum sample time per run).	Performance test (Method 6 or 6c at 40 CFR part 60, appendix A–4).
Fugitive ash	Visible emissions for no more than 5% of the hourly observation period.	Three 1-hour observation periods	Visible emission test (Method 22 at 40 CFR part 60, appendix A–7).

[1] The date specified in the state plan can be no later than 3 years after the effective date of approval of a revised state plan or February 7, 2018.

[2] All emission limitations are measured at 7 percent oxygen, dry basis at standard conditions. For dioxins/furans, you must meet either the total mass basis limit or the toxic equivalency basis limit.

[3] In lieu of performance testing, you may use a CEMS or, for mercury, an integrated sorbent trap monitoring system, to demonstrate initial and continuing compliance with an emissions limit, as long as you comply with the CEMS or integrated sorbent trap monitoring system requirements applicable to the specific pollutant in §§ 60.2710 and 60.2730. As prescribed in § 60.2710(u), if you use a CEMS or integrated sorbent trap monitoring system to demonstrate compliance with an emissions limit, your averaging time is a 30-day rolling average of 1-hour arithmetic average emission concentrations.

[4] Incorporated by reference, see § 60.17.

TABLE 7 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO ENERGY RECOVERY UNITS AFTER MAY 20, 2011 [DATE TO BE SPECIFIED IN STATE PLAN] [1]

For the air pollutant	You must meet this emission limitation [2]		Using this averaging time [3]	And determining compliance using this method [3]
	Liquid/gas	Solids		
Cadmium	0.023 milligrams per dry standard cubic meter.	Biomass-0.0014 milligrams per dry standard cubic meter. Coal-0.0017 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Carbon monoxide	35 parts per million dry volume.	Biomass-260 parts per million dry volume. Coal-95 parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxins/furans (total mass basis).	2.9 nanograms per dry standard cubic meter.	Biomass-0.52 nanograms per dry standard cubic meter. Coal-5.1 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meter).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	0.32 nanograms per dry standard cubic meter.	Biomass-0.12 nanograms per dry standard cubic meter. Coal-0.075 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).

TABLE 7 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO ENERGY RECOVERY UNITS AFTER MAY 20, 2011 [DATE TO BE SPECIFIED IN STATE PLAN] [1]—Continued

For the air pollutant	You must meet this emission limitation [2]		Using this averaging time [3]	And determining compliance using this method [3]
	Liquid/gas	Solids		
Hydrogen chloride	14 parts per million dry volume.	Biomass-0.20 parts per million dry volume. Coal-58 parts per million dry volume.	3-run average (for Method 26, collect a minimum of 120 liters; for Method 26A, collect a minimum volume of 1 dry standard cubic meter).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	0.096 milligrams per dry standard cubic meter.	Biomass-0.014 milligrams per dry standard cubic meter. Coal-0.057 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Mercury	0.0024 milligrams per dry standard cubic meter.	Biomass-0.0022 milligrams per dry standard cubic meter. Coal-0.013 milligrams per dry standard cubic meter.	3-run average (For Method 29 and ASTM D6784–02 (Reapproved 2008),[4] collect a minimum volume of 2 dry standard cubic meters per run. For Method 30B, collect a minimum sample as specified in Method 30B at 40 CFR part 60, appendix A).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008).[4]
Nitrogen oxides	76 parts per million dry volume.	Biomass-290 parts per million dry volume. Coal-460 parts per million dry volume.	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter filterable	110 milligrams per dry standard cubic meter.	Biomass-11 milligrams per dry standard cubic meter. Coal-130 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meter).	Performance test (Method 5 or 29 at 40 CFR part 60, appendix A–3 or appendix A–8) if the unit has an annual average heat input rate less than or equal to 250 MMBtu/hr; or PM CPMS (as specified in § 60.2710(x)) if the unit has an annual average heat input rate greater than 250 MMBtu/hr.
Sulfur dioxide	720 parts per million dry volume.	Biomass-7.3 parts per million dry volume. Coal-850 parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 6 or 6c at 40 CFR part 60, appendix A–4).
Fugitive ash	Visible emissions for no more than 5 percent of the hourly observation period.	Visible emissions for no more than 5 percent of the hourly observation period.	Three 1-hour observation periods.	Visible emission test (Method 22 at 40 CFR part 60, appendix A–7).

[1] The date specified in the state plan can be no later than 3 years after the effective date of approval of a revised state plan or February 7, 2018.

[2] All emission limitations (except for opacity) are measured at 7 percent oxygen, dry basis at standard conditions. For dioxins/furans, you must meet either the total mass basis limit or the toxic equivalency basis limit.

[3] In lieu of performance testing, you may use a CEMS or, for mercury, an integrated sorbent trap monitoring system, to demonstrate initial and continuing compliance with an emissions limit, as long as you comply with the CEMS or integrated sorbent trap monitoring system requirements applicable to the specific pollutant in §§ 60.2710 and 60.2730. As prescribed in § 60.2710(u), if you use a CEMS or integrated sorbent trap monitoring system to demonstrate compliance with an emissions limit, your averaging time is a 30-day rolling average of 1-hour arithmetic average emission concentrations.

[4] Incorporated by reference, see § 60.17.

TABLE 8 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO WASTE-BURNING KILNS AFTER MAY 20, 2011 [DATE TO BE SPECIFIED IN STATE PLAN] [1]

For the air pollutant	You must meet this emission limitation [2]	Using this averaging time [3]	And determining compliance using this method [3 4]
Cadmium	0.0014 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8).

TABLE 8 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO WASTE-BURNING KILNS AFTER MAY 20, 2011 [DATE TO BE SPECIFIED IN STATE PLAN] [1]—Continued

For the air pollutant	You must meet this emission limitation [2]	Using this averaging time [3]	And determining compliance using this method [3 4]
Carbon monoxide	110 (long kilns)/790 (preheater/precalciner) parts per million dry volume.	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxins/furans (total mass basis)	1.3 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	0.075 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 4 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Hydrogen chloride	3.0 parts per million dry volume	3-run average (collect a minimum volume of 1 dry standard cubic meter), or 30-day rolling average if HCl CEMS is being used.	If a wet scrubber or dry scrubber is used, performance test (Method 321 at 40 CFR part 63, appendix A of this part). If a wet scrubber or dry scrubber is not used, HCl CEMS as specified in § 60.2710(j).
Lead	0.014 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 2 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8).
Mercury	0.011 milligrams per dry standard cubic meter. Or 58 pounds/million tons of clinker	30-day rolling average	Mercury CEMS or integrated sorbent trap monitoring system (performance specification 12A or 12B, respectively, of appendix B and procedure 5 of appendix F of this part), as specified in § 60.2710(j).
Nitrogen oxides	630 parts per million dry volume	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter filterable	13.5 milligrams per dry standard cubic meter.	30-day rolling average	PM CPMS (as specified in § 60.2710(x)).
Sulfur dioxide	600 parts per million dry volume	3-run average (for Method 6, collect a minimum of 20 liters; for Method 6C, 1 hour minimum sample time per run).	Performance test (Method 6 or 6c at 40 CFR part 60, appendix A–4).

[1] The date specified in the state plan can be no later than 3 years after the effective date of approval of a revised state plan or February 7, 2018.

[2] All emission limitations are measured at 7 percent oxygen (except for CEMS and integrated sorbent trap monitoring system data during start-up and shutdown), dry basis at standard conditions. For dioxins/furans, you must meet either the total mass basis limit or the toxic equivalency basis limit.

[3] In lieu of performance testing, you may use a CEMS or, for mercury, an integrated sorbent trap monitoring system, to demonstrate initial and continuing compliance with an emissions limit, as long as you comply with the CEMS or integrated sorbent trap monitoring system requirements applicable to the specific pollutant in §§ 60.2710 and 60.2730. As prescribed in § 60.2710(u), if you use a CEMS or integrated sorbent trap monitoring system to demonstrate compliance with an emissions limit, your averaging time is a 30-day rolling average of 1-hour arithmetic average emission concentrations.

[4] Alkali bypass and in-line coal mill stacks are subject to performance testing only, as specified in 60.2710(y)(3). They are not subject to the CEMS, integrated sorbent trap monitoring system, or CPMS requirements that otherwise may apply to the main kiln exhaust.

TABLE 9 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO SMALL, REMOTE INCINERATORS AFTER MAY 20, 2011 [DATE TO BE SPECIFIED IN STATE PLAN] [1]

For the air pollutant	You must meet this emission limitation [2]	Using this averaging time [3]	And determining compliance using this method [3]
Cadmium	0.95 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters per run).	Performance test (Method 29 at 40 CFR part 60, appendix A–8).
Carbon monoxide	64 parts per million dry volume	3-run average (1 hour minimum sample time per run).	Performance test (Method 10 at 40 CFR part 60, appendix A–4).
Dioxins/furans (total mass basis)	4,400 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters per run).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Dioxins/furans (toxic equivalency basis).	180 nanograms per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters).	Performance test (Method 23 at 40 CFR part 60, appendix A–7).
Fugitive ash	Visible emissions for no more than 5 percent of the hourly observation period.	Three 1-hour observation periods	Visible emissions test (Method 22 at 40 CFR part 60, appendix A–7).

TABLE 9 TO SUBPART DDDD OF PART 60—MODEL RULE—EMISSION LIMITATIONS THAT APPLY TO SMALL, REMOTE INCINERATORS AFTER MAY 20, 2011 [DATE TO BE SPECIFIED IN STATE PLAN] [1]—Continued

For the air pollutant	You must meet this emission limitation [2]	Using this averaging time [3]	And determining compliance using this method [3]
Hydrogen chloride	300 parts per million dry volume	3-run average (For Method 26, collect a minimum volume of 120 liters per run. For Method 26A, collect a minimum volume of 1 dry standard cubic meter per run).	Performance test (Method 26 or 26A at 40 CFR part 60, appendix A–8).
Lead	2.1 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters).	Performance test (Method 29 at 40 CFR part 60, appendix A–8). Use ICPMS for the analytical finish.
Mercury	0.0053 milligrams per dry standard cubic meter.	3-run average (For Method 29 and ASTM D6784–02 (Reapproved 2008),[3] collect a minimum volume of 2 dry standard cubic meters per run. For Method 30B, collect a minimum sample as specified in Method 30B at 40 CFR part 60, appendix A).	Performance test (Method 29 or 30B at 40 CFR part 60, appendix A–8) or ASTM D6784–02 (Reapproved 2008).[4]
Nitrogen oxides	190 parts per million dry volume	3-run average (for Method 7E, 1 hour minimum sample time per run).	Performance test (Method 7 or 7E at 40 CFR part 60, appendix A–4).
Particulate matter (filterable)	270 milligrams per dry standard cubic meter.	3-run average (collect a minimum volume of 1 dry standard cubic meters).	Performance test (Method 5 or 29 at 40 CFR part 60, appendix A–3 or appendix A–8).
Sulfur dioxide	150 parts per million dry volume	3-run average (for Method 6, collect a minimum of 20 liters per run; for Method 6C, 1 hour minimum sample time per run).	Performance test (Method 6 or 6c at 40 CFR part 60, appendix A–4).

[1] The date specified in the state plan can be no later than 3 years after the effective date of approval of a revised state plan or February 7, 2018.

[2] All emission limitations (except for opacity) are measured at 7 percent oxygen, dry basis at standard conditions. For dioxins/furans, you must meet either the total mass basis limit or the toxic equivalency basis limit.

[3] In lieu of performance testing, you may use a CEMS or, for mercury, an integrated sorbent trap monitoring system, to demonstrate initial and continuing compliance with an emissions limit, as long as you comply with the CEMS or integrated sorbent trap monitoring system requirements applicable to the specific pollutant in §§ 60.2710 and 60.2730. As prescribed in § 60.2710(u), if you use a CEMS or integrated sorbent trap monitoring system to demonstrate compliance with an emissions limit, your averaging time is a 30-day rolling average of 1-hour arithmetic average emission concentrations.

[4] Incorporated by reference, see § 60.17.

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Part IV

Department of Transportation

14 CFR Chapter II
Elimination of Obsolete Provisions and Correction of Outdated Statutory References in Aviation Economic Regulations; Final Rule

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Chapter II

[Docket No. DOT–OST–2014–0140]

RIN 2105–AD86

Elimination of Obsolete Provisions and Correction of Outdated Statutory References in Aviation Economic Regulations

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The Department is amending various provisions regarding its aviation economic regulations to eliminate any further remaining obsolete provisions and correct outdated statutory references. This final rule aligns with the Department's retrospective regulatory review initiatives to modify, streamline, or repeal regulations that are obsolete or out-of-date.

DATES: This final rule is effective May 16, 2019.

ADDRESSES: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and follow the online instructions for accessing the docket.

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SUPPLEMENTARY INFORMATION:

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II. Discussion of the Final Rule
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B. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)
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List of Subjects
The Amendment

I. Background

In 1994, the Federal Aviation Act was revised and codified within Subtitle VII of Title 49 of the United States Code (Pub. L. 103–272, July 5, 1994). Since the codification, the Department has made numerous amendments to make the CFR consistent with the provisions of the current statute (49 U.S.C., Subtitle VII). Some provisions, however, remained unchanged, due in part to the complexity of certain issues, such as antitrust immunity, agreements, and waivers. This rule updates the economic regulations by modifying language to reflect current statutory provisions related to these remaining issues. The revised language does not diminish any existing Civil Aeronautics Board (CAB) provisions or precedent still in effect.

II. Discussion of the Final Rule

This rule updates the regulatory language throughout 14 CFR parts 200 through 399 in the following ways: (1) Where references to the CAB are no longer relevant, replaces the term ''Board'' or ''CAB'', where appropriate, with ''Department'', ''DOT'' or ''Predecessor''; (2) removes citations to the ''Federal Aviation Act'' or ''Act'' and adds citations to the appropriate sections of Title 49 of the United States Code; (3) inserts current names of forms in place of outdated references to CAB forms; (4) adds up-to-date titles for offices within the Department; and (5) updates the authority citations, where needed.

Additional changes are as follows:

Part 204 describes the data the Department uses to support carrier fitness determinations. Section 204.4 discusses carrier obligations for proposing to provide essential air service. The section is no longer in use and is obsolete. As such, the section is removed in its entirety.

Parts 207 and 208 address U.S. scheduled and charter air carrier requirements with respect to charter trips. Both parts refer to 14 CFR part 212 in describing carrier obligations on charter air transportation and contain no independent obligations of their own. As such, these parts are obsolete and are removed.

Part 221 describes carrier obligations with respect to tariffs. This rule revises part 221 by broadening the language used to refer to international treaties. The current regulation refers to the Warsaw Convention, which is no longer the relevant international treaty applicable to travelers on many itineraries. The rule updates and simplifies existing passenger notification requirements and consolidates such requirements into a single section. Specifically, the rule consolidates separate notice requirements for liability from death or injury and liability from damage to baggage into a single notice requirement that better reflects the current international landscape, including references to the 1999 Montreal Convention, which governs many international itineraries originating or terminating in the United States. Currently, a carrier's liability can be limited under the 1999 Montreal Convention to 4,694 SDR for damages caused by the delay of passengers and 1,131 SDR for damages resulting from the destruction, loss, damage, or delay of baggage. This rule removes references to agreements approved by CAB order. Carriers are provided until December 31, 2019, to comply with the signage requirements of this part, while compliance with the ticket notification changes is required on the effective date of this final rule. Airlines for America recommends that current stocks of paper notices be allowed to be used until exhausted. However, the change in liability amounts occurred in 2009 and we do not believe carriers still have significant stocks of paper notices with outdated information. *See* Inflation Adjustments to Liability Limits Governed by the Montreal Convention Effective December 30, 2009, 74 FR 59017 (Nov. 16, 2009). Moreover, the Department has consistently required that paper and e-ticket notices used to inform consumers of their rights and airline policies regarding such liability provide accurate information. Accordingly, we do not believe it is appropriate to allow airlines to continue to distribute inaccurate paper notices to the extent any are doing so.

Part 223 sets forth rules regarding free and reduced-rate transportation. This rule updates part 223 by removing references to specific sections of the ''Act'' such as ''under section 408 of the Act.'' Additionally, in § 223.1, the term ''handicapped passenger'' is used to describe a person with a disability. However, under the Americans with Disabilities Act (ADA), the current practice is to use ''person-first'' terminology (*e.g.,* changes ''handicapped person'' to ''person with a disability''). Where applicable, as the Department reviews its regulations, the term ''handicapped'' is replaced with the person-first terminology in alignment with the ADA. This rule removes the term ''Handicapped passenger'' and replaces it with the term ''passenger with a disability.''

Part 232 established procedures for a party aggrieved by an order of the Postmaster General to request a review by DOT. In 2008, amendments to 49 U.S.C. 41902 removed from the statute the authority for the Secretary of Transportation to amend, modify, suspend, or cancel an order of the Postal Service (Pub. L. 110–405, Jan. 4, 2008). Accordingly, the statutory basis for part

232 regulations no longer exists and part 232 is removed.

Part 234 describes the requirements for filing airline service quality performance reports. The existing citation of authorities for this part contains an error. This rule corrects the error.

Part 241 describes a uniform system of accounts and reports for large carriers. This rule removes section 01 of part 241 which restated outdated statutory text and could lead to confusion if retained.

Part 272 established essential air service procedures for the Freely Associated States comprising the Federated States of Micronesia (Ponape, Truk and Yap), the Marshall Islands (Majuro and Kwajalein), and Koror in Palau. The procedures include requirements for airlines to file notice before suspending service, an obligation to continue to provide service when subsidy is available, and carrier-selection criteria. Section 272.12 states, ''These provisions shall terminate on October 1, 1998, unless the essential air service program to the Federated States of Micronesia, the Marshall Islands and Palau is specifically extended by Congress.'' Congress did not extend the program (Pub. L. 101–219, Sec. 110(b), (Dec.12,1989)). Thus, the statutory basis for the regulation no longer exists and part 272 is removed.

Part 300 sets forth the rules of conduct in DOT proceedings involving aviation economic and enforcement matters. Many of these rules set forth standards of ethical conduct applicable to DOT employees with respect to aviation economic matters. DOT employees are also subject to the ethics requirements of 49 CFR 99.735–1. In order to reduce the duplicative nature of both sets of ethics requirements and to minimize the potential for confusion over such requirements, several sections of part 300 are removed under this rule. The resulting regulations ensures consistent ethical standards across all employees of the agency.

Part 302 sets forth the Rules of Practice in Proceedings before the DOT. Part 305 describes the Rules of Practice for Informal Nonpublic Investigations undertaken by the Office of Aviation Enforcement and Proceedings. Part 385 sets forth the authorities and functions of various DOT officials. On August 17, 2012, the Department issued an extensive revision to 49 CFR part 1 (Organization and Delegation of Powers and Duties) [77 FR 49965]. The Department is revising parts 302, 305, and 385 to reflect the changes set forth in the revision to part 1.

Part 330 established procedures implementing the airline compensation section of the Air Transportation Safety and System Stabilization Act, which was enacted following the terrorist attacks of September 11, 2001, Public Law 107–42, (Sept. 22, 2001) (the Stabilization Act). Section 103 of the Stabilization Act appropriated up to $5 billion, to be administered by the Department of Transportation, to compensate air carriers for losses they incurred due to the attacks. Part 330 set out carrier eligibility criteria; forms for applying for the compensation payments; details on types of losses that would and would not be eligible for compensation; audit procedures; and details on a set-aside program for certain air taxis, commuter carriers, and other small carriers. Of the 427 applications processed, 407 applicants were deemed eligible under part 330. These carriers received payments in a total amount of $4.6 billion. All eligible appropriations were completed and payments processed and paid, and all functions and responsibilities under this section were fulfilled. As a result, part 330 serves no further purpose and is removed.

Part 374 specifies the Department's responsibility for enforcing air carrier and foreign air carrier compliance with the applicable requirements of the Consumer Credit Protection Act. This rule revises part 374 by updating the language in § 374.3 regarding references to Regulation B, 12 CFR part 202, and Regulation Z, 12 CFR part 226. Enforcement responsibility for parts 202 and 226 has been divided and reassigned among Federal government agencies. Accordingly, the language in § 374.3 is revised to reference the current applicable regulations, 12 CFR part 1026.

Part 380 is applicable to public charter air transportation in interstate or foreign air transportation. This rule revises part 380 by updating appendices A and B. Part 380 sets forth the Department's rules governing Public Charter air transportation of passengers whether furnished by direct air carriers or Public Charter Operators. Appendices A and B to part 380, respectively, contain the format for the Public Charter Operator's Surety Bond and the Public Charter Surety Trust Agreement. Since the existing appendices A and B to part 380 were published in 1998, various changes have been made to both documents. Therefore, appendices A and B is updated to provide the most current format for the Public Charter Operator's Surety Bond and the Public Charter Surety Trust Agreement.

In part 385, the Secretary of Transportation delegates certain continuing assignments of authority to Secretarial Officers regarding the Department's functions of issuing orders or other determinations pursuant to 49 U.S.C. 322 and 49 CFR part 1. The Secretary determined that several of the items currently prepared for decision at the Assistant Secretary level could be handled more efficiently at the Office Director level, thereby providing more time for the Assistant Secretary and immediate secretarial staff to concentrate on controversial and policy-sensitive issues. This action ensures that routine items are processed in a much more timely and efficient manner. Thus, this rulemaking amends §§ 385.12 and 385.13 to reflect the expanded assignments of authority to the Director of the Office of Aviation Analysis and the Director of the Office of International Aviation, both in the Office of the Assistant Secretary for Aviation and International Affairs.

Section 385.12 defines the authority of the Director of the Office of Aviation Analysis. This rule authorizes the Director to issue Essential Air Service (EAS) Requests for Proposals and certain final EAS selection orders. This expanded delegation alone relieves the Assistant Secretary for Aviation and International Affairs of reviewing nearly sixty orders per year, saving over three hundred (300) hours of senior management time and approximately one hundred twenty (120) hours of staff time in the Office of Aviation Analysis. This rule expands the Director's authority to issue quarterly fuel rate adjustments to Alaskan bush and mainline mail rates and to issue certain procedural orders in antitrust immunity cases processed under 49 U.S.C. 41308 and 41309. This rule also removes paragraphs (f), (h), and (i) of § 385.12, as these requirements are placed under the authority of the Director of the Office of International Aviation in § 385.13. Accordingly, paragraphs (g), (j), and (k) are re-designated.

Section 385.13 defines the authority of the Director of the Office of International Aviation. This rule amends paragraph (a) of § 385.13 to grant the Director the authority to issue final orders on uncontested tariff exemptions. This rulemaking also amends paragraph (b) to authorize the Director to issue final orders on uncontested applications for U.S. carrier certificate and foreign air carrier permit authority. Further, this action adds two new subsections regarding fares and tariffs and amends § 385.13(r)(1) to give the Director the authority to exempt

IATA [1] agreements under section 41309; this is in addition to the Director's existing authority to approve or disapprove such agreements. This rule also adds new paragraphs (z) through (dd) that: (1) Authorize the Director to issue orders and notices adjusting the Standard Foreign Fare Level; (2) authorize the Director to issue notices updating the list of country-pair markets in tariff-filing categories under part 293 of this chapter; (3) give the Director assigned authority as to certain matters processed by the Office of International Aviation's U.S. Air Carrier Licensing/Special Authorities Division; and (4) add requirements moved from § 385.12(f), (h), and (i).

Sections 385.14 and 385.15 define the authority of the General Counsel and Deputy General Counsel, respectively. Consistent with the delegation of duties assigned in 49 CFR part 1, as revised on August 16, 2012, by 77 FR 49964, the Secretary assigned several duties to the General Counsel. Sections 385.14 and 385.15 are revised to reflect this assignment of duties. This rule removes § 385.15 and transfers its functions to § 385.14.

Part 389 describes fees and charges for special services. This rule amends part 389 by (1) removing references to organizations and position titles that no longer exist and replacing them with references to appropriate organizations and positions, (2) correcting the filing fees charged for special services to reflect a recent rulemaking action, (3) allowing for payment of filing fees using the internet, and (4) revising the descriptions of licenses for which the Department charges filing fees.

Part 398 establishes guidelines for the determination of basic essential air service. The Department amends part 398 by removing an outdated provision for funding reductions in § 398.11. Section 398.11 was superseded by Public Law 106–69, Title III, section 332, October 9, 1999, 113 Stat. 1022.

Part 399, subpart C, sets forth the Department's policies related to rates and tariffs. This rulemaking action removes fourteen sections from this subpart (§§ 399.30, 399.31, 399.32, 399.33, 399.34, 399.37, 399.40, 399.41, 399.42, 399.43, 399.44, 399.63, 399.101, and 399.111). These sections are obsolete because of the Airline Deregulation Act of 1978 and the Civil Aeronautics Board Sunset Act of 1984.

While not originally proposed in the notice of proposed rulemaking (NPRM) published on May 9, 2018 (83 FR 21684), this final rule also updates the section reference for the definition of small aircraft found in § 399.73 from ''§ 298.3'' to ''§ 298.2''. Under the Administrative Procedure Act, an agency may waive the normal notice and comment procedures if the agency, for good cause, finds that those procedures are impracticable, unnecessary, or contrary to the public interest. See 5 U.S.C. 553(b)(B). Since this amendment is merely a minor technical correction, notice and comment are unnecessary.

III. Comment Discussion

OST received two comments in response to the NPRM and is adopting one drafting correction and a change in characterization of the coverage limits of the Montreal Convention that were proposed in the Airlines 4 America (A4A) comment. The second comment was filed by the International Air Transport Association (IATA).

The Department appreciates the constructive input by both commenters. However, as this rulemaking is intended as an administrative ''clean-up'' action, the majority of the IATA and A4A comments propose policy changes to the Department's regulations that were not contemplated in the NPRM underlying this final rule. Because the changes requested by the commenters are outside the scope of the NPRM, the Department declines to adopt them as part of this final rule. However, the Department will continue to consider them as we review our existing regulations as announced in an October 2, 2017, Notification of Regulatory Review (82 FR 45750).

OST is also adopting an additional, minor modification to a reference in § 399.73, as noted above. These changes are described further in the Discussion of the Final Rule section above.

IV. Regulatory Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

This rulemaking is not a significant regulatory action under Executive Order 12866 and the Department's Regulatory Policies and Procedures. Its provisions involve technical amendments to update statutory references and to update the titles and addresses of offices. The rule also removes certain appendices, sections, and forms that are no longer relevant. This rule does not create any major policy changes or impose significant new costs or burdens.

B. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

This final rule is considered an E.O. 13771 deregulatory action. This final rule repeals a number of sections and whole parts from the Code of Federal Regulations that have been identified as outdated, unnecessary, or ineffective, thus reducing the Department's regulatory footprint. This final rule also modifies the Department's other regulations to ensure that they are consistent with existing laws, procedures, and practice. Cost savings associated with this deregulatory action are not quantifiable.

C. Regulatory Flexibility Act

Pursuant to section 605 of the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), I hereby certify that this rulemaking does not have a significant impact on a substantial number of small entities. The final rule imposes no duties or obligations on small entities.

D. Executive Order 13132 (Federalism)

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. The Department has analyzed this rulemaking in accordance with the principles and criteria contained in the Order and determined that it does not have implications for federalism, since it merely makes technical amendments to the existing regulations. This final rule does not have a substantial direct effect on, or sufficient federalism implications for, the States, nor does it limit the policymaking discretion of the States.

E. Executive Order 13175

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments''). Because this rulemaking does not significantly or uniquely affect the communities of the Indian tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13175 do not apply.

F. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that DOT consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from the Office of Management and Budget (OMB) for each collection of

[1] International Air Transport Association.

information it conducts, sponsors, or requires through regulations. The DOT has determined there are no new information collection requirements associated with this final rule.

G. National Environmental Policy Act

The agency has analyzed the environmental impacts of this action pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, Oct. 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). The purpose of this rulemaking is to make editorial corrections, remove obsolete references, and update outdated provisions in the Department's aviation economic regulations. The agency does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

List of Subjects

14 CFR Part 200

Air transportation.

14 CFR Part 201

Air carriers, Reporting and recordkeeping requirements.

14 CFR Part 203

Air carriers, Air transportation, Foreign relations, Insurance, Reporting and recordkeeping requirements.

14 CFR Part 204

Air carriers, Reporting and recordkeeping requirements.

14 CFR Part 205

Air carriers, Freight, Insurance, Reporting and recordkeeping requirements.

14 CFR Part 207

Air carriers, Charter flights.

14 CFR Part 208

Air carriers, Charter flights.

14 CFR Part 211

Administrative practice and procedure, Air carriers, Pacific Islands Trust Territory, Reporting and recordkeeping requirements.

14 CFR Part 212

Charter flights, Confidential business information, Reporting and recordkeeping requirements, Surety bonds.

14 CFR Part 214

Air carriers, Charter flights.

14 CFR Part 215

Air carriers, Reporting and recordkeeping requirements, Trade names.

14 CFR Part 216

Air carriers.

14 CFR Part 217

Air carriers, Reporting and recordkeeping requirements.

14 CFR Part 218

Air carriers, Aircraft, Airmen.

14 CFR Part 221

Air rates and fares, Freight, Reporting and recordkeeping requirements.

14 CFR Part 222

Air carriers, Freight, Intermodal transportation, Reporting and recordkeeping requirements.

14 CFR Part 223

Air rates and fares, Government employees, Reporting and recordkeeping requirements.

14 CFR Part 232

Administrative practice and procedure, Air carriers, Postal Service.

14 CFR Part 234

Air carriers, Consumer protection, Reporting and recordkeeping requirements.

14 CFR Part 240

Air carriers, Uniform System of Accounts.

14 CFR Part 241

Air carriers, Reporting and recordkeeping requirements, Uniform System of Accounts.

14 CFR Part 243

Air carriers, Aircraft, Charter flights, Reporting and recordkeeping requirements.

14 CFR Part 247

Air carriers, Airports.

14 CFR Part 248

Air carriers, Reporting and recordkeeping requirements, Uniform System of Accounts.

14 CFR Part 249

Air carriers, Reporting and recordkeeping requirements, Truth in lending, Uniform System of Accounts.

14 CFR Part 253

Air carriers, Consumer protection.

14 CFR Part 257

Air carriers, Air rates and fares, Consumer protection, Reporting and recordkeeping requirements.

14 CFR Part 258

Air carriers, Consumer protection, Reporting and recordkeeping requirements.

14 CFR Part 271

Air carriers, Grant programs-transportation.

14 CFR Part 272

Air carriers, Grant programs-transportation, Pacific Islands Trust Territory.

14 CFR Part 291

Administrative practice and procedure, Air carriers, Freight, Reporting and recordkeeping requirements.

14 CFR Part 294

Air taxis, Canada, Charter flights, Reporting and recordkeeping requirements.

14 CFR Part 296

Air carriers, Freight forwarders, Research.

14 CFR Part 297

Air carriers, Freight forwarders.

14 CFR Part 298

Air taxis, Reporting and recordkeeping requirements.

14 CFR Part 300

Administrative practice and procedure, Conflict of interests.

14 CFR Part 302

Administrative practice and procedure, Air carriers, Airports, Postal Service.

14 CFR Part 303

Administrative practice and procedure, Air carriers, Antitrust, Reporting and recordkeeping requirements.

14 CFR Part 305

Administrative practice and procedure, Air carriers, Investigations.

14 CFR Part 323

Administrative practice and procedure, Air carriers, Reporting and recordkeeping requirements

14 CFR Part 325

Administrative practice and procedure, Air transportation,

Intergovernmental relations, Reporting and recordkeeping requirements.

14 CFR Part 330

Administrative practice and procedure, Air carriers, Grant programs-transportation

Reporting and recordkeeping requirements.

14 CFR Part 372

Charter flights, Military air transportation, Reporting and recordkeeping requirements, Surety bonds.

14 CFR Part 374

Air carriers, Consumer protection, Credit.

14 CFR Part 374a

Air carriers, Credit, Political candidates, Reporting and recordkeeping requirements.

14 CFR Part 375

Administrative practice and procedure, Aircraft, Foreign relations, Reporting and recordkeeping requirements.

14 CFR Part 377

Administrative practice and procedure, Air carriers.

14 CFR Part 380

Charter flights, Reporting and recordkeeping requirements, Surety bonds.

14 CFR Part 385

Organization and functions (Government agencies).

14 CFR Part 389

Administrative practice and procedure, Reporting and recordkeeping requirements.

14 CFR Part 398

Air transportation.

14 CFR Part 399

Administrative practice and procedure, Air carriers, Air rates and fares, Air taxis, Consumer protection, Small businesses.

The Amendment

In consideration of the foregoing, and under the authority of 49 U.S.C. 322, the Department amends title 14, chapter II of the Code of Federal Regulations as follows:

PART 200—DEFINITIONS AND INSTRUCTIONS

■ 1. The authority citation for part 200 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 411, 413, 415, 417, and 461.

■ 2. Section 200.1 is revised to read as follows:

§ 200.1 Terms and definitions.

For purposes of this chapter—

(a) Unless otherwise specifically stated, words and phrases other than those listed in this section have the meaning defined in 49 U.S.C. Subtitle VII.

(b) *Department* or *DOT* means the Department of Transportation.

(c) *Predecessor* means the Civil Aeronautics Board (CAB).

(d) *Order* refers to the rules, regulations, and orders prescribed by the Department pursuant to the 49 U.S.C. Subtitle VII or its orders that are, by law, still in effect.

(e) *FAA* means the Federal Aviation Administration, U.S. Department of Transportation.

(f) *OST–R* means the Office of the Assistant Secretary for Research and Technology, U.S. Department of Transportation.

(g) *Secretary* means the Secretary of Transportation, U.S. Department of Transportation.

PART 201—AIR CARRIER AUTHORITY UNDER SUBTITLE VII OF TITLE 49 OF THE UNITED STATES CODE

■ 3. The authority citation for part 201 continues to read as follows:

Authority: 5 U.S.C. 1008; 49 U.S.C. Chapters 401, 411, 413, 415, 417.

■ 4. Revise the heading for part 201 to read as set forth above.

■ 5. Throughout part 201, remove the phrase ''of the Statute'' and add in its place ''of 49 U.S.C. Subtitle VII''.

§ 201.1 [AMENDED]

■ 6. In § 201.1(b), remove the words ''DOT Dockets, 1200 New Jersey Avenue SE, Washington, DC 20590–0002'' and add in their place the words ''Docket Operations Office, U.S. Department of Transportation, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001''.

§ 201.7 [AMENDED]

■ 7. In § 201.7(e), remove the words ''Office of Aviation Analysis'' and add in their place the words ''Office of International Aviation''.

PART 203—WAIVER OF WARSAW CONVENTION LIABILITY LIMITS AND DEFENSES

■ 8. The authority citation for part 203 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 411, 413, 415, 417.

■ 9. Section 203.3 is revised to read as follows:

§ 203.3 Filing requirements for adherence to Montreal Convention.

All direct U.S. and foreign air carriers shall have and maintain in effect and on file in the Department's Docket Operations Office (DOT–OST–1995–236) on OST Form 4523 a signed counterpart to Agreement 18900, an agreement relating to liability limitations of the Warsaw Convention and Hague Protocol, (the Montreal Agreement), dated May 13, 1966, and/or a signed counterpart of any amendment or replacement to such Agreement that may be approved by the Department and to which the air carrier or foreign air carrier becomes a party. U.S. air taxi operators registering under part 298 of this chapter and Canadian charter air taxi operators registering under part 294 of this chapter may comply with this requirement by filing completed OST Forms 4507 and 4523, respectively, in accordance with the provisions of those parts.

§ 203.4 [AMENDED]

■ 10. Amend § 203.4 as follows:

■ a. In paragraph (a), remove the words ''Tariffs Division'' and add in their place the words ''Pricing and Multilateral Affairs Division''.

■ b. In paragraph (b), remove the reference ''§ 221.175'' and add in its place the reference ''§ 221.105''.

PART 204—DATA TO SUPPORT FITNESS DETERMINATIONS

■ 11. The authority citation for part 204 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 411, 417.

■ 12. Throughout part 204, remove the words ''the Statute'' and add in their place ''49 U.S.C. Subtitle VII''.

■ 13. In § 204.2, paragraphs (b) and (e) are revised to read as follows:

§ 204.2 Definitions.

* * * * *

(b) *Certificate authority* means authority to provide air transportation granted by the Secretary of Transportation in the form of a certificate of public convenience and necessity under 49 U.S.C. 41102 or an all-cargo air transportation certificate to perform all-cargo air transportation under 49 U.S.C. 41103. *Certificated carriers* are those that hold certificate authority, including those carriers operating by law under the regulatory provisions under the Department's predecessor.

* * * * *

(e) *Eligible place* means a place in the United States that meets the specified criteria outlined in 49 U.S.C. Chapter 417.

* * * * *

§ 204.4 [REMOVED AND RESERVED]

■ 14. Section 204.4 is removed and reserved.

§ 204.5 [AMENDED]

■ 15. Amend § 204.5 as follows:

■ a. In paragraph (c), remove the words ''Washington, DC 20590, or by electronic submission at *http://dms.dot.gov*.'' and add in their place the words ''1200 New Jersey Avenue SE, Washington, DC 20590, or by electronic submission at *http://www.regulations.gov*.''

■ b. In paragraph (d), remove the words ''Washington, DC 20590.'' and add in their place the words ''1200 New Jersey Avenue SE, Washington, DC 20590.''

§ 204.7 [AMENDED]

■ 16. In § 204.7(b), remove the words ''Documentary Services Division, Department of Transportation'' and add in their place the words ''Docket Operations Office, U.S. Department of Transportation.''

PART 205—AIRCRAFT ACCIDENT LIABILITY INSURANCE

■ 17. The authority citation for part 205 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 411, 413, 417.

§ 205.4 [AMENDED]

■ 18. In § 205.4(a), remove the reference ''*http://ostpxweb.dot.gov*'' and add in its place ''*https://www.transportation.gov/policy/aviation-policy/licensing/US-carriers*''.

■ 19. In § 205.6, revise the section heading and paragraph (b)(2) to read as follows:

§ 205.6 Prohibited exclusion of coverage.

* * * * *

(b) * * *

(2) Liability assumed by the carrier under an agreement to raise the liability limitations of the Warsaw Convention by signing a counterpart to an agreement of carriers (such as the Montreal Agreement, 18900, signed May 13, 1966, agreeing to a limit on the carrier's liability for injury or death of passengers of $75,000 per passenger), or any amendment to such agreement that may be approved by the Department and to which the carrier becomes a party.

PART 206—CERTIFICATES OF PUBLIC CONVENIENCE AND NECESSITY: SPECIAL AUTHORIZATIONS AND EXEMPTIONS

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

Authority: 49 U.S.C. Chapters 401, 415, 417, 419.

■ 21. Throughout part 206, remove the phrase ''of the Statute'' and add in its place ''of 49 U.S.C. Subtitle VII''.

PART 207—[REMOVED]

■ 22. Part 207 is removed.

PART 208—[REMOVED]

■ 23. Part 208 is removed.

PART 211—APPLICATIONS FOR PERMITS TO FOREIGN AIR CARRIERS

■ 24. The authority citation for part 211 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 411, 413, 415, 417.

§ 211.2 [AMENDED]

■ 25. In § 211.2(b), remove the words ''subpart F'' and add in their place the words ''subpart E''.

§ 211.20 [AMENDED]

■ 26. In § 211.20(c)(2)(i), remove the colon and add in its place a semicolon.

§ 211.31 [AMENDED]

■ 27. In § 211.31(d), remove the period and add in its place ''; and''.

§ 211.32 [AMENDED]

■ 28. In § 211.32, remove the words ''section 801(a) of the Federal Aviation Act'' and add in their place ''49 U.S.C. 41307''.

PART 212—CHARTER RULES FOR U.S. AND FOREIGN DIRECT AIR CARRIERS

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

Authority: 49 U.S.C. 40101, 40102, 40109, 40113, 41101, 41103, 41504, 41702, 41708, 41712, 46101.

§ 212.3 [AMENDED]

■ 30. In § 212.3, paragraph (c)(i) is redesignated as paragraph (c)(1).

§ 212.10 [AMENDED]

■ 31. In § 212.10(e)(1), remove the words ''part in interest'' and add in their place the word ''person''.

§ 212.11 [AMENDED]

■ 32. In § 212.11(b)(1), remove the words ''authority sought to covered'' and add in their place the words ''authority sought is covered''.

PART 213—TERMS, CONDITIONS AND LIMITATIONS OF FOREIGN AIR CARRIER PERMITS

■ 33. The authority citation for part 213 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 411, 413, 415, 417.

§ 213.1 [AMENDED]

■ 34. In § 213.1, remove ''This regulation'' and add in its place ''This part''.

§ 213.2 [AMENDED]

■ 35. In § 213.2, remove ''Rule 14 of part 302'' and add in its place ''§ 302.14 of this chapter (Rule 14 of part 302)''.

§ 213.5 [AMENDED]

■ 36. In § 213.5(c), remove ''Rule 14 of part 302 of this chapter'' and add in its place ''§ 302.14 of this chapter (Rule 14 of part 302)''.

PART 214—TERMS, CONDITIONS, AND LIMITATIONS OF FOREIGN AIR CARRIER PERMITS AUTHORIZING CHARTER TRANSPORTATION ONLY

■ 37. Add an authority citation for part 214 to read as follows:

Authority: 49 U.S.C. 40101, 40102, 40109, 40113, 41504, 41708, 41712, and 46101.

PART 215—USE AND CHANGE OF NAMES OF AIR CARRIERS, FOREIGN AIR CARRIERS AND COMMUTER AIR CARRIERS

■ 38. The authority citation for part 215 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 411, 413, 417.

■ 39. Section 215.1 is revised to read as follows:

§ 215.1 Applicability.

This part applies to all certificated air carriers, commuter air carriers, and foreign direct air carriers and to initial and amended applications for authority, applications for certificate or permit transfers or reissuances, and registration of business names.

§ 215.4 [AMENDED]

■ 40. Amend § 215.4 as follows:

■ a. In paragraph (a), remove the words ''Licensing Division'' and add in their place the words ''Foreign Air Carrier Licensing Division''.

■ b. In paragraph (b), remove ''Docket 17325'' and add in its place ''Docket DOT–OST–1995–236.''

PART 216—COMMINGLING OF BLIND SECTOR TRAFFIC BY FOREIGN AIR CARRIERS

■ 41. The authority citation for part 216 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 413, 417.

■ 42. Throughout part 216, remove the words ''Board'' and ''Board's'' wherever they appear and add in their place the words ''Department'' and ''Department's'', respectively.

§ 216.1 [AMENDED]

■ 43. Amend § 216.1 as follows:
■ a. In paragraph (a), remove the definition for ''Act''.
■ b. In paragraph (b), remove the words ''section 101 of the Act'' and add in their place ''49.U.S.C. 40102''.

§ 216.3 [AMENDED]

■ 44. In § 216.3, remove the words ''section 402 of the Act'' and add in their place ''49 U.S.C. 41301''.

§ 216.4 [AMENDED]

■ 45. In § 216.4(a), remove the words ''Director, Bureau of International Aviation'' and add in their place the words ''Director, Office of International Aviation''.

§ 216.5 [AMENDED]

■ 46. In § 216.5, remove the words ''part 375 of the Department's Special Regulations'' and add in their place ''part 375 of this chapter (the Department's Special Regulations)''.

PART 217—REPORTING TRAFFIC STATISTICS BY FOREIGN AIR CARRIERS IN CIVILIAN SCHEDULED, CHARTER, AND NONSCHEDULED SERVICES

■ 47. The authority citation for part 217 is revised to read as follows:

Authority: 49 U.S.C. 329, 41102, 41301, 41708, and 41709.

§ 217.5 [AMENDED]

■ 48. In § 217.5, remove ''the appendix to § 217.10 of this part'' everywhere it appears and add in its place ''appendix A of this part''.

§ 217.6 [AMENDED]

■ 49. In § 217.6(a), remove ''the appendix to § 217.10 of this part'' and add in its place ''appendix A of this part''.

§ 217.8 [AMENDED]

■ 50. In § 217.6, remove ''the Appendix to § 217.10 of this part'' and add in its place ''appendix A of this part''.

§ 217.10 [AMENDED]

■ 51. Amend § 217.10 as follows:
■ a. Remove ''the appendix to this section'' and add in its place ''appendix A to this part''.
■ b. Remove the appendix to the section.

§ 217.11 [AMENDED]

■ 52. In § 217.11(b), remove the words ''subject to a maximum fine of $10,000 or imprisonment for not more than 5 years, or both,''.
■ 53. Add appendix A to read as follows:

Appendix A to Part 217—Instructions to Foreign Air Carriers for Reporting Traffic Data on Form 41 Schedule T–100(f)

(a) General instructions.

(1) Description. Form 41 Schedule T–100(f) provides flight stage data covering both passenger/cargo and all cargo operations in scheduled and nonscheduled services. The schedule is used to report all flights which serve points in the United States or its territories as defined in this part.

(2) Applicability. Each foreign air carrier holding a section 41302 permit or exemption authority shall file Schedule T–100(f).

(3) Reports required by this section shall be submitted to the Bureau of Transportation Statistics in a format specified in accounting and reporting directives issued by the Bureau of Transportation Statistics' Director of Airline Information.

(4) Filing period. Form 41 Schedule T–100(f) shall be filed monthly and is due at the Department thirty (30) days following the end of the reporting month to which the data are applicable.

(b) Preparation of Form 41 Schedule T–100(f):

(1) Explanation of nonstop segments and on-flight markets. There are two basic categories of data, one pertaining to nonstop segments and the other pertaining to on-flight markets. For example, the routing (A–B–C–D) consists of three nonstop segment records A–B, B–C, and C–D, and six on-flight market records A–B, A–C, A–D, B–C, B–D, and C–D.

(2) Guidelines for reporting a nonstop segment. A nonstop segment is reported when one or both points are in the United States or its territories. These data shall be merged with that for all of the other reportable nonstop operations over the same segment. Nonstop segment data must be summarized by aircraft type, under paragraph (h)(1) of this appendix, and class of service, paragraph (g)(1)(v) of this appendix.

(3) Rules for determining a reportable on-flight market. On-flight markets are reportable when one or both points are within the U.S., with the following exceptions: (i) Do not report third country to U.S. markets resulting from flight itineraries which serve a third country prior to a homeland point in flights passing through the homeland bound for the U.S.; and (ii) do not report U.S. to third country markets resulting from itineraries serving third country points subsequent to a homeland point in flights outbound from the U.S. and passing through the homeland. In reporting data pertaining to these two exceptions, the traffic moving to or from the U.S. relating to the applicable prior or subsequent third countries (referred to as ''behind'' or ''beyond'' traffic) is to be combined with the applicable foreign homeland gateway point, just as though the traffic were actually enplaned or deplaned at the homeland gateway, without disclosure of the actual prior or subsequent points. Applicable flights are illustrated in examples (6) and (7) under paragraph (c) of this appendix.

(c) Examples of flights. Following are some typical flight itineraries that show the reportable nonstop segment and on-flight market entries. The carrier's homeland is the key factor in determining which on-flight markets are reportable.

(1) SQ flight # 11 LAX—NRT—SIN. This is an example of a flight with an intermediate foreign country. It is not necessary to report anything on the NRT—SIN leg.

SQ—Singapore Airlines
LAX—Los Angeles, USA
NRT—Tokyo-Narita, Japan
SIN—Singapore, Singapore

A–3—Airport code	A–4—Airport code	A–5—Service class (mark an X)					By aircraft type—				Sum of all aircraft types—	
Origin	Destination	F	G	L	P	Q	B–1—Aircraft type code	B–2—Revenue aircraft departures	B–3—Revenue passengers transported	B–4—Revenue freight transported (kg)	C–1—Total revenue passengers in market	C–2—Total revenue freight in market (kg)
LAX	NRT	X	....	....	....	....	8161	12	2400	4800	400	500
LAX	SIN	X	....	....	....	....	.....	.....	.....	.....	2000	4300

(2) SQ flight #15 LAX—HNL—TPE—SIN. This is an example of two U.S. points, an intermediate third country, and a homeland point. Information is reportable on only the on-flight markets and nonstop segments that consist of one or both U.S. points.

SQ—Singapore Airlines
LAX—Los Angeles, USA
HNL—Honolulu, USA
TPE—Taipei, Taiwan
SIN—Singapore, Singapore

A–3—Airport code	A–4—Airport code	A–5—Service class (mark an X)					By aircraft type—				Sum of all aircraft types—	
Origin	Destination	F	G	L	P	Q	B–1—Aircraft type code	B–2—Revenue aircraft departures	B–3—Revenue passengers transported	B–4—Revenue freight transported (kg)	C–1—Total revenue passengers in market	C–2—Total revenue freight in market (kg)
LAX	HNL	X	....	....	....	....	8161	12	2700	5300	0	0
LAX	TPE	X	....	....	....	....	.....	.....	.....	.....	700	1300
LAX	SIN	X	....	....	....	....	.....	.....	.....	.....	2000	4000
HNL	TPE	X	....	....	....	....	8161	12	2200	6800	1200	800
HNL	SIN	X	....	....	....	....	.....	.....	.....	.....	1000	6000

(3) LB flight # 902 LPB–VVI–MAO–CCS–MIA. This flight serves two homeland points and two different foreign countries before terminating in the U.S. Nonstop segment information is required only for the nonstop segment involving a U.S. point. On-flight market information is required in 4 of the 10 markets, LPB–MIA and VVI–MIA, since these involve homeland and U.S. points; MAO–MIA is necessary to show traffic carried into the U.S., and CCS–MIA for the same reason, and also because in all cases where a nonstop segment entry is required, a corresponding on-flight market entry must also be reported.

LB—Lloyd Aero Boliviano
LPB—La Paz, Bolivia
VVI—Santa Cruz-Viru Viru, Bolivia
MAO—Manaus, Brazil
CCS—Caracas, Venezuela
MIA—Miami, USA

A–3—Airport code	A–4—Airport code	A–5—Service class (mark an X)					By aircraft type—				Sum of all aircraft types—	
Origin	Destination	F	G	L	P	Q	B–1—Aircraft type code	B–2—Revenue aircraft departures	B–3—Revenue passengers transported	B–4—Revenue freight transported (kg)	C–1—Total revenue passengers in market	C–2—Total revenue freight in market (kg)
CCS	MIA	X	....	....	....	....	8161	31	6900	71000	0	0
LPB	MIA	X	....	....	....	....	.....	.....	.....	.....	1100	20000
VVI	MIA	X	....	....	....	....	.....	.....	.....	.....	4000	30000
MAO	MIA	X	....	....	....	....	.....	.....	.....	.....	1000	12000

(4) LY flight #005 TLV–AMS–ORD–LAX. This flight serves a single foreign intermediate point and two U.S. points after its homeland origination. The information on the TLV–AMS leg is not reportable.

LY—El Al Israel Airlines
TLV—Tel Aviv, Israel
AMS—Amsterdam, Netherlands
ORD—Chicago, USA
LAX—Los Angeles, USA

A–3—Airport code	A–4—Airport code	A–5—Service class (mark an X)					By aircraft type—				Sum of all aircraft types—	
Origin	Destination	F	G	L	P	Q	B–1—Aircraft type code	B–2—Revenue aircraft departures	B–3—Revenue passengers transported	B–4—Revenue freight transported (kg)	C–1—Total revenue passengers in market	C–2—Total revenue freight in market (kg)
AMS	ORD	X	....	....	....	....	8161	1	350	10000	50	1500
TLV	ORD	X	....	....	....	....	.....	.....	.....	.....	150	4000
TLV	LAX	X	....	....	....	....	.....	.....	.....	.....	125	3000
ORD	LAX	X	....	....	....	....	8161	1	150	4500	0	0
AMS	LAX	X	....	....	....	....	.....	.....	.....	.....	25	1500

(5) QF flight #25 SYD—BNE—CNS—HNL—YVR. This flight serves three homeland points, a U.S. point, and a subsequent third country. Nonstop segment information is required on the respective legs into and out of the United States. All on-flight market entries involving the U.S. point HNL are also required. Data are not required on the homeland to homeland markets, or the homeland—third country markets.

QF—Qantas Airways (Australia)
SYD—Sydney, Australia
BNE—Brisbane, Australia
CNS—Cairns, Australia
HNL—Honolulu, USA
YVR—Vancouver, Canada

A–3—Airport code	A–4—Airport code	A–5—Service class (mark an X)					By aircraft type—				Sum of all aircraft types—	
Origin	Destination	F	G	L	P	Q	B–1—Aircraft type code	B–2—Revenue aircraft departures	B–3—Revenue passengers transported	B–4—Revenue freight transported (kg)	C–1—Total revenue passengers in market	C–2—Total revenue freight in market (kg)
CNS	HNL	X	....	....	....	....	8161	5	2200	41000	400	8000
SYD	HNL	X	....	....	....	....	.....	.....	.....	.....	600	10000
BNE	HNL	X	....	....	....	....	.....	.....	.....	.....	600	9000
HNL	YVR	X	....	....	....	....	8161	5	750	15700	150	1700

(6) JL flight #002 HKG—NRT—SFO. This flight originates in a third country prior to the homeland. No data is required on the HKG–NRT leg, but the HKG–SFO passengers and cargo shall be shown as enplanements in the NRT–SFO on-flight market entry. These volumes are included by definition in the passenger and cargo transported volumes of the NRT–SFO nonstop segment entry.

JL—Japan Air Lines
HKG—Hong Kong, Hong Kong

NRT—Tokyo-Narita, Japan SFO—San Francisco, USA

A–3—Airport code	A–4—Airport code	A–5—Service class (mark an X)					By aircraft type—				Sum of all aircraft types—	
Origin	Destination	F	G	L	P	Q	B–1—Aircraft type code	B–2—Revenue aircraft departures	B–3—Revenue passengers transported	B–4—Revenue freight transported (kg)	C–1—Total revenue passengers in market	C–2—Total revenue freight in market (kg)
NRT	SFO	X	....	....	....	....	8161	3	1200	18000	1200	18000

(7) JL flight #001 SFO–NRT–HKG. This flight is the reverse sequence of flight #002 above; it requires a nonstop segment entry covering SFO–NRT, and a single on-flight market entry also for SFO–NRT. In this case, the on flight traffic enplaned at SFO and destined for HKG, a beyond homeland point, shall be included in the SFO–NRT entry; a separate SFO–HKG entry is not required.

JL—Japan Air Lines
SFO—San Francisco, USA
NRT—Tokyo-Narita, Japan
HKG—Hong Kong, Hong Kong

A–3—Airport code	A–4—Airport code	A–5—Service class (mark an X)					By aircraft type—				Sum of all aircraft types—	
Origin	Destination	F	G	L	P	Q	B–1—Aircraft type code	B–2—Revenue aircraft departures	B–3—Revenue passengers transported	B–4—Revenue freight transported (kg)	C–1—Total revenue passengers in market	C–2—Total revenue freight in market (kg)
SFO	NRT	X	....	....	....	....	8161	1	400	20000	400	20000

(8) BA flight #5 LHR–ANC–NRT–OSA. This example contains a single homeland point and a single U.S. point followed by two third country points. It is necessary to report the nonstop segments into and out of the U.S., and all three of the on-flight markets which have the U.S. point ANC as either an origin or destination.

BA—British Airways
LHR—London, England
ANC—Anchorage, USA
NRT—Tokyo-Narita, Japan
OSA—Osaka, Japan

A–3—Airport code	A–4—Airport code	A–5—Service class (mark an X)					By aircraft type—				Sum of all aircraft types—	
Origin	Destination	F	G	L	P	Q	B–1—Aircraft type code	B–2—Revenue aircraft departures	B–3—Revenue passengers transported	B–4—Revenue freight transported (kg)	C–1—Total revenue passengers in market	C–2—Total revenue freight in market (kg)
LHR	ANC	X	....	....	....	....	8161	10	3000	50000	100	1000
ANC	NRT	X	....	....	....	....	8161	10	3150	55000	100	2500
ANC	OSA	X	....	....	....	....	.....	.....	.....	.....	150	1500

(d) Provisions to reduce paperwork:

(1) Nonstop Segment Entries. The flight stage data applicable to nonstop segment entries must be summarized to create totals by aircraft equipment type, within service class, within pairs-of-points.

(2) On-flight Market Entries. The applicable on-flight market entries shall be summarized to create totals by service class within pair-of-points.

(e) Preparation of Schedule T–100 (f):

(1) Section A—Indicative and flight pattern information. A copy of Schedule T–100(f) is shown at the end of this appendix. Section A defines the origin and destination points and the service class code to which the nonstop segment data in Section B and the on-flight market data in Section C are applicable. Section A information, along with the carrier code and report date, must be included on each schedule.

(2) Section B—Nonstop segment information. Section B of the schedule is used for reporting nonstop segment information by aircraft type. To reduce the number of schedules reported, space is provided for including data on multiple different aircraft types. Similarly, the on-flight market section has been included on a single Schedule T–100(f), along with the nonstop segment data, rather than on a separate schedule.

(3) Section C—On-flight market information. Section C of the schedule is used for reporting on-flight market data. There will always be an on-flight market that corresponds to the nonstop segment. Because the on-flight market data are reported at the service class level rather than by aircraft type, a specific flight may produce more on-flight markets than nonstop segments, (see examples in paragraph (c) of this appendix), resulting in data reported in sections A and C only.

(f) [Reserved]

(g) Data element definitions:

(1) Service pattern information.

(i) Line A–1 Carrier code. Use the carrier code established by the Department. This code is provided to each carrier in the initial reporting letter from the Office of Airline Information (OAI). If there are any questions about these codes, contact the OAI Data Administration Division at the address in paragraph (a)(3) of this appendix.

(ii) Line A–2 Report date. This is the year and month to which the data are applicable. For example, 200009 indicates the year 2000, and the month of September.

(iii) Line A–3 Origin airport code. This is the departure airport, where an aircraft begins a flight segment, and where the passengers originate in an on-flight market. Use the 3-letter code from the City/Airport Codes section of the Official Airline Guide Worldwide Edition. If no 3-letter code is available, OAI will assign one; the address is in paragraph (a)(3) of this appendix.

(iv) Line A–4 Destination airport code. This is the arrival airport, where an aircraft stops on a flight segment, and where passengers deplane (get off the flight) after reaching their destination in a market. Use the 3-letter code from the source described in paragraph (g)(1)(iii) of this appendix.

(v) Line A–5 Service class code. Select one of the following single letter codes which describes the type of service being reported on a given flight operation.

F = Scheduled Passenger/cargo Service
G = Scheduled All-cargo Service
L = Nonscheduled Civilian Passenger/Cargo Charter
P = Nonscheduled Civilian All-Cargo Charter
Q = Nonscheduled Services (Other than Charter)

(2) Nonstop segment information:

(i) Line B–1 Aircraft type code. Use the four digit numeric code prescribed in paragraph (h)(1) of this appendix. If no aircraft type code is available, OAI will

assign one. The address is in paragraph (a)(3) of this appendix.

(ii) Line B–2 Aircraft departures performed. This is the total number of physical departures performed with a given aircraft type, within service class and pair-of-points.

(iii) Line B–3 Revenue passengers transported. This is the total number of revenue passengers transported on a given nonstop segment. It represents the total number of revenue passengers on board over the segment without regard to their actual point of enplanement.

(iv) Line B–4 Revenue freight transported. This item is the total weight in kilograms (kg) of the revenue freight transported on a given nonstop segment without regard to its actual point of enplanement.

(3) On-flight market information:

(i) Line C–1 Total revenue passengers in market. This item represents the total number of revenue passengers, within service class, that were enplaned at the origin airport and deplaned at the destination airport.

(ii) Line C–2 Total revenue freight in market. This item represents the total weight in kilograms (kg) of revenue freight enplaned at the origin and deplaned at the destination airport.

(h) [Reserved]

(i) Joint Service.

(1) The Department may authorize joint service operations between two direct air carriers. Examples of these joint service operations are:

Blocked-space agreements;

Part-charter agreements;

Code-sharing agreements;

Wet-lease agreements, and similar arrangements.

(2) Joint-service operations shall be reported on BTS Form 41 Schedules T–100 and T–100(f) by the air carrier in operational control of the flight, *i.e.,* the air carrier that uses its flight crew to perform the operation. If there are questions about reporting a joint-service operation, contact the BTS Assistant Director—Airline Information at the address in paragraph (a)(3) of this appendix.

(j) [Reserved]

PART 218—LEASE BY FOREIGN AIR CARRIER OR OTHER FOREIGN PERSON OF AIRCRAFT WITH CREW

■ 54. The authority citation for part 218 is revised to read as follows:

Authority: 49 U.S.C. 40113 and 41301.

§ 218.2 [AMENDED]

■ 55. In § 218.2, remove the words ''section 402 of the Act'' and add in their place ''49 U.S.C. 41301''.

§ 218.3 [AMENDED]

■ 56. Amend § 218.3 as follows:

■ a. In paragraph (a)(1), remove the words ''section 402 of the Act'' and add in their place ''49 U.S.C. 41301''.

■ b. In paragraph (a)(2), remove the words ''section 416 of the Act'' and add in their place ''49 U.S.C. 40109''.

■ c. In paragraphs (a)(2) and (3), remove the word ''Board'' and add in its place the word ''Department''.

§ 218.5 [AMENDED]

■ 57. In § 218.5, remove the word ''Board'' each place it appears and add in its place the word ''Department''.

§ 218.6 [AMENDED]

■ 58. In § 218.6, remove the word ''Board'' and add in its place the word ''Department''.

PART 221—TARIFFS

■ 59. The authority citation for part 221 continues to read as follows:

Authority: 49 U.S.C. 40101, 40109, 40113, 46101, 46102, chapter 411, chapter 413, chapter 415 and chapter 417, subchapter I.

■ 60. Throughout part 221, remove the words ''of the statute'' and add in their place ''of 49 U.S.C. Subtitle VII''.

§ 221.3 [AMENDED]

■ 61. In § 221.3, remove the definitions for ''Department'' and ''Statute''.

■ 62. Section 221.105 is revised to read as follows:

§ 221.105 Special notice of limited liability under international treaty.

(a)(1) In addition to the other requirements of this subpart, each air carrier and foreign air carrier which, to any extent, avails itself of the limitation on liability to passengers provided by an international treaty, shall, at the time of delivery of the ticket, furnish to each passenger whose transportation is governed by the international treaty and whose place of departure or place of destination is in the United States, the following statement in writing:

Advice to International Passengers on Limitations of Liability

Passengers embarking upon a journey involving an ultimate destination or a stop in a country other than the country of departure are advised that the provisions of an international treaty (the Warsaw Convention, the 1999 Montreal Convention, or other treaty), as well as a carrier's own contract of carriage or tariff provisions, may be applicable to their entire journey, including any portion entirely within the countries of departure and destination. The applicable treaty governs and may limit the liability of carriers to passengers for death or personal injury, destruction or loss of, or damage to, baggage, and for delay of passengers and baggage.

Additional protection can usually be obtained by purchasing insurance from a private company. Such insurance is not affected by any limitation of the carrier's liability under an international treaty. For further information please consult your airline or insurance company representative.

(2) The statement prescribed in paragraph (a)(1) of this section shall be printed or displayed in type at least as large as 10-point modern type and in a form that contrasts with the stock or background on:

(i) Each ticket, including electronic tickets;

(ii) A piece of paper either placed in the ticket envelope with the ticket or attached to the ticket; or

(iii) The ticket envelope.

(3) When a carrier is a signatory of a Department-approved intercarrier agreement implementing an international treaty, and such agreement contains specific text a carrier may use as a notice to international passengers regarding carrier liability, the carrier may substitute the exact text contained in the intercarrier agreement in lieu of the required text of the notice quoted in paragraph (a)(1) of this section.

(b) By December 31, 2019, each air carrier and foreign air carrier which, to any extent, avails itself of the limitation on liability to passengers provided by an international treaty, shall also cause to be displayed continuously in a conspicuous public place at each desk, station, and position in the United States which is in the charge of a person employed exclusively by it or by it jointly with another person, or by any agent employed by such air carrier or foreign air carrier to sell tickets to passengers whose transportation may be governed by an international treaty and whose place of departure or destination may be in the United States, a sign which shall have printed thereon the statement prescribed in paragraph (a)(1) of this section.

(c) It shall be the responsibility of each carrier to ensure that travel agents authorized to sell air transportation for such carrier comply with the notice provisions of paragraphs (a) and (b) of this section.

(d) Any air carrier or foreign air carrier subject to the provisions of this section which wishes to use a notice of limited liability of its own wording, but containing the substance of the language prescribed in paragraphs (a) and (b) of this section, may substitute a notice of its own wording upon approval by the Department.

(e) The requirements as to time and method of delivery of the notice (including the size of type) specified in paragraphs (a) and (b) of this section and the requirement with respect to travel agents specified in paragraph (c) of this section may be waived by the Department upon application and

showing by the carrier that special and unusual circumstances render the enforcement of the regulations impractical and unduly burdensome and that adequate alternative means of giving notice are employed.

(f) Applications for relief under paragraphs (d) and (e) of this section shall be filed with the Department's Office of International Aviation not later than 15 days before the date on which such relief is requested to become effective.

(g) Notwithstanding any other provisions of this section, no air taxi operator subject to part 298 of this subchapter shall be required to give the notices prescribed in this section, either in its capacity as an air carrier or in its capacity as an agent for an air carrier or foreign air carrier.

§ 221.106 [REMOVED AND RESERVED]

■ 63. Section 221.106 is removed and reserved.

PART 222—INTERMODAL CARGO SERVICES BY FOREIGN AIR CARRIERS

■ 64. The authority citation for part 222 is revised to read as follows:

Authority: 49 U.S.C. 40113 and 41301.

§ 222.2 [AMENDED]

■ 65. In § 222.2(a) and (d), remove the word ''Board'' each place it appears and add in its place the word ''Department''.

■ 66. In § 222.3, paragraphs (a) and (b) are revised to read as follows:

§ 222.3 Application for Statement of Authorization.

(a) Application for a Statement of Authorization shall be filed with the Department's Foreign Air Carrier Licensing Division, Office of International Aviation, in duplicate, on OST Form 4500. In most cases, the Department will act upon applications for Statements of Authorization within 60 days.

(b) Persons objecting to an application for a Statement of Authorization shall file their objections with the Foreign Air Carrier Licensing Division, Office of International Aviation, within 28 days of the filing date of the application. The Department will list the names and nationalities of all persons applying for Statements of Authorization in its Weekly Summary of Filings.

* * * * *

§ 222.4 [AMENDED]

■ 67. Amend § 222.4 as follows:

■ a. In paragraph (a) introductory text, remove the word ''Board'' and add in its place the word ''Department''.

■ b. In paragraph (a)(1), remove ''CAB Form 222'' and ''Form 222'' and add in their place ''OST Form 4500'' and ''Form 4500'', respectively.

■ c. In paragraph (b), remove the word ''Board's'' and add in its place the word ''Department's''.

§ 222.5 [AMENDED]

■ 68. In § 222.5, remove the word ''Board'' each place it appears and add in its place the word ''Department''.

Appendix A to Part 222 [REMOVED]

■ 69. Appendix A to part 222 is removed.

PART 223—FREE AND REDUCED-RATE TRANSPORTATION

■ 70. The authority citation for part 223 is revised to read as follows:

Authority: 49 U.S.C. 40113, 40114, and 41711.

■ 71. Section 223.1 is revised to read as follows:

§ 223.1 Definitions.

As used in this part, unless the context otherwise requires:

Affiliate of a carrier means a person:

(1) Who controls that carrier, or is controlled by that carrier or by another person who controls or is controlled by that carrier; and

(2) Whose principal business in purpose or in fact is:

(i) The holding of stock in one or more carriers;

(ii) Transportation by air or the sale of tickets therefor;

(iii) The operation of one or more airports, one or more of which are used by that carrier or by another carrier who controls or is controlled by that carrier or that is under common control with that carrier by another person; or

(iv) Activities related to the transportation by air conducted by that carrier or by another carrier that controls or is controlled by that carrier or which is under common control with that carrier by another person.

Air carrier means the holder of a certificate of public convenience and necessity issued by the Department under 49 U.S.C. 41102 authorizing the carriage of persons. This definition is applicable to a holder of a certificate issued by the Civil Aeronautics Board before its sunset in 1984.

Attendant means any person required by a passenger with a disability in order to travel, whether or not that person's services are required while the passenger with a disability is in an aircraft.

Carrier means:

(1) An air carrier;

(2) An all-cargo air carrier operating under 49 U.S.C. 41102, 41103;

(3) A foreign air carrier;

(4) An intrastate carrier;

(5) An air taxi (including a commuter air carrier) operating under part 294 or 298 of this chapter; and

(6) Any person operating as a common carrier by air, or in the carriage of mail by air, or conducting transportation by air, in a foreign country.

Delivery flight means a flight from a point in the United States where a carrier has taken delivery of a newly manufactured aircraft to any point or points on its route system.

Foreign air carrier means the holder of a permit issued by the Department under 49 U.S.C. 41302 authorizing the carriage of persons. This definition is applicable to a holder of a certificate issued by the Civil Aeronautics Board before its sunset in 1984.

Free transportation means the carriage by an air carrier or foreign air carrier of any person or property (other than property owned by that carrier) in air transportation without compensation therefore.

Inaugural flight means a flight on an aircraft type being introduced by a carrier for the first time on a route, even if that aircraft type has been used by that carrier on other routes or on that route by other carriers.

Passenger with a disability means any person who has a physical or mental impairment (other than drug addiction or alcoholism), that substantially limits one or more major life activities.

Pass means a written authorization, other than actual ticket stock, issued by a carrier for free or reduced-rate transportation of persons or property.

Reduced-rate transportation means the carriage by an air carrier or foreign air carrier of any person or property (other than property owned by such carrier) in air transportation for a compensation less than that specified in the tariffs of that carrier on file with the Department and otherwise applicable to such carriage.

Retired means:

(1) With respect to carrier directors, officers, and employees, persons receiving retirement benefits from any carrier; and

(2) With respect to the general public, persons not regularly working at a full-time paying job, and not intending to do so in the future.

§ 223.2 [AMENDED]

■ 72. In § 223.2, remove the words ''section 401 of the Act'' everywhere they appear and add in their place ''49 U.S.C. 41102''.

§ 223.6 [AMENDED]

■ 73. In § 223.6(c), remove the word ''Board'' and add in its place the word ''Department''.

§ 223.21 [AMENDED]

■ 74. In § 223.21(a), remove the words ''section 403(b) of the Act'' and add in their place ''49 U.S.C. 41511''.

§ 223.22 [AMENDED]

■ 75. In § 223.22:
■ a. In the introductory text, remove the words ''sections 403 and 404(b) of the Act'' and add in their place ''49 U.S.C. 41510 and 41310(b)''.
■ b. In paragraphs (b) introductory text and (b)(1), remove the word ''Board'' and add in its place the word ''Department''.

§ 223.23 [AMENDED]

■ 76. In § 223.23(a), remove the word ''Board'' and add in its place the word ''Department''.

§ 223.25 [AMENDED]

■ 77. In § 223.25(c), remove the word ''Board'' and add in its place the word ''Department''.

PART 232—[REMOVED]

■ 78. Part 232 is removed.

PART 234—AIRLINE SERVICE QUALITY PERFORMANCE REPORTS

■ 79. The authority citation for part 234 is revised to read as follows:

Authority: 49 U.S.C. 329, 41708, and 41709.

PART 240—INSPECTION OF ACCOUNTS AND PROPERTY

■ 80. Add an authority citation for part 240 to read as follows:

Authority: 49 U.S.C. 40113, 40114, 41711, 41708, and 41709.
■ 81. Section 240.1 is revised to read as follows:

§ 240.1 Interpretation.

(a) In the exercise of the authority granted by 49 U.S.C. 41709, the authority of any special agent or auditor to inspect and examine lands, buildings, equipment, accounts, records, memorandums, papers or correspondence shall include the authority to make such notes and copies thereof as he or she deems appropriate.

(b) The terms ''special agent'' and ''auditor'' are construed to mean any employee of the Office of Aviation Enforcement and Proceedings and any other employee of the Department specifically designated by it or by the Director, Office of Security.

(c) The issuance in the form set forth in this paragraph (c) of an identification card and credentials to any such employee shall be construed to be an order and direction of the Department to such individual to inspect and examine lands, buildings, equipment, accounts, records, and memorandums in accordance with the authority conferred on the Department by 49 U.S.C. Subtitle VII.

THE UNITED STATES OF AMERICA, DEPARTMENT OF TRANSPORTATION, OFFICE OF THE SECRETARY OF TRANSPORTATION

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IS APPOINTED

[title]

The bearer of this credential whose name and photograph appear hereon is authorized to enter upon, to inspect, and examine lands, buildings (including airport facilities), and equipment (including aircraft) of air carriers and foreign air carriers, and to inspect and copy records and papers of air carriers, foreign air carriers and ticket agents, in performance of his/her duties under 49 U.S.C. 41709, related acts, and regulations of the Department.

BY DIRECTION OF THE SECRETARY

§ 240.2 [AMENDED]

■ 82. Amend § 240.2 as follows:
■ a. Remove the word ''Board'' and add in its place the word ''Department''.
■ b. Remove the word ''him'' and add in its place the words ''him or her''.
■ c. Remove ''(a)'' and ''(b)''.
■ d. Remove the word ''he'' and add in its place the words ''he or she''.

PART 241—UNIFORM SYSTEM OF ACCOUNTS AND REPORTS FOR LARGE CERTIFICATED AIR CARRIERS

■ 83. The authority citation for part 241 is revised to read as follows:

Authority: 49 U.S.C. 329, 41101, 41708, and 41709.

Section 01 [REMOVED AND RESERVED]

■ 84. Section 01 is removed and reserved.
■ 85. In Section 03, remove the definition for ''Act'' and revise the definitions for ''Air transportation, charter'' and ''Route, certificated'' to read as follows:

Section 03 Definitions for Purposes of This System of Accounts and Reports.

* * * * *

Air transportation, charter. Air transportation authorized pursuant to 49 U.S.C. 41102.

* * * * *

Route, certificated. The route(s) over which an air carrier is authorized to provide air transportation by a Certificate of Public Convenience and Necessity issued by the Department of Transportation pursuant to 49 U.S.C. 41102. This definition is applicable to an air carrier issued a Certificate of Public Convenience by the Civil Aeronautics Board before its sunset in 1984.

* * * * *

Section 04 [AMENDED]

■ 86. In Section 04(b), remove the words ''The Office of Airline Statistics'' and add in their place ''The Office of Airline Information''.

Section 12 [AMENDED]

■ 87. In Section 12, under heading 77, in paragraph (b), remove the words '', in the absence of such action by the Civil Aeronautics Board,''.

Sec. 19–6 [AMENDED]

■ 88. In Sec. 19–6(b)(2), remove the words ''Department under Title IV of the Federal Aviation Act of 1958, as amended,'' and add in their place the words ''Department under 49 U.S.C. Subtitle VII,''.
■ 89. Amend Sec. 19–7 as follows:
■ a. In paragraph (a), in the last sentence, remove ''K–25'' and add in its place ''RTS–42''.
■ b. In appendix A, subsection I.B., in the first paragraph, revise the last sentence.

The revision reads as follows:

Sec. 19–7 Passenger origin-destination survey.

* * * * *

Appendix A to § 19–7—Instructions to Air Carriers for Collecting and Reporting Passenger Origin-Destination Survey Statistics

* * * * *

I. * * *

B. * * *

* * * The authority for these instructions is found in 14 CFR part 241, sec. 19–7.

* * * * *

Section 21 [AMENDED]

■ 90. Amend Section 21(a) as follow:
■ a. Remove the words ''subject to the Federal Aviation Act of 1958, as amended,''.
■ b. Remove the words ''Civil Aeronautics Board'' and add in their place the word ''BTS''.
■ 91. Amend Section 22 as follows:
■ a. In paragraph (a), in the table entitled ''List of Schedules in the BTS Form 41 Report'', revise the entry for Schedule No. P–2.

■ b. In paragraphs (c) and (j), remove the word ''Board'' each place it appears and add in its place the word ''BTS''.

The revision reads as follows:

Section 22 General Reporting Instructions.

(a) * * *

LIST OF SCHEDULES IN BTS FORM 41 REPORT

[See footnotes at end of table]

Schedule No.	Title	Filing frequency	Applicability by carrier group		
			I	II	III
*	*	* * *	*	*	
P–2	Notes to BTS Form 41 report	Q	(1)	X	X
*	*	* * *	*	*	

* * * * *

Section 24 [AMENDED]

■ 92. In Section 24, Schedule P–5.1, in paragraph (e), remove the words ''Board's Information Management Division'' and add in their place the words ''Office of Airline Information, RTS–42''.

PART 243—PASSENGER MANIFEST INFORMATION

■ 93. The authority citation for part 243 continues to read as follows:

Authority: 49 U.S.C. 40101, 40101nt., 40105, 40113, 40114, 41708, 41709, 41711, 41501, 41702, 41712, 44909, 46301, 46310, 46316; section 203 of Pub. L. 101–604, 104 Stat. 3066 (22 U.S.C. 5501–5513), Title VII of Pub. L. 104–264, 110 Stat. 3213 (22 U.S.C. 5501–5513) and Pub. L. 105–148, 111 Stat. 2681 (49 U.S.C. 41313.)

§ 243.11 [AMENDED]

■ 94. In § 243.11(c), remove the words ''Family Support Services'' and add in their place the words ''Transportation Disaster Assistance''.

§ 243.13 [AMENDED]

■ 95. Amend § 243.13(c) as follows:

■ a. Remove the words ''Dockets Facility (SVC–121.30)'' and add in their place the words ''Dockets Management Facility (M–90)''.

■ b. Remove the words ''by July 1, 1998, or, for covered airlines beginning operations after July 1, 1998,''.

PART 247—DIRECT AIRPORT-TO-AIRPORT MILEAGE RECORDS

■ 96. The authority citation for part 247 continues to read as follows:

Authority: 49 U.S.C. chapter 401.

§ 247.1 [AMENDED]

■ 97. In § 247.1, remove the words ''Titles IV and X of the Federal Aviation Act of 1958, as amended'' and add in their place ''49 U.S.C. Subtitle VII (Transportation)''.

§§ 247.2 through 247.10 [ADDED AND RESERVED]

■ 98. Add reserved §§ 247.2 through 247.10.

PART 248—SUBMISSION OF AUDIT REPORTS

■ 99. The authority citation for part 248 is revised to read as follows:

Authority: 49 U.S.C. 329, 41102, 41708, and 41709.

§ 248.2 [AMENDED]

■ 100. In § 248.2(b), remove the words ''Board's Office of the Comptroller'' and add in their place the words ''Bureau of Transportation Statistics' (BTS) Office of Airline Information''.

PART 249—PRESERVATION OF AIR CARRIER RECORDS

■ 101. The authority citation for part 249 continues to read as follows:

Authority: 49 U.S.C. 329 and chapters 401, 411, 413, 417.

§§ 249.6 and 249.10 [AMENDED]

■ 102. In §§ 249.6(a) and 249.10, remove ''this regulation'' and add in its place ''this part''.

§ 249.7 [AMENDED]

■ 103. In § 249.7(b), remove the word ''Board'' and add in its place the word ''Department''.

§ 249.9 [AMENDED]

■ 104. In § 249.9, remove ''these regulations'' and add its place ''this part''.

PART 251—CARRIAGE OF MUSICAL INSTRUMENTS

■ 105. The authority citation for part 251 continues to read as follows:

Authority: 49 U.S.C. 41724.

§ 251.1 [AMENDED]

■ 106. In § 251.1, remove the definition for ''FAA''.

PART 253—NOTICE OF TERMS OF CONTRACT OF CARRIAGE

■ 107. The authority citation for part 253 is revised to read as follows:

Authority: 49 U.S.C. 40113, 40114, 41501, 41504, 41506, 41509, 41510, 41511, 41702, and 41711.

§ 253.1 [AMENDED]

■ 108. In § 253.1, remove the words ''of this rule'' and add in their place ''of this part''.

§ 253.2 [AMENDED]

■ 109. In § 253.2, remove the words ''This rule'' and add in their place ''This part''.

§ 253.7 [AMENDED]

■ 110. In § 253.7, remove the reference ''§ 399.87'' and add in its place the reference ''§ 399.88''.

PART 257—DISCLOSURE OF CODE-SHARING ARRANGEMENTS AND LONG-TERM WET LEASES

■ 111. The authority citation for part 257 continues to read as follows:

Authority: 49 U.S.C. 40113(a) and 41712.

§ 257.3 [AMENDED]

■ 112. Amend § 257.3 as follows:

■ a. Revise the definition of ''Designator code''.

■ b. Redesignate paragraph (g) as an undesignated paragraph.

■ c. In the definition of ''Ticket agent'', remove ''49 U.S.C. 40102(40)'' and add in its place ''49 U.S.C. 40102(45)''.

The revision reads as follows:

§ 257.3 Definitions.

* * * * *

Designator code means the airline designations originally allotted, administered, and prescribed by the Department of Transportation (DOT), by operation of law, pursuant to 49 U.S.C. Subtitle VII or its predecessor's statutory provisions still in effect by law.

* * * * *

PART 258—DISCLOSURE OF CHANGE-OF-GAUGE SERVICES

■ 113. The authority citation for part 258 continues to read as follows:

Authority: 49 U.S.C. 40113(a) and 41712.

§ 258.3 [AMENDED]

■ 114. In § 258.3(d), remove the reference ''40102(40)'' and add in its place the reference ''40102(a)(45)''.

PART 259—ENHANCED PROTECTIONS FOR AIRLINE PASSENGERS

■ 115. The authority citation for part 259 continues to read as follows:

Authority: 49 U.S.C. 40101(a)(4), 40101(a)(9), 40113(a), 41702, and 41712.

§ 259.4 [AMENDED]

■ 116. In § 259.4(d) and (f), remove ''this rule'' and add in its place ''this section''.

PART 271—GUIDELINES FOR SUBSIDIZING AIR CARRIERS PROVIDING ESSENTIAL AIR TRANSPORTATION

■ 117. The authority citation for part 271 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 417.

■ 118. In § 271.2, the definition for ''Eligible place'' is revised to read as follows:

§ 271.2 Definitions.

* * * * *

Eligible place means a place in the United States that meets the specified criteria outlined in 49 U.S.C. Chapter 417.

* * * * *

PART 272—[REMOVED AND RESERVED]

■ 119. Part 272 is removed and reserved.

PART 291—CARGO OPERATIONS IN INTERSTATE AIR TRANSPORTATION

■ 120. The authority citation for part 291 is revised to read as follows:

Authority: 49 U.S.C. 329, 41103, 41708, and 41709.

■ 121. Throughout part 291, remove the words ''of the Statute'' and add in their place ''of 49 U.S.C. Subtitle VII''.

§ 291.45 [AMENDED]

■ 122. In § 291.45, remove the appendix to the section.

■ 123. Add appendix A to subpart E to read as follows:

Appendix A to Subpart E of Part 291—Instructions to U.S. Air Carriers for Reporting Traffic and Capacity Data on Schedule T–100

(a) *Format of reports*—(1) *Automatic Data Processing (ADP) magnetic tape.* Refer to paragraph (d) of this appendix for instructions pertaining to mainframe and minicomputer reporting. The Department will issue ''Accounting and Reporting Directives'' to make necessary technical changes to these T–100 instructions. Technical changes which are minor in nature do not require public notice and comment.

(2) *Microcomputer diskette*—(i) *Optional specification.* If an air carrier desires to use its personal computers (PC's), rather than mainframe or minicomputers to prepare its data submissions, the following specifications for filing data on diskette media apply.

(ii) *Reporting medium.* Microcomputer ADP data submission of T–100 information must be on IBM compatible disks. Carriers wishing to use a different ADP procedure must obtain written approval to do so from the BTS Assistant Director—Airline Information. Requests for approval to use alternate methods must disclose and describe the proposed data transmission methodology. Refer to paragraph (i) of this appendix for microcomputer record layouts.

(iii) *Microcomputer file characteristics.* The files will be created in ASCII delimited format, sometimes called Data Interchange Format (DIF). This form of recording data provides for variable length fields (data elements) which, in the case of alphabetic data, are enclosed by quotation marks (") and separated by a comma (,) or tab. Numeric data elements that are recorded without editing symbols are also separated by a comma (,) or tab. The data are identified by their juxtaposition within a given record. Therefore, each record must contain the exact number of data elements, all of which must be juxtapositionally correct. Personal computer software including most spreadsheets, data base management programs, and BASIC are capable of producing files in this format.

(b) *Filing date for reports.* The reports must be received at BTS within 30 days following the end of each reporting period.

(c) *Address for filing.* Data Administration Division, RTS–42, Office of Airline Information, Bureau of Transportation Statistics, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

(d) *ADP format for magnetic tape*—(1) *Magnetic tape specifications.* IBM compatible 9-track EBCDIC recording. Recording density of 6250 or 1600 bpi. The order of recorded information is:

(i) Volume label.

(ii) Header label.

(iii) Data records.

(iv) Trailer label.

(2) [Reserved]

(e) *External tape label information.* (1) Carrier name.

(2) Report date.

(3) File identification.

(4) Carrier address for return of tape reel.

(f) *Standards.* It is the policy of the Department to be consistent with the American National Standards Institute and the Federal Standards Activity in all data processing and telecommunications matters. It is our intention that all specifications in this application are in compliance with standards promulgated by these organizations.

(g) *Volume, header, and trailer label formats*—(1) *Use standard IBM label formats.* The file identifier field of the header labels should be ''T–100.SYSTEM''.

(h) *Magnetic tape record layouts for T–100*—(1) *Nonstop segment record layout.*

Field No.	Positions	Mode	Description
1	1	1T	Record type code (S = nonstop segment).
2	2–6	5T	Carrier entity code.
3	7–12	6T	Report date (YYYYMM).
4	13–15	3T	Origin airport code.
5	16–18	3T	Destination airport code.
6	19	1T	Service class code (F, G, L, N, P or R).
7	20–23	4T	Aircraft type code.
8	24–28	5N	Revenue departures performed (F, G, L, N, P, R510).
9	29–38	10N	Available capacity payload (lbs) (F, G, L, N, P, R270).
10	39–45	7N	Available seats (F, L, N310).
11	46–52	7N	Passengers transported (F, L, N130).
12	53–62	10N	Rev freight transported (F, G, L, N, P, R237) (in lbs).

Field No.	Positions	Mode	Description
13	63–72	10N	Revenue mail transported (F, G, L, N, P, R239) (in lbs).
14	73–77	5N	Revenue aircraft departures scheduled (F, G520).
15	78–87	10N	Rev hrs, ramp-to-ramp (F, G, L, N, P, R630) (in minutes).
16	88–97	10N	Rev hrs, airborne (F, G, L, N, P, R610) (in minutes).

T = Text.
N = Numeric.

(2) *On-flight market record layout.*

Field No.	Positions	Mode	Description
1	1	1T	Record type: M = on-flight market record.
2	2–6	5T	Carrier entity code.
3	7–12	4T	Report date (YYYYMM).
4	13–15	3T	Origin airport code.
5	16–18	3T	Destination airport code.
6	19	1T	Service class code (F, G, L, N, P or R).
7	20–26	7N	Total passengers in market (F, L, N110).
8	27–36	10N	Rev freight in market (F, G, L, N, P, R217) (in lbs).
9	37–46	10N	Revenue mail in market (F, G, L, N, P, R219) (in lbs).

T = Text.
N = numeric.

(i) *Record layouts for microcomputer diskettes.* The record layouts for diskette are generally identical to those shown for magnetic tape, with the exception that delimiters (quotation marks, tabs and commas) are used to separate fields. It is necessary that the order of fields be maintained in all records.

(1) *File characteristics.* The files will be created in ASCII delimited format, sometimes called Data Interchange Format (DIF). This form of recording data provides for variable length fields (data elements) which, in the case of alphabetic data, are enclosed by quotation marks ('') and separated by a comma (,) or tab. Numeric data elements that are recorded without editing symbols are also separated by a comma (,) or tab. The data are identified by their juxtaposition within a given record. Therefore, it is critical that each record contain the exact number of data elements, all of which must be juxtapositionally correct. PC software including most spreadsheets, data base management programs, and BASIC produce minidisk files in this format.

(2) *File naming conventions for diskettes.* For microcomputer reports, each record type should be contained in a separate DOS file on the same physical diskette. The following DOS naming conventions should be followed:

(i) Record type S = SEGMENT.DAT

(ii) Record type M = MARKET.DAT

§ 291.60 [AMENDED]

■ 124. In § 291.60(b)(2), remove the words ''Title IV of the Federal Aviation Act of 1958, as amended'' and add in their place the words ''49 U.S.C. Subtitle VII (Transportation)''.

PART 294—CANADIAN CHARTER AIR TAXI OPERATORS

■ 125. The authority citation for part 294 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 417.

■ 126. Throughout part 294:

■ a. Remove the words ''Special Authorities Division'' and add in their place the words ''U.S. Air Carrier Licensing/Special Authorities Division''.

■ b. Remove the words ''of the Statute'' and add in their place ''of 49 U.S.C. Subtitle VII''.

■ c. Remove the words ''of the Federal Aviation Regulations'' and add in their place ''of this title (the Federal Aviation Regulations)''.

■ d. Add the words ''in 14 CFR chapter I'' immediately following the words ''FAA regulations''.

§ 294.10 [AMENDED]

■ 127. In § 294.10, add a period at the end of paragraph (d).

§ 294.30 [AMENDED]

■ 128. In § 294.30(c), remove the words ''exemption under section 41701'' and add in their place the words ''exemption under 49 U.S.C. 40109''.

PART 296—INDIRECT AIR TRANSPORTATION OF PROPERTY

■ 129. The authority citation for part 296 continues to read as follows

Authority: 49 U.S.C. Chapters 401, 417.

■ 130. Throughout part 296, remove the words ''of the Statute'' and add in their place ''of 49 U.S.C. Subtitle VII''.

§ 296.3 [AMENDED]

■ 131. In § 296.3, remove the words ''the Civil Aeronautics Board'' and add in their place the words ''its predecessor to the extent that those actions, by law, are still in effect''.

PART 297—FOREIGN AIR FREIGHT FORWARDERS AND FOREIGN COOPERATIVE SHIPPERS ASSOCIATIONS

■ 132. The authority citation for part 297 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 417.

■ 133. Throughout part 297:

■ a. Remove the words ''Aviation Analysis'' and add in their place the words ''International Aviation''.

■ b. Remove the words ''Special Authorities Division'' and add in their place the words ''U.S. Air Carrier Licensing/Special Authorities Division''.

■ c. Remove the words ''of the Statute'' and add in their place ''of 49 U.S.C. Subtitle VII''.

§ 297.3 [AMENDED]

■ 134. In § 297.3(b), remove the words ''bona fide asociation'' and add in their place the words ''bona fide association''.

PART 298—EXEMPTIONS FOR AIR TAXI AND COMMUTER AIR CARRIER OPERATIONS

■ 135. The authority citation for part 298 continues to read as follows:

Authority: 49 U.S.C. 329 and chapters 401, 411, and 417.

■ 136. Throughout part 298, remove the words ''of the Statute'' and add in their place the words ''of 49 U.S.C. Subtitle VII''.

■ 137. Amend § 298.2 as follows:

■ a. The definition for ''Eligible place'' is revised.

■ b. In the definitions for ''Maximum payload capacity'' and ''Nonrevenue passenger'', add the words ''in 14 CFR

chapter I'' immediately following the words ''FAA regulations''.
■ c. Remove the definition for ''Statute''.
The revision reads as follows:

§ 298.2 Definitions.

* * * * *

Eligible place means a place in the United States that meets the specified criteria outlined in 49 U.S.C. Chapter 417.

* * * * *

§ 298.21 [AMENDED]

■ 138. Amend § 298.21 as follows:
■ a. In paragraph (a), remove the words ''Program Management Branch'' and add in their place the words ''Technical Programs Branch''.
■ b. In footnote 6 to paragraph (c)(1), remove the words ''Program Management Branch, Federal Aviation Administration, AFS–260, or on the World Wide Web at *http://www.faa.gov/avr/afs/afs200/afs260/Part298.cfm*'' and add in their place the words ''Technical Programs Branch, Federal Aviation Administration, AFS–260 at (202) 267–8166, or on the internet at *https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/afx/afs/afs200/afs260/exemptions/*''.
■ c. In paragraph (d), in the first sentence, remove the words ''Program Management Branch (AFS–260), 800 Independence Avenue SW, Washington, DC 20591'' and add in their place the words ''Technical Programs Branch (AFS–260), 800 Independence Avenue SW, Room 831, Washington, DC 20591''.

§ 298.23 [AMENDED]

■ 139. Amend § 298.23(b) as follows:
■ a. Remove the words ''Program Management Branch (AFS–260), 800 Independence Avenue SW, Washington, DC 20591'' and add in their place the words ''Technical Programs Branch (AFS–260), 800 Independence Avenue SW, Room 831, Washington, DC 20591''.
■ b. Remove the words ''Alaskan Region Headquarters (AAL–230), 222 West 7th Avenue, Box 14, Anchorage, Alaska 99513'' and add in their place the words ''Alaskan Region Headquarters Technical Standards Branch, (AAL–231), 222 West 7th Avenue, Box 14, Anchorage, Alaska 99513''.
■ 140. Amend § 298.50 as follows:
■ a. Revise paragraph (a)(3).
■ b. In paragraph (b), remove the words ''Department of Transportation Dockets,'' and add in their place the words ''Docket Operations Office, U.S. Department of Transportation,''.
The revision reads as follows:

§ 298.50 Application.

(a) * * *

(3) A $670 filing fee submitted in accordance with the provisions of § 389.21 of this chapter.

* * * * *

■ 141. In § 298.60, revise paragraph (a) to read as follows:

§ 298.60 General reporting instruction.

(a) Each commuter air carrier and each small certificated air carrier shall file with the Department's Bureau of Transportation Statistics (BTS) the applicable schedules of BTS Form 298–C, ''A Report of Financial and Operating Statistics for Small Aircraft Operators'', and Schedule T–100, ''U.S. Air Carrier Traffic and Capacity Data by Nonstop Segment and On-Flight Market'', as required by this section.

* * * * *

§ 298.61 [AMENDED]

■ 142. Amend § 298.61 as follows:
■ a. In paragraph (a), remove the words ''AU.S. Air Carrier Traffic and Capacity Data by Nonstop Segment and On-Flight Market.'' '' and add in their place the words ''U.S. Air Carrier Traffic and Capacity Data by Nonstop Segment and On-Flight Market.''
■ b. In paragraph (b), remove the reference '''''298.60'' and add in its place ''§ 298.60''.
■ c. In paragraph (e)(2), remove the organizational code ''K–14'' and add in its place ''RTS–42''.

§ 298.70 [AMENDED]

■ 143. In § 298.70(d)(2), remove the words ''Title IV of the Federal Aviation Act of 1958, as amended'' and add in their place the words ''49 U.S.C. Subtitle VII (Transportation)''.

PART 300—RULES OF CONDUCT IN DOT PROCEEDINGS UNDER THIS CHAPTER

■ 144. The authority citation for part 300 continues to read as follows:

Authority: 49 U.S.C. subtitle I and chapters 401, 411, 413, 415, 417, 419, 421, 449, 461, 463, and 465.

§ 300.0a [REMOVED]

■ 145. Remove § 300.0a.

§ 300.2 [AMENDED]

■ 146. In § 300.2(c)(5), remove the words ''this rule'' and add in their place the words ''this section''.

§ 300.3 [AMENDED]

■ 147. Amend § 300.3 as follows:
■ a. In paragraph (b)(1), remove ''(DMS)'' and add in its place ''(*http://www.regulations.gov*)'' and remove the words ''and Media Management.''
■ b. In paragraph (b)(3), remove ''*http://dms.dot.gov*'' and add in its place ''*www.regulations.gov*''.
■ c. In paragraph (c)(1), remove the words ''and Media Management.''
■ 148. Amend § 300.4 as follows:
■ a. In paragraph (c), remove the reference ''paragraph (a)'' and in its place add the reference ''paragraph (b) of this section''.
■ b. Revise paragraph (d).
The revision reads as follows:

§ 300.4 Separation of functions in hearing cases.

* * * * *

(d) In enforcement cases, the Office of the Assistant General Counsel for Aviation Enforcement and Proceedings, under the supervision of the career Deputy General Counsel and the General Counsel, will conduct all enforcement proceedings and related investigative functions, while the non-career Deputy General Counsel will advise the DOT decisionmaker in the course of the decisional process. The Office of the Assistant General Counsel for Aviation Enforcement and Proceedings will report to the career Deputy General Counsel and the General Counsel. To ensure the independence of these functions, this Office and the General Counsel, for the purpose of this section, shall be considered an ''office'' as that term is used in paragraph (b) of this section, separate from the non-career Deputy General Counsel and the rest of the Office of the General Counsel.

§§ 300.8, 300.9, 300.10, 300.10a, 300.11, 300.12, 300.13, and 300.14 [REMOVED]

■ 149. Remove §§ 300.8, 300.9, 300.10, 300.10a, 300.11, 300.12, 300.13, and 300.14.

§ 300.15 [REDESIGNATED AS § 300.8 AND AMENDED]

■ 150. Redesignate § 300.15 as § 300.8 and amend newly redesignated § 300.8 by removing paragraph (b) and redesignating paragraph (a) as an undesignated paragraph.

§ 300.16 [REMOVED]

■ 151. Remove § 300.16.

§§ 300.17 through 300.20 [REDESIGNATED AS §§ 300.9 through 300.12]

■ 152. Redesignate §§ 300.17 through 300.20 as §§ 300.9 through 300.12, respectively.

PART 302—RULES OF PRACTICE IN PROCEEDINGS

■ 153. The authority citation for part 302 is revised to read as follows:

Authority: 39 U.S.C. 5402; 42 U.S.C. 4321, 49 U.S.C. Subtitle I and Chapters 401, 411, 413, 415, 417, 419, 461, 463, and 471.

■ 154. Throughout part 302, remove the words ''of the Statute'' and add in their

place the words ''of 49 U.S.C. Subtitle VII''.

§ 302.2 [Amended]

■ 155. In § 302.2, remove the definition for ''Statute''.

§ 302.3 [AMENDED]

■ 156. Amend § 302.3 as follows:

■ a. In paragraph (a)(1), remove the words ''the DOT Dockets Management System (DMS) internet website'' and add in their place ''*http://www.regulations.gov*''.

■ b. In paragraph (c), remove the words ''the specified DOT DMS internet website'' and add in their place ''*http://www.regulations.gov*''.

■ c. In paragraph (d)(1)(ii), remove the words ''the DOT DMS internet website'' and add in their place ''*http://www.regulations.gov*''.

§ 302.4 [AMENDED]

■ 157. In § 302.4, remove the words ''the DOT DMS internet website'' each place they appear and add in their place ''*http://www.regulations.gov*''.

§ 302.7 [AMENDED]

■ 158. In § 302.7, remove ''§ 302.4(a)(2)(iv)'' each place it appears and add in its place ''§ 302.4(a)(2)(i)(D)''.

■ 159. In § 302.24, paragraphs (g)(1)(iii) through (vi), (viii), (xii), and (xiv) through (xx) and (g)(2) and (3) are revised to read as follows:

§ 302.24 Evidence.

* * * * *

(g) * * *

(1) * * *

(iii) Reports of Traffic and Financial Data of all U.S. Air Carriers issued by the Department or by its predecessor.

(iv) Airline Traffic Surveys and Passenger Origin-Destination Surveys, Domestic or International, compiled by the Department or its predecessor and published and/or made available either to the public or to parties in proceedings.

(v) Compilations of data relating to competition in the airline industry and made available to the public by the Department or its predecessor.

(vi) Passenger, mail, express, and freight data submitted to the Department and its predecessor as part of ER–586 Service Segment Data by U.S. carriers, or similar data submitted to the Department by U.S. air carriers (T–100) or (T–100F) that are not confidential.

* * * * *

(viii) Service Mail Pay and Subsidy for U.S. Certificated Air Carriers published by the Department or its predecessor, including any supplemental data and subsequent issues published by the Department or its predecessor.

* * * * *

(xii) Chart Supplements, issued by the FAA.

* * * * *

(xiv) Monthly, quarterly and annual reports of the Immigration and Naturalization Service, U.S. Department of Justice.

(xv) All forms and reports required by the U.S. Postal Service to be filed by air carriers authorized to transport mail.

(xvi) All orders of the Postmaster General designating schedules for the transportation of mail.

(xvii) Publications of the Bureau of the Census of the U.S. Department of Commerce (DOC) relating, but not necessarily limited, to population, manufacturing, business, statistics, and any yearbooks, abstracts, or similar publications published by DOC.

(xviii) All Official Airline Guides, including the North American, Worldwide, All-Cargo and quick reference editions, including electronic versions.

(xix) Official Railways Guide and Russell's Official National Motor Coach Guide.

(xx) The Rand McNally Commercial Atlas and Marketing Guide, and the Rand McNally Road Atlas, United States, Canada, and Mexico.

* * * * *

(2) Any fact contained in a document belonging to a category enumerated in paragraph (g)(1) of this section shall be deemed to have been physically incorporated into and made part of the record in such proceedings. However, such taking of official notice shall be subject to the rights granted to any party or intervener to the proceeding under section 7(d) of the Administrative Procedure Act (5 U.S.C. 557(d)).

(3) The decisions of the Department and its administrative law judges may officially notice any appropriate matter without regard to whether or not such items are contained in a document belonging to the categories enumerated in paragraph (g)(1) of this section. However, where the decision rests on official notice of a material fact or facts, it will set forth such items with sufficient particularity to advise interested persons of the matters that have been noticed.

* * * * *

■ 160. Throughout subpart D, remove the word ''Deputy'' wherever it appears.

§ 302.401 [AMENDED]

■ 161. In § 302.401, remove the words ''Subtitle VII of''.

■ 162. In § 302.603, paragraph (b) is revised to read as follows:

§ 302.603 Contents of complaint or request for determination.

* * * * *

(b) All exhibits and briefs prepared on electronic spreadsheet or word processing programs should be accompanied by standard-format electronic media containing those submissions. Parties should submit three copies the electronic media to Department of Transportation Dockets Operations Office: One copy for the docket, one copy for the Office of Hearings, and one copy for the Office of Aviation Analysis. Filers should ensure that files on the electronic media are unalterably locked.

* * * * *

PART 303— REVIEW OF AIR CARRIER AGREEMENTS

■ 163. The authority citation for part 303 continues to read as follows:

Authority: 49 U.S.C. chapters 401, 413, 417.

■ 164. Section 303.01 is revised to read as follows:

§ 303.01 Purpose.

This part sets forth the procedures by which applications may be made to the Department of Transportation under 49 U.S.C. 41308 and 41309 and procedures governing proceedings to enforce these provisions. These procedures supplement the rules described in part 302 of this chapter, which also apply to the review of air carrier agreements.

■ 165. Section 303.02 is revised to read as follows:

§ 303.02 Definitions.

(a) The term *Assistant Secretary* means the Assistant Secretary for Aviation and International Affairs, or as delegated. As provided in 49 CFR 1.21, the Secretary or Deputy Secretary may exercise any authority in lieu of the Assistant Secretary under the provisions of this part.

(b) The term *documents* means:

(1) All written, recorded, transcribed or graphic matter including letters, telegrams, memoranda, reports, studies, forecasts, lists, directives, tabulations, logs, or minutes and records of meetings, conferences, telephone or other conversations or communications; and

(2) All information contained in data processing equipment or materials. The term does not include daily or weekly statistical reports in whose place an annual or monthly summary is submitted.

(c) The term *hearing* means either a show-cause proceeding as provided in § 303.44 or a full evidentiary hearing as provided in § 303.45, whichever is determined by the Assistant Secretary to be appropriate.

(d)–(g) [Reserved]

(h) The term *Section 41309 transaction* means any contract, agreement or discussion of a cooperative working arrangement within the scope of 49 U.S.C. 41309.

(i) [Reserved]

■ 166. Section 303.03 is revised to read as follows:

§ 303.03 Requirement to file application.

A person who seeks approval of a section 41309 transaction must file the application with the Docket Operations Office, M–30, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, or by electronic submission at *http://www.regulations.gov.* The application must conform to the requirements set forth in §§ 303.04 and 303.05.

■ 167. Amend § 303.04 as follows:

■ a. In paragraph (a), remove the words ''these regulations'' and add in their place the words ''this part''.

■ b. Revise paragraph (i).

The revision reads as follows:

§ 303.04 General rules governing application content, procedure and conditions of approval.

* * * * *

(i) The person submitting the application to the Department shall send a complete copy of the application to the Chief, Transportation Section, Antitrust Division of the Department of Justice, at the same time as it is filed with the Docket Operations Office.

* * * * *

■ 168. Section 303.05(a) is revised to read as follows:

§ 303.05 Applications requesting antitrust immunity.

(a) Each application must state explicitly whether or not the applicant seeks antitrust immunity under the provisions of 49 U.S.C. 41308. If antitrust immunity is requested, the application should specify whether the applicant seeks full immunity or immunity only from the provisions of sections 4, 4a and 4c of the Clayton Act, 15 U.S.C. 15, 15a, 15c. Each application seeking antitrust immunity shall contain a statement explaining why the applicant believes immunity is in the public interest and necessary in order for the transaction to proceed.

* * * * *

■ 169. Section 303.06 is revised to read as follows:

§ 303.06 Review of antitrust immunity.

The Assistant Secretary may initiate a proceeding to review any antitrust immunity previously conferred by the Department's predecessor or the Department in any section 41309 transaction. The Assistant Secretary may terminate or modify such immunity if the Assistant Secretary finds after notice and hearing that the previously conferred immunity is not consistent with the provisions of section 41308. In any proceeding to review such immunity, the proponents of the immunity shall have the burden of justifying the continuation of previously conferred immunity under the provisions of section 41308.

■ 170. Section 303.07 is revised to read as follows:

§ 303.07 Transitional rule.

If a section 41309 application or a request for antitrust immunity under section 41308 is pending on May 16, 2019, such application or request shall be deemed made pursuant to the provisions of this part as amended May 16, 2019.

■ 171. The heading of subpart D is revised to read as follows:

Subpart D—Section 41309 Applications

■ 172. In § 303.30, the introductory text and paragraph (c) are revised to read as follows:

§ 303.30 General provisions concerning contents of applications.

A section 41309 application shall contain the following general information:

* * * * *

(c) If the contract, agreement or request for authority to discuss a cooperative working arrangement is evidenced by a resolution or other action of an air carrier association, the application shall contain the resolution or other action and a certification by an authorized employee of the association that the resolution or other action was duly adopted on a certain date. The authorized employee shall also specify in such certification the name of each air carrier that concurred in such resolution or other action and the name of each air carrier member that did not concur.

■ 173. Section 303.31 is revised to read as follows:

§ 303.31 Justification for the application.

A section 41309 application shall explain the nature and purpose of the contract, agreement or request to discuss a cooperative working arrangement and describe how it changes any price, rule, or practice existing under a previously approved application. The application also, consistent with Department of Transportation and the precedent of DOT's predecessor, shall contain factual material, documentation, and argument in support of the application. Economic analyses, when required, shall include full explanatory details, including data sources and allocation methods. If the applicants intend to rely upon market data sources, other than those available to the public by the Department, the complete market data shall be included with the application at the time of filing. If the applicants intend to rely on public benefits to justify approval, they shall describe these benefits, including foreign policy and comity considerations.

§ 303.32 [AMENDED]

■ 174. In § 303.32(a), remove ''412 application'' and add in its place ''41309 application''.

■ 175. In § 303.42, paragraph (a) is revised to read as follow:

§ 303.42 Comments on application.

(a) Unless a different comment period is specified by notice or order, or in a notice of filing published in the **Federal Register**, any person may file comments, responses to the application, and/or a request for a hearing, within 21 days of the filing of an application.

* * * * *

§ 303.43 [AMENDED]

■ 176. In § 303.43(b), remove ''412 application'' each place it appears and add in its place ''41309 application''.

§ 303.45 [AMENDED]

■ 177. In § 303.45(c), remove the words ''these regulations'' and add in their place ''this part''.

PART 305—RULES OF PRACTICE IN INFORMAL NONPUBLIC INVESTIGATIONS

■ 178. The authority citation for part 305 continues to read as follows:

Authority: 49 U.S.C. chapters 401, 417, 461; 5 U.S.C. 555, 556.

■ 179. Throughout part 305, remove the word ''Deputy'' wherever it appears.

§ 305.1 [AMENDED]

■ 180. In § 305.1, remove ''Title IV or sections 101(3), 1002, 1003, or 1108(b) of the Act'' and add in its place ''49 U.S.C. Subtitle VII, Chapter 411 or 49 U.S.C. 40102(2), 41502, 41507, 41508, 41509, 41702, 41703, or 46101''.

■ 181. Section 305.7(b) is revised to read as follows:

§ 305.7 Issuance of investigation subpenas.

* * * * *

(b) Witnesses subpoenaed to appear shall be paid the fees and mileage prescribed in § 302.27(c) of the Rules of Practice (14 CFR 302.27(c)). Service of such subpoenas shall be made in accordance with the provisions of § 302.7 of the Rules of Practice (14 CFR 302.7).

§ 305.10 [AMENDED]

■ 182. In § 305.10, add the words ''of this chapter'' immediately following ''302.12''

§ 305.11 [AMENDED]

■ 183. Amend § 305.11 as follows:
■ a. Remove the words '', and any documentary evidence obtained in the investigation will be returned to the persons who produced it''.
■ b. Remove the words ''of the Rules of Practice'' and add in their place the words ''of this chapter (the Rules of Practice)''.

PART 313—IMPLEMENTATION OF THE ENERGY POLICY AND CONSERVATION ACT

■ 184. The authority citation for part 313 continues to read as follows:

Authority: 42 U.S.C. 6362(b), 49 U.S.C. Chapter 401.

■ 185. Throughout part 313, remove the words ''of the Statute'' and add in their place the words ''of 49 U.S.C. Subtitle VII''.

§ 313.3 [AMENDED]

■ 186. Remove § 313.3(e).

PART 323—TERMINATIONS, SUSPENSIONS, AND REDUCTIONS OF SERVICE

■ 187. The authority citation for part 323 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 411, 417.

■ 188. Throughout part 323, remove the words ''of the Statute'' and add in their place the words ''of 49 U.S.C. Subtitle VII''.

§ 323.2 [AMENDED]

■ 189. In § 323.2, the definitions for ''Certificated carrier'' and ''Eligible place'' are revised and the definitions for ''FAA'' and ''Statute'' are removed to read as follows:

§ 323.2 Definitions.

* * * * *

Certificated carrier means a direct air carrier holding authority to provide air transportation granted by the Department in the form of a certificate of public convenience and necessity under 49 U.S.C. 41102 (Transportation) or an all-cargo air transportation certificate to perform all-cargo air transportation under 49 U.S.C. 41103.

Eligible place means a place in the United States that meets the specified criteria outlined in 49 U.S.C. Chapter 417.

* * * * *

PART 325—ESSENTIAL AIR SERVICE PROCEDURES

■ 190. The authority citation for part 325 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 417.

■ 191. Throughout part 325, remove the words ''point'' and ''points'' and add in their place ''place'' and ''places'', respectively.

§ 325.1 [AMENDED]

■ 192. In § 325.1, remove the words ''under section 419 of the Act'' and add in their place ''under 49 U.S.C. 41732''.
■ 193. Section 325.2 is revised to read as follows:

§ 325.2 Applicability.

This part applies to essential air service determinations for communities designated as eligible under 49 U.S.C. 41731 and to eligible place designations and essential air service determinations for communities that qualify under 49 U.S.C. 41732 and 41733. It applies to the gathering of data by the Department, and to the participation of State, local, and other officials and other interested persons in the designation and determination processes.

Note to § 325.2: Criteria for designating eligible points under section 419(b) are contained in part 270 of this chapter. Guidelines for deciding essential air service levels are contained in part 398 of this chapter.

■ 194. Section 352.3 is revised to read as follows:

§ 325.3 Definitions.

As used in this part, *eligible place* means a place in the United States that meets the specified criteria outlined in 49 U.S.C. Chapter 417.

§ 325.4 [AMENDED]

■ 195. Amend § 325.4 as follows:
■ a. In paragraph (a) introductory text, remove the words ''section 419(b) of the Act'' and add in their place the words ''49 U.S.C. 41731''.
■ b. In paragraph (a)(1), remove the words ''section 401 certificate'' each place it appears and add in their place the words ''section 41102 certificate''.
■ c. In paragraph (b):
■ i. Remove the words ''Documentary Services Division'' and add in their place the words ''Docket Operations Office''.
■ ii. Remove the words ''section 419(f) of the Act'' and add in their place ''49 U.S.C. 41737''.
■ d. In paragraph (c), remove the words ''Documentary Services Division'' and add in their place the words ''Docket Operations Office''.
■ 196. Section 325.5 is revised to read as follows:

§ 325.5 Determinations and designations.

DOT will issue a determination of the essential level of air service for a place within 6 months after each of the following events:

(a) A notice is received that service to an eligible place will be reduced to only one carrier that holds a section 41102 certificate;

(b) A place is designated as an eligible place under 49 U.S.C. 41731 and either paragraph (c) or (d) of this section or § 325.7(e); or

(c) A review was conducted of essential air service of that place under § 325.6.

§ 325.6 [AMENDED]

■ 197. In § 325.6(c), remove the words ''under section 419(b) of a community as an eligible place to determine whether that place continues'' and add in their place the words ''under 49 U.S.C. 41733 to determine whether the community designated as an eligible place continues''.

PART 330 [REMOVED AND RESERVED]

■ 198. Part 330 is removed and reserved.

PART 372—OVERSEAS MILITARY PERSONNEL CHARTERS

■ 199. The authority citation for part 372 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 411, 413, 417.

■ 200. Throughout part 372, remove the words ''of the Statute'' and add in their place the words ''of 49 U.S.C. Subtitle VII''.

§ 372.2 [AMENDED]

■ 201. In § 372.2, remove the definition of ''Statute''.

§ 372.3 [AMENDED]

■ 202. In § 372.3, remove ''this regulation'' and add in its place ''this part''.

§ 372.30 [AMENDED]

■ 203. Amend § 372.30 as follows:
■ a. In paragraph (a) introductory text, remove the words ''Office of Aviation

Analysis'' and add in their place the words ''Office of International Aviation''.

■ b. In paragraph (a)(9), remove the word ''applicant'' and add in its place the word ''applicants''.

■ 204. Revise appendix A to part 372 to read as follows:

Appendix A to Part 372—Overseas Military Personnel Charter Operator's Surety Bond Under Part 372 of the Regulations of the Department of Transportation (14 CFR Part 372)

Know all persons by these presents, that we _____ (name of charter operator) of _____ (address) as Principal (hereinafter called ''Principal''), and _____ (name of surety) a corporation created and existing under the laws of the State of _____ (State) as Surety (hereinafter called ''Surety'') are held and firmly bound unto the United States of America in the sum of _____ (see § 372.24(a), 14 CFR part 372) for which payment, well and truly to be made, we bind ourselves and our heirs, executors, administrators, successors, and assigns, jointly and severally firmly by these presents.

Whereas Principal is an overseas military personnel charter operator pursuant to the provisions of part 372 of the Department's regulations and other rules and regulations of the Department relating to security for the protection of charter participants, and has elected to file with the Department of Transportation such a bond as will insure financial responsibility with respect to all monies received from charter participants for services in connection with overseas military personnel charters to be operated subject to part 372 of the Department's Special Regulations in accordance with contracts, agreements, or arrangements therefor, and

Whereas this bond is written to assure compliance by Principal as an authorized charter operator with part 372 of the Department's regulations, and other rules and regulations of the Department relating to security for the protection of charter participants, and shall inure to the benefit of any and all charter participants to whom Principal may be held legally liable for any damages herein described.

Now, therefore, the condition of this obligation is such that if Principal shall pay or cause to be paid to charter participants any sum or sums for which Principal may be held legally liable by reason of Principal's failure faithfully to perform, fulfill and carry out all contracts, agreements, and arrangements made by Principal while this bond is in effect with respect to the receipt of moneys from charter participants, and proper disbursement thereof pursuant to and in accordance with the provisions of part 372 of the Department's regulations, then this obligation shall be void, otherwise to remain in full force and effect.

The liability of Surety with respect to any charter participant shall not exceed the charter price paid by or on behalf of such participant.

The liability of Surety shall not be discharged by any payment or succession of payments hereunder, unless and until such payment or payments shall amount in the aggregate to the penalty (face amount) of the bond, but in no event shall Surety's obligation hereunder exceed the amount of said penalty.

Surety agrees to furnish written notice to the Office of International Aviation, Department of Transportation, forthwith of all suits or claims made and judgments rendered, and payments made by Surety under this bond.

This bond shall cover the following Charters: [1]

Surety company's bond No. _____

Date of flight departure _____

Place of flight departure _____

This bond is effective on the _____ of _____, 20_____, 12:01 a.m., standard time at the address of Principal as stated herein and as hereinafter provided. Principal or Surety may at any time terminate this bond by written notice to: U.S. Air Carrier Licensing/Special Authorities Division, Office of International Aviation, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, such termination to become effective thirty (30) days after the actual receipt of said notice by the Department. Surety shall not be liable hereunder for the payment of any damages hereinbefore described which arise as a result of any contracts, agreements, undertakings, or arrangements for the supplying of transportation and other services made by Principal after the termination of this bond as herein provided, but such termination shall not affect the liability of the bond hereunder for the payment of any damages arising as a result of contracts, agreements, or arrangements for the supplying of transportation and other services made by Principal prior to the date that such termination becomes effective. Liability of Surety under this bond shall in all events be limited only to a charter participant or charter participants who shall within sixty (60) days after the termination of the particular charter described herein give written notice of claim to the charter operator or, if it is unavailable, to Surety, and all liability on this bond shall automatically terminate sixty (60) days after the termination date of each particular charter covered by this bond except for claims made in the time provided herein.

In witness whereof, the said Principal and Surety have executed this instrument on the _____ day of _____, _____.

PRINCIPAL

Name _____

By: Signature and title _____

Witness _____

SURETY

Name _____

By: Signature and title _____

Witness _____

Only corporations may qualify to act as surety and they must meet the requirements set forth in § 372.24(c) of part 372.

[1] These data may be supplied in an addendum attached to the bond.

PART 374—IMPLEMENTATION OF THE CONSUMER CREDIT PROTECTION ACT WITH RESPECT TO AIR CARRIERS AND FOREIGN AIR CARRIERS

■ 205. The authority citation for part 374 is revised to read as follows:

Authority: 15 U.S.C. 1601–1693r; 49 U.S.C., Subtitle VII; and 12 CFR parts 1002 and 1026.

§ 374.3 [AMENDED]

■ 206. Amend § 374.3(b) as follows:

■ a. Remove ''12 CFR part 202'' and add in its place ''12 CFR part 1002''.

■ b. Remove ''12 CFR part 226'' and add in its place ''12 CFR part 1026''.

PART 374a—EXTENSION OF CREDIT BY AIRLINES TO FEDERAL POLITICAL CANDIDATES

■ 207. The authority citation for part 374a continues to read as follows:

Authority: 49 U.S.C. chapters 401, 411, 415, 417.

■ 208. Section 374a.1 is revised to read as follows:

§ 374a.1 Purpose.

The purpose of this part is to issue rules pursuant to the Federal Election Campaign Act of 1971, as amended, in accordance with the Department's responsibility thereunder.

§ 374a.2 [AMENDED]

■ 209. In § 374a.2, remove ''This regulation'' and add in its place ''this part''.

§ 374a.3 [AMENDED]

■ 210. In § 374a.3, in the definition of ''Air carrier'', remove the words ''section 401 of the Federal Aviation Act of 1958, as amended'' and add in their place the words ''49 U.S.C. 41102''.

■ 211. Section 374a.5 is revised to read as follows:

§ 374a.5 Exemption authority.

Air carriers are exempt from the following provisions of 49 U.S.C. Subtitle VII:

(a) Section 41510.

(b) Section 41310, and any and all other provisions of 49 U.S.C. Subtitle VII, to the extent necessary to enable air carriers to comply with the provisions of this part.

PART 375—NAVIGATION OF FOREIGN CIVIL AIRCRAFT WITHIN THE UNITED STATES

■ 212. The authority citation for part 375 continues to read as follows:

Authority: 49 U.S.C. 40102, 40103, and 41703.

§ 375.1 [AMENDED]

■ 213. Amend § 375.1 as follows:
■ a. Remove the definition for ''Act''.
■ b. In the definition for ''Air transportation'', remove the words ''(see section 101 (10) and (23) of the Federal Aviation Act, 49 U.S.C. 1301)'' and add in their place ''(see 49 U.S.C. 40102 (a)(5) and (a)(24))''.
■ c. In the definition for ''Exemption'', remove the words ''under section 416(b) of the Act'' and add in their place ''under 49 U.S.C. 40109''.
■ d. In the definition for ''Foreign air carrier permit'', remove the words ''section 402 of the Act'' and add in their place ''49 U.S.C. 41301''.
■ e. In the definition for ''Foreign aircraft permit'', remove the words ''section 1108(b) of the Act'' and add in their place the words ''49 U.S.C. 41703''.

§ 375.19 [AMENDED]

■ 214. In § 375.19, remove the words ''section 1108(b) of the Act'' each place it appears and add in their place ''49 U.S.C. 41703''.

§ 375.22 [AMENDED]

■ 215. In § 375.22, add ''in 14 CFR chapter I'' immediately following ''Federal Aviation Administration''.

§ 375.33 [AMENDED]

■ 216. In § 375.33, remove the word ''safey'' and add in its place the word ''safety''.

§ 375.35 [AMENDED]

■ 217. In § 375.35(a)(2), remove the words ''section 402 permit'' and add in their place the words ''section 41301 permit''.
■ 218. Amend § 375.43 as follows:
■ a. Revise paragraph (a).
■ b. In paragraph (e)(1), remove the words ''Aviation Operations'' and add in their place the words ''International Aviation''.

The revision reads as follows:

§ 375.43 Application for foreign aircraft permit.

(a) Applications for foreign aircraft permits shall be submitted on OST Form 4509 (see appendix A to this part), in duplicate, addressed to the Chief, Foreign Air Carrier Licensing Division, X–45, Office of International Aviation. Applications should be submitted by email; see ''Application Procedures under Part 375'' at *www.transportation.gov/policy/aviation-policy/licensing/foreign-carriers.*

* * * * *

§ 375.50 [AMENDED]

■ 219. Amend § 375.50 as follows:
■ a. In paragraph (b), remove the words ''Chief, Discrete Operations Branch, Licensing Division, P–45, Office of Aviation Operations'' and add in their place the words ''Chief, Foreign Air Carrier Licensing Division, X–45, Office of International Aviation''.
■ b. In paragraph (e), remove the words ''section 1108(b) of the Act'' and add in their place ''49 U.S.C. 41703''.
■ c. In paragraph (h):
■ i. Remove the words ''Federal Aviation Act'' and add in their place ''49 U.S.C. Subtitle VII''.
■ ii. Remove the words ''section 402 or 416(b) of the Act'' and add in their place ''49 U.S.C. 41301 or 41709''.
■ 220. Section 375.60 is revised to read as follows:

§ 375.60 Penalties.

The operation of a foreign aircraft within the United States or over adjacent territorial waters in violation of the provisions of this part constitutes a violation of 49 U.S.C. Subtitle VII and of this chapter, and may, in addition, constitute a violation of the rules of the Federal Aviation Administration. Such operation makes the person or persons responsible for the violation or violations subject to a civil penalty as provided in 49 U.S.C. 46301, and to the alteration, amendment, modification, suspension or revocation of any permit issued under this part and of any U.S. certificate involved as provided in 49 U.S.C. 44709. Engaging in air transportation as defined in 49 U.S.C. Subtitle VII by a foreign aircraft without a foreign air carrier permit issued pursuant to 49 U.S.C. 41301 or an exemption, or in violation of the terms of such authority constitutes not only a violation of this part but of Title 49, subtitle VII, as well, which entails a criminal penalty as set forth in 49 U.S.C. 46316.

PART 377—CONTINUANCE OF EXPIRED AUTHORIZATIONS BY OPERATION OF LAW PENDING FINAL DETERMINATION OF APPLICATIONS FOR RENEWAL THEREOF

■ 221. The authority citation for part 377 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 461; 5 U.S.C. 558, 559.

§ 377.1 [AMENDED]

■ 222. In § 377.1, in the definition for ''Authorization'', remove the words ''sections 101(3), 401, 402, 408, 409, 412 and 416 of the Federal Aviation Act of 1958, as amended'' and add in their place ''49 U.S.C. 40102, 41102, 41302, 41309, and 41708''.

§§ 377.2, 377.3, 377.4, 377.5, 377.10 and 377.11 [AMENDED]

■ 223. In §§ 377.2, 377.3, 377.4, 377.5, 377.10, and 377.11, remove the word ''Board'' each place it appears and add in its place the word ''Department''.

§§ 377.3, 377.4, and 377.10 [AMENDED]

■ 224. In §§ 377.3, 377.4, and 377.10, remove the words ''section 401 of the Act'' and add in their place ''49 U.S.C. 41102''.

§ 377.10 [AMENDED]

■ 225. Amend § 377.10 as follows:
■ a. In paragraphs (b) and (c) introductory text, remove the word ''Board's'' and add in its place the word ''Department's''.
■ b. In paragraph (c)(3), remove the words ''section 402 of the Act and exemptions issued under section 416'' and add in their place the words ''49 U.S.C. 41301 and exemptions issued under 49 U.S.C. 41708''.

PART 380—PUBLIC CHARTERS

■ 226. The authority citation for part 380 continues to read as follows:

Authority: 49 U.S.C. 40101, 40102, 40109, 40113, 41101, 41103, 41301, 41504, 41702, 41708, 41712, 46101.

■ 227. Throughout part 380:
■ a. Remove the words ''Office of Aviation Analysis'' and add in their place the words ''Office of International Aviation''.
■ b. Remove the words ''Special Authorities Division'' and add in their place the words ''U.S. Air Carrier Licensing/Special Authorities Division''.
■ c. Remove the words ''of the Statute'' and add in their place the words ''of 49 U.S.C. Subtitle VII''.

§ 380.1 [AMENDED]

■ 228. In § 380.1, remove the words '', formerly Title IV of the Federal Aviation Act of 1958, as amended''.

§ 380.2 [AMENDED]

■ 229. In § 380.2, remove the word ''opertor'' and add in its place the word ''operator'' and remove the definition for ''Statute.''

§ 380.3 [AMENDED]

■ 230. In § 380.3(b), remove the word ''and'' and add in its place the word ''through''.

§ 380.14 [AMENDED]

■ 231. In § 380.14, remove the word ''Noting'' and add in its place the word ''Nothing''.

§ 380.15 [AMENDED]

■ 232. In § 380.15, remove the word ''Subsititues'' and add in its place the word ''Substitutes''.

§ 380.32 [AMENDED]

■ 233. Amend § 380.32 as follows:
■ a. In paragraph (j), remove the words ''That is a charter'' and add in their place the words ''That if a charter''.
■ b. In paragraph (q), remove the words ''That is the operator'' and add in their place the words ''That if the operator''.
■ c. In paragraph (t), remove the words ''That the participants'' and add in their place the words ''That the participant's''.
■ d. In paragraph (v), remove the words ''date or arrival'' and add in their place the words ''date of arrival''.

§ 380.34 [AMENDED]

■ 234. In § 380.34(b)(2)(i), remove the words ''credit cared'' and add in their place the words ''credit card''.
■ 235. Revise appendices A and B to part 380 to read as follows:

Appendix A to Part 380—Public Charter Operator's Surety Bond Under Part 380 of the Regulations of the Department of Transportation (14 CFR PART 380)

Know all persons by these presents, that we _____ (name of charter operator) _____ of_____ (city) _____ (state) as Principal (hereinafter called Principal), and _____ (name of surety) a corporation created and existing under the laws of the State of _____ (State) as Surety (hereinafter called Surety) are held and firmly bound unto the United States of America in the sum of $_____ _____(see 14 CFR 380.34) for which payment, well and truly to be made, we bind ourselves and our heirs, executors, administrators, successors, and assigns, jointly and severally, firmly by these presents.

Whereas Principal intends to become a Public Charter operator pursuant to the provisions of 14 CFR part 380 and other rules and regulations of the Department relating to insurance or other security for the protection of charter participants, and has elected to file with the Department of Transportation such a bond as will insure financial responsibility with respect to all moneys received from charter participants for services in connection with a Public Charter to be operated subject to part 380 of the Department's regulations in accordance with contracts, agreements, or arrangements therefore, and

Whereas this bond is written to assure compliance by Principal as an authorized charter operator with 14 CFR part 380 and other rules and regulations of the Department relating to insurance and other security for the protection of charter participants, and shall inure to the benefit of any and all charter participants to whom Principal may be held legally liable for any damages herein described.

Now, therefore, the condition of this obligation is such that if Principal shall pay or cause to be paid to charter participants any sum or sums for which Principal may be held legally liable by reason of Principal's failure faithfully to perform, fulfill and carry out all contracts, agreements, and arrangements made by Principal while this bond is in effect with respect to the receipt of moneys from charter participants, and proper disbursement thereof pursuant to and in accordance with the provisions of 14 CFR part 380, then this obligation shall be void, otherwise to remain in full force and effect.

The liability of Surety with respect to any charter participant shall not exceed the charter price paid by or on behalf of such participant.

The liability of Surety shall not be discharged by any payment or succession of payments hereunder, unless and until such payment or payments shall amount in the aggregate to the penalty of the bond, but in no event shall Surety's obligation hereunder exceed the amount of said penalty.

Surety agrees to furnish written notice to the U.S. Air Carrier Licensing/Special Authorities Division, X–44, Office of International Aviation, Department of Transportation, forthwith of all suits or claims filed and judgments rendered, and payments made by Surety under this bond.

The bond shall cover the following charters [1]

Surety company's bond No. _____

Date of flight departure _____

Place of flight departure _____

This bond is effective on the ____ day of _____, 20__, 12:01 a.m., standard time at the address of Principal as stated herein and as hereinafter provided. Principal or Surety may at any time terminate this bond by written notice to: ''U.S. Air Carrier Licensing/Special Authorities Division (X–44), Office of International Aviation, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W–86–445, Washington, DC 20590,'' such termination to become effective thirty (30) days after the actual receipt of said notice by the Department. Surety shall not be liable hereunder for the payment of any damages hereinbefore described which arise as a result of any contracts, agreements, undertakings, or arrangements for the supplying of transportation and other services made by Principal after the termination of this bond as herein provided, but such termination shall not affect the liability of the bond hereunder for the payment of any damages arising as a result of contracts, agreements, or arrangements for the supplying of transportation and other services made by Principal prior to the date that such termination becomes effective. Liability of Surety under this bond shall in all events be limited only to a charter participant or charter participants who shall within sixty (60) days after the termination of the particular charter described herein give written notice of claim to the charter operator or, if it is unavailable, to Surety, and all liability on this bond shall automatically terminate sixty (60) days after the termination date of each particular charter covered by this bond except for claims made in the time provided herein.

In witness whereof, the said Principal and Surety have executed this instrument on the ____ day of _____, 20__.

PRINCIPAL

Name _____

By: Signature and title _____

Witness _____

Bonding or surety company must be listed in Best's Insurance Reports (Fire and Casualty) with a general policyholders' rating of ''A'' or better or in the Department of the Treasury listing of companies holding certificates of authority as acceptable sureties on Federal bonds. In addition, the bonding or surety company shall be one legally authorized to issue bonds of that type in the State(s) in which the charter flight(s) originate. Agents must provide satisfactory proof that they have the requisite authority to issue this bond.

Appendix B to Part 380—Public Charter Operators's Surety Trust Agreement

This Trust Agreement is entered into between _____ (charter operator) incorporated under the laws of __ _____ with its principal place of business being _____ _____ (hereinafter called ''Operator''), and _____ _____(Bank) with its principal place of business being_____ _____ (hereinafter called ''Trustee''), for the purpose of creating a trust to become effective as of the _____ day of _____, 20__, which trust shall continue until terminated as hereinafter provided.

Operator intends to become a Public Charter operator pursuant to the provisions of part 380 of the Department's regulations and other rules and regulations of the Department relating to insurance or other security for the protection of charter participants, and has elected to file with the Department of Transportation such a Surety Trust Agreement as will insure financial responsibility with respect to all monies received from charter participants for services in connection with a Public Charter to be operated subject to part 380 of the Department's regulations in accordance with contracts, agreements, or arrangements therefore.

This Surety Trust Agreement is written to assure compliance by Operator with the provisions of part 380 of the Department's regulations and other rules and regulations of the Department relating to insurance or other security for the protection of charter participants. It shall inure to the benefit of any and all charter participants to whom Operator may be held legally liable for any of the damages herein described.

It is mutually agreed by and between Operator and Trustee that Trustee shall manage the corpus of the trust and carry out the purposes of the trust as hereinafter set forth during the term of the trust for the benefit of charter participants (who are hereinafter referred to as ''Beneficiaries.'')

[1] These data may be supplied in an addendum attached to the bond.

Beneficiaries of the trust created by this Agreement shall be limited to those charter participants who meet the following requirements:

1. Those for whom Operator or Operator's agent has received payment toward participation in one or more charters operated by or proposed to be operated by Operator.

2. Who have legal claim or claims for money damages against Operator by reason of Operator's failure faithfully to perform, fulfill, and carry out all contracts, agreements, and arrangements made by Operator while this trust is in effect with respect to the receipt of monies and proper disbursement thereof pursuant to part 380 of the Department's regulations; and

3. Who have given notice of such claim or claims in accordance with this Trust Agreement, but who have not been paid by Operator.

The operator shall convey to Trustee legal title to the trust corpus, which has a value of $_____ by the time of the execution of this Agreement.

Trustee shall assume the responsibilities of Trustee over the said trust corpus and shall distribute from the trust corpus to any and all Beneficiaries to whom Operator, in its capacity as a Public Charter operator, may be held legally liable by reason of Operator's failure faithfully to perform, fulfill, and carry out all contracts, agreements, and arrangements made by Operator, while this trust is in effect with respect to the receipt of monies and proper disbursement thereof pursuant to part 380 of the Department's regulations in connection with said charters, such damages as will discharge such liability while this trust is in effect; *Provided, however,* that the liability of the trust to any Beneficiary shall not exceed the charter price (as defined in part 380 of the Department's regulations) paid by or on behalf of any such Beneficiary; *Provided, further,* that there shall be no obligation of the trust to any Beneficiary if Operator shall pay or cause to be paid to any Beneficiary any sum or sums for which Operator may be held legally liable by reasons of its failure faithfully to perform, fulfill, and carry out all contracts, agreements, and arrangements made by Operator in its capacity as Public Charter Operator while this trust is in effect with respect to the receipt of monies and proper disbursement thereof pursuant to part 380 of the Department's regulations; *and provided still further,* that the liability of the trust as administered by Trustee shall not be discharged by any payment or succession of payments hereunder, unless and until such payment or payments, shall amount in the aggregate to $_____. Notwithstanding anything herein to the contrary, in no event shall the obligation of the trust or Trustee hereunder exceed the aggregate amount of $_____.

Trustee agrees to furnish written notice to the U.S. Air Carrier Licensing/Special Authorities Division, X–44, Office of International Aviation, Department of Transportation, forthwith of all suits or claims filed and judgments rendered (of which it has knowledge), and of payments made by Trustee under the terms of this trust.

The trust shall not be liable hereunder for the payment of any damages hereinbefore described which arise as a result of any contracts, agreements, undertakings, or arrangements for the supplying of transportation and other services made by Operator after the termination of this trust as herein provided, but such termination shall not affect the liability of the trust hereunder for the payment of any damages arising as a result of contracts, agreements, or arrangements for the supplying of transportation and other services made by Operator prior to the date that such termination becomes effective.

Liability of the trust shall in all events be limited only to a Beneficiary or Beneficiaries who shall within sixty days after the termination of the particular charter give written notice of claim to Operator or, if it is unavailable, to Trustee, and all liability of the trust with respect to participants in a charter shall automatically terminate sixty days after the termination date of each particular charter covered by this trust except for claims made in the time provided herein.

Sixty-one days after the completion of the last charter covered by this Trust Agreement, the trust shall automatically terminate except for claims of any Beneficiary or Beneficiaries previously made in accordance with this Agreement still pending on and after said sixty-first day. To the extent of such claims, the trust shall continue until those claims are discharged, dismissed, dropped, or otherwise terminated. After all remaining claims which are covered by this Trust Agreement pending on and after the said sixty-first day have been discharged, dismissed, dropped, or otherwise terminated; Trustee shall convey forthwith the remainder of the trust corpus, if any, to Operator.

Either Operator or Trustee may at any time terminate this trust by written notice to: ''U.S. Air Carrier Licensing/Special Authorities Division, X–44, Office of International Aviation, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W–86–445, Washington, DC 20590,'' such termination to become effective thirty days after the actual receipt of said notice by the Department.

In the event of any controversy or claim arising hereunder, Trustee shall not be required to determine same or take any other action with respect thereto, but may await the settlement of such controversy or claim by final appropriate legal proceedings, and in such event shall not be liable for interest or damages of any kind.

Any Successor to Trustee by merger, consolidation, or otherwise, shall succeed to this trusteeship and shall have the powers and obligations set forth in this Agreement.

The trust created under this Agreement shall be operated and administered under the laws of the State of _____.

In Witness Whereof, Operator and Trustee have executed this instrument on the date(s) shown below.

Operator _____ _____
(signature)
Date _____
Name _____
(typed or printed)
Title _____
Trustee _____
(signature)
Date _____
Name _____
(typed or printed)
Title _____

PART 385—STAFF ASSIGNMENTS AND REVIEW OF ACTION UNDER ASSIGNMENTS

■ 236. The authority citation for part 385 is revised to read as follows:

Authority: 49 U.S.C. 329, 40101, 41101, 41301, and 41701.

■ 237. Throughout part 385, remove the words ''of the Statute'' and add in their place the words ''of 49 U.S.C. Subtitle VII''.

§ 385.1 [AMENDED]

■ 238. Amend § 385.1 as follows:

■ a. Remove the definition for ''Department''.

■ b. In the definition of ''Precedent'', remove the words ''by the Board'' and add in their place the words ''by its predecessor''.

■ c. In the definition of ''Reviewing Official'', remove the word ''Deputy''.

■ d. Remove the definition for ''Statute''.

§ 385.2 [AMENDED]

■ 239. In § 385.2, remove the words ''and the Director, Bureau of Transportation Statistics (BTS)''.

§ 385.7 [AMENDED]

■ 240. In § 385.7, remove the word ''Deputy''.

■ 241. Amend § 385.12 as follows:

■ a. Paragraphs (f), (h), and (i) are removed.

■ b. Paragraphs (g), (j), and (k) are redesignated as paragraphs (f), (g), and (h), respectively.

■ c. Newly redesignated paragraphs (f), (g), and (h) are revised.

■ d. New paragraph (i) is added.

The revisions read as follows:

§ 385.12 Authority of the Director, Office of Aviation Analysis.

* * * * *

(f) To approve certificates of insurance filed with the Department on behalf of U.S. and foreign air carriers in accordance with the provisions of part 205 of this chapter.

(g) With respect to mail rates:

(1) To issue show-cause orders proposing to make modifications of a technical nature in the mail rate formula applicable to temporary or final service mail rate orders.

(2) To issue final orders establishing temporary and final service mail rates:

(i) In those cases where no objection has been filed following release of the show-cause order, and where the rates established are the same as those proposed in the show-cause order; and

(ii) In those cases where it is necessary to make modifications of a technical nature in the rates proposed in the show-cause order.

(3) To issue final orders amending mail rate orders of air carriers to reflect changes in the names of the carriers subject to the orders.

(4) To issue a letter, in the case of air mail contracts filed with the Department under part 302 of this chapter against which no complaints have been filed, stating that the contract will not be disapproved by the Department and may become effective immediately.

(5) To issue final orders making quarterly fuel rate adjustments to Alaska bush and mainline mail rates set by the Department under 49 U.S.C. 41901, 41902, and 41903.

(h) With respect to essential air service (EAS) proceedings:

(1) To establish procedural dates.

(2) To issue orders setting interim rates of compensation for carriers required to provide essential air service.

(3) To issue orders approving a carrier's alternate service pattern if:

(i) The resulting level of service at the eligible place would be equal to or greater than the level of service earlier determined to be essential for that place;

(ii) The community concerned does not object to the carrier's implementation of the alternate service pattern; and

(iii) The carrier is not receiving a subsidy for the service or implementation of the alternate service pattern would not increase the carrier's subsidy.

(4) To issue orders adjusting the operational and/or financial unit rates of the payout formula for a carrier receiving subsidy under section 41732 of 49 U.S.C. Subtitle VII where the adjustment will not increase the total amount of compensation that the carrier will receive.

(5) To renew, up to five times in succession, an order under section 41734 of 49 U.S.C. Subtitle VII to an air carrier to continue providing essential air service while the Department attempts to find a replacement carrier.

(6) To request service and subsidy proposals from carriers interested in providing essential air service to an eligible place.

(7) To issue final orders establishing interim or final subsidy rates under section 41732 or final adjustments of compensation for continued service under section 41732 in those cases where no objection has been filed to a show-cause order, and where the rates established are the same as or less than those proposed in the approved show-cause order.

(8) With respect to provisions for terminations, suspensions, or reductions of service under part 323 of this chapter:

(i) To require any person who files a notice, objection, or answer to supply additional information.

(ii) To require service of a notice, objection, or answer upon any person.

(iii) To accept late-filed objections or answers, upon motion, for good cause shown.

(iv) To extend the time for filing objections for answers, when the initial notice has been filed earlier than required under § 323.5 of this chapter.

(9) To issue final air carrier selection orders establishing final subsidy rates for EAS provided under 49 U.S.C. 41733:

(i) Where the compensation to be paid is the same as or less than the existing rate, and where the community does not object to the selected option;

(ii) For EAS eligible Alaska communities, when the subsidy rate to be paid is less than $125,000, and where the community does not object to the selected option; and

(iii) In cases where only one air carrier submitted one service or subsidy option.

(10) With respect to provisions for terminations, suspensions, or reductions of service under part 323 of this chapter:

(i) To require any person who files a notice, objection, or answer to supply additional information.

(ii) To require service of a notice, objection, or answer upon any person.

(iii) To accept late-filed objections or answers, upon motion, for good cause shown.

(iv) To extend the time for filing objections for answers, when the initial notice has been filed earlier than required under § 323.5 of this chapter.

(i) To issue procedural orders or notices in antitrust immunity cases filed under part 303 of this chapter with respect to:

(1) Granting or denying requests for adjustments to procedural deadlines where there is no objection;

(2) Making other adjustments to a procedural schedule where the policy is clear and consistent with precedent;

(3) Granting parties to a proceeding access to confidential documents filed under a request for public non-disclosure pursuant to § 302.12 of this chapter, where providing such access is consistent under current policy and precedent; and

(4) In uncontested proceedings, ordering the filing of additional documents deemed relevant to the Department's consideration of the application, including the filing of documents for in-camera review, where doing so is consistent with past policy and precedent.

■ 242. Amend § 385.13 as follows:

■ a. Remove the word ''and'' at the end of paragraph (b)(3).

■ b. Remove paragraph (b)(4).

■ c. Redesignate paragraphs (b)(2) and (3) as (b)(3) and (4), respectively.

■ d. Add new paragraphs (b)(2), (5), and (6).

■ e. Revise paragraphs (r) introductory text and (r)(1).

■ f. Add paragraphs (z) through (dd).

The additions and revisions to read as follows:

§ 385.13 Authority of the Director, Office of International Aviation.

* * * * *

(b) * * *

(2) For general tariff exemptions that apply to all U.S. and foreign air carriers pursuant to 14 CFR part 293;

* * * * *

(5) Issue orders granting uncontested applications by U.S. carriers to provide foreign air transportation where the carrier has already been found fit, willing, and able to provide service of the same basic scope or character; and

(6) Issue orders granting uncontested applications by foreign air carriers to provide foreign air transportation where the course of action is clear under current policy or precedent.

* * * * *

(r) With respect to International Air Transport Association (IATA) agreements filed with the Department pursuant to sections 41309 and 41308 of 49 U.S.C. Subtitle VII, or agreements filed pursuant to previous statutory authority of the Department's predecessor:

(1) Issue orders approving, disapproving, or exempting IATA agreements relating to fare and rate matters under section 41309, and granting or denying antitrust immunity under section 41308, where the course of action is clear under current policy and precedent.

* * * * *

(z) Issue orders and notices adjusting the Standard Foreign Fare Level to reflect percentage changes in actual operating costs per available seat mile.

(aa) Issue notices updating the list of country-pair markets.

(bb) With respect to Canadian charter air taxi operations:

(1) To approve applications for registration, or require that a registrant submit additional information, or reject

an application for registration for failure to comply with part 294 of this chapter.

(2) To cancel, revoke, or suspend the registration of any Canadian charter air taxi operator using small aircraft registered under part 294 of this chapter that:

(i) Filed with the Department a written notice that it is discontinuing operations;

(ii) Is no longer designated by its home government to operate the services contemplated by its registration;

(iii) Holds a foreign air carrier permit under section 41302 to operate large aircraft charters between the United States and Canada;

(iv) Fails to keep its filed certificate of insurance current;

(v) No longer is substantially owned or effectively controlled by persons who are:

(A) Citizens of Canada;

(B) The Government of Canada; or

(C) A combination of both; or

(vi) No longer holds current effective Operations Specifications issued by the FAA.

(3) To grant or deny requests for a waiver of part 294 of this chapter, where grant or denial of the request is in accordance with current policy or precedent.

(cc) With respect to foreign air freight forwarders:

(1) To approve applications for registration, or require that a registrant submit additional information, or reject an application for registration for failure to comply with part 297 of this chapter.

(2) To cancel the registration of any foreign air freight forwarder or foreign cooperative shippers association that files a written notice with the Department indicating the discontinuance of common carrier activities.

(3) To exempt the registrant from the requirement contained in § 297.20 of this chapter that substantial ownership and effective control reside in citizens of the country that the applicant claims as its country of citizenship, where the course of action is clear under current precedent or policies.

(dd) With respect to charter operations:

(1) To grant or deny requests for waiver of parts 212, 372, and 380 of this chapter, where grant or denial of the request is in accordance with established precedent.

(2) To approve or disapprove direct air carrier escrow agreements filed pursuant to part 212 of this chapter.

(3) To reject or accept Public Charter prospectuses filed under part 380 of this chapter.

(4) With respect to the procedures for the registration of foreign charter operators under subpart E of part 380 of this chapter:

(i) To approve applications for registration, or require that a registrant submit additional information, or reject an application for registration for failure to comply with part 380 of this chapter.

(ii) To notify the applicant that its application will require further analysis or procedures, or is being referred to the Assistant Secretary for Aviation and International Affairs for formal action.

(iii) To cancel the registration of a foreign charter operator if it files a written notice with the Department that it is discontinuing its charter operations.

(iv) To waive provisions of subpart E of part 380 of this chapter.

■ 243. Revise § 385.14 to read as follows:

§ 385.14 Authority of the General Counsel.

The General Counsel has authority to:

(a) Issue proposed or final regulations for the purpose of making editorial changes or corrections to the Department's rules and regulations to carry out Subparts I, II and IV of Part A of Subtitle VII of the Transportation Code at 49 U.S.C. 40101 *et seq.,* with the concurrence of the staff offices primarily responsible for the parts or sections involved: Provided, that any final regulation so issued shall have an effective date not less than 20 days after its date of publication in the **Federal Register**, and shall include a brief reference to the review procedures established in subpart C of this part.

(b) Where a petition for review is duly filed, reverse any rulemaking action taken pursuant to paragraph (a) of this section by withdrawing a proposed or final regulation issued thereunder. Any action taken by the General Counsel, pursuant to the authority of this section, shall not be subject to the review procedures of this part.

(c) Issue orders deferring action until after oral argument on motions submitted by parties subsequent to the issuance of an Administrative Law Judge's initial or recommended decision.

(d) Reissue existing regulations for the purpose of incorporating prior amendments adopted by the Department.

(e) Compromise any civil penalties being imposed in enforcement cases.

(f) Issue orders initiating and terminating informal nonpublic investigations under part 305 of this chapter (Procedural Regulations).

(g) Issue orders requiring air carriers to prepare and submit within a specified reasonable period, special reports, copies of agreements, records, accounts, papers, documents, and specific answers to questions upon which information is deemed necessary. Special reports shall be under oath whenever the General Counsel so requires.

(h) Institute and prosecute in the proper court, as agent of the Department, all necessary proceedings for the enforcement of the provisions of the act or any rule, regulation, requirement, or order thereunder, or any term, condition, or limitation of any certificate or permit, and for the punishment of all violations thereof. Any action taken by the General Counsel, pursuant to the authority of this section, shall not be subject to the review procedures of this part.

(i) Make findings regarding the reasonable necessity for the application of the Department's authority to obtain access to lands, buildings, and equipment, and to inspect, examine, and make notes and copies of accounts, records, memorandums, documents, papers, and correspondence of persons having control over, or affiliated with, any person subject to regulation under Subparts I, II, and IV of Part A of Subtitle VII of the Transportation Code at 49 U.S.C. 40101 *et seq.* through issuance of an appropriate order, letter, or other transmittal.

(j) Issue orders denying or granting conditional or complete confidential treatment of information supplied by any person to the Office of Aviation Enforcement and Proceedings. Confidential treatment may only be granted upon a finding that, if the information were in the Department's possession and a Freedom of Information Act (FOIA) request were made for the information:

(1) At the time of the confidentiality request, the FOIA request would be denied on the basis of one or more of the FOIA exemptions; and

(2) At any later time, the FOIA request would also be denied, absent a material change in circumstances (which may include a demonstration that the asserted exemption does not apply).

§ 385.15 [REMOVED AND RESERVED]

■ 244. Remove and reserve § 385.15.

§ 385.18 [AMENDED]

■ 245. In § 385.18, remove the words ''Chief, Coordination Section, Documentary Services Division'' wherever they appear and add in their place the words ''Docket Officer, Docket Operations Office''.

§ 385.19 [AMENDED]

■ 246. In § 385.19, remove the words ''Office of Aviation Information''

wherever they appear and add in their place the words ''Office of Airline Information''.

§ 385.32 [AMENDED]

■ 247. In § 385.32, remove ''this regulation'' and add in its place ''this part''.

■ 248. Part 389 is revised to read as follows:

PART 389—FEES AND CHARGES FOR SPECIAL SERVICES

Subpart A—General Provisions

Sec.
389.1 Policy and scope.

Subpart B—Fees for Special Services

389.10 Applicability of subpart.
389.11 Available services and resources.
389.12 Payment of fees and charges.
389.13 Fees for services.

Subpart C—Filing and Processing License Fees

389.20 Applicability of subpart.
389.21 Payment of fees.
389.22 Failure to make proper payment.
389.23 Application for waiver or modification of fees.
389.24 Foreign air carriers.
389.25 Schedule of processing fees.
389.26 Special rules for tariff page filings.
389.27 Refund of fee.

Authority: 49 U.S.C. 40113, 40114, 41711; 31 U.S.C. 9701; and 5 U.S.C. 552.

Subpart A—General Provisions

§ 389.1 Policy and scope.

Pursuant to the provisions of 31 U.S.C. 9701, Fees and charges for Government services and things of value, and as implemented by the Office of Management and Budget's Circular A–25, dated July 8, 1993, the Department sets forth in this part fees and charges to be paid for the use of certain services and resources of the Department as prescribed in this part.

Subpart B—Fees for Special Services

§ 389.10 Applicability of subpart.

This subpart describes certain services and resources made available by the Department and prescribes the fees and charges for those services and resources.

§ 389.11 Available services and resources.

Upon request and payment of fees as provided in this part, there are available, with respect to documents subject to inspection, services as follows:

(a) Locating and copying records and documents;

(b) Certification of copies of documents under seal of the Department; and

(c) Transcripts of hearings and proceedings.

§ 389.12 Payment of fees and charges.

The fees charged for services and resources shall be paid for electronically at *http://www.pay.gov,* a secure government-wide collection portal, except for charges for reporting services that are performed under competitive bid contracts with non-Government firms. Fees for reporting are payable to the firms providing the services. Payments to *pay.gov* can be made directly from a bank account or by credit/debit card.

§ 389.1 3 Fees for services.

Fees for services and resources described in this subpart and subpart C of this part are pursuant to those fees set forth in 49 CFR part 7, subpart F, §§ 7.41 through 7.43, 7.45 and 7.46.

Subpart C—Filing and Processing License Fees

§ 389.20 Applicability of subpart.

(a) This subpart applies to the filing of certain documents and records with the Department by non-government parties, and prescribes fees for their processing.

(b) For the purpose of this subpart, record means an electronic tariff record submitted to the Department under subpart R of 14 CFR part 221, and contains a set of information that describes one (1) tariff fare, or a set of information that describes one (1) related element associated with such tariff fare.

§ 389.21 Payment of fees.

(a) Except as provided in paragraph (b) of this section, any document for which a filing fee is required by § 389.25 shall be paid for electronically at *http://www.pay.gov,* a secure government-wide collection portal, unless a waiver or modification of the filing fee has been requested and approved. Payments can be made directly from a bank account or by credit/debit card.

(b) Registration for all air taxi operators shall be accompanied by an 8 dollar ($8) registration filing fee in the form of a check, draft, or postal money order payable to the U.S. Department of Transportation.

(c) Where a document seeks authority or relief in the alternative and therefore would otherwise be subject to more than one filing fee, only the highest fee shall be required.

(d) Where a document relating to a single transaction or matter seeks multiple authorities or relief and therefore would otherwise be subject to more than one filing fee, only the highest fee shall be required. Where a document relating to more than one transaction or matter seeks multiple authorities or relief, the required filing fee shall be determined by combining the highest fees for each transaction or matter. For purposes of this paragraph (d), a specific number of charters or inclusive tours described in one application will be regarded as a single transaction or matter.

(e) No fee shall be returned after the document has been filed with the Department, except as provided in §§ 389.23 and 389.27.

§ 389.22 Failure to make proper payment.

In accordance with 49 CFR part 7, subpart F, § 7.42, the Department will assess interest on unpaid fees on the 31st day following the day on which a notice of the amount due is first mailed to the requestor, unless the Department has granted an application for waiver or modification of the fees.

§ 389.23 Application for waiver or modification of fees.

(a) Applications may be filed asking for waiver or modification of any fee paid under this subpart. Each applicant shall set forth the reasons why a waiver or modification should be granted, and by what legal authority.

(b) Applications asking for a waiver or modification of fees shall be sent to the Director, Office of Aviation Analysis, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. This provision is in accordance § 385.30 of this chapter. When no petition for review is filed with the Department, or when the Department reviews the Director's decision, if the amount found due is not paid within 10 days after receipt of notification of the final determination, the document shall be returned to the filing party.

§ 389.24 Foreign air carriers.

A foreign air carrier, or such carriers, if from the same country, acting jointly, may apply for a waiver of the requirements of this part based on reciprocity for U.S. air carriers contained in the requirement of their home governments, or as provided in a treaty or agreement with the United States. To apply for a waiver under this section, foreign air carriers shall send waiver requests to the Director, Office of International Aviation. The request should include applicable official government rules, decisions, statements of policy, or comparable evidence concerning filing fees for U.S. air carriers, or for all carriers serving that country. Once a waiver has been granted for a specific country, no further waiver

applications need be filed for that country.

§ 389.25 Schedule of processing fees.

(a) *Document-filing fees.*

Code	Document	
	Interstate Air Transportation	
	Certificate of Public Convenience and Necessity (49 U.S.C. Chapter 411)	
1	Application for Certificate of Public Convenience and Necessity Interstate Air Transportation—Charter Authority Only.	850
2	Application for Certificate of Public Convenience and Necessity Interstate Air Transportation—Scheduled Service.	850
3	Dormant Authority	290
4	Application for Certificate of Public Convenience and Necessity Interstate Air Transportation—Cargo Authority Only.	670
5	Application to transfer Certificate of Public Convenience and Necessity Interstate Air Transportation	290
6	Air Taxi Registration	8
7	Application for Commuter Air Carrier Authorization	670
8	Change of Name (registration of trade name or reissuance of certificate)	56
9	*Exemption Request—General (49 U.S.C. Chapter 401)*	
10	Request for an Exemption from 49 U.S.C. Chapter 415	53
11	Request for an Exemption from 49 U.S.C Chapter 411	280
12	Request for an Exemption from 49 U.S.C Chapter 417	120
13	Request for a Service Mail Rate Petition 49 U.S.C. Chapter 419	420
	Foreign Air Transportation—U.S. Carriers *(49 U.S.C. Chapter 411)*	
14	Application for Certificate of Public Convenience and Necessity Foreign Air Transportation—Scheduled Service.	900
15	Amendment to Application for Certificate of Public Convenience and Necessity Foreign Air Transportation—Scheduled Service.	425
16	Application for Certificate of Public Convenience and Necessity Foreign Air Transportation—Charter Service	600
17	Amendment to Application for Certificate of Public Convenience and Necessity Foreign Air Transportation—Charter Service.	200
18	Transfer of Certificate of Public Convenience and Necessity Foreign Air Transportation—Scheduled or Charter Service.	255
19	Change of Name (registration of trade name or reissuance of certificate)	56
	Foreign Air Carrier Permit (49 U.S.C. Chapter 413)	
20	Foreign Air Carrier Permit—Initial Application	760
21	Foreign Air Carrier Permit—Amendment/Renewal of permit	475
22	Foreign Air Carrier Permit—Amendment to application for a permit	215
	Exemption (49 U.S.C. Chapter 401)	
23	Request for an Exemption from 49 U.S.C. Chapter 415	53
24	Request for an Exemption from 49 U.S.C. Chapters 411/413 (10 or fewer flights)	77
25	Request for an Exemption from 49 U.S.C. Chapters 411/413 (More than 10 flights)	360
26	Request for an Exemption from 49 U.S.C. Chapters 411/413 (Filed less than 10 days before effective date requested).	[1] 17
27	Other (U.S. and foreign air carriers)	360
28	Emergency cabotage (49 U.S.C. Chapter 401)	360
29	Relief for U.S. and foreign indirect air carriers (49 U.S.C. Chapter 401)	370
	Undocketed Items	
30	Canadian Charter Air Taxi Registration	30
31	Foreign Freight Forwarder Registration	11
32	Foreign Tour Operator Registration	10
33	Foreign Aircraft Permit (14 CFR part 375)	25
34	Special Authorization (14 CFR part 375)	12
35	Charter Statement of Authorization	8
36	Intermodal Statement of Authorization	10
37	Special Authority (14 CFR part 216)	37
38	Fee for filing items 33–37 if filed less than time required before effective date	[1] 11
39	IATA resolutions	61
	Other (U.S. and Foreign Air Carriers)	
	Charters:	
40	Public Charter Prospectus	39
41	OMPC Operation Authorization	665
42	Waiver of Charter Regulations	39

Code	Document	
	Tariffs:	
43	Pages	2
44	Special Tariff Permission	12
45	Waiver of Tariff Regulations	12
46	Exemption request	371
	Agreements filed under 49 U.S.C. Chapter 413	
47	Prior Approval (docketed)	1,080
48	Routine (non-docketed)	64
49	Application for free and reduced-rate transportation	16

[1] Additional.

(b) *Electronic tariff filing fees.* The filing fee for one (1) or more transactions proposed in any existing record, or for any new or canceled records, shall be 5 cents per record; *Provided:* That no fee shall be assessed for those records submitted to the Department pursuant to 14 CFR 221.500(b).

§ 389.26 Special rules for tariff page filings.

(a) *Tariffs issued by carriers.* The filing fee for tariff pages filed by U.S. air carriers will be charged even if the tariff includes matters involving participating foreign air carriers. It will also be charged if the tariff is issued by a foreign air carrier and includes matters involving participating U.S. air carriers, unless the foreign air carrier has obtained a waiver under § 389.24. The fee will not be charged for a blank looseleaf page unless it cancels matter in the preceding issue of the page.

(b) *Tariffs issued by publishing agents.* (1) If the tariff is issued for one or more air carriers exclusively, the fee will be charged for each page.

(2) If the tariff is issued for one or more air carriers and one or more foreign air carriers, the fee will be charged for each page, except for those pages that the issuing agent states contain only:

(i) Matters pertaining exclusively to foreign air carriers that have been granted a waiver; or

(ii) Changes in matters pertaining to foreign air carriers that have been granted a waiver and that are included on the same page with other matters that are reissued without change.

(3) The fee will not be charged for a blank looseleaf page unless it cancels matters in the preceding page.

(4) No fee will be charged when two pages are published back-to-back, one page is not subject to the fee under paragraph (b)(2) of this section, and the page on the reverse is issued without substantive change.

(5) The fee will be charged for two looseleaf pages containing a correction number check sheet unless all other pages of the tariff are exempt from the fee.

§ 389.27 Refund of fee.

Any fee charged under this part may be refunded in full or in part upon request if the document for which it is charged is withdrawn before final action is taken. Such requests shall be filed in accordance with § 389.23.

PART 398—GUIDELINES FOR INDIVIDUAL DETERMINATIONS OF BASIC ESSENTIAL AIR SERVICE

■ 249. The authority citation for part 398 continues to read as follows:

Authority: 49 U.S.C. Chapters 401, 417; Airport and Airway Safety and Capacity Expansion Act of 1987 (Pub. L. 100–223, Dec. 30, 1987).

§ 398.11 [Removed]

■ 250. Section 398.11 is removed.

PART 399—STATEMENTS OF GENERAL POLICY

■ 251. The authority citation for part 399 continues to read as follows:

Authority: 49 U.S.C. 41712.

■ 252. Throughout part 399, remove the words ''Board'' and ''Board's'' wherever they appear and add in their place the words ''Department'' and ''Department's'', respectively.

§ 399.2 [AMENDED]

■ 253. In § 399.2(c), remove the words ''section 102 of the Act'' and add in their place ''49 U.S.C. 40101''.

§ 399.4 [AMENDED]

■ 254. In § 399.4, remove the word ''the Act'' and add in its place the words ''49 U.S.C.''.

§§ 399.30, 399.31, 399.32, 399.33, and 399.34 [REMOVED]

■ 255. Sections 399.30, 399.31, 399.32, 399.33, and 399.34 are removed.

■ 256. Section 399.35 is revised to read as follows:

§ 399.35 Special tariff permission.

The Secretary of Transportation may approve, under such terms as the Secretary may require, a carrier's application for Special Tariff Permission to file a tariff for foreign air transportation required under part 293 of this chapter on less than the notice required by 49 U.S.C. 41504(b).

§§ 399.37, 399.40, 399.41, 399.42, 399.43, and 399.44 [REMOVED]

■ 257. Sections 399.37, 399.40, 399.41, 399.42, 399.43, 399.44 are removed.

Table following § 399.44 [Designated as Appendix A to Subpart C of Part 399]

■ 258. Designate the table entitled ''Example of SIFL Adjustment'', which follows § 399.44, as appendix A to subpart C and add a heading for appendix A to read as follow:

Appendix A to Subpart C of Part 399—Example of SIFL Adjustment

§ 399.60 [AMENDED]

■ 259. In § 399.60(a), remove the words ''applications under section 408 of the Act for approval of consolidations or acquisitions of control;''.

§ 399.73 [AMENDED]

■ 260. In § 399.73, remove ''298.3'' and add in its place ''298.2''.

§ 399.80 [AMENDED]

■ 261. In § 399.80, in the introductory text, remove ''(m)'' and add in its place ''(n)''.

§ 399.81 [AMENDED]

■ 262. Amend § 399.81 as follows:

■ a. In paragraph (c)(1), remove the words ''This section'' and add in their place the words ''This paragraph (c)''.

■ b. In paragraph (c)(2), remove the words ''this section'' and add in their place the words ''this paragraph (c)''.

■ c. In paragraph (c)(3), remove the words ''this paragraph'' and add in their place the words ''this paragraph (c)''.

§ 399.82 [AMENDED]

■ 263. Amend § 399.82 as follows:

■ a. Remove paragraphs (b)(2) and (3).

■ b. Redesignate paragraphs (b)(4) and (5) as (b)(2) and (3).

■ c. Add the word ''or'' at the end of newly redesignated paragraph (b)(2).

§ 399.83 [AMENDED]

■ 264. In § 399.83, remove the words ''section 411 of the Act'' and add in their place ''49 U.S.C. 41712''.

■ 265. Section 399.91 is revised to read as follows:

§ 399.91 Air carrier participation in programs of technical assistance to airlines of less developed countries.

This policy shall apply to proceedings under 49 U.S.C. 41309 in which the Department is required to make any determination as to the public interest or consistency with 49 U.S.C. Subtitle VII of any agreement or relationship sought to be entered into by an air carrier, or officer or director thereof, with a foreign airline in connection with the performance of some activity pursuant to a technical assistance contract financed by an agency of the U.S. Government.

Subparts I and J—[REMOVED AND RESERVED]

■ 266. Subparts I and J, consisting of §§ 399.101 and 399.111, respectively, are removed and reserved.

§ 399.120 [AMENDED]

■ 267. In § 399.120, remove the words ''section 401(d)(8) of the Federal Aviation Act'' and add in their place ''49 U.S.C. 41102 and 41110''.

Issued in Washington, DC, on: February 7, 2019.

Elaine L. Chao,

Secretary of Transportation.

[FR Doc. 2019–02511 Filed 4–15–19; 8:45 am]

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